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Germany

Food and Agricultural Import Regulations and

Standards

Country Report

2003

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Report Highlights:

This report outlines the requirements for food and agricultural imports into Germany. The report aims to assist U.S. exporters with labeling, packaging, permitted ingredient list and other relevant information. It also provides points of contact for German government bodies and food laboratories.

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DISCLAIMER: This report was prepared by the USDA/Foreign Agricultural Service in Berlin, Germany, 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

Germany as a member of the European Union (EU) follows all EU directives, regulations and obligations. It is therefore recommended that this report is read in conjunction with the Food and Agricultural Import Regulations and Standards (FAIRS) report produced by the US Mission to the EU in Brussels, Belgium, available at www.useu.be/agri/usda.html as well as at www.fas.usda.gov/scriptsw/attacherep/default.asp.

The vast majority of food laws of the EU member countries have already been fully harmonized into EU law. Areas such as vitamins, minerals and other physiological substances as well as health claims are still awaiting EU harmonization. In the summer of 2003, the European Commission is expected to present a draft proposal for these open topics. Final harmonized EU rules are earliest to be expected by the end of 2004. Maximum tolerance levels for pesticide residues in foods and feeds are also not yet fully harmonized. For many substances Germany applies national tolerance levels, see

www.verbraucherministerium.de/verbraucher/verbraucherinfos.htm

Based on the EU single market principle, all food products legally imported and distributed in one member country of the EU can generally also be distributed in all other member countries, except in those cases when a country can prove health concerns about the product or an ingredient of a product intended for import. However, a separate application for approval of imports is still necessary for all those products containing substances not yet harmonized (Art. 47a LMBG - Basic German Food Law).

The German Food Law, hereafter referred to as the Food Law, consists of about 230 different ordinances, including the Food Labeling Ordinance, Packaging Ordinance, Dietetic Foods Ordinance, various hygienic and veterinary requirements, as well as numerous other special product or product group rules and regulations. The provisions on the Food Law are voluminous, frequently quite complicated and often subject to interpretation. Ultimately the German importer has final responsibility for the marketability of any imported products into Germany. The German law enforcement agencies hold the German importer solely responsible for any

violations of the Food Law since they cannot take action against foreign products including those in other EU countries. Violations of the Food Law by the importer constitute a punishable offence.

Basic regulations of the German food law are laid down in 61 articles of the Lebensmittel- und Bedarfsgegenstaendegesetz (LMBG), last amended September 1997. The act defines general food safety and health protection rules, addresses labeling requirements, regulates inspection, detention and seizure rules of suspect food. These rules apply to domestically produced as well as to imported food products.

The German Food Law is a federal law whose enforcement is the responsibility of the federal states (German Laender). This implies that on occasion, a minor infraction to the food law may be tolerated in one state but not in another. However, major violations are persecuted in all federal states. Domestic and foreign goods are equally being checked by random sampling methods by government laboratories at the point of sale. German government laboratories, in addition to looking for prohibited ingredients, evaluate the general nature of a product in terms of honest trading practices and general consumer expectations. Whenever, a product violates the Food Law and presents a risk to public health, regardless of whether it is a domestic or foreign product, this becomes known to the press which will mention the brand name, importer or producer when informing the consumer.

In 2003, the German government reformed and reorganized its consumer protection and food safety supervising systems. Prior to that, in 2001, the former Federal Ministry Food, Agriculture and Forestry had already been reorganized and gained responsibility for consumer protection issues and is now named Federal Ministry of Consumer Protection, Food and Agriculture. Responsible for monitoring compliance with German food law regulations under the supervision of the Federal Ministry of Consumer Protection, Food and Agriculture is

Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (BVL) (Federal Office of Consumer Protection and Food Safety) Rochusstrasse 65

53123 Bonn, Germany Tel.: +49 228 6198 0 Fax: +49 228 6198 120

E-mail: poststelle@bvl.bund.de
Homepage: www.bvl.bund.de

The BVL has been established as an independent higher federal authority and also meets tasks of risk management. BVL, inter alia, exercises authority over substances and products that harbor potential risks and that are directly or indirectly related to food safety (plant protection products and veterinary drugs).

It is involved in formulating general administrative rules to implement laws in the fields of consumer health protection and food safety, as well as in the preparation and monitoring of surveillance schemes and plans by the Laender. In addition, BVL acts as coordinator in the runup to inspections carried out by the European Food and Veterinary Office (FVO) in Grange,

Great Britain, and accompanies these inspections. It is responsible for implementing the European rapid alert system in the fields of consumer health protection and food safety in Germany. The national reference laboratory for the detection of residues and the Community reference laboratory for the detection of residues are also part of BVL.

Product registration is not required for foods in Germany. An official agency which could answer questions on the interpretation of Germany's extensive food law requirements for label registration, review, product clearance and approval does not exist in Germany. In some instances, German inspection agencies at the point of entry may require the importer to arrange for further inspection of an imported product to satisfy the importers' legal duty to exercise due care and diligence. To protect the consumer the importer may be required to engage a private food chemist to determine if the importers' product is free of illegal substances and residues. German importers frequently use the assistance of officially certified commercial food chemists. Fees for these services vary greatly, depending on the expertise and work required. (For a list of food laboratories see Appendix B - German Laboratories.)

Section II. Labeling Requirements

A. General Requirements

All imported food products must comply with the German Food Law. If any indication required under the German Labeling Regulation is missing, goods can be prevented from being sold. All foods must be labeled in German. Multi-language labels are allowed. Labeling can also include illustrations. It is forbidden to show ingredients on the label that are not contained in the product, e.g. illustrations of fruits if only artificial flavors are used or a multi-fruit juice may only show pictures of those fruits contained in the product. There are numerous other special labeling requirements pertaining to specific foods or food groups. Since many other requirements are applicable, such as the actual size of letters and placing of the various elements on the label and picture shown, U.S. food manufacturers and exporters are urged to contact their potential German importer before making changes in labels on products labeled for distribution in Germany.

Some importers may agree to adhering computer generated, **adhesive labels** in Germany for smaller quantities during a test-marketing phase.

All food and beverage products imported into Germany for retail sale must be labeled in German and provide the following information as laid down in the Lebensmittel-Kennzeichnungsverordnung (LMKV - Food Labeling Ordinance of Dec. 1999):

Name of the product as commonly used in the trade

This may be the name prescribed by law or a name customary in the area where the food is sold or a precise name to be distinguished from products with which it could be confused. The name may be a name or a description. Trade, brand or fantasy names are permitted but may not be substituted for the name of the food.

The product name, the statement of quantity and the indication of minimum shelf life (or a reference to it) must all appear in the same field of vision.

C List of ingredients and food additives

The list of ingredients should start with the word 'Zutaten'. Ingredients should be listed in descending order of weight as used at the time of preparation. Ingredients used in concentrated or dehydrated form and which reconstitute during preparation of the food may be listed as if reconstituted.

Certain ingredients may be designated by the name of their category group rather than the specific name. These include refined vegetable oils excluding olive oil, refined fats, flour blends, starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose sirup, milk protein, cocoa butter, crystalized fruit, vegetables and wine. The sequence listing for coloring agents is free.

• Quantitative ingredient declaration (QUID)

If in a label, special emphasis is placed on the presence of an ingredient, the minimum amount as a % must be declared either next to the name of the food or near the name of the ingredient in the ingredient list

Alcohol content

Alcoholic beverages containing more than 1.2% alcohol measured at 20 degree Celsius, need to be shown as 'Alkohol (or alc.) ...% vol'

Uncoded minimum shelf-life date (interpreted as the date until which the product maintains its maximum level of quality under proper storage conditions). The words to be used are 'Mindestens haltbar bis ...' Determination of the minimum shelf-life lies entirely in the hands of the manufacturer or importer.

Declaration of minimum shelf-life is not necessary for fresh fruits and vegetables, alcoholic beverages of more than alc. 10%, portioned ice cream, table salt, crystal sugar, flavored and/or colored sugar candies, chewing gum, wine-like beverages.

If the product for microbiological reasons may cause a health threat after a certain storage period, it has to carry an uncoded latest consumption date using the words 'verbrauchen bis ...'

• Storage Conditions

Any special storage conditions or conditions of use should be stated. Instructions for use should be given as necessary.

C Metric units for all measurements

Net quantity of prepackaged food stuffs expressed in metric units (liter, centiliter, mililiter, kilogram or gram)

C Name and address of manufacturer, packer or importer in Germany/EU

Coded lot identification

A coded lot identification is needed for all products which do not show a minimum shelf-life containing day and month identification. The marking shall be preceded by the letter 'L' except in cases where it is clearly distinguishable from other indications on the label.

Bar codes

Germany uses the European Article Number (EAN) also refered to as International Article Number (IAN) system with 13 digits while the U.S. uses Universal Product Codes (UPC) with 12 digits. U.S. bar codes will work perfectly in Germany and other EU countries.

B. Medical / Health Claims

Health Claims

Medical claims or images attributing to a foodstuff the property of preventing, treating or curing human diseases are explicitly prohibited in the German/EU labeling directive. This rule does not apply to dietetic foods.

Dietetic Foods Ordinance:

The German Dietetic Food Law defines the properties foods must have in order for the manufacturer to label them as dietetic. It requires that foods and beverages labeled as dietetic must differ substantially from other regular foods. A simple listing of the nutrient content, bread units, and/or caloric value on the label is not sufficient to allow the use of the term "dietetic." Health-related statements are strictly limited. Examples for such statements are:

Diaetetisches Lebensmittel geeignet zur Behandlung von ...

(Dietetic food suited to cure ...)

Diaetetisches Lebensmittel geeignet zur Behandlung von ... nur unterstaendiger aerztlicher Kontrolle verwenden.

(Dietetic food suited to cure ... only use if under continuous medical supervision) zur besonderen Ernaehrung bei ... im Rahmen eines Diaetplanes (special diet for ... if part of a diet plan)

It is strongly recommended that U.S. exporters consult with a German food laboratory before making any dietary claims for products to be marketed in Germany.

Nutritional Value Labeling Ordinance:

Nutritional value labeling is not mandatory in Germany and other EU countries unless a nutrition claim is made on the label or in advertising messages. The EU NutritionalValue Labeling Directive 90/496/EEC establishes rules for the separate labeling of the caloric and nutritional values of foods. Though not mandatory for all foods, it establishes certain conditions which must be fulfilled if the industry wishes to provide information that either emphasize a particularly low caloric content or a particularly high nutritional value of a certain food.

Where nutritional labeling is provided, the information to be given should consist of either of the following orders:

- the energy value, plus the amount of protein, carbohydrates and fat or
- the energy value, plus the amount of protein, carbohydrates, sugar, fat, saturates, fibre and sodium.

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance.

The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser.

Section III. Packaging and Container Regulations

A. Consumer Packaging Ordinance and Law on Weights and Measures:

The German Law on Weights and Measures provided the legislative basis for the *Consumer Packaging Ordinance (CPO)*. It contains certain provisions establishing standard sizes for containers of pre-packaged foods, as well as numerous labeling and gauging requirements for consumer-ready containers. The quantity of fill must be indicated when marketed.

By weight:	In grams or kilograms.
By volume:	In milliliters, centiliters or liters.
By length:	In centimeters or meters.
By area:	In square centimeters or square meters.

For solid food packed in "liquid," the drained weight must be shown in addition to the total quantity of fill. The CPO provided for minimum heights of numbers is used on the label designating the quantity of fill. The Container Ordinance lays down specific container sizes (either mandatory or recommended) for individual products. As the main purpose of packaging material is to protect the contained product, the size of packaging must not be misleading to the consumer and must not lead to the expectation of a higher than actual fill.

Mandatory container sizes are established for following product groups

Wine, incl. Fruit wine

Beer

Liquer

Milk

Water

Lemonade

Fruit juice

Sugar

Chocolate

Cocoa

In addition to the EU mandatory container sizes, Germany permits additional national container sizes for the different product groups.

Underfilling tolerances are strictly regulated.

Container Size in g or ml	Permitted Negative Tolerance	
	in % of Quantity	in g or ml
5 to 50	9	-
50 to 100	-	4.5
100 to 200	4.5	-
200 to 300	-	9
300 to 500	3	-
500 to 1000	-	15
1000 to 10000	1.5	-

An over-filling or under-labeling of the actual container fill is not generally prohibited. However, based on the regulations of the German competition law a regular over-filling which is not technically necessary may be judged as misleading and challenged by competitor companies.

B. Materials in Contact with Foodstuffs

Regulations for materials in contact with food have been EU-harmonized, see www.useu.be/agri/packaging.html. EU directives have been transfered into German law and are laid down in the 'Bedarfsgegenstaendeverordnung'. Materials in contact with foodstuffs have to bear an indication 'fuer Lebensmittel' which can be replaced by a specific symbol designated in Council Directive 80/590/EEC.

C. Packaging Disposal Regulations:

Germany is widely regarded as being in the forefront of European environmental legislation, including that on packaging. There has been longstanding public concern over the excessive use of packaging material in Germany.

The German Packaging and Waste Avoidance Law

With the tremendous growth of waste and disposal problems, Germany has established legislation to keep packaging separate from the municipal waste stream and shift the responsibility for waste disposal over to the retailers and distributors by forcing them to take back used packaging materials and to handle disposal or recycling or institute a nation-wide system to collect and recycle packaging waste. The "Duales System Deutschland" (DSD) was established by the German industry to certify product packaging materials which could be recycled, reused or otherwise legally disposed of independent of the existing public waste disposal system. Participating companies receive guaranteed pick up, on a regular basis, of their materials against a license fee. DSD set up a nation-wide collection system for packaging materials carrying the "Der Gruene Punkt"-symbol. Under this law German consumers collect packaging material other than paper and glass in a separate container system to be picked up on a

regular schedule by contract companies of the DSD. Paper and glass are collected in public containers located at designed locations spread all over the metropolitan areas.

Green Dot System

Because the German Packaging and Waste Avoidance Law established specific rules for packaging material the "Green Dot" (Der Gruene Punkt) system was developed. The "Green Dot" is a recycling symbol which is found on the packaging material of virtually all products retailed in Germany. While packaging material for products retailed in Germany is not legally required to carry the "Green Dot," it is almost impossible to market a product in Germany without it. Typically, the producer or the importer pays a licence fee to use the Green Dot, dependent on the type and amount of packaging, and provides the exporter with the information necessary.

For further information on the Green Dot packaging material disposal and recycling program you may wish to make direct contact with your potential German importer and/or with the following company:

Duales System Deutschland GmbH (DSD)

Frankfurter Strasse 720-726 Tel: (49-2203) 937-0

D-51145 Koeln, Germany Fax: (49-2203) 937-190 or 495

Internet: www.gruener-punkt.de

Mandatory Refund for One-way Beverage Packages

As of Jan 2003, a mandatory refund system was put in place for one-way beverage packages. The refund is collected at the retail level and applies to domestically produced or filled products as well as to imported drinks. Excluded from this refund system are primarily multi-layer carton packages since they are regarded to be the least environmentally disturbing. Wine, spirits and milk are also excluded from the refund system.

Section IV. Food Additives Regulation

Food additives have been already fully harmonized within the EU, see www.useu.be/agri/additive.html. German and EU food law prohibits all food additives or other substances which are not specifically approved for use. With the exception of a smaller number of additives, which are approved for general use, most food additives are only approved for specific purposes and foods.

The German definition of "food additive" is fairly broad. "Technical aid substances" are substances required only during the processing of a food product and tolerated if either totally removed or technically unavoidable during the processing. Labeling of technical aid substances is not required. The use of food additives, food coloring substances, artificial sweeteners and preservatives is regulated by the Food Additives Ordinance. Only certain food additives are approved for use with foods, and only under conditions specified in this ordinance. Food

additives must appear clearly visible on the label, written in easily legible print (minimum character height of 2mm) and in combination with the product name or identification.

Vitamin - Enriched Foods

The use of vitamins is still awaiting EU harmonization. The German Bill on Food Vitaminization establishes rules for the use of vitamins in foods. Vitamin-enriched foods must be clearly labeled in the list of ingredients or immediately next to the trade name of the product. The label must indicate the type of vitamin and the quantity based on 100 grams of food. The following vitamins may be freely added to any type of food and must be shown in the list of ingredients, but need not be shown as food additives.

E 301 Sodium-L-Ascorbate:

E 302 Potassium-L ascorbate,

Calcium-L-ascorbate:

E 304 Ascorbyl Palmitate;

Thiamin-chloride-hydrochloride;

Thiamin nitrate;

Riboflavin-5-phosphate-sodium;

Pyridoxin-hydrochloride;

Sodium-and-calcium-D-pantothenate;

alpha-and-beta-tocopherylacetate;

alpha-and-beta-tocopherysuccinate;

Nicotinic acid (Niacin) and

Nicotinic acid amid.

The following vitamins can only be added to specific foods with given limitations:

Vitamin-A-acetate and

Vitamin-A-palmitate;

Ergocalciferol,

Cholecalciferol,

Cholecalciferol-cholesteric.

Since vitamins are not yet harmonized importation of modern food supplements such as vitamin concentrations may require a special import permit for Germany if the product is already legally marketed in another EU-country. As a rule of thumb, German authorities only tolerate a vitamin concentration of three times of the daily recommended allowance (RDA). However, upon specific request higher vitamin concentrations may be tolerated if a risk assessment approves this approach.

Section V. Pesticides and other Contaminants

To date, only about 30 percent of the tolerance levels for pesticide residues have been

harmonized within the EU. The German Pesticide Residue Bill establishes maximum tolerances for a large number of pesticides in foods derived from both animals and plants. It also includes tolerances for a considerable number of pesticides which are not approved for use in Germany, and thus allows the importation of certain foods and food products which have been treated with certain pesticides approved for use in the country of origin, as long as such foods meet the established German maximum tolerances.

A list of the most recent approved maximum residue levels is available on the homepage of the German Federal Ministry of Consumer Protection,

www.verbraucherministerium.de/verbraucher/verbraucherinfos.htm click on Verbraucherinfos' click on Lebensmittelrecht'
Rueckstands-Hoechstmengenverordnung'

For application of an import tolerance for a not yet regulated substance contact the

Federal Ministry of Consumer Protection, Food and Agriculture Referat 313 - Rueckstaende u. Kontaminanten in Lebensmitteln Rochusstr. 1

53123 Bonn, Germany Tel.: +49 228 529 4659 Fax: +49 228 529 4262

Internet: www.verbraucherministerium.de

Section VI. Other Regulations and Requirements

A. Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. In case of non-compliance, the EU hygiene directive (Com. Reg. 93/43/EEC) allows the Commission to suspend imports from third countries or introduce special conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized, but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses (Council Directives 89/397/EEC and 93/99/EEC). Specific detailed inspection requirements exist for animal products. Inspections are done under supervision of a veterinarian at a limited list of ports and border inspection posts.

Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards. Details about the conformity checks are laid down in EU regulation 1148/2001. These have been established for apples and pears, apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, brussels sprouts, cabbage, carrots,

cauliflowers, celery, cherries, citrus fruit, courgettes (zucchini), cucumbers, garlic, kiwis, leeks, lettuce, curly and escarole chicory, melons, onions, peaches and nectarines, peas for shelling, plums, spinach, strawberries, sweet peppers, table grapes, tomatoes, watermelons, witloof chicory, for miniature produce, walnuts and hazelnuts. Marketing standards can be downloaded from www.useu.be/agri/Fruit-Veg.html

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described below.

Inspection fees differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see section 7). The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this request has to be sent to the Commission's Health and Consumer Protection Directorate. Importers of organic products (see section 7) are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses (see section 7) needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

B. Certification and Documentation Requirements

AGRIM Certificates

The EU requires import licences (AGRIM certificates) for most agricultural products for which it provides market support, including grains, milk, meat, olive oil, most fruits and vegetables, wine and sugar. In order to obtain a licence, an application form must be submitted and security fee must be paid to the issuing Member State. Licences vary in validity with most expiring three months after the month of issuance.

Health Certificates

Plant Products www.useu.be/agri/plantcertif.html

Phytosanitary certificates issued by APHIS have to accompany fruit, vegetable and nut shipments to the EU.

Animal Products www.useu.be/agri/certification.html

The European Community is in the process of harmonizing legislation on imports of animal products. This is a three-stage process that starts with the recognition of a country to export a certain animal product. The U.S. is recognized by the EU for nearly all animal products.

In a second stage, lists of EU approved establishments are drawn up in recognized countries. 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 can take several months. At present, the following products must come from an EU-approved establishment:

red meat	ratites	equine semen
meat products	bovine embryos	animal casings
farmed game meat	bovine semen	fish and fishery products
wild game meat	porcine semen	milk & milk products
gelatin		

Lists can be accessed through www.useu.be/agri/estab.html

The third level is the requirement that all shipments be accompanied by animal health and/or public health certificates signed by U.S. officials to guarantee that individual lots or shipments of products meet Community requirements.

For other products the Community has not yet completed harmonization of import requirements. In these cases import regulations are still under the control of the individual Member States. This often results in the 15 Member States maintaining different sets of lists of third countries, lists of establishments, certificate requirements, and inspection programs.

Contact information for the agencies issuing export certificates is available from our website.

Processed Foods www.useu.be/agri/foodcertif.html

All animal products imported into the EU need animal or public health certification. For processed foods containing animal product, 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 necessitate certification. However, the specific EU legislation applicable to the animal product in question contains certain provisions on certification.

Red meat & poultry meat: Products containing <u>any amount</u> of red meat or poultry meat must be certified.

Egg products & dairy: Certification of products containing egg products or dairy products depends on the composition of the product in relation to the definitions in the relevant Community legislation.

As a rough guideline, if foodstuffs contain more than 50 percent egg products/dairy products, the Commission believes they should be considered as such. More details are available from the above shown website. Further, the competent authorities of the importing EU Member State

should be contacted for their interpretation of the Commission's guidelines.

Although there are no harmonized EU certificates for processed foods such as canned vegetables, soup broths, etc., EU member states often require that shipments be accompanied by a certificate signed by U.S. officials. Exporters should check with their importer or with the Office of Agricultural Affairs in the importing Member State to determine which documentation is required.

Section VII. Other Specific Standards

A. Genetically Modified Foods

German/EU politicians claim that German/EU consumers oppose foods derived from genetically modified plants. Whether such a statement is true or not can not be verified since no such labeled products are on the market. Since 1998 a defacto moratorium for further approvals of GMO events is in place in the EU with the result that no food products containing GMOs are being imported. In July 2003, the EU finalized new legislation for labeling GMO derived food and feed products and for implementing a tracing system identifying what kind of GMO events have been used in the production of the food/feed product. First such labeled products are expected to appear on retail shelves by the spring of 2004. Since the EU will require a process labeling approach it will not be necessary any longer that GMOs can actually be found in the final product such as refined oils or sugars. The new regulations require that an adventitious presence of more than 0.9 percent GMO in one single ingredient has to be labeled on the final product, see also www.useu.be/agri/GMOs.html

Relevant authority for the approval of new GMO event and the monitoring of trade with products derived from GMOs is the Federal Ministry of Consumer Protection, Food and Agriculture, see Section I

B. Novel Foods

Novel foods and feeds are not only products derived from GMOs. This term also applies to food and feed products actually new to the EU. These can be exotic fruits and juices which have not to a significant extent been marketed in Europe. The EU novel food regulation requires an evaluation process for these novelties including a risk assessment process. Just recently, nonijuice and a DHA rich oil extracted from the algae schizochytrium sp. received EU approval.

C. Functional Foods - Food Supplements

The problem of functional foods in many cases is its definition and demarcation from pharmaceutical products which require special product approval, foods don't. A recent German Federal Court ruling determines that products may be classified as foods if a pharmaceutical effect is not evident to the consumer and consumers do not expect pharmaceutical effects if they consume the product according to the producers dosage advice. In particular, the improvement of physical fitness and muscle-building with the assistance of foods and/or food supplements is

increasingly regarded as a positive effect of food intake.

D. Animal Products

Meat and poultry (including game and fowl) products can only be imported from U.S. plants approved by the European Union (EU). All meat products (beef, pork, veal, lamb, etc.) in any form (including canned, frozen, soups, stews, etc.) must also be accompanied by the following certificates issued at the slaughtering or processing plant by a U.S. Department of Agriculture meat and poultry inspector.

FSIS Form 9060-5	Meat and Poultry Export Certificate of Wholesomeness
MP 150	Animal Health Certificate
MP 157	Public Health Certificate
MP 410-10	Beef and Other Meats
MP 410-11	For Processed Meats Only
MP 410-12	For Pork Products Only
MP 410-13	Domestic Ruminants *Hormone-Free Certification

All poultry products (chicken, turkey, duck, quail, etc.) must be accompanied by the following products:

FSIS Form 9060-5	Meat and Poultry Export Certificate of Wholesomeness
MP 70	Sanitary Certificate
MP 58	Fresh Poultry
MP 59	Processed Poultry Products

Beef labeling

In the EU, a compulsory beef labeling scheme has been in place since September 2000. Full implementation of the beef labeling scheme went into effect on January 1, 2002. Under this scheme, labels for all bovine meat must indicate the following information:

- "geboren in: name of third country" born in
- "gemaestet in: name of third country or third countries" reared in.
- For beef derived from animals born, raised and slaughtered in the same third country, the above indications may be combined as "Origin: name of third country"

- a reference number ensuring the link between the meat and the animal or animals
- "geschlachtet in: third country / approval number of slaughterhouse"
- "zerlegt in: third country / approval number of cutting plant"
- A traceability code linking the meat to the animal or a group of animals representing the production of maximum one day.

In addition to the compulsory labeling program, the German food industry initiated a 'Quality and Safety' program (QS) which shall assure the consumer that the production of such labeled products is fully controlled and recorded based on legal requirements and additional industry-determined production process criteria. The quality and safety program is certified by the German government. Since the German farmers' association as well as processors and retailers strongly encourage participation in this system it is highly likely that QS labeled meat will soon be the standard product.

QS Qualitaet und Sicherheit Margarethenstr 1 53175 Bonn (Friesdorf) Phone +49 228 350680 Fax +49 228 3506 810 Dr. Hermann-Josef Nienhoff nienhoff@q-s.de www.q-s.info

Meat and Poultry - Import Derogation for Product Samples:

Companies planning to exhibit or send meat samples to Germany in any form must request a derogation from the German government prior to shipping the product samples. All beef product samples must be hormone-free and must have a certification stating that the product has not been treated with hormones. An address list of relevant authorities to request a derogation is shown in the Market Brief 'German Food and Veterinary Agencies', report no.: GM9027. The report can be found on the FAS-homepage: www.fas.usda.gov.

E. Seafood Products

Seafood products can only be imported from U.S. firms approved by the Food and Drug Administration. All seafood must be accompanied by certificates issued by the U.S. Food and Drug Administration, Division of Seafood district office or the National Marine Fisheries Service, U.S. Department of Commerce district office. For information on certification requirements for *seafood products to the EU* contact the FDA Office of Seafood Programs on Tel: (202)418-3150; Fax: (202)418-3196. The address is 200 C Street SW, Washington, DC 20204.

On retail level fishery products have to be labeled with origin indication and production method:

"gefangen in ..." (caught in ... catch region) or

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"aus Binnenfischerei in ..." (caught in freshwater in ... country) or "aus Aquakultur in ... " (farmed in ... country) or "gezuechtet in ... " (cultivated in ... country).
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F. Fruits and Vegetables:

Fresh fruits and vegetables and unprocessed/raw nuts must be accompanied by a U.S. Department of Agriculture phytosanitary certificate or PPQ577. The certificate is issued upon inspection of the commodity being exported to determine that it is free of insects, plant diseases, and other organisms considered harmful by the receiving country. The phytosanitary certificate must be issued by an official USDA Animal, Plant Health Inspection Service (APHIS) inspector. To arrange for an inspection you must make a written application to your nearest APHIS office. For more information on the phytosanitary certificate contact USDA/APHIS PPQ (Plant Protection and Quarantine), 4700 River Road, Unit 140, Riverdale, MD 20737, Tel: (301) 734-8537, Fax: (301) 734-5786.

G. Frozen Foodstuffs

The German Frozen Food Ordinance of October 1991 (Verordnung ueber tiefgefrorene Lebensmittel (TLMV)) sets the rule that quick frozen foods have to be kept at minimum minus 18 degrees Celsius at any time. In addition to the normal label information, the frozen food has to show following terms: 'tiefgefroren', 'tiefgekuehlt', 'Tiefkuehlkost' or 'gefrostet'; the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required, the indication 'nach dem Auftauen nicht wieder einfrieren' (do not freeze after defrosting) and a batch identification.

H. Irradiation of Food for Sterilization:

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval, see www.useu.be/agri/irradiation.html. In Germany, treatment with ionizing rays is only permitted for dried aromatic herbs and spices and for monitoring purposes. Ultraviolet rays may be used to sterilize drinking water, fruit surfaces and hard cheese during storage. Treated products have to be labeled as 'bestrahlt' or 'mit ionisierenden Strahlen behandelt'.

Treated herbs and spices or products containing treated herbs and spices imported from a non-EU country have to be accompanied by a certificate providing the name and address of the treatment installation, type of treatment, company name ordering the treatment, recipient of the treated products, date of treatment, type of packing material during treatment, parameters describing the supervision of the treatment process and validated test results.

I. Organic Foods

Foodstuffs which shall be marketed as organic products have to meet requirements laid down in EU Council Directive 2092/91 amended by Regulation 1804/99 to include livestock products. Responsible for the implementation of these regulations are the EU member countries, see also www.useu/be/agri/organic.html. Applications for import authorizations of organic products into Germany should be directed to

Bundesanstalt fuer Landwirtschaft und Ernaehrung

Ferdinand-Lasalle-Str. 1-5 53168 Bonn, Germany Tel.: +49 228 6845 332 Fax: +49 228 6845 787

Internet: www.ble.de
Contact: Klaus Budde
Mail: klaus.budde@ble.de

APPENDIX A - List of Major Regulatory Agencies

Bundesministerium fuer Verbraucherschutz, Ernaehrung und Landwirtschaft

(Federal Ministry of Consumer Protection, Food and Agriculture

Rochusstr. 1

53123 Bonn, Germany Tel: (49-228) 529-0 Fax: (49-228) 529-4262

Homepage: http://www.verbraucherministerium.de

Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit

(Federal Office of Consumer Protection and Food Safety)

Rochusstr. 65

53123 Bonn, Germany Tel: (49-228) 6198 0 Fax: (49-228) 6198 120

E-mail: poststelle@bvl.bund.de
Homepage: http://www.bvl.bund.de

Robert-Koch-Institut

(responsible for registration and approval of novel foods)

Nordufer 20

13353 Berlin, Germany Tel: (49-30) 45474 Fax: (49-30) 4547-2328 E-Mail: Zentrale@rki.de Homepage: http://www.rki.de

Biologische Bundesanstalt fuer

Land- und Forstwirtschaft

(Federal Biological Research Institute - approval of plant protection chemicals)

Messeweg 11/12

38104 Braunschweig, Germany

Tel: (49-531) 2995 Fax: (49-531) 299-3000 E-mail: <u>Pressestelle@bba.de</u> Homepage: http://www.bba.de

APPENDIX B - German Food Laboratories

Bundesverband der Lebensmittelkontrolleure Deutschlands (BVLK)

(Federal Association of Food Chemists in Germany)

Herderstr. 1a

38350 Helmstedt, Germany Tel.: (49-5351) 595301 Fax: (49-5351) 595302

E-mail: <u>lebensmittelkontrolleure@t-online.de</u>
Homepage: http://www.lebensmittelkontrolle.de

The federal association of food chemists in Germany is in the position to provide assistance in finding a licenced food laboratory who will assist in developing proper food labels and determine whether the product meets German/EU food regulations.

Following is a partial list of food laboratories for your information only with the understanding that no discrimination is intended and no guarantee of reliability implied.

Analytec Labor fuer Lebensmitteluntersuchung

Laufener Str. 83

83395 Freilassing, Germany

Tel: (49-8654) 62322 Fax: (49-662) 438102 E-mail: office@analytec.de

Homepage: http://www.analytec.de

Analytisches Institut Wulf Bostel

Florianstr. 13

70188 Stuttgart, Germany Tel: (49-711) 285280 Fax: (49-711) 2852855 e-Mail: <u>institut@bostel.de</u>

Homepage: http://www.bostel.de

Arotop Food Creation GmbH & Co. KG

Dekant-Laist-Str. 9 55129 Mainz, Germany Tel: (49-6131) 583800 Fax: (49-6131) 5838080

E-mail: arotop@arotop.de

Homepage: http://www.arotop.de

Institute for taste research, development of new products, food monitoring, analytical food chemistry, food judgement, national and EG legal requirements, representations before authorities and court cases, expert certifications.

Chemisches Laboratorium Luebeck GmbH

Hochofenstr. 23-25

23569 Luebeck, Germany Tel: (49-451) 307840 Fax: (49-451) 307-8449 E-mail: info@cll-gmbh.de

Homepage: http://www.cll-gmbh.de

Dr. Fintelmann und Dr. Meyer

Handels- und Umweltschutzlaboratorien GmbH

Mendelssohnstrasse 15D 22761 Hamburg, Germany Tel: (49-40) 899 664 0 Fax: (49-40) 899 664 50

E-mail: info@inlabco.com

Homepage: http://www.inlabco.de

GeneScan Europe AG

Engesserstr. 4

79108 Freiburg, Germany Tel.: (49-761) 5038 0 Fax: (49-761) 5038 111 E-mail: info@genescan.com

Homepage: http://www.hanse-analytik.de

Food laboratory also specialized in testing for gene-modified ingredients.

ICCS International Commodity Control Services GmbH

Brook 1

20457 Hamburg, Germany Tel: (49-40) 3698290 Fax: (49-40) 36982920

E-mail: germany@controlunion.com
Homepage: http://www.iccshamburg.com

Quality control organization.

Institut Fresenius

Im Maisel 14

65232 Taunusstein, Germany

Tel: (49-6128) 744-0 Fax: (49-6128) 744-890 E-mail: <u>info@fresenius.com</u>

Homepage: http://www.institut-fresenius.de

Dr. Kaiser & Dr. Woldmann GmbH

Stresemannstrasse 313 a 22761 Hamburg, Germany Tel: (49-40) 8530-40

Fax: (49-40) 8530-4222

E-mail: gomolzig@novalytik.de
Homepage: http://www.alge.de

Dr. Mielke & Streck

Kleine Johannisstr. 20 20457 Hamburg, Germany Tel: (49-40) 3741210

Fax: (49-40) 366835

E-mail: MSA-lawyer@t-online.de

Law firm providing specialized assistance in questions of food advertizing and labeling from a legal perspective. Long standing experience with numerous U.S. firms in various food and agricultural fields. Excellent English services.

SGS Controll-Co. mbH

Raboisen 28

20095 Hamburg, Germany

Tel: (49-40) 301010 Fax: (49-40) 326331

E-mail: sgscontroll germany@sgs.com

Homepage: http://sgs.com

Member of the world's largest private testing and certifying organization with 205 offices in 140 countries. Food Lab analysis, residue testing, organic certification and cargo certification.

German headquarters is in Hamburg.

Dr. Specht & Partner Chemische Laboratorien GmbH

St. Anscharplatz 10 20354 Hamburg, Germany Tel: (49-40) 300 86 0

Fax: (49-40) 300 86 101 E-mail: <u>info@labor-specht.de</u> Homepage:http://labor-specht.de

Sweet Service GmbH

Auf dem Troppenbruch 7 52146 Wuerselen, Germany

Tel: (49-2405) 94055 Fax: (49-2405) 95543

Specializes in sweets; assists with product's basic marketing ability, labeling, evaluation of ingredient listing, acceptability of the labels, organization of official chemical tests.

Dr. Helmut Weiss Handelslabor

Spaldingstr. 130

20097 Hamburg, Germany

Tel: (49-40) 233429 Fax: (49-40) 230912

Dr. Wessling Laboratorien GmbH

Oststrasse 7

48341 Altenberge, Germany

Tel.: (49-2505) 896 25 Fax.: (49-2505) 896 20

E-mail: <u>Im-labor@wessling-gruppe.de</u> Homepage: http://www.wessling-gruppe.de

Dr. Wiertz-Dipl. Chem. Eggert-Dr. Joerissen GmbH

Stenzelring 14b

21107 Hamburg, Germany

Tel: (49-40) 7527090 Fax: (49-40) 75270935 E-mail: info@wej.de

Homepage: http://www.wej.de

Experts for foodstuffs, dried fruits, fats, oils, oilseeds, animal feeds, drugs, radio-activity measurements, microbiology of foods, drinking & process water, trade & residue analysis, sampling, consulting, quality assurance.

APPENDIX C - World Trade Organization (WTO) Enquiry Point

Each member government is responsible for the notification procedures associated with the agreement under the World Trade Organization (WTO). Examples here relate to the Sanitary and PhytoSanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include notifying any trade significant proposals which are not substantially the same as international standards to the WTO, providing copies of the proposed regulation upon request, allowing time for comments, and also providing upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on the country's regulations, standards and certification procedures can also be obtained through the Enquiry Point(s) listed below:

Deutsches Informationszentrum fuer technische Regeln (DITR) (German Information Centre for Technical Rules)
Burggrafenstr. 4-10
10772 Berlin, Germany

Tel: (49-30) 2601-600 Fax: (49-30) 2601-1231

E-mail: postmaster@din.de

Homepage: http://www.ditr.din.de

The DITR is being established by DIN, the German Standards Institute, in co-operation with the Federal Government. This body is the central point to which to address all questions concerning technical rules in the Federal Republic of Germany.

The Centre provides information on all technical rules (including standard, technical regulations and certification systems) valid in the Federal Republic of Germany, irrespective of whether the technical rules have been issued by federal or local authorities or by non-governmental bodies. At present the computer-aided DITR databank has information on 36,000 technical rules either in force or in the draft stage.