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The Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Copenhagen, Denmark prepared this report for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

SECTION 1. FOOD LAWS

In November 2007, the Danish Veterinary and Food Administration which, since September 2004 was a part of the Ministry of Family and Consumer Affairs, was transferred back to the Ministry for Food, Agriculture and Fisheries.

The Danish Ministry of Food, Agriculture and Fisheries provides assistance to the Minister regarding policy development for agriculture and fisheries including EU policies for 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. The Ministry has a staff of 135.

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. The Administration is the head office of 3 Regional offices posted in different parts of Denmark, 10 local district control-offices, 3 inspection districts and 3 laboratories. The Administration has approximately 2,880 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. In 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 authorised. 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

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. A web address is accepted. (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 may be 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 in 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. Allowable group names are defined in the labeling regulations. Labeling of composite ingredients is now required under an EU harmonized rule. However, there exist a list of Danish exceptions. The ingredient list must start with the word "Ingredienser".

Beverages with an alcohol content of more than 1.2% vol. must be declared with the actual percent by volume. Some categories of foods are exempted from requirement of ingredients list, e.g. alcoholic beverages, some dairy products, untreated and unpeeled fresh fruit and vegetables and products with only one ingredient.

Net weight.

Net content (weight or volume) must be stated in metric system. Drained net weight must be stated as well when appropriate. Number of pieces can be stated as well. Net weight is not necessary when the weight is below 5 g or 5 ml (does not apply for spices and herbs), and for certain packed sugar products with a weight below 20 g.

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 excepted from shelf-life information.

Other labelling requirements:

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 labelling 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 labelling requirements (e.g. claims or nutritional information, which does not appear 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 labelling requirements.

For sample-size and institutional packed products in small packages where the biggest surface is less than 10 square 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. labelling does not match standard Danish labelling at several points. For example food additives may have different names 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 originates. It is not allowed to call a product e.g. "American barbecue" if it is not produced in the 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 labelling 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. The district offices grant such dispensations.

Food additives must be declared in the ingredients list by functional class followed by specific name or E-no., as defined in the labelling regulation and positive additive list. Flavours can

be declared merely as “aroma” and it is possible to state “natural, nature identical or artificial” in accordance with the definitions in the flavour regulation.

Nutrients can be added after authorization from the authorities. This is because Denmark has not fully implemented the EC rules regarding addition of vitamins and minerals and of certain other substances to foods (2003/0262 (COD)).

Misleading the consumer by using claims and pictures is much in focus with the Danish authorities. A running campaign is forcing companies to change misleading labelling.

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 flavour or a minimal part of the ingredient is not enough, unless the product is candy, where a minimal part is accepted.

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

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 pr. 100 g or ml (“Anbefalet daglig tilførsel”/ Recommended daily intake) – the values of which differ to some extent from US-RDA values.

The Nutritional Labelling Requirements apply to all foods except natural mineral waters and food supplements. A nutritional declaration can be “short” (Big 4) or “long” (4+4) meaning either consisting of *energy (kJ/kcal)*, *protein*, *carbohydrate and fat* or *energy (kJ/kcal)*, *protein*, *carbohydrates*, *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 must be given per daily dose instead of per 100 g.

Nutrient content claims are described in guidelines, one general and one specifically related to *Light*. 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.

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.

Specific guidelines regarding nutritional claims:

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 allowed in Denmark, if they are supported by scientific evidence. Health claims stating that a product is specifically suitable for diabetics are forbidden.

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

Food in Plastic and ceramic containers.

New Danish rules (effective May 1, 2008) require that manufacturers and wholesalers of plastics or ceramics intended to come into contact with food are able to provide relevant documentation of the quality of their products. In addition to this, the certificates that must accompany these products when imported into Denmark now have to contain even greater detailed information.

If food products are imported into Denmark in plastic containers, the deliveries must be accompanied by certificates which contain detailed information whereby the employed materials and substances in the plastic product can be identified. This includes information of the name and address of the business operator who manufactures or imports the plastic materials.

SECTION IV. FOOD ADDITIVES 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 labelling rules are implemented in Danish food additive regulations. These are the directives governing colours, sweeteners, flavours and miscellaneous food additives and in addition the labelling directive.

The Danish Positive Additive List regulates the use of colours, preservatives and miscellaneous food additives in all foods in accordance with the EC-directives.

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 EC directives and the Danish Positive additive list do not include flavours, bacterial cultures and most enzymes, but the Danish Positive additive list additionally covers the use of nutrients, which is still partly nationally regulated. A negative list of naturally occurring flavouring matters also exists in the flavour regulation.

The Danish Positive additive list is only available in the Danish language. The list is available at the Internet at www.fvst.dk (select "publikationer" and select "Bestilling af publikationer").

Then look under "P" and select "positive List). The list can also be bought in bookshops or from "Statens Information".

Labelling 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 labelling directive and implemented in the Danish labelling 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:

Nitrite: The EU has accepted the Danish request to maintain the specific lower limits for addition of nitrate in meat products. The low maximum levels are provisionally valid for two years up to June 1, 2010.

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.

Microorganisms. 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 nitrites in meat products, than the rules provided in the European Community Directive. The Danish government finds that the commonly accepted levels give rise to unacceptable health concerns. Commission Decision of May 23 2008 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products announces maximum amounts of nitrites that may be added during manufacture as well as maximum residual levels. As for the sulphites Denmark must observe the levels provided in the European Community Directive.

Vitamins and minerals. The Danish Positive food additives list complements Regulation 1925/2006/EC concerning 'addition of vitamins and minerals and of certain other substances

to foods' and includes a list of accepted vitamin and mineral sources and their specifications for identity and purity.

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

EU pesticide legislation has not been fully harmonized. Community maximum residue levels (MRL's) take into account the work done by Codex Alimentarius and by the OECD but exceptions exist.

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

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 also applies 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 pig kidney.

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.

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.

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.

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.

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.

The Danish Plant Directorate which controls the sort, the quality and the labelling of potatoes administers regulations on potatoes for breeding and for consumption.

Trans fatty acids

Effective January 1, 2004, Denmark introduced maximum levels of trans fatty acids in food to the ultimate consumer, such as cookies, biscuits, chocolate bars and popcorns for micro wave ovens. The maximum level for trans fatty acids is 2 grams per 100-gram oil/fat in all products sold to consumers. In products labeled "free of trans fatty acid" the maximum content is 1 gram per 100 gram of each single oil or single fat in the final product.

SECTION VII. OTHER SPECIFIC STANDARDS.

Vitamin and mineral enrichment requirements in foods.

The general conditions for adding of nutrients to foods are:

The added nutrients must fulfill the 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 a nutritional information.

Dietetic and special use foods.

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 harmonisation, 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, labelling and warnings. Other special use foods might exist. These will be subject to national regulations.

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 certifies the production. Third country inspection bodies must conform to 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 labelling purposes, if a part of the food production is carried out in Denmark (e.g. packaging process).

Health foods and Dietary supplements.Vitamins and minerals.

Vitamin and mineral supplements can be classified as food supplements as well as drugs (medicine) depending on their strength. A list of maximum value for each nutrient as dietary supplement exists. If the value exceeds the limit on the list, 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. Until detailed EC legislation is developed on this area it is possible to get a dispensation from the Danish Authorities.

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 published scientific data. Only recognised 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 recognised nutrients and certain specified sources of them are accepted. Products have to be notified and 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).

Herbal products.

These components can be classified as drugs (Danish Medicines Agency authorization) or as food supplements (no registration necessary) depending 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.

Special labelling requirements and mandatory warnings exist.

Section VIII COPYRIGHT AND/OR 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.

The sole and exclusive right of a trademark may be obtained by using the trademark or by registering it.

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. 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 2,350 (+ additional DDK 600 for certain products).

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

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 value added tax (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.

Appendix I GOVERNMENT REGULATORY AGENCY CONTACTS*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: fvst@fvst.dk

Publications:

IT- og Telestyrelsen
Holsteinsgade 63
DK-2100 Copenhagen O
Tel: +45 33 45 00 00
E-mail: itst@itst.dk

SECTION V:

The Danish Plant Directorate
Skovbrynet 20
DK-2800 Lyngby
Tel: +45 45 26 36 00
E-mail: pdir@pdir.dk

The Danish Environmental Protection Agency
Strandgade 29
DK-1401 Copenhagen 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 Copenhagen O ?
Tel: +45 35 46 60 00
Fax: +45 35 46 60 01

The Danish Medicines Agency
Axel Heides Gade 1
DK-2300 Copenhagen S
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Appendix II OTHER IMPORT SPECIALIST CONTACTS

Danish Veterinary and Food Administration, regional offices (responsible for import control and inspection):

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