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Food and Agricultural Import Regulations and Standards

Annual

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Report Highlights:
This report outlines the requirements for food and agricultural imports into Denmark. The report is meant to assist U.S. exporters with labeling, lists of permitted ingredients, packaging rules and import documentation requirements. It also provides contact information for Danish government and inspection services which oversee and control the importing process. Major revisions to previous reports include reference to EU regulations and the EU labeling and traceability requirements effective April 18, 2004, (See Section VII).

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Table of Contents

SECTION I. FOOD LAWS

Harmonization within the EU

Originally created as a customs union, the EU is slowly becoming a single market and is harmonizing legislation between the 15 Member States. Regulation EC No. 178/2002, published in January 2002, sets out the general principles and requirements of EU harmonized food law. Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete.

The EU has followed a dual approach in harmonizing food laws. "Horizontal" legislation covers aspects, which are common to all food products. "Vertical" legislation covers aspects, which are product specific. Still under discussion are legislative initiatives for issues such as standards for vitamins, fortified foods (allowed in some Member States and prohibited in others), minerals, certain pesticide residues and requirements for allergen labeling.

Exporters should be aware that there may also be some variation among Member States in applying EU harmonized legislation: there may be temporary waivers or exemptions and in certain cases there may be room for interpretation of EU harmonized legislation or certain aspects which are not regulated in detail at the EU level may be handled differently in different Member States. In addition, there is a wide variation in inspection fees, registration fees and in the time required to evaluate dossiers on products used in the course of the food production process (www.useu.be/agri/harmonization.html).

Denmark

The Danish Ministry of Food, Agriculture and Fisheries

The Ministry provides assistance to the Minister regarding policy development for food, agriculture and fisheries. Policies are designed in co-operation with the government, Parliament and agricultural, trade and consumer organizations. The main objectives of the ministry are to promote profitable production and sales in the sectors pertaining to the Ministry, to ensure healthy and high quality products, and to provide a high level of information. The Ministry has a staff of 195.

The Danish Veterinary and Food Administration administers Danish food legislation by providing information, counseling and inspection. The Administration is also designed to protect consumers against misinformation, ensure equal conditions for retailers and producers, and promote healthy food habits. At the local level 12 district offices, 2 meat inspection districts and 9 border inspection posts represent the Administration. The Administration has 1,410 employees.

The Danish Plant Directorate is responsible for the quality of vegetable products, environmental regulation of agricultural production, and control of EU agricultural subsidy schemes. The Plant Directorate has a staff of 510.

The Danish Directorate for Fisheries carries out management and control of EC regulations and national rules in the fisheries sector. It also performs quality inspections in companies and in import/export transactions in order to ensure healthy food products. The directorate has a staff of 325.

The Danish Food Act applies to all foods sold in Denmark. Under the scope of The Food Act a number of regulations and guidelines have been issued. Most of the regulations are in accordance with directives and ordinances adopted in the European community. The

enforcement of the rules is very effectively carried out by the district offices, which inspect every food establishment authorized. That includes producers, importers, wholesalers, catering establishments and retailers.

The enforcement of the regulations is further supported by inspections which retailers conduct on their own initiative. All in all it is very important to ensure that any food product is in compliance with all the relevant regulations prior to marketing. Otherwise problems are unavoidable.

Important note:
It is not possible to obtain a pre-approval of products (composition, labeling, etc.) from Danish authorities. It is the responsibility of the producer, the Danish importer and the retailer to ensure the product's legality.

SECTION II. LABELING REQUIREMENTS

General requirements
[Community regulations]

General rules on the labeling, presentation and advertising of foodstuffs marketed in the EU are laid down in European Parliament and Council Directive 2000/13/EC + Corrigendum (English version of Annex III). This new directive consolidates general labeling directive 79/112/EEC and all its amendments in a single text. It applies to food products intended for supply to restaurants, hospitals and other similar mass caterers (food service) and to food products intended for sale to the ultimate consumer (food retail). See: www.useu.be/agri/label.html.

Most foods are covered by the general regulation on labeling of foods, but certain foods are covered by specific regulations as well, e.g. fish products, chocolate, fruit juice, marmalade products and food supplements.

All foods sold in Denmark must be marked with a batch-identifying code (a lot number or a date of production). This is true for "bulk packed" products as well as prepacked products – **and is the only requirement for "bulk packed" products**. All other information may be handed over to the importer in document form.

Normally **all prepacked foods** intended for the final consumer or catering establishments must be labeled according to the general rules prior to retail sale or catering service:

Name and address

Name and address of either the producer, the packaging establishment or a sales company within The European Community. (That means it is enough to state the name and address of an American producer or packer).

Product designation

The designation must describe the product in a proper way or maybe a name stated by law. A fantasy name or a trademark cannot replace the product designation. Pictures or claims regarding a certain component as well as naming of specific ingredients in the product designation requires a quantitative declaration of that ingredient either in accordance with the product designation or in the ingredients list. (QUID = Quantitative Ingredients Declaration).

Composition

The composition of a food must be declared as an ingredients list, listing all ingredients used in order of falling weight at the time of production. Some groups of ingredients, e.g. vegetable oils, can be declared by a group name. Allowed group names are defined in the labeling regulations. Composite ingredients well known to consumers, e.g. margarine need not be specified, if the content is below 25% of the total weight of the product. The ingredients list must start with the word "Ingredienser".

Beverages with an alcohol content of more than 1,2% vol. must be declared with the actual % vol. Some categories of foods are exempted from requirement of ingredients list, e.g. alcoholic beverages, some dairy products and products with only one ingredient.

Net weight

Net content (weight or volume) must be stated in metric system. Drained net weight should be stated as well when appropriate. Number of pieces can be stated as well. Net weight is not necessary when the weight is below 50 g, and for food supplements in tablet form where the number of tablets is sufficient.

Durability

The durability must be stated by best before/best before end date ("Mindst holdbar til"/"Mindst holdbar til og med"). Very perishable foods must be marked with last day of consumption ("Sidste anvendelsesdato"). The durability statements must be followed by storage instructions and instructions for use, if it is necessary in order to ensure correct use and storage.

Certain food categories such as confectionery, salt, vinegar and wine are exempt from shelf-life information.

Other labeling requirements
[Community and national regulations]

Language requirements. The labeling language must be Danish. Certain words from other languages, which are very similar to Danish in spelling, may be used. In practice though, most of the labeling will have to be in Danish.

Foreign labels. Products cannot be sold with a standard U.S. label only. Stick-on labels can be used in addition to a U.S. label, or to cover certain text on the original label, which is not in conformity with Danish labeling requirements (e.g. claims or nutritional information, which is not appearing in Danish).

The Danish label or stick-on label must be applied prior to retail sale or sale to catering establishments. Before that, there are no labeling requirements.

For sample-size and institutional packed products in small packages where the biggest surface is less than 10 cm? , it is sufficient to state product designation, net weight and durability (and lot no., if durability does not include the date). For products in bigger packages all requirements must be fulfilled.

Standard U.S. labeling does not match standard Danish labeling on several points. For example, the language used for food additives is different, health claims are not allowed in Denmark, and RDAs are different as well. It is advisable to always make a proper adaptation of the label to meet the Danish requirements, as they are enforced in detail.

Country of origin must be declared, if exclusion of that information can mislead the consumer as to where the product origins. Besides it is not allowed to call a product e.g. "American barbecue", if it is not produced in USA – even if you state the actual country of origin. In that case the product must be designated e.g. "Barbecue American Style" Produced in ...

Exceptions to the labeling regulations are not granted beforehand. In certain cases a dispensation can be obtained to use a faulty label until reprinting, if the fault is minor. Such dispensations are granted by the district offices.
[National procedure]

Food additives must be declared in the ingredients list by functional class followed by specific name or E-no., as defined in the labeling regulation and positive additive list. Flavors must be declared merely as "aroma" and it is possible to state "natural, nature identical or artificial" in accordance with the definitions in the flavor regulation.

Nutrients can be added after permission from the authorities, but the use allowed is very limited. Added nutrients cannot be claimed on the label, but can only be declared in the ingredients list and in nutritional information.
[National regulation]

Misleading of the consumer by using claims and pictures is much in focus with the Danish authorities. A campaign has recently been run, forcing companies to change misleading labeling. Examples are as follows:

Pictures of fruit or other ingredients can only occur when the ingredient is actually in the food product in an appropriate amount. A flavor or a minimal part of the ingredient is not enough.

The word *fresh* can only be used if the product is sold to the consumer within a few hours after production.

When a product is claimed to be *luxury*, it must be possible to document the better quality. Claims like *real, true and pure* must be possible to document as well.

The use of geographic names and national symbols is mentioned above.

Requirements Specific to Nutritional Labeling
[Community and national regulations]

Nutritional labeling is regulated on an EC level (EC Directive 90/496/EEG). Nutritional labeling is voluntary unless a nutritional claim is made, on the basis of which nutritional labeling becomes compulsory and must be provided in a prescribed format. "Nutrition Labeling" means any information on the label that relates to energy value and to the following nutrients: protein, carbohydrate, fat, fiber, sodium, vitamins and minerals present in significant amounts. This information and the format differ from those of the standard U.S. nutritional fact panel, which cannot be used for Denmark and the rest of the EU (http://www.useu.be/agri/label.html#Nutrition).

The standard U.S. nutritional fact panel is not quite acceptable for use on Danish labels. First of all, the information must be presented in the Danish language and use the specific terminology defined in the nutritional declaration regulations.

The information must always be given according to 100 g or ml of the product as presented to the consumer in the sales container. In addition, if appropriate, the facts can be given related to a piece, a serving or to 100 g or ml of prepared food.

Naturally occurring vitamins and minerals in the food can only be declared, if they exceed 15% of ADT ("Anbefalet daglig tilfoersel"/ Recommended daily intake) – the values of which differ to some extent from US-RDA values.

The Nutritional Labeling Requirements apply to all foods except natural mineral waters and food supplements. The labeling is voluntary in general, but if a nutritional claim is made or, if a vitamin/mineral is added, the nutritional labeling becomes mandatory.

A nutritional declaration can be "short" or "long" meaning either consisting of *energy (kJ/kcal), protein, carbohydrate and fat* or *energy (kJ/kcal), protein, carbohydrate, sugars, fat, saturates, fibers and* sodium. Both versions can be supplemented by several other nutrients. If unsaturated fatty acids are declared, declaration of saturates is mandatory. That combination is also possible in the short version.

If vitamins/minerals are declared, it is mandatory to state the % of ADT accordingly.

Natural mineral water and food supplements are exempted from the declaration of energy and energy-supplying nutrients. Nutritional declaration of food supplements can be given per daily dose instead of per 100 g.
[National regulation on food supplements]

Nutrient content claims are described in guidelines, one general and one specifically related to *Light*. Nutritional claims are restricted to naturally occurring nutrients (not allowed for added vitamins and minerals), and must be followed by a nutritional declaration. All nutrient claims result in a nutritional declaration, except from claims related to salt and alcohol, which are not regarded as nutrients (salt is not but sodium is). The nutrient claim must be nutritionally relevant seen in relation to general nutritional recommendations and/or to comparable food products. It is forbidden to claim that a food has reached a better nutritional standard by adding of nutrients (vitamins/ minerals), and vitamins/minerals added as e.g. antioxidants or colors must not be declared as nutrients.

Both *absolute descriptors* and *relative descriptors* can be used. Implied claims are not described in the guidelines. As long as they are not misleading to the consumer, they will be accepted.
[National regulation]

Specific guidelines regarding nutritional claims
[National regulation]

Fibers. High fiber content can be claimed at content between 4-8 g per MJ, and "rich in fibers" can be claimed at contents above 8 g per MJ.

Fat. Light or low with regard to fat can be claimed, if the fat content is reduced by at least 50% *and* the energy content is reduced by at least 30%. This is with reference to comparable reference products.

Sugar. Light or low with regard to sugar can be claimed when the content of energy contributing carbohydrates is reduced by at least 30% *and* the energy content is reduced by 30% as well, also compared to reference product.

Sodium. The term "light" is not recommended in relation to sodium. The terms "low" or "reduced" are preferred instead.

Health claims and *functional claims* are not allowed in Denmark. Due to this, *functional foods* are difficult to market in Denmark and only a few products in this category exist on the market.

SECTION III. PACKAGING AND CONTAINER REGULATIONS [Community and national regulations]

Council Directive 76/211/EEC provides rules for container sizes, acceptable tolerances on container content and requirements for the size of the figures indicating container content (www.useu.be/agri/packaging.html).

Product Recycling Regulations
Member States are required to take measures to limit packaging waste and must introduce systems for re-use, recovery and recycling of packaging materials (Council Directive 94/62/EC). Commission Decision 2001/524/EC relates to the publication of references for certain EN standards in the Official Journal, which do not fully meet the essential requirements of Directive 94/62/EC. To facilitate collection, re-use and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary (http://www.useu.be/agri/packaging.html).

SECTION IV. FOOD ADDITIVES REGULATIONS [Community and national regulations]

Danish food additive regulations are primarily based on common regulations within the European Community. Four major EC-directives on the use of additives and the labeling rules are implemented in Danish food additive regulations. These are the directives governing colours, sweeteners, flavors and miscellaneous food additives and in addition the labeling directive. The EC regulation also provides requirements as to identity and purity of approved food additives.

1. European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs. The annex to this directive lists maximum usable doses for sweeteners in selected foodstuffs.

2. European Parliament and Council Directive 94/36/EC on colors for use in foodstuffs.
Annex I: List of permitted food colors. Only substances listed in this annex may be used
Annex II: Foodstuffs, which may not contain added colors.
Annex III: Foodstuffs to which only certain permitted colors may be added.
Annex IV: Colors permitted for certain uses only.
Annex V: Colors permitted in general and the conditions of use. Colors permitted following the "quantum satis" principle (no maximum specified) are listed in the Appendix.

3. European Parliament and Council Directive 95/2/EC, as amended, the so-called miscellaneous additives directive on food additives other than colors and sweeteners.
Annex I: List of food additives permitted for use in foodstuffs (excl. those listed in Annex II) following the "quantum satis" principle.

Annex II: List of foodstuffs in which only a limited number of additives of Annex I may be used. These include cocoa and chocolate products, fruit juices and nectars, jam and jelly, dehydrated milk and cream, fruits and vegetables, rice, oils and fats, certain cheeses, minced meat, bread and pasta, wines and beer.
Annex III: List of conditionally permitted preservatives and antioxidants.
Annex IV: List of other permitted additives.
Annex V: List of permitted carriers and carrier solvents.
Annex VI: List of additives permitted in foods for infants and young children.

All three of these directives and their lists can be downloaded from the FAS/USEU webpage www.useu.be/agri/additive.html.

Labeling requirements for additives and flavorings are laid down in Directive 2001/13/EC (general labeling directive), Regulation 50/2000/EC (GM additives) and Directive 89/107/EEC.

The Danish Positive Additive List regulates the use of colors, preservatives and miscellaneous food additives in all foods in accordance with the EC-directives. The Danish authorities have tried to introduce a more restricted regulation on sulphur dioxide and sulphites, nitrate and nitrites than the EC-rules, as Denmark has used the derogation clause referring to consideration of public health. This has been turned down by the Commission, but the case will be taken to court. In the meantime, the Danish regulation matches the EC regulation, but the Danish retailers will only sell goods confirming with the proposed Danish restrictions.

CODEX evaluations of the safety of food additives have been considered in the development of the community regulations, but the list of CODEX approved food additives for imported foodstuffs is not applicable as such.

The Danish Veterinary and Food Administration is not authorized to add new food additives to the list or to change the conditions for use of existing ones. This has to be applied for through an EC procedure.

The said directives and the Danish Positive Additive List does not include flavors, bacterial cultures and most enzymes, but the Danish Positive additive list additionally covers the use of nutrients, which is nationally regulated. A negative list of naturally occurring flavoring matters also exists in the flavor regulation.

The Danish Positive Additive List is only available in the Danish language. The list can be bought in bookshops or from "Statens Information".

Labeling of food additives in foods shall consist of a category designation followed by the specific name or the E-number of the additive used. The category designations are defined in the labeling directive and implemented in the Danish labeling regulation. The specific names and E-numbers of the food additives are specified in the directives and in Danish Positive Food Additives List.

Special Danish rules for food additives

Flavors. In Denmark all *smoke flavors* have to be approved by the Danish Veterinary and Food Administration prior to use. The application must follow the guidelines issued by the EC body SCF (Scientific Committee for Food), which include information regarding production method, chemical composition and toxicological data. An approval obtained in another EC country and based on the same information can be accepted as documentation in Denmark.

Enzymes. In Denmark all enzymes have to be approved by the Danish Veterinary and Food Administration prior to use in production of foods or as ingredients. A guideline concerning the data requested is printed as an appendix to the food additives regulations.

Micro-organisms. In Denmark all bacteria, yeast and fungi cultures have to be approved by the Danish Veterinary and Food Administration prior to use in production of foods or as ingredients. A guideline concerning the data requested is printed as an appendix to the food additives regulations.

Preservatives. Denmark has tried to adopt more restricted rules for the use of sulphites in general and nitrate and nitrites in meat products, than the rest of the European Community has adopted according to the Directive. The Danish government finds that the commonly accepted levels give rise to unacceptable health concerns. It is questionable whether Denmark can maintain these national standards as the EC Commission has refused to accept the Danish position and has taken it to court. Until the matter is decided in court, Denmark is obliged to accept the EC limits for products on the market.

Vitamins and minerals. The Danish Positive Food Additives List includes a list of accepted vitamin and mineral sources and their specifications for identity and purity. Only nutrients from this list can be added to foods.

SECTION V. PESTICIDE AND OTHER CONTAMINANTS [Community and national regulations]

EU pesticide legislation has not been fully harmonized. Community maximum residue levels (MRLs) take into account the work done by Codex Alimentarius and by the OECD, but exceptions exist. Overviews of all compounds for which harmonized MRLs have been developed are available from the FAS/USEU webpage www.useu.be/agri/pesticides.html. The complete list of MRL/commodity combinations can be downloaded from the Commission's web server at http://europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm. Pesticide MRLs for processed or composite products are based on the MRLs for the raw agricultural ingredients.

1. Residues in Animals and Animal Products

Maximum Residue Levels for veterinary pharmaceutical products in foodstuffs of animal origin were established in Council Regulation 2377/90. Updated lists for these MRLs are available at webpage http://dg3.eudra.org/F2/mrl/index.htm.

The monitoring of residues in animals and animal products is addressed separately in Council Directive 96/23/EC. This directive covers the monitoring of the above-mentioned pesticide residues, and includes also the monitoring of residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition on the use of hormones in meat production is addressed in Council Directive 96/22/EEC.

For the registration of a new pesticide in the EU, including the establishment of an MRL, an application needs to be prepared and reviewed by the relevant authorities and committees at Member State and EU level. Pesticides currently on the EU market are under review. For pesticides, which are not or no longer authorized at Community level, an import tolerance may be requested. Application dossiers are first submitted for approval within an individual member state. The complete procedure is described on the Commission's web server at http://europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm.

Danish pesticide regulation is primarily based on common regulation within the European Community.

CODEX maximum residue limits have been considered in the development of the community regulations, but the list of CODEX MRLs is not necessarily followed in detail. Besides the EC lists, specific Danish maximum limits for a range of pesticides found in fruit, vegetables, cereals and fish are contained in the regulation.

The pesticide regulation consists of positive lists of maximum limits for a range of pesticides in different foods and animal feed. Food products must not be sold, if the pesticide residues exceed the maximum limits.

The Danish Plant Directorate conducts the control of residues in animal feed, and the district offices of food control conduct the control of foods.

The evaluation of new pesticides is conducted by the *Danish Environmental Protection Agency*, which also can provide information regarding approved pesticides.

Information regarding residues of pesticides can be obtained from the *Danish Veterinary and Food Administration.*

Other contaminants
[Community and national regulations]

Certain metals. Maximum limits for lead, mercury, cadmium and tin in foods are set. It is forbidden to import or sell foods with contents exceeding the maximum limits. In addition, a survey limit list exists. This contains lower limits, which should preferably be met. Control findings exceeding the survey limits are reported by the district units to the directorate.

Erucic acid. The content of erucic acid in fats and oils must not exceed 5%. This is also applying to fats and oils as ingredients in foods with more than 5% fat or oil added.

Mycotoxins. Maximum limits for content of different aflatoxins are set for certain foods, such as peanuts, dried fruits, cereals and milk. National limits are set additionally for content of aflatoxins in foods in general and for ochratoxin A in cereals.

Ethylene oxide. In Denmark a ban on the use of ethylene oxide exists. This means that it is totally forbidden to market food products or ingredients (e.g. spices) treated with ethylene oxide.
[National regulation]

Irradiation. Irradiation of foods and ingredients cannot take place until a national approval has been obtained. So far very few approvals have been issued, mainly for spices. When an irradiated food or ingredient is marketed, the irradiation must be stated on the label.

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

Certification and documentation requirements for shipments into EU member states differ depending on the product. For some product groups, requirements are harmonized, but not for others. For most products the EU requires import licenses.

1. Animal Products

Import legislation has been harmonized for all main animal categories, including cattle, pigs, poultry, horses, goats and sheep, fish and even exotic birds. Non-harmonized animal categories include amphibians and reptiles, elk and deer and honeybees. Import of animal products is allowed from establishments on the lists of EU-approved establishments in recognized countries. The U.S. is recognized by the EU for nearly all animal products. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Establishments are subject to EU inspections prior to listing and/or to occasional EU audits after listing. Exporters should be aware that getting a plant listed has been extremely difficult for the U.S. At present only five beef processors and no pork or poultry plants are approved. Health certificates corresponding to the animal category are required. Lists of EU approved establishments can be accessed through the FAS/USEU webpage www.useu.be/agri/estab.html.

For processed foods containing animal products, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to require certification. Products containing any amount of red meat or poultry meat must be certified. Certification of products containing egg products or dairy depends on the composition of the product.

The U.S. is not included on the European Commission's list of countries with processing systems and health standards equivalent to the EU for fishery products for human consumption or bivalve mollusks. U.S. is under a derogating regime allowed to export seafood to the EU (Decision 95/408/EC last amended by Council Decision 2003/912/EC). This last Decision extends the derogation to December 31, 2005.

Each shipment must be accompanied by a health certificate using the model provided by Commission Decision 2001/67/EC for fishery products and by Commission Decision 96/333/EC for mollusks, echinoderms, tunicates and marine gastropods. In the U.S., both the Food and Drug Administration and the National Marine Fisheries Service have the authority to issue certificates for export to the EU. More details about requirements for fish exports to the EU are available on the webpage http://www.nmfs.noaa.gov/trade/EUCONTENTS.htm.

1. Plant products

For fruit and vegetable imports, generally import certificates are not required. However, phytosanitary certificates issued by APHIS are requested for fruit, vegetable and nut shipments to the EU. For processed fruit and vegetable products, APHIS issues export certificates. Imports of fruits and vegetables also need to meet the marketing standards for fruit and vegetables as listed in Council Regulation 2200/96. Trading standards and controls are described by Council Regulation 1148/2001. Import must also comply with CITES rules for endangered species (http://europa.eu.int/eur-lex/en/search/search_oj.html).

1. Other Processed Products

Documentation requirements and import regulations for other processed food products will depend on ingredients. In general, Council Directive 93/43/EEC laying down the rules of hygiene for foodstuffs further supplements Council Directive 89/397/EEC. These rules, as set out in the annex, must be observed at the time of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale and supply of foodstuffs. Food businesses are required to use the HACCP system to ensure the safety of foodstuffs. See http://www.useu.be/agri/hygiene.html.

Some food products, including cocoa and chocolate, coffee and chicory extracts, sugars, honey, fruit juices and similar products, fruit jam, jellies and marmalades, are subject to "vertical legislation". For these food categories, more information is available at the FAS/USEU webpage www.useu.be/agri/vertic.html.

SECTION VII. OTHER SPECIFIC STANDARDS

Weights and measures
[Community regulation]

Weights must be stated in metric system (weight or volume). An optional directive on package sizes exists. Denmark has not adopted the rules so package sizes are optional for ordinary food products.

Prepacked products marketed with constant nominal content, can be covered by an official measure control and be marked with an "e" in connection with the weight labeling. Imported foods can be covered by the e-marking as well, provided the importer effects a notification and establishes an agreement regarding control with the competent authority. The responsible authority in Denmark is the Danish Agency for Trade and Industry.

Vitamin and mineral enrichment requirements in foods
[National regulation]

In Denmark it is only allowed to add a limited number of vitamins and minerals to certain foods. The authorized additions are based on the principles of fortification/enrichment (iodine in salt), substitution (vitamin A and D in margarine) and restoration (vitamin B in cereals, vitamin C in fruit juices). These principles are in accordance with the definitions of CODEX.

In the case of e.g. restoration of vitamins and minerals in wheat flour it is only allowed to add B1, B2, Calcium and Iron, which is not equal to the rules in USA. According to discussions with the Danish authorities, they will allow further enrichment according to the mandatory US requirements in order to avoid the introduction of a technical trade barrier. This is when the flour is used as an ingredient in a compound food. This principle might be relevant for other foods as well.

The general conditions for adding of nutrients to foods are:

The added nutrients must fulfill the Danish specification requirements, as stated in the Positive Additive List.

The enrichment must be notified to the Danish Veterinary and Food Administration with information about type and amount of nutrients added. A fee is charged.

It is mandatory to add iodine (13 mg/kg salt) to edible salt and salt used as ingredient in bakery products. The total content (naturally occurring and added) of nutrients must be declared in the ingredients list and in nutritional information.

Novel foods/GMOs
[Community regulation]

Novel foods are defined as foods not previously consumed in significant quantities within Europe. Also new combinations of ingredients may be considered novel according to Danish interpretation of the directive.

Novel foods, including GMOs, can be used after EC certification. Once a GMO is approved for use in foods, no product specific registration is necessary. GMO products as well as ingredients (including food additives and flavours) deriving from GMO, which can be analytically detected (DNA or protein containing), must be declared as genetically modified in connection with the product designation or in the ingredients list. Accidental content of an EU approved GMO in combined foods and single ingredient foods at a level below 0.9% need not be declared.

Genetically Modified Food Labeling (Processed Food)

Intro

On October 18, 2003, the EU published two regulations on "Genetically Modified Food and Feed" (European Parliament and Council Regulation 1829/2003) and "Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms" (European Parliament and Council Regulation 1830/2003). The new rules entered into force on April 18, 2004.

Labeling

Articles 12 and 13 of Regulation 1829/2003 establish labeling requirements for foods, which are to be delivered as such to the final consumer or mass caterer and which:

- contain or consist of genetically modified organisms (GMOs) | GMOs authorized
- are produced from or contain ingredients produced from GMOs | by the EU

The new labeling rules do not apply to foods containing no more than 0.9 percent of genetically modified ingredients or, if the presence of such material is technically unavoidable. Operators must supply evidence to the competent authorities that appropriate steps have been taken to avoid the presence of GM material.

Specific labeling requirements apply to:

a) Foods consisting of more than one ingredient: The words "genetically modified" in parentheses immediately following the ingredient concerned or "produced from genetically modified (name of the ingredient)" must be included in the list of ingredients (list of ingredients: Ref. Article 6 of General Labeling Directive 2000/13/EC).

b) Ingredients designated by the name of a category (e.g. vegetable oil): The words "contains genetically modified (name of organism)" or "contains (name of ingredient) produced from genetically modified (name of organism)" must be included in the list of ingredients.

The indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they must be printed in a font of at least the same size as the list of ingredients.

c) Foods for which there is no list of ingredients: The words “genetically modified” or “produced from genetically modified (name of organism)” must appear clearly on the label.

d) For prepackaged food in small containers of which the largest surface has an area of less than 10 cm^2: the required information must be indicated on the packaging material in a font sufficiently large for it to be easily identified and read.

Novel Foods containing or produced from GMOs

The new rules also affect Novel Foods Regulation 258/97. The authorization of novel foods and novel food ingredients containing or produced from GMOs no longer falls within the scope of the Novel Food Regulation, but will be regulated by GM Food and Feed Regulation 1829/2003. Any characteristics or properties, as specified in the EU’s GM authorization, must be indicated on the label of food products which are different from their conventional counterparts as regards composition, nutritional value or nutritional effects, intended use of the food or implications for the health of certain sections of the population or, if the food product gives rise to ethical or religious concerns.

The label of novel foods, which do not have a conventional counterpart, must also contain appropriate information about the nature and the characteristics of the foods concerned.

Traceability

Operators who market products produced from GMOs must ensure that the following information is transmitted in writing to the operator receiving the product:

- an indication of each of the food ingredients or additives produced from GMOs.
- in the case of products for which no list of ingredients exist, an indication that the product is produced from GMOs.

Operators must have a system and standardized procedure in place to hold the information mentioned above and to allow the identification of all the different operators by whom and to whom the GM foods were made available. This information must be kept for a period of five years. The traceability requirements do not apply to products containing less than 0.9 percent of GMOs, provided that the traces of GMOs are adventitious or technically unavoidable.

In cases where Community legislation provides for specific identification systems, such as lot numbering for prepackaged products, operators are not obliged to hold the traceability information, provided that this information and the lot number is clearly marked on the package and that information about lot numbers is held for a period of five years.

Dietetic and special use foods
[Community and national regulation]

Special regulations on dietetic foods cover:

Slimming foods (VLCD and LCD diets)
Baby and infant formulas
Nutritional preparations for special medicinal uses

Baby and infant formulas intended for healthy children, and low calorie diets and special medicinal diets are subject to EC harmonization, and these products need no specific approval prior to marketing.

Very low calorie diets are subject to a national registration procedure. The regulations cover standards and requirements regarding composition, labeling and warnings. Other special use foods might exist. These will be subject to national regulations.
[Community and national regulation]

Organic foods

A product can be marketed as organically grown or under given circumstances as organic ingredients in composite foods, provided an accredited inspection body grants the production. Third country inspection bodies must conform with the standard of EC member state inspection bodies, which is described in an EN and ISO standard.

The name of the inspection body in question must be stated on the label, and the logo can be used as well.

The national Danish logo for organic products controlled by the Danish district offices can only be used for labeling purposes, if a part of the food production is carried out in Denmark (e.g. packaging process).

Health foods and Dietary supplements
[National regulation]

Vitamins and minerals
Vitamin and mineral supplements can be classified as food supplements as well as drugs (medicine) dependent on their strength. A list of maximum value for each nutrient as dietary supplement exists. E.g. vitamin C has a maximum of 90 mg a day as dietary supplement. If this limit is exceeded, the product will be classified as a drug. If only one nutrient in a combined product is over its limit, the product is a drug.

Vitamins and minerals as drugs
Products must be authorized by the Danish Medicines Agency according to a national application with efficacy and safety based on bibliographic data. Only recognized nutrients are allowed as active substances, and it is not possible to mix with herbals or other substances.

Vitamins and minerals as food supplements
Only recognized nutrients and certain specified sources of them are accepted. Products have to be approved by the food authorities. A guiding minimum value for each nutrient exists, because the addition of a nutrient has to be nutritionally relevant. It is possible to mix with herbals and other food ingredients (e.g. fish oils). Propionic bacteria cultures are not accepted as food supplements as they provide no direct nutritional function.

Herbal drugs
These components can be classified as drugs (Danish Medicines Agency authorization) or as food supplements (no registration necessary) dependent on the degree of safety data, well established use, efficacy documentation and claims used. Normally no health or functional claims are allowed for food supplements. For drugs only, minor difficulties suitable for self-medication are accepted as indication.

Special labeling requirements and mandatory warnings exist.

Fruits and vegetables
[Community regulation]

Fruits and vegetables can be sold unpacked by piece or by weight. Country of origin must be stated and also any surface treatment must be informed. Surface treatment of fruits is regulated through the food additives regulation.

Regulations on potatoes for breeding and for consumption are administered by the Danish Plant Directorate who controls the sort, the quality and the labeling of potatoes.

Processed fruits and vegetables are in general covered by the ordinary food regulations. Jams, jellies and marmalade as well as fruit and vegetable juices are subject to special standards and labeling requirements, which are based on EC directives.

SECTION VIII. TRADEMARK LAWS

Application: A trademark may be applied anywhere in the marketing efforts. E.g. letterheads, prints, sales letters, newspaper and TV advertising, on the packaging and on the food item itself.

Obtaining the sole and exclusive right of a trade mark:

The sole and exclusive right of a trademark may be obtained by:

1. Using the trademark.
2. Registration of a trademark.

If a trademark is without specific characteristics, it will not be protected by itself. To obtain the sole and exclusive right, it has to be used intensively in order to make it known within the industry as a symbol for the company.

Besides the use of the trademark only, registration ensures practical advantages, e.g. noting of a license. The sole right obtained by registration is extended to commodities and services not yet in use/marketed.

Registration of a trademark in Denmark may be obtained through the filing of an application with the Danish Patent and Trademark Office, Ministry of Trade and Industry, Helgeshoej Alle 81, DK-2630 Taastrup, Tel: +45 4350 8000, Fax: +45 4350 8001/E-mail: pvs@dkpto.dk, Web: www.dkpto.dk. A trademark registration may be obtained for distinctive marks, which may be reproduced by graphic means.

The Office will examine whether the trademark complies with registration conditions, such as if the mark lacks distinctiveness, is illegal or misleading. If the mark is confusingly similar to an existing registered trademark or a trademark applied for, a company name or a name of a person, the applicant will be notified of these rights. The applicant may then choose to either make amendments to the application or let the Office register the trademark. The registration of the trademark will be published in the Danish Trademarks Gazette. An opposition may be filed against the registration within 2 months after the publication.

By having a trademark registered, the owner ensures that other applicants for Danish and international trademarks and EU trademarks obtain knowledge of the mark and thus a possibility of avoiding a conflict.

A trademark registration may be renewed every 10 years. Obligation to use a registered trademark means that continuous maintenance of the registration will be best ensured, if the trademark is put to use within the first 5 years after registration.

The applicant will receive the result of the examination performed by the Office within 2 to 3 months.

The basic fee for a trademark application is DKK 2,300.

To meet the needs for international protection, two international registration systems were introduced April 1, 1996.

EU Trademark. With only one application, a trademark can be registered with validity in all EU member countries. An EU application can be sent directly to the EU trademark office in Alicante, Spain or through the Danish Patent and Trademark Office.

The Madrid - Protocol. On the basis of one trademark applied for or registered domestically in a country joining the Madrid-Protocol (e.g. United States of America) the applicant can have the trademark registered in all Madrid-Protocol countries by one application.

SECTION IX. IMPORT PROCEDURES

Council Regulation 2913/92 establishes the Community Customs Code. The Code lists all the customs procedures applicable to the trade in goods with third countries. Import duties are determined by the tariff classification of goods and by the customs value. With the implementation of the Code, the 15 member states of the European Union form a customs union, meaning that all member states apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one member state, it can move freely throughout the EU. See http:/www.useu.be/agri/import.html and http://www.useu.be/agri/customs.html. The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: The first six digits refer to the HS headings, the two following digits represent the CN subheadings. The EU's on-line customs database can be consulted to look up commodity codes and relevant import duties: http://europa.eu.int/comm/taxation_customs/dds/en.htm. It is also possible to obtain Binding Tariff Information (BTI) from a member state's customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI is legally binding in all the member states. A list of customs authorities can be found on the Internet at: http://europa.eu.int/comm/taxationm_customs/databases/bti/EN.pdf. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Goods are only released after payment of the import duty and other taxes that may be due. Duties payable on goods imported into the EU may include:

- Import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces).
- Additional duties on flour and sugar (processed products).
- Entry price (fruit and vegetables).

- Environmental taxes (not harmonized).
- Inspection fees (not harmonized).

- Value added tax (VAT) (not harmonized).
- Excise duties (alcohol and tobacco) (not harmonized).

VAT for Denmark is 25 percent for all products.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at: http://europa.eu.int/comm/taxation_customs/publications/info_doc/taxation/c4_excise_tables.pdf.

Customs clearance

The entire customs clearance is rapid, provided the U.S. exporter has furnished all necessary documentation (including necessary sanitary/phytosanitary certificate if need be). Also, it is recommended that the exporter be fully aware of the necessary shipping documents required for their product. As this information is not readily available, exporters should contact their importer or the Office of Agricultural Affairs in Copenhagen to obtain this information.

LIST OF DANISH AUTHORITIES

SECTIONS II, IV, V and VII:

The Danish Veterinary and Food Administration
Moerkhoej Bygade 19
DK-2860 Soeborg
Tel: +45 33 95 60 00
E-mail: fdir@fdir.dk

Publications:

Statens Information
Noerre Farimagsgade 65
DK-1009 K? benhavn K
Tel: +45 33 37 92 28
E-mail: si@si.dk

SECTION V:

The Danish Plant Directorate
Skovbrynet 20
DK-2800 Lyngby
Tel: +45 45 96 66 00
E-mail: pdir@pdir.dk

The Danish Environmental Protection Agency
Strandgade 29
DK-1401 K? benhavn K
Tel: +45 32 66 01 00
E-mail: mst@mst.dk

SECTION VII:

The Danish Agency for Trade and Industry
Langelinje Alle? 17
DK-2100 Koebenhavn ?
Tel: +45 35 46 60 00
Fax: +45 35 46 60 01

The Danish Medicines Agency
Frederikssundsvej 378
2700 Broenshoej
Tel: +45 44 88 91 11
Fax: +45 44 88 91 11
E-mail: dkma@dkma.dk

District inspection offices:

Nordjylland: Tel: +45 98 78 10 00

Viborg: Tel: +45 87 28 14 00

Herning: Tel: +45 99 29 18 00

Aarhus:	Tel: +45 89 44 33 23
Vejle:	Tel: +45 79 43 22 00
Esbjerg:	Tel: +45 79 16 12 00
Soenderjylland:	Tel: +45 73 53 16 00
Fyn:	Tel: +45 66 61 28 01
Ringsted:	Tel: +45 57 68 20 00
Nordsjaelland:	Tel: +45 44 52 30 00
Koebenhavn:	Tel: +45 33 85 24 00
Bornholm:	Tel: +45 56 90 26 00