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Germany

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

Approved By:

Bobby Richey, Jr.

Prepared By:

Dietmar Achilles

Report Highlights:

The 2009 FAIRS Annual Report contains a number of editorial updates and new paragraphs about the voluntary labeling option “without biotech” and a proposed new system for nutritional labeling.

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.

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.

Section I. Food Laws

The vast majority of food laws of the EU member countries have already been fully harmonized into EU law. Regulations governing vitamins, minerals and other physiological substances as well as health claims are still awaiting final EU harmonization. **A partial list of permitted substances has already been approved at the EU level, however, a list of maximum levels of vitamins and mineral still needs to be worked out.** A Commission proposal in this area was released in early 2009 but no decision has been taken. The EU is currently in the process of developing a uniform list of permissible health claims. In 2008, EU member states generated their national lists of health claims which are now under consideration of the European Food Safety Agency (EFSA). EU law requires that the harmonized EU list of health claims has to be finalized by the end of January 2010. Maximum tolerance levels for pesticide residues in foods and feeds have been harmonized in 2008.

Maximum tolerances set for mycotoxins in grains, grain products and coffee have been harmonized in the EU and went into effect in 2006. National German maximum levels for DON, ZEA, fumosins and ochratoxin have been replaced by the new EU levels.

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 of 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 producers 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. In addition to the LMBG, in 2005 Germany developed a central Food and Feed Law Book (Lebensmittel-, Bedarfsgegenstaende- und Futtermittelgesetzbuch - LFGB), providing basic definitions, procedural rules and goals of the German food law. Both acts define general food safety and health protection rules, address labeling requirements, regulate 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 or any other point in the trade chain or at the processing location. German government laboratories, in addition to looking for prohibited ingredients or proper labeling, 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. A general administrative agreement regarding food safety requires German food safety authorities to take five samples per thousand inhabitants annually. This includes samples at any location of the production and trade chain.

The responsible agency for monitoring compliance with German food law regulations is BVL. It is under the supervision of the Federal Ministry of Food, Agriculture and Consumer Protection.

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

Bundesallee 50

38116 Braunschweig

Tel.: +49 531 21497 0

Fax: +49 531 21497 299

E-mail: poststelle@bvl.bund.de

Homepage: www.bvl.bund.de

The BVL was established as an independent higher federal authority and is also responsible for 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 (such as 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 run-up to inspections carried out by the European Food and Veterinary Office (FVO). 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. The importer may engage a private food chemist to determine if the product is free of illegal substances and residues and labeled properly. 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 affix 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-Kennzeichnungs-Verordnung (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.

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 syrup, milk protein, cocoa butter, crystallized fruit, vegetables and wine. While required, there is no regulation

covering the order of coloring agents.

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.

Metric units for all measurements

Net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram)

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

Coded lot identification

A coded 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 referred 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. Health / Medical 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. An EU harmonized regulation on health claims was finalized in 2006. The European Food Safety Agency (EFSA) is currently in the process of evaluating the claims applied for approval and has not yet published a list.

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:

Diaetisches Lebensmittel geeignet zur Behandlung von ...

(Dietetic food suited to treat ...);

Diaetisches Lebensmittel geeignet zur Behandlung von ... nur unter staendiger aertzlicher Kontrolle verwenden; and

(Dietetic food suited to treat ... 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 unless a nutrition claim is made on the label or in advertising messages. The EU Nutritional Value 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 emphasizes 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 one of the following: the energy value, plus the amount of protein, carbohydrates and fat; or the energy value, plus the amount of protein, carbohydrates, sugar, fat, saturated fats, fiber 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.

In 2007, the German government unveiled a national action to plan to deal with the increasing weight problems among the German population. The plan, called the "4 plus 1" model, calls for nutrition labeling guidelines encompassing education and information on diet, physical activity and health. It also recommends expanded nutritional information on the caloric content and levels of sugar, fat, saturated fatty acids and salt in food products complemented by a color marker green, yellow or red. The implementation of a mandatory nutritional labeling system is still being deliberated in the German government. Consumer organizations favor and demand a traffic light labeling system as promoted by the UK Food Standards Agency for the following components: fat, saturated fatty acids, sugar and salt.

Section III. Packaging and Container Regulations

A. Consumer Packaging Ordinance and Law on Weights and Measures

The German Law on Weights and Measures provides 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 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, liqueur, milk, water, lemonade, fruit juice, sugar, chocolate and 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. 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.

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	-

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 transferred 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 Waste Recycling - Green Dot System

Amendments to the German Packaging and Waste Avoidance Law requires importers of consumer products, including food stuffs, to enter into a contract for recycling of packaging material with one of the licensed national recycling companies. Traditionally, the German industry has been using the "Green Dot" symbol to assure that packaging material will be recycled in a controlled system. The "Green Dot" is found on the packaging material of virtually all products retailed in Germany. As of January 1, 2009, the new recycling law no longer requires that the "Green Dot" to be printed on product packaging to prove that the material will be recycled in a proper manner. However, if the manufacturer or the importer chooses to continue using the Green Dot symbol, a licensing contract needs to be signed with the Duales System Deutschland GmbH (DSD).

Since the Green Dot symbol is also used in other European countries, it is recommended to have the symbol printed on the package. Typically, the national producer or the importer pays a license fee to use the Green Dot, depending on the type and amount of packaging being used. It also provides the exporter with the information necessary for price calculation.

For further information on the Green Dot packaging material disposal and recycling program contact your potential German importer and/or one of the following companies, which are registered as Green Dot recycling enterprises.

Der Grüne Punkt – Duales System Deutschland GmbH, Köln - www.gruener-punkt.de
BellandVision GmbH, Pegnitz - www.bellandvision.de
EKO-PUNKT GmbH, Mönchengladbach - www.eko-punkt.de
INTERSEROH Dienstleistungs-GmbH, Köln - www.interseroh.de
Landbell AG, Mainz - www.landbell.de
Redual GmbH & Co. KG, Köln - www.redual.de
Vfw GmbH, Köln - www.vfw-gmbh.eu
Verlo GmbH & Co. KG, Dormagen - www.verlo.org
Zentek GmbH & Co. KG, Köln - www.zentek.de

Mandatory Deposit System for One-way Beverage Packages

As of May 2006, a Germany-wide uniform mandatory refund system was put in place for one-way beverage packages with a content volume of 0.1 to 3.0 liter. The deposit is collected at the retail level and applies to domestically produced or bottled products as well as to imported beverages.

Excluded from this deposit system are containers holding: fruit and vegetable juices and nectars; milk and milk mix beverages containing minimum 50 percent milk; dietetic drinks, except for special sports beverages; spirits and wine including mix drinks containing minimum 50 percent wine; and multi-layer carton packages since they are regarded to be the least environmentally

disturbing.

The refund option has to be shown on the label. Detailed information about the deposit system is available through the DPG Deutsche Pfandsystem GmbH.

DPG Deutsche Pfandsystem GmbH

Luisenstr. 46

10117 Berlin, Germany

Tel.: +49 30 800 974 0

Fax: +49 30 800 974 111

www.dpg-pfandsystem.de

info@dpg-pfandsystem.de

Section IV. Food Additives Regulations

Food additives are fully harmonized within the EU, see www.useu.be/agri/additive.html. However, the EU is currently in the process of amending the directives on additives, colors and sweeteners to bring these several directives together into one single regulation. 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

Regulations governing the use of vitamins in food preparation are still awaiting final EU harmonization. The basic rules for foods containing added vitamins are defined in Regulation EC 1925/2006. The European Commission is committed to provide a draft list of prohibited substances, substances with limited use, and substances which are under EU consideration by January 2009. The German Bill on Food Vitamin Fortification 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 added to any type of food preparation 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-tocopherylacetae
alpha-and-beta-tocopherysuccinate
Nicotinic acid (Niacin)
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 fully 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 the recommended daily 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

Tolerance levels for pesticide residues were harmonized within the EU in 2008.
An EU database on pesticide MRLs is available at
http://ec.europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm.

For application of an import tolerance for a not yet regulated substance in Germany contact the BMELV.

Federal Ministry of Food, Agriculture and Consumer Protection
Referat 313 - Rueckstaende u. Kontaminanten in Lebensmitteln
Rochusstr. 1
53123 Bonn, Germany
Tel.: +49 228 529 4661
Fax: +49 228 529 4262
Internet: www.bmelv.de

The responsible agency for scientific evaluation of pesticide residues in Germany is the Bundesamt

fuer Verbraucherschutz und Lebensmittelsicherheit (BVL).

Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (BVL)
(Federal Office of Consumer Protection and Food Safety)
Bundesallee 50
38116 Braunschweig
Tel.: +49 531 21497 0
Fax: +49 531 21497 299
E-mail: poststelle@bvl.bund.de
Homepage: www.bvl.bund.de

Special Industry Standards for Pesticide Tolerance Levels

Since 2007, a private environmental protection organization has been intensively testing fruits and vegetables for pesticide residues. Test results are announced in press statements, which continue to receive nationwide attention. In reaction to this development, the leading German retail chains implemented stringent quality control requirements. Under these private requirements, pesticide residue levels should not exceed 70 percent of the permitted legal levels. Reports indicate that suppliers violating the new contract standard are at risk to be delisted from the approved suppliers list of the particular retail chain.

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 (see also Section 1 – Food Law).

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.

On July 1, 2009, Commission Regulation 1221/2008 entered into force. This regulation repeals existing marketing standards for 26 products (apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, Brussels sprouts, carrots, cauliflowers, cherries, courgettes (zucchini), cucumbers, cultivated mushrooms, garlic, hazelnuts in shell, headed cabbage, leeks, melons, onions, peas, plums, ribbed celery, spinach, walnuts in shell, water melons and chicory) and replaces them with a general marketing standard. Specific marketing standards, set out in Part B of Annex I to Regulation 1221/2008, are being maintained for 10 products: apples, citrus fruit, kiwi fruit, lettuces, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes. Fruit and

vegetables not covered by a specific standard must conform to the general marketing standard. Products that are in conformity with any applicable standards adopted by the United Nations Economic Commission for Europe (UNECE) will be considered as conforming the general marketing standard. Marketing standards include criteria such as quality, size, labeling, packaging and presentation and can be downloaded from www.useu.be/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 less likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see Section VII). 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 VII) 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 VII) 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 licenses (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 license, an application form must be submitted and security fee must be paid to the issuing Member State. Licenses vary in validity with most expiring three months after the month of issuance. The license is applied for by the importer.

Health Certificates

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

Phytosanitary certificates issued by APHIS have to accompany plant, fruit, vegetables 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 AND STAMPED 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 27 Member States maintaining different sets of lists of third countries, lists of establishments, certificate requirements, and inspection programs.

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 any amount 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.

Other processed products: 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 Engineered Foods and Feeds

German/EU politicians claim that German/EU consumers oppose foods derived from genetically engineered plants. Whether or not such a statement is true cannot be verified since there are very few products labeled as “genetically modified” on the market. Since 1998, a de facto moratorium for further approvals of genetically engineered events has been in place in the EU, restricting the importation of bulk corn and other products. In April 2004, the new EU legislation for labeling food and feed products derived from genetically engineered plants, and for implementing a tracing system became effective. Under the EU labeling regulations, processed products produced from biotech crops, such as soybean oil, must have a “GMO” label even though no “GMOs” are present in the final processed product. The new regulations require that an adventitious presence of more than 0.9 percent genetically engineered material in one single ingredient has to be labeled on the final product. See www.useu.be/agri/GMOs.html.

The relevant authority for the approval of new biotech events and for monitoring the trade of products derived from biotechnology is the Federal Ministry of Food, Agriculture and Consumer Protection. See Section I.

In Germany effective July 2008, a new labeling option claiming that the food has not been derived from biotech plants has been available. The label “without biotech” is voluntary and the German government and NGOs hope that the food industry develops a new third product market aside from conventional and organic foods where the consumer can choose between biotech-free and biotech food products.

In order to better identify products labeled “without biotech” the German Federal Ministry of Food, Agriculture and Food Safety launched a new logo which can be used cost-free by food companies. So far, only a very small number of companies have made use of the German labeling option “without biotech.”

B. Novel Foods

Novel foods and feeds are not only products derived from biotechnology. 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.

C. Functional Foods – Food Supplements

In Germany, the marketing challenge of functional foods in many cases is its definition and demarcation from pharmaceutical products, which require special and specific product approval. A German Federal Court ruling determined that products may only 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. German consumers

increasingly associate the improvement of physical fitness and muscle-building with functional food and/or food supplements. German health authorities carefully monitor this to prevent abuse of these products.

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.

Certificates necessary for red meat exports to Germany

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 certificates.

Certificates necessary for poultry and poultry product exports to Germany

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 2000. Under this scheme, labels for all bovine meat must indicate the following sets of information.

1. "geboren in: name of third country" - born in
"gemaestet in: name of third country or third countries" - reared in
2. 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"

3. 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) to 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 an approved certification organization. The objective of the QS system is to render foodstuff production processes transparent to consumers from the field and stable to the sales counter, thus increasing consumer confidence in the production, processing and marketing of foodstuffs. The system is open for domestic and imported products.

QS Qualitaet und Sicherheit

Margarethenstr 1

53175 Bonn (Friesdorf)

Phone +49 228 350680

Fax +49 228 3506 810

info@q-s.info

www.q-s.info

- Meat and Poultry - Import Derogation for Product Samples:

Sample shipments of food products containing meat, poultry or cheese from plants not approved for export to the EU require a derogation (special import permit) from the (state) veterinary authority at the first port of entry into the European Union. For shipments to Germany, this is often Frankfurt airport. Frankfurt airport is located in the State of Hesse; consequently, the veterinary office in Wiesbaden, the capital of Hesse, is responsible for issuing the import permit.

Hessisches Ministerium fuer Umwelt, laendlichen Raum und Verbraucherschutz

(Ministry of Environment, Rural Regions and Consumer Protection of the State of Hesse)

Mainzer Strasse 80

65189 Wiesbaden, Germany

Tel.: +49 611 815 1465

Fax: +49 611 44789 770

E-Mail: veteinfuhr@hmulv.hessen.de

The request for derogation can be made informally by letter, fax, or email stating the quantity, origin, and composition (e.g. raw or cooked meat) of the product as well as the intended purpose (machinery testing, trade show display, product competition, etc.) and place of destination. Based on this information the veterinary office will issue the import permit, specifying the veterinary certificates they require in that particular case.

The import permit is in German and the veterinary office charges a small fee. Because of language, time difference, and distance (the permit will be sent by commercial mail), it is recommended that the German recipient of the product handle the application for the import permit, wherever feasible. If the point of entry is different from Frankfurt, please contact AgBerlin for information on the applicable veterinary office.

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. See USEU website: <http://useu.usmission.gov/agri/seafood2.html>.

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

"gefangen in ..." (caught in ... catch region) or
"aus Binnenfischerei in ..." (caught in freshwater in .. country) or
"aus Aquakultur in ..." (farmed in ... country) or
"gezuechtet in ..." (cultivated in ... country).

F. Fruits, Vegetables and Nuts

Fresh fruits and vegetables and unprocessed/raw nuts must be accompanied by a U.S. Department of Agriculture phytosanitary certificate 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.

Almonds must be accompanied by a Voluntary Aflatoxin Sampling Program – VASP certificate issued by laboratories approved for the VASP program. Peanuts must be tested and certified prior to export based on the EU Pre-Export Certification Program.

G. Frozen Foodstuffs

In contrast to fresh fruits and vegetables frozen foodstuffs do not require phytosanitary certificates. See EU Directive 2000/29.

H. Irradiation of Foodstuffs 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.

Other EU Member States are much more liberal with regard to the use of ionizing rays. The Official Journal of the European Union No. C112/6 provides a detailed list of products, which may be ionized, including poultry and chicken meat. See http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/c_112/c_11220060512en00060007.pdf.

Per special approval, it is possible that ionized products legal in other EU Member States may be imported into Germany. Applications need to be directed to BVL.

Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (BVL)
(Federal Office of Consumer Protection and Food Safety)
Bundesallee 50
38116 Braunschweig
Tel.: +49 531 21497 0
Fax: +49 531 21497 299
E-mail: poststelle@bvl.bund.de
Homepage: www.bvl.bund.de

I. Organic Foods

Foodstuffs which shall be marketed as organic products have to meet requirements laid down in EU Regulation 2092/91 amended by Regulation 1804/99 to include livestock products. Imports of organic products are regulated by EU Regulation 1991/2006. 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 BLE.

Bundesanstalt fuer Landwirtschaft und Ernaehrung (BLE)
Deichmannsaue 29
53179 Bonn, Germany
Tel.: +49 228 6845 3332
Fax: +49 228 6845 3787
Internet: www.ble.de
Contact: Klaus Budde
Mail: klaus.budde@ble.de

Appendix I. Government Regulatory Agency Contacts:

A. List of Major Regulatory Agencies

Bundesministerium fuer Ernaehrung,
Landwirtschaft und Verbraucherschutz, BMELV
(Federal Ministry of Food, Agriculture and Consumer Protection)
Rochusstr. 1
53123 Bonn, Germany
Tel: (49-228) 529-0
Fax: (49-228) 529-4262
Homepage: <http://www.bmelv.de>

Bundesamt fuer Verbraucherschutz und Lebensmittelsicherheit (BVL)
(Federal Office of Consumer Protection and Food Safety)
Bundesallee 50
38116 Braunschweig
Tel.: +49 531 21497 0
Fax: +49 531 21497 299
E-mail: poststelle@bvl.bund.de
Homepage: www.bvl.bund.de

The biotech division and the novel foods/feeds division of BVL are responsible for registration and approval of biotech products and novel foods.

B. List of German Food Laboratories

Analytec Labor fuer Lebensmitteluntersuchung
Laufener Str. 83
83395 Freilassing, Germany
Tel: (49-8654) 62322 (German line)
Fax: (43-662) 434 109 19 (Austrian line)
E-mail: office@analytec.de
Homepage: <http://www.analytec.de>

Arotop Food & Environment GmbH
Dekan-Laist-Str. 9
55129 Mainz, Germany
Tel: (49-6131) 583800
Fax: (49-6131) 5838080
E-mail: arotop@arotop.de
Homepage: <http://www.arotop.de>

Eurofins Analytik GmbH
Wiertz-Eggert-Joerissen
Neulaender Kamp 1
21079 Hamburg, Germany
Tel: (49-40) 492 940
Fax: (49-40) 492 94 111
E-mail: info@wej.de
Homepage: <http://www.wej.de>

GeneScan Analytics GmbH
Engesserstr. 4
79108 Freiburg, Germany
Tel.: (49-761) 5038 200
Fax: (49-761) 5038 111
E-mail: info@genescan.com
Homepage: <http://www.genescan.com>

SGS Institut Fresenius GmbH
Im Maisel 14
65232 Taunusstein, Germany
Tel: (49-6128) 744-0
Fax: (49-6128) 744-9890
E-mail: info@institut-fresenius.de
Homepage: <http://www.institut-fresenius.de>

Dr. Wessling Gruppe
Oststrasse 6
48341 Altenberge, Germany
Tel.: (49-2505) 896 25
Fax.: (49-2505) 896 20
E-mail: info@wessling-gruppe.de
Homepage: <http://www.wessling-gruppe.de>

C. World Trade Organization (WTO) Inquiry Post

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, 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.

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 was 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.