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Food and Agricultural Import Regulations and Standards

Country Report Update

2000

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FAIRS REPORT ON DANISH FOOD LAW

SECTION I. FOOD LAWS

The Danish Veterinary and Food Administration is part of the Ministry of Food, Agriculture and Fisheries and was established July 1, 1997 by the merger of the National Food Agency and the Danish Veterinary Service. The aim of the merger was to co-ordinate, simplify, and increase the efficiency of both food inspection and food legislation. A single authority is thus now responsible for all inspection and control of food, from stable to table.

By providing information, advice and inspection, the Administration aims to ensure that consumers can enjoy wholesome food and that livestock is healthy and treated according to animal welfare regulations. This is the now the aim of Danish food policy.

The new Danish Food Act of 98.07.01. provides the foundation for the establishment of one overall national food and veterinary inspection authority. All inspection, etc., will be carried out by 11 district offices. These district offices will be established on the basis of the existing food inspection units and national supervisory authorities, i.e. regional and border veterinary service, meat inspection units and the relevant parts of the inspection system of the Danish Directorate for Fisheries and the Danish Plant Directorate. Following this amalgamation, which was enforced January 1, 2000, the Danish Veterinary and Food Administration employs a staff of around 2000 persons.

The Danish Food Act, which applies for all foods sold in Denmark will over time supersede the existing Food Act from 1973, which covers food in general as well as several specific food acts covering e.g. meat, eggs, fish and milk. This will gradually take place during the next years.

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, who inspect every food establishment authorised. That is producers, importers, wholesalers, catering establishments and retailers.

The enforcement of the regulations is further supported by the inspections the retailers organizations 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]

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.

Labeling of food additives (as such or in foods) is covered by a specific regulation on food additives.

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 cannot be a fantasy name, such as marsh mellows, but must describe the product in a proper way. 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 excepted 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 can not 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^2, 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 at several points. For example declaration of food additives in foods is different in naming, 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 into detail.

Country of origin must be declared, if exclusion of that information can mislead the consumer as to where the product origins. On the other hand 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 food additives 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 granting from the authorities, but the use allowed is very limited. Added nutrients can not be claimed on the label, but can only be declared in the ingredients list and in a 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]

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 prepared food.

Naturally occurring vitamins and minerals in the food can only be declared if they exceed 15% of ADT ("Anbefalet daglig tilførsel"/ Recommended daily intake) – the values of which differ to some extend 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, 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 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 on 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 fibre content can be claimed at a 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 with at least 50% *and* the energy content is reduced with 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 with at least 30% *and* the energy content is reduced with 30% as well, also compared to reference product.

Sodium. The term "light" is not recommended in connection with 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 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. That is the directives governing colors, sweeteners, flavors and miscellaneous food additives and in addition the labeling directive.

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 regulation of sulphur dioxide and sulphites, nitrate and nitrites tends to be more restricted than the EC-rules, as Denmark has used the derogation clause referring to consideration of public health. This is until further turned down by the Commission, but the case will be taken to court. In the meantime, the Danish retailers will only sell goods confirming with the proposed 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 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 food additive 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 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. 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. A guideline concerning the data requested is printed as an appendix to the food additives regulations.

Preservatives. Denmark has adopted 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 just refused to accept the Danish position. The issue will probably be tried at the EC court. Until the courts decision Denmark is obliged to accept the EC values 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]

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 control of residues in animal feed is conducted by *the Danish Plant Directorate*, and the control of foods is conducted by the *district offices* of food control.

The evaluation of new pesticides is conducted by the *Danish Environmental Protection Agency*, who also can inform 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. Besides 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.

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 can not 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.

Dioxin. Due to recent findings of PCB in foods from Belgium, focus has been set on contamination with dioxin. In the actual case the Danish Ministry of Food has issued a regulation on foods contaminated with dioxin, setting limits for PCB.

SECTION VII. OTHER SPECIFIC STANDARDS.

Weights and measures.
[Community regulation]]

Weights must be stated in metric system (weight or volume). 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 fulfil 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.

The total content (naturally occurring and added) of nutrients must be declared in the ingredients list and in a nutritional information.

Novel foods/ GMO´s.
[Community regulation]

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 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 contents of GMO in combined foods at a level below 1% need not be declared.

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 dietary uses.

Baby and infant formulas intended for healthy children, and Low Calorie Diets are subject to EC harmonisation, and these products need no specific approval prior to marketing.

Very Low Calorie Diets and special nutritional preparations are subject to a national registration procedure. The regulations cover standards and requirements regarding composition, labeling and warnings.

Organic foods.
[Community and national regulation]

A product can be marketed as organically grown or under given circumstances as organic ingredient in composite foods, provided the production is granted by an accredited inspection body. 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 purpose, if a part of the food production is carried out in Denmark (e.g. packaging or labeling process).

Health foods and Dietary supplements.
[National regulation]

<u>Vitamins and minerals.</u>
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 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 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 authorisation) 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.

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.

LIST OF DANISH AUTHORITIES

SECTIONS II, IV, V and VII:

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

Publications:
Statens Information
Nørre Farimagsgade 65
DK-1009 København 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: plantedir@plantedir.dk

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

SECTION VII:

The Danish Agency for Trade and Industry
Langelinje Allé 17
DK-2100 København Ø
Tel: +45 35 46 60 00
Fax: +45 35 46 60 01

The Danish Medicines Agency

Frederikssundsvej 378
2700 Brønshøj
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
Århus:	Tel: +45 89 44 33 23
Vejle:	Tel: +45 79 43 22 00
Esbjerg:	Tel: +45 79 16 12 00
Sønderjylland:	Tel: +45 73 53 16 00
Fyn:	Tel: +45 66 61 28 01
Ringsted:	Tel: +45 57 68 20 00
NordØstsjælland:	Tel: +45 44 52 30 00
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Bornholm:	Tel: +45 56 90 26 00