

**A Guide to Importing and Exporting Prepared Food Products:
What American Exporters and Importers Should Know**

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Abstract

Food is regarded to be one of the most important necessities throughout the world. It is food that brings the world together, and it is food that drives the relationships of all nations. Because food borne illness may result in sickness and even death, food safety regulations have been at the forefront of agricultural trade and remain an important issue in the importation and exportation of prepared food products. Many of these regulations have not only been promulgated by individual countries, but have also been established by the World Trade Organization in the hopes of preventing food borne illnesses. Although many issues regarding prepared food are similar, different regions deal with these issues in different manners. Countries have developed many rules and regulations covering prepared food imports and exports. American producers must understand and follow many of these rules and regulations to be able to import and export prepared food products. This paper seeks to provide a guide American exporters and importers can use when trying to ensure their final products follow food safety standards and prevent difficulties in importing and exporting prepared food. This paper will first examine packaging requirements the United States imposes on all imported prepared food products. Next, this paper will examine four topics including packaging, labeling, additives, and certificates across four major trading regions: Europe, Asia, Australia/New Zealand & Africa, and the Americas. Important differences within a particular region are highlighted.

In a globalizing economy, manufacturing and packaging have taken a central role in effective cost management and compliance for import/export companies. The Food and Drug Administration (“FDA”) consider these issues a matter of public safety. For example, a multi-national corporation with manufacturing operations in another country can potentially source human resources, equipment and packaging suppliers within that country at a lower cost than it would in the United States. However, as these companies cut their costs, how many have standard operating procedures (“SOP’s”) in place to effectively manage the risk in manufacturing and importing or exporting prepared food products? One can imagine disastrous scenarios involving non-compliant food products exported to the United States, but consider having an entire product line recalled from the market for safety issues and a manufacturing plant being closed for failure to follow good manufacturing practices (“GMP’s”) or a lawsuit resulting from a product that was packaged in a plastic not approved by the FDA. This section will discuss manufacturing equipment, processing and packaging regulations for prepared foods and how the FDA implements those regulations in the United States.

PREPARED FOOD MANUFACTURING

The Bioterrorism Preparedness and Response Act of 2002, an amendment to the Food, Drug & Cosmetic Act (“FD&C”), details new regulatory requirements for manufacturers, processors, packers and holders of food products for introduction into the United States.¹ First, these types of facilities must register with the FDA’s Center for Food Safety and Applied Nutrition (“CFSAN”) regardless of whether they are foreign or domestic facilities. Registration may be completed in an FDA Form 3537. The FDA implements this registration through Code

¹ See generally Federal Food Drug and Cosmetics Act, as amended by, Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C. 301 *et seq.* (2002).

of Federal Regulations, 21 C.F.R. Part 1 Subpart H. A registering facility must provide information as to the type of food category(s) that the facility handles, in addition to its mailing address and legal structure. Foreign facilities have the additional requirement of appointing a U.S. registered agent for its facility.² Practitioners should be mindful that although this is a painless formality, failure to register a facility with the FDA may cause a shipment to be detained and refused entry.³

On the other hand, there are certain facilities that are exempt from registration under Subpart H because they do not manufacture, process pack or hold “food” as defined under 21 U.S.C. § 321(f).⁴ Thus, manufacturers, processors, packers and holders of only Food Contact Substances (“FCS”) are not required to register their facility with the FDA because they only manufacture the packaging materials and not food. Regulations pertaining to these types of manufactures will be discussed in more detail herein.

The regulatory structure of the manufacturing regulations is primarily found within 21 C.F.R. Part 110. The regulations are divided into three main sections: building and facilities, equipment and production and process controls.⁵ The regulations only serve as a general guide to compliant manufacturing of prepared food products.

The building regulations prescribe the manner in which manufacturing facilities should be constructed and methods for ensuring sanitary operations and controls. For example, a

² 21 C.F.R. §1.232(c).

³ 21. U.S.C. §801(l).

⁴ *See* 21 C.F.R. § 1.227(b)(4).

⁵ *See generally* 21 C.F.R. Subparts A, B, C and E. (2008).

building must be inspected inside and outside, literally, in order to prevent contamination of the food therein. Outside inspections include adequate maintenance of drainage disposal systems, removal of litter, weeds and grass that may become a breeding ground for microorganisms that can contaminate food.⁶ Indoor inspections include interior drainage systems, backflow of waste pipes into pipes that deliver water to food, covering of equipment and ensuring adequate space between walls and equipment so as to provide ample space for cleaning.⁷

Subpart C to Part 110 governs equipment and utensils. All equipment must be of such grade and workmanship that it will preclude the adulteration of food with which it comes into contact.⁸ Each surface that food comes into contact with must be corrosion-resistant.⁹ Subpart C also discusses the seams on food contact surfaces, manufacture systems, coolers, freezers and measuring utensils. The regulations merely prescribe that all of these components must be kept free from the growth of microorganisms, food additives or anything that would risk contamination and adulteration. How a company may implement the appropriate safeguards is as much a scientific and engineering issue as it is legal. Thus, an attorney for a food manufacturer should frequently consult with its client's resident scientists and engineers, or outside professionals, to determine the types of equipment that present the biggest risk of contamination.

⁶ 21 C.F.R. § 110.20. (2008)

⁷ *Id.*

⁸ 21 C.F.R. § 110.40(a).

⁹ *Id.*

The processing and control regulations detail the manner in which food products are to be manufactured from treating the raw materials through the manufacturing processing.¹⁰ For example, the water used to clean the raw materials must come from a sanitary source and be disposed of in a way that does not risk cross-contamination of other flowing water.¹¹ All products that are stored in a cooler must be kept at 45 degrees Fahrenheit [7.2 degrees Celsius] and all frozen goods must be kept in a frozen state.¹² Section 110 also details temperature requirements on heated foods. Throughout the manufacturing processes, food will almost always come into contact with machines composed of metal and other extraneous items that migrate into the food. Manufacturers must ensure that this risk is guarded against through the use of magnets, metal detectors or any other device that will remove such metals or extraneous items.¹³

PACKAGING

The registration requirements and the equipment and manufacturing regulations discussed above lay the foundation for the packaging regulatory construct. Packaging in prepared food products are known as “indirect food additives.” The FD&C defines a food additive as, “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or other affecting the characteristic of any food; if such substance is not Generally Recognized As Safe (“GRAS”) or sanctioned prior

¹⁰ 21 C.F.R. § 110.80

¹¹ 21 C.F.R. § 110.80(a)(1)

¹² 21 C.F.R. § 110.80(b)(3)

¹³ 21 C.F.R. § 110.80(b)(8)

to 1958 or otherwise excluded from the definition of food additives.¹⁴ Thus, an indirect food additive is defined as food additives that come into contact with food as part of the packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. The finished packaging product is known as a food contact article (“FCA”).

The FDA recognizes a hierarchy in the process to manufacture FCA’s. At the top of the hierarchy is the food contact substance (“FCS”). A FCS is defined under section 409 of the FD&C as “any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.¹⁵” A FCS is the subject of a food contact notification (“FCN”), which is a prior notice by the manufacturer of the *identity* of the FCS, products intended use, *specifications* and *limitations* on the conditions of use.¹⁶ If the FDA does not object with-in the prescribed 120 day period, the FCS may be used.¹⁷

However, FCN’s are specific to the manufacture, meaning that a FCS for an effective FCN must be obtained from the manufacturer that submitted the effective notification. This is an important compliance regulation for practitioners to note, because often times companies may find it more cost effective to use an identical approved FCS made by a cheaper vendor. This type of business decision contravenes section 409(h)(2)(C) (21 U.S.C. § 348(h)(2)(C)), which

¹⁴ Federal Food, Drug and Cosmetics Act § 201, 21 U.S.C. § 321(s) (2008).

¹⁵ Federal Food, Drug and Cosmetics Act § 409, 21 U.S.C. § 348 (2008).

¹⁶ See Center for Food Safety and Applied Nutrition “Food Substances Notification Program,” www.cfsan.fda.gov. (last visit July 20, 2008).

¹⁷ See 21 C.F.R. § 170.104.

states that an FCN is effective for the manufacturer and a similar or identical substance prepared by another manufacturer is not permitted.

A FCN must comply with the requirements of 21 C.F.R. Part 170. Only one FCS may be used per FCN application. However, if multiple uses of the same FCS are being submitted for approval, then all intended uses may be included on a single application. Receipt of the application will be acknowledged by the FDA in writing and a 120-day period to object will commence.¹⁸ If the application is incomplete or withdrawn, then the 120-day period will toll pending completion of the application or resubmission with additional data.¹⁹

Additionally, the FCN must contain all relevant chemistry and toxicology information.²⁰ Any laboratory data which may appear inconsistent with the manufacturer's determination that the FCS is safe must be explained away in the FCN application. A statement of good laboratory practice must also be provided for every non-clinical study conducted to support the FCN. Also, the applicant must submit information concerning the FDA's responsibility under the National Environmental Policy Act, either in the form of a categorical exclusion or an environmental assessment in compliance with 21 C.F.R. § 25.40. If a manufacturer receives approval, the next step is to convert the FCS into an FCA; typically through the use of food contact material.

Food contact material ("FCM"), which is made from an FCS and other substances such as an antioxidant in a polymer. Thus the FCM is a further processed version of the FCS. At the

¹⁸ 21. C.F.R §170.104.

¹⁹ *Id.*

²⁰ See Form FDA 3480, available at: www.fda.gov. (last visit July 21, 2008).

bottom of the hierarchy is the finished product known as a food contact article (“FCA”). This is the finished film, tray or container that is made from the FCM. One example of this is diethylhexyl adipate (“DEHA”). DEHA is commonly used in cling food wrap and FDA approved for that intended use.²¹ Dioxins are a class of potentially harmful compounds that were incorrectly linked to food wraps and microwavable containers.²² Dioxins are produced when the specimen is heated at 700 degrees Fahrenheit or over.²³ This next subpart will discuss how practitioners may ensure their clients are in compliance with the packaging regulations.

When approached by a client with an FCS that it wishes to use, the first place to begin is to consult 21 C.F.R. Parts 174-179 to determine if the use is currently a regulated indirect food additive. These regulations discuss food additives generally and go into detail as one progresses through the regulations. Within these parts, the regulations are divided into subcategories including, *inter alia*, the following: components used for adhesives, components for coatings, components used for paper and paperboard, polymers and irradiation used on packaged food products.²⁴ If a client’s FCS is listed within Parts 174 through 179, then it must meet the *identity, specifications* and *limitations* on the conditions of its use. This information is listed in tables found in the regulations.

If the FCS is not regulated in Parts 174-179, then one must consult 21 C.F.R. Parts 182-186 to determine if the component is Generally Recognized as Safe (“GRAS”). Part 182 details

²¹ Society of the Plastics Industry, *Busting Myths about Plastics*, available at: www.plasticsindustry.org/industry/mythbusters.htm. (last visit July 20, 2008).

²² *Id.*

²³ *Id.*

²⁴ *See generally*, 21 C.F.R. Parts 174-179.

the general provisions for various GRAS substances including direct and indirect food additives. Part 186 concerns only indirect food additives. Most if not all GRAS substances contain no limitations on use or are limited to good manufacturing practices (“GMP”). Nonetheless, if the FCS is found on the GRAS list, it must meet the *identity, specifications* and *limitations* on its intended use. Manufacturers may also inform the FDA of their own GRAS determinations via a GRAS notice.²⁵ The FDA will respond accordingly and, if approved, the new GRAS substance will be available on the CFSAN website under “Summary of all GRAS Notices.”²⁶

In the event that the FCS is not listed as GRAS, the next step is to determine if the use of the component is prior sanctioned. Prior sanctioned components are those which were approved by the FDA prior to the enactment of the FD&C in 1958.²⁷ These components may be found in Part 181 to the Code of Federal Regulations. If the component meets the *identity, specifications* and *limitations* on its intended use, then no further action is necessary.

If the component is not prior sanctioned or does not meet the regulations on its intended use, then the levels of the component found in the packaged item must be ascertained and checked against the Threshold of Regulation Exemptions (“TRE”). TRE lists substances which are exempt from a petition or FCN as the substance forms a component of food at levels below the threshold of regulations.²⁸ If a manufacturer is unsure of his or her client’s compliance in

²⁵ *Determining the Regulatory Status of Components of a Food Contact Material*, Center for Food Safety and Applied Nutrition, available at: www.cfsan.fda.gov. (last visit, July 20, 2008).

²⁶ See generally, www.cfsan.fda.gov. (last visit July 20, 2008).

²⁷ See Federal Food, Drug and Cosmetic Act § 409(s)(4), 21 U.S.C. § 321(s)(4) (2008).

²⁸ See 21 C.F.R. Part 181.

this department, a request for exemption may be submitted pursuant to 21 C.F.R. § 170.39. Once again, the substance must meet the *identity, specifications* and *limitations* contained within the regulations.

Should the FCS exceed the criteria found under the TRE and it is not prior sanctioned, the FDA maintains a list of the FCN's which have been applied for and approved.²⁹ This list provides the date of submission, the FCS at being applied for, the manufacturer and any objections issued by the FDA.³⁰ The FCN's are specific to the manufacture (proprietary) and thus any approved FCS must be obtained from the manufacturer and be traceable to that manufacturer.

If your client cannot satisfy any of the above-referenced categories, then there are three more expensive alternatives. The first is to submit a TRE and prove to the FDA's satisfaction that the FCS at issue is safe and comprises such small component of the food that it should be recognized as exempt. The second option, which has been discussed above, is to submit an FCN to establish the FCS as safe when used for a specific purpose and subject to those conditions and limitations on its use. The third option is to satisfy the criteria for GRAS status, which may require different methods of chemical engineering to manipulate the FCS to conform to the regulations.

For those manufacturers of various FCA's, there exists an additional compliance tool that may be used called a Food Contact Formulation Notification ("FCF"). An FCF is used to verify

²⁹ *Determining the Regulatory Status of Components of a Food Contact Material*, Center for Food Safety and Applied Nutrition, available at: www.cfsan.fda.gov. (last visit July 22, 2008).

³⁰ *Id.*

compliance with a FCM (food contact material).³¹ These manufacturers are not seeking to prove the safety of the FCM, but rather they seek to establish that the components being added to the FCS are legal and do not authorize the creation of a new FCS. Thus, an FCF can be used to circumvent the need to submit an FCN, thereby reducing the production burden and potentially saving professional expenses. An FCF is submitted on an FDA Form 3479.

Practitioners should be conscious of the fact that the food safety industry is constantly changing, and thus, the FDA publishes many notices on several databases that do not necessarily make their way to the Code of Federal Regulations. For example, the Priority based Assessment of Food Additive database (“PAFA”) is CFSAN’s “institutional memory” for administrative chemical and toxicological effects of indirect and direct food additives.³² Within PAFA lies the “Everything Added to Food in the United States” database (“EAFUS”). EAFUS is a more comprehensive list in that it displays information on all food and color additives, GRAS and prior sanctioned substances.³³ There is also the Select Committee On GRAS Substances (“SCOGS”) which is a pact between the FDA and the Life Sciences Research Office of the Federation of American Societies for Experimental Biology. This committee independently performs safety and health reviews of the GRAS substances in evaluations known as “SCOGS reports.”³⁴

³¹ *Id.*

³² *Food Ingredients and Packaging Terms*, Center for Food Safety and Applied Nutrition, available at www.cfsan.fda.gov. (last visit July 23, 2008).

³³ *Id.*

³⁴ *Id.*

In conclusion, FDA practitioners must be aware of the comprehensive nature of the food safety regulations as they address food safety from the manufacturers facility to its equipment and all the way down to the papers, plastics, and other FCA's that are produced. These regulations are administered by the FDA's Center for Food Safety and Applied Nutrition. The above described process is the approach recommended by the FDA on its website and provides practitioners with a systematic approach to indirect food additive compliance. The food safety regulations worldwide may vary as to certifying substances that can be used on prepared food products and thus practitioners should be weary of the fact that just because the FDA authorizes an FCS or a GRAS substance, another corresponding agency in a different country or trading bloc may prescribe different regulations. Finally, a close eye should be kept on these regulations and databases maintain by the FDA to keep updated on modifications or additions to the indirect food additive list.

The U.S. State Department recognizes 194 countries in the world. This means that there are at least 194 sets of regulations with which an American exporter of food would need to comply. It would be impractical for a food producer to know all 194 sets of regulations and maintain 194 different procedures for production. Having to comply with only a handful of regulations with would simplify the production and export process. That is the goal of this paper.

This paper will examine four topics: packaging, labeling, additives, and certificates. These topics will be contrasted across four major trading regions: Europe, Asia, Australia/New Zealand & Africa, and the Americas. Important differences within a particular region will be highlighted.

The U.S. Certificate Program

Regardless of the destination of the food, the exporter should be aware of the available sources of law for food-importing nations and the procedures that need to followed in the U.S. to

effect compliant exports. The USDA and FDA administer a joint program that certifies food for export.³⁵

FDA will not certify that U.S.-produced food is in compliance with a foreign nation's laws.³⁶ Instead, FDA issues a certificate that affirms that the product was manufactured and marketed in the United States.³⁷ The certificate also states that the manufacturer does not have any unresolved enforcement actions by the FDA.³⁸ Known as a Certificate of Free Sale, the certificate is accepted by many foreign nations as congruent compliance with their own laws.³⁹ A list of foreign countries that require a Certificate of Free Sale can be found at <http://www.fas.usda.gov/scripts/w/attacherep/default.asp>. FDA-CFSAN or the individual state governments may issue these certificates.

The certificate does not pertain any particular lot or consignment and is valid for two years.⁴⁰ CFSAN charges \$10 for most types of certificates and takes between three and eight weeks to process.⁴¹

³⁵ Food Export Certificate Project, USDA Foreign Agricultural Service, found at <http://www.fas.usda.gov/itp/ofsts/exportcertif/intro.asp>, last visited July 14, 2008.

³⁶ FDA-Issued/Supported Export Certificates for Foods, U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, found at <http://www.cfsan.fda.gov/~lrd/certif3.html>, last visited July 14, 2008.

³⁷ Export Certificates for Foods and Cosmetics: Questions and Answers, U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, found at <http://www.cfsan.fda.gov/~lrd/exp-cert.html>, last visited on July 14, 2008.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

When applying for a certificate, the exporter will need to complete form FDA 3613e.⁴²

Generally speaking, the form requires this information:

1. original label(s),
2. additional information, if needed, to identify the product(s),
3. identification of the manufacturer,
4. information on where the certificate should be sent, and
5. affirmation of compliance with 18 USC 1001.

Europe

European Union regulations have probably been the leading edge of international food regulation. With 27 member nations in one trading bloc (comprising nearly all of Europe and diverse in language and culture), it was obviously necessary for the EU to standardize as much of the import regulations as possible. This section reviews the EU standards and makes note of significant areas of exception of which the U.S. food importer needs to be aware.

The EU's regulations seem to be the most transparent and accessible to U.S. food exporters compared to the rest of the world. The EU makes its regulations accessible on the internet at <http://eur-lex.europa/en/index/htm>. The USDA Foreign Agricultural Service also summarizes and updates EU food import regulations via Global Agriculture Information Network (GAIN) Reports. However, the USDA warns that U.S. exporters should always verify compliance with the EU regulations with the EU importer and that although the EU has, in most

⁴¹ *Id.*

⁴² *Id.*

cases, promulgated the rule, it is up to the importing country's interpretation of the rule that will determine admissibility.

Harmonization of EU member food safety began with the EU's White Paper on Food Safety in 2000. The White Paper recommended creation of a body, later known as the European Food Safety Authority, which would provide independent scientific advice and communication on European food issues.⁴³ The White Paper looked to take a "farm to table" approach covering all areas of labeling, packaging, production, marketing, and emergency response.⁴⁴

EU Rules come in two forms: Directives (which states a desired result but leaves the method of implementation up to the member states) and Regulations (which have the force of law and are binding on all member states). It is important for the exporter to note the difference when reviewing these rules.

Labeling

Directive 2000/13 sets out much of the general provisions on the labeling rules. It is important to note that the standard compliant U.S. label does not comply with EU labeling laws. Therefore, the exporter must take note of the EU requirements and be prepared to make adjustments for EU-bound food.

2000/13 requires the following:

-The product's name (under which it is sold)

-The list of ingredients (in order by weight)

⁴³ White Paper on Food Safety, Commission of the European Communities (12 January 2000).

⁴⁴ *Id.*

Some ingredients need not be listed specifically but may be listed as general categories.

They are: fats, oils, starch, fish, cheese, spices, herbs, gum base, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables, and wine.

-The quantity of the item, in metric units.

-Special conditions relating to storage or use.

-Name and address of the manufacturer, packager, or vendor within the EU.

-Details on origin where the absence of such information might tend to mislead the consumer.

-The lot number, preceded by the letter “L”.

-The date of minimum durability.

This date must be in day-month-year format. For highly perishable foods, the date must be preceded by the words “Use by”. Other foods must use the words “Best before.”

Quantitative Ingredients Declaration (QUID)

Article 7 of Directive 1979/112 states:

1. Where the labeling of a foodstuff places emphasis on the presence or low content of one or more ingredients which are essential to the specific properties of the foodstuff, or where the description of the foodstuff has the same effect, the minimum or maximum percentage, as the case may be, used in the manufacture thereof shall be stated.

The Directive established a requirement for a Quantitative Ingredients Declaration, or QUID. A QUID is a declaration, in percentage form, of essential ingredients of a foodstuff. It is required when:

1. The ingredient appears in the name of the foodstuff
2. The ingredient is usually associated with the name of the foodstuff
3. The ingredient is emphasized on the label via words, graphics, or pictures

If the QUID is not made in the list of ingredients, it must be made immediately next to or under the name of the product.

Examples:

-A blueberry tart would require disclosure of the percentage of blueberries.

-A frozen gyro would require disclosure of the percentage of meat.

-A frozen pizza with the notation of “real cheese” would require disclosure of the percentage of real cheese.

-A chocolate bar with the words “Milk Chocolate” in large print would require disclosure of the percentage of milk.

-A picture of a cow on cream cheese would require a disclosure of the percentage of dairy product.

Allergenic

Directives 2003/89 and 2006/142 laid out labeling requirements for potential allergenic ingredients. Exporters must declare on their labels if their products contain any of the following

products: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products, nuts and nut products, sesame seeds, soybeans, sulphites, mustard, celery, lupin and lupin products, and mollusk and mollusk products.

Additive Labeling

Directive 2000/13 also established categories and labeling rules for additives and flavorings. The category name must be listed followed by the additive's specific name or EEC number. The categories are: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, ant-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, humectant, bulking agent, and propellant gas.

Special note should be taken for quinine, caffeine, licorice, and phytosterols/phytostanols. See Directives 2002/67 and 2004/77 and Regulation 608/2004 for more information on these items.

Labeling Languages

The most important issue of non-uniform practice throughout the EU is the language that must appear on the label. Below is a chart of the required languages⁴⁵:

EU Member State	Language
Austria	German
Belgium	French AND Dutch, German also recommended
Bulgaria	Bulgarian

⁴⁵ GAIN Report E47056, USDA Foreign Agricultural Service at 10, (July 12, 2007).

Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	British English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	French or German
Malta	Maltese or English or Italian
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovene
Spain	Spanish
Sweden	Swedish
United Kingdom	British English

Packaging

Food exporters to the EU must be in compliance with Regulation 1935/2004, which sets out the requirements for material that comes into contact with foodstuffs. Annex I to the Regulation sets out the specific lists of approved and prohibited materials. The words “for food contact” or the symbol appearing in Annex II must appear on all packaging that contacts foodstuffs.

Additives

Food additives are generally not permitted unless the additive is included on the harmonized positive list published by the EU.⁴⁶ Excluded from the scope of such additives are processing aids, flavorings, and nutrients.⁴⁷ The lists are published in three directives: 94/35/EC (for sweeteners), 94/36/EC (for colors) and 95/2/EC (for everything else.) The exporter must be sure to comply with the quantity limits on these lists; if not quantity is listed, the exporter must keep the additive quantity within limits of “good manufacturing practice.”⁴⁸ It is important to note that the EU does not permit chlorine, bromates, or peroxides for use as flour bleaching agents.⁴⁹

Genetically Modified Foods (GMOs)

⁴⁶ Council Directive 89/107

⁴⁷ GAIN Report E47056, *supra* note 11 at 16

⁴⁸ *Id.*

⁴⁹ *Id.*

The import of GM food into Europe is one of the most controversial issues today. The EU continues to restrict import of GM products as only nine GM products have been authorized for marketing in the EU to date.⁵⁰ Despite the approval of these nine products, Austria, Denmark, France, Germany, Greece and Luxembourg continue to ban marketing of these products.⁵¹

Even if an exporter's GM product is permitted entry, the exporter still must comply with the special labeling of GM food laid out in Regulation 1829/2003. The general rule is that the label must explicitly say "genetically modified [product]" or "made from genetically modified [product]".

The regulations cover all food products that contain or consist of GMOs, are produced from GMOs, or contain ingredients produced from GMOs.⁵² The regulation applies even if there is no longer any detectable GMO in the product.⁵³ The exceptions to this rule are food below the allowable adventitious levels⁵⁴ and meat, milk, or eggs from animals that have been fed GM feed or treated with GM medicine.⁵⁵

⁵⁰Biotechnology, FOREIGN AGRICULTURAL SERVICE U.S. MISSION TO THE EUROPEAN UNION, found at <http://useu.usmission.gov/agri/GMOs.html>, last updated July 3, 2008.

⁵¹ *Id.*

⁵² GAIN Report E47056, *supra* note 11 at 23

⁵³ *Id.*

⁵⁴ 0.9 percent for approved varieties and 0.5 percent non-approved varieties that have positive EU risk assessment.

⁵⁵ *Id.*

Specially Processed Foods

Quick-frozen foodstuffs that are sold to the final consumer require the following:⁵⁶

- An indication of “quick-frozen” on the label.
- The date of minimum shelf life.
- The period for which the consumer may store the product.
- The storage temperature.
- Batch identification.
- “Do not re-freeze after defrosting”.

Irradiated foodstuffs require:

- A notation of “irradiated” or “treated with ionizing radiation”.⁵⁷
- Special note: most irradiated products have not been approved for import into the EU (only dried aromatic herbs, spices, and vegetable seasonings have approval) and the product should be checked with the member state first.⁵⁸

General EU Import Procedures

⁵⁶ Council Directive 89/108/EEC

⁵⁷ Framework Directive 1999/2/EC

⁵⁸ GAIN Report E47056, *supra* note 11 at 28 and Implementing Directive 1999/3/EC

First and foremost, the EU is a customs union, meaning that tariffs are uniform throughout the EU and once cargo is imported into one of the member nations, it can move to another member nation without duty or restriction.⁵⁹ As a member of the WTO, the EU's tariff schedule is harmonized to the first six digits of the rest of the WTO's members.⁶⁰ The EU classification is eight digits long and duty rates can be checked at http://ec.europa.eu/taxation_customs/dds/en/tarhome.htm.

Unlike the United States, EU Customs require duty payment on the CIF price rather than the FOB price,⁶¹ meaning that duties are paid on the freight and insurance costs of the shipment. Also unlike the United States, duties must be paid prior to the release of cargo.⁶² The food exporter also needs to be aware that EU members charge VAT (varies according to member nation) and many food products will be inspected (inspection fees vary).⁶³

Asia

The increasing world-wide food safety concern has caused lots of changes to the food safety law of many countries. Asia which has been an important U.S. food export market is not an exception. Studying the food safety laws of Asia is not an easy job because it consists with various types of countries; however, they do not have unified regulations. Furthermore, now, many of the Asian countries are on an active process of establishing or changing the food safety regulation, and we need to keep it mind that the some present regulations are likely to be

⁵⁹ GAIN Report E47056, *supra* note 11 at 31

⁶⁰ Council Regulation 2913/92

⁶¹ GAIN Report E47056, *supra* note 11 at 31

⁶² *Id.*

⁶³ *Id.*

changed. In this part, we will briefly see the import food safety regulations of some of Asian countries⁶⁴ and discuss whether or not Asian countries use its food safety regulations to secure domestic agriculture, but, to disrupt WTO free trade principle

I. The Explanation of Import Food Safety Standard⁶⁵

1. Japan

Food import in Japan has been increasing, and it relies sixty percent of food domestic consumption on the imported food.⁶⁶ Japan has established the food safety laws very well, and they are known to be stringent.

(1) Governing major laws⁶⁷: The Food Safety Basic Law, the Food Sanitation Law(FSL), and the Japan Agricultural Standards Law(JASL) are three major food safety laws. Among these, Ministry of Health, Labor, and Welfare(MHLW) set the Food Sanitation Law which has the food safety standards including imported foods. Ministry of Agriculture, Forestry and Fisheries(MAFF) set JASL mainly for the food labeling and organic food standard.

⁶⁴ I have picked up Japan, South Korea, China, Taiwan, and ASEAN either because it is one of the most top U.S. export market or because it is a rising country which many exporter may concern.

⁶⁵ Most of the regulations in Part I comes from the United States Department of Agriculture, Gain Reports

⁶⁶ Jiyong Park, Improvements in Operational Administrative System of Imported Foods, 104 (Yonsei Univ. eds., 2006) (2006), <http://rnd.kfda.go.kr/documentReport/documentReportResult.do>

⁶⁷ 2007 USDA GAIN Rep. JA7043. pt. 3-10, http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

(2) Labeling Requirements

A. Under the FSL by MHLW

- Mandatory: Name of the product; country of origin; name of the importer; ingredient, other than additives; Food additives; the net weight in metric units only; “Best-before date” or “Expiry of consumption”; Method of use, storage instructions, or preparation, when established by MHLW for the product or when its absence could cause confusion; Labeling of certain biotechnology ingredients where the genetically modified content of the labeled ingredient exceeds five percent(certain limited foods such as foods made from corn, soybeans, rapeseed, and cottonseeds, etc.); allergen labeling(any of the five ingredients -wheat, buckwheat, egg, milk and peanuts).

The items shall be declared in a conspicuous place on the package without opening the package. Besides these, there are additional requirements to a specific food. For example, if it is a product obtained by freezing a manufactured or processed food, a label needs to state whether or not the food requires heating before consumption. And if a frozen food requiring heating before consumption, it needs to state whether or not the food was heated just before it was frozen. Also, if a frozen product of filleted fresh fish or shucked fresh shellfish, a statement of whether or not the product is intended to be consumed raw should be on the label.⁶⁸

- Voluntary: Nutritional Labeling is voluntary; but, if MHLW requires to provide, it must be in Japanese and include the following five items: Calories, protein, fat, sugar, sodium and other components to be labeled. Also, MHLW regulates certain health-related claims and components such as dietary fiber, protein, calcium, Vitamin A, etc. with additional requirements.

⁶⁸ Japan Food Sanitation Law, Enforcement Regulations, art. 17. aa~cc,
<http://www.jetro.go.jp/market/regulations/index.html>

B. Under the JAS law by MAFF

MAFF controls labeling of the following three processed foods: Place of origin for all perishable food; ingredients derived from biotechnology (foods from corn, soybeans and potatoes when the genetically modified content exceeds 5 percent); organic labeling, including mandatory third party certification for products labeled as “organic” name. For these items, name of the product, ingredients, net amount of contents, best-before date, name of the manufacturer and importer, method of preservation are required on labels.

(3) Packaging and Container Regulations

Under the Article 16 of the MHLW FSL, “no person shall ...import with the intent to sell or use in business any...package which contains or bears toxic or injurious substances and may injure human health,... which may injure human health by having harmful influence on foods and additives through contact therewith.” To prevent the use of harmful containers or packaging material, there are standards for methods of manufacturing them. Synthetic resins, metal cans, containers/packages made of glass, ceramic, enamel, or rubber are the items designated by the Ministerial Ordinance which have their own specifications.

(4) Food Additives

Japan has a positive lists system; therefore, only the additives on the list of approved additives by MHLW can be used in a food product. Many food additives which are commonly used in the United States, such as some food coloring and preservatives, cannot be used in Japan, and foods containing even traces of such additives cannot be imported. Although approved, there are restrictions limiting the amounts of the additive used in the final food preparation and also

limiting use on a specific product. In sum, the approved food additive list shows the additives that are approved for use in food products, the purpose that the additive must be used for (preservative, antioxidant, etc.), the foods that the additives are allowed to be used in, and the maximum tolerances allowed in the food. The following information should be provided at the time of import: the chemical names and content in parts of all synthetic additives having tolerance levels set by MHLW; names of all natural food additives; artificial colors identified by their chemical name and international color index number; natural color descriptions; artificial flavors identified as appeared on the Japanese approved additive list for the specific product exported.

(5) Pesticides and Other Contaminants

These are also governed by positive lists, and food containing residues exceeding the MRL levels on the positive list are regarded as violations of the FSL and are rejected at the port. After 2 violations of a particular MRL, the entire U.S. industry for that product could be subjected to very strict sanctions. Japan usually treats the violation as a product-by-product basis, rather than a producer basis. The followings are some examples of the contaminants suspected as harmful: aflatoxin levels in peanuts, peanut products; poisonous fish; shellfish poisons; cyanogens; methanol in distilled liquors and wines; gossypol in cottonseeds other than for oil extraction; salmonella; listeria in some cheeses; trichina in game birds, etc; radioactive substances; decomposed or deteriorated foods of all kinds.

(6) Others

- Biotechnology Food: No foods or beverages or their ingredients may contain materials produced through recombinant DNA techniques that have not been approved by the Government of Japan. As of 2007, Japan has approved 77 biotech events for food, 50 for feed, 55 for planting and 14 for food additives. MHLW monitors imports for unapproved varieties of biotechnology products in order to enforce its zero tolerance. Any shipment found to contain an unapproved variety may not be imported into Japan.

- U.S. Laboratories Certified by Japan Government: MHLS has certified certain U.S. laboratories to test foods and beverages for Japan's FSL. If approved by those laboratories, U.S. products will not need to be tested upon arrival to Japan.

2. South Korea⁶⁹

Korea has lots of relevant government agencies and relevant rules. The present Government announced a plan to reduce some agencies. The Ministry of Health & Welfare declared its plan to strengthen food safety regulations. Therefore, the requirements which we will discuss below are likely to be changed.

(1) Governing major laws:

⁶⁹ 2006 USDA GAIN Rep. KS6080,
http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

<p>Ministry of Health & Welfare (MHW)</p>	<ul style="list-style-type: none"> - Relinquished the most of regulation authorities to KFDA - Food Sanitation Act; Functional Food Act
<p>Korea Food & Drug Administration (KFDA)</p>	<ul style="list-style-type: none"> - The principle government agency for food & medicine safety - Setting & implementing standards & specifications both to domestically produced and imported food products - “Inspection Guidelines for Imported Food, etc” <ul style="list-style-type: none"> a. Food Code: standards for manufacturing, usage, cooking, storage of food and equipment, packaging, MRLs of chemicals, antibiotics, synthetic antibiotics, hormones, radioactive ray, testing methods, etc. b. Food Additive Code: positive list of approved food additives. c. Labeling Standards for Food and Recombinant Food d. Functional Food Code
<p>Ministry of Agriculture & Forestry (MAF)</p>	<ul style="list-style-type: none"> - Regulations related to agricultural products, including livestock and dairy products - National Agricultural Product Quality Management Service(NAQS): official inspection agency for testing of GMO products; responsible for setting quality standards and grades enforcing country of origin marks, GMO labeling requirements, and organic labeling for fresh food
<p>Ministry of Maritime Affairs & Fisheries (MOMAF)</p>	<ul style="list-style-type: none"> - Policies, plans, and overseeing all operations related to maritime affairs and fisheries
<p>Ministry of Commerce,</p>	<ul style="list-style-type: none"> - Establishing trade policy related to export and imports of goods

Industry & Energy (MOCIE)	- Import approval, mandatory risk assessment, labeling of GMO commodities
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(2) Labeling Requirements: There are several labeling standards governed by different agencies. We will look at only the ones which are related to prepared foods.

A. Labeling Standard by KFDA (Labeling Standards for Food & Recombinant Food)

Under the Article 10 of the Food Sanitation Act, “All imported food products are required to be labeled necessary information in Korean.” Stickers may be used instead of manufacturer-printed Korean language labels for general food products. But, should not be easily removable and not cover the original labeling.

- Mandatory: Product name & type; Importer’s name and address, and the address where products may be returned or exchanged in the event of defects; manufacture date(month, and year); shelf life(if various kinds of products are packaged together, the shelf life expiration date of the product with the shortest life should be noted on the label); contents(weight, volume or number of pieces); ingredient names and content(in Korean; only the named of the composite raw ingredient must be listed on the Korean language label; in order of predominance by weight; for food additives by full names, abbreviated name, or purpose on the label. e.g. Ferric Citrate, or nutrient fortified substance; food allergens, even if eggs, milk, buckwheat, peanuts, soybeans, wheat, mackerel, crab, port, peaches and tomatoes are added as part of a mix at minimal levels, must be indicated); Nutrients(only special nutritional foods, supplement foods, breads, noodles, retort foods, products for which nutritional labels, also, foods frequently consumed by children

such as chocolate, candy, snacks, cakes, jams, beverages, etc.; serving size and to require listing of sugar, trans fat(newly added in 2006), cholesterol, etc. on the nutritional label); other items designated by the detailed labeling standards for food(such as cautions and standards for use or preservation, that is, drained weight for canned products, radiation-processed products)

- Standards for Recombinant Food

When the primary ingredient is subject to MAF biotech labeling requirements (presently soybeans, corn and bean sprouts only, and not potatoes; the GM ingredient is one of five major raw materials used in the product; or recombinant DNA or foreign proteins are present in the final product), the products fall in this categories. Special requirements such as distinguishable color label, non-detachable sticker, or non-affix for certain non-GMO products are added. There are some exemptions for the certain qualified certificates. (e.g., Identity Preserved (IP) documentation, a government-issued certificate equivalent to an IP handling certification, or test certificates issued by a domestic commercial laboratory, foreign government or foreign commercial laboratory). If the imported product arrives without appropriate documentation, it can be tested in Korea prior to Custom clearance.

- Optional

a. Nutritional Labeling Requirements (under the “Labeling Standards for Food”)

This is the optional for most food products. However, if it should be labeled, it must be in Korean, use Korean nutrient reference values. However, if a product is not mandatorily required, it can carry the standard U.S. nutritional fact panel as is. No health efficacy claims is allowed on food product except for products that meet the criteria of functional foods. However, terms such as “low,” “non,” “high,” “rich in...,” and “contains...” may be used when the certain general standards for nutrient claims are met.

b. High Caffeine Content Labeling Requirements

Products with artificially added caffeine and liquid products, except coffee or tea, made from raw material containing caffeine where the level of caffeine in the liquid product exceeds 0.15 mg/ml are required to state that the product has “high caffeine content.”

c. Organic Labeling Requirements

There are lots of additional labeling requirements for organic food depending on the food categories. Whether or not an imported food meets the specific standards may be based on a certificate issued by organization which satisfies the qualifications to be a certifying entity under the relevant regulations of A) the exporting country, or B) a reliable organization certified by a recognized international body, such as IFOAM (International Federation of Organic Agricultural Movements). KFDA has recognized 296 foreign organic certifiers. Of those, 55 are USDA-accredited certifying agents located in the United States. Also, KFDA formalized its zero tolerance policy for biotech components in organic processed products and, as in the past, continues to test organic food products on a random basis. However, it will test product at the request of non-governmental organizations if the organization is able to provide test results indicating that the product contains biotech content. Labeling may be done in the following manner depending on the content of organic agricultural ingredients in a food product: (1) 100%; (2) Not less than 95%; (3) Less than 95% but more than 70%; (4) Others.

B. Labeling Regulations for Unprocessed GMO by MAF

If three percent or more of the shipment contains biotech-enhanced ingredients, mandatory labeling is required. Soybeans, bean sprouts, corn, and potatoes are excluded from the three percent maximum threshold allowance in the unprocessed GMO commodities. The examples of the labeling are the followings: raw GMO agricultural commodities as “Genetically Modified

XX (*the name of the product*)”; Agricultural commodities containing a GMO component as “Containing Genetically Modified XX (*the name of the product*)”; Agricultural commodities that possibly may contain a GMO agricultural component (but the importer is not certain) as “May contain Genetically Modified XX (*the name of the product*)”; raw unprocessed agricultural commodities that are 100-percent GMO free as “Non-GMO” or “GMO Free” on a voluntary basis. However, usage of the terms “Non-GMO” or “GMO Free” is limited to products under the MAF. KFDA does not permit such terms to be used for products under its control.

C. Country of Origin (COO) by MAF

Under the 2006 revision, many agricultural products, including most imported products, must be labeled by origin. As for imported products, the Korea Customs Service enforces COO requirements prior to Customs clearance.

(3) Packaging and Container Regulations

“Standards & Specifications for Equipment and Container/Packaging” by KFDA in the Chapter 6 of the Korean Food Code; the regulations covering PVC shrink wrap packaging by the Ministry of Environment; the Act on the Promotion of Saving and Recycling of Resources(containers or packages that can be recycles must carry a “separation and discharge” sign) are governing laws and regulations.

These regulations are less strict than the ones in Japan.⁷⁰

⁷⁰ Jiyong Park, Improvements in Operational Administrative System of Imported Foods, 104 (Yonsei Univ. eds., 2006) (2006), <http://rnd.kfda.go.kr/documentReport/documentReportResult.do>

(4) Food Additives

Like Japan, KFDA has positive lists of 627 approved food additives and 1,834 synthetic flavorings lists as of 2006 year. The food additives are grouped into three categories: (a) chemical synthetics, (b) natural additives, and (c) mixture substances. Most additives and/or preservatives are approved and tolerance levels are established on a product-by-product basis in Korea.

(5) Pesticides and Other Contaminants

Three agencies of KFDA, MAF, and MOE handle this matter. KFDA, by MRL in the Food Code, regulates pesticide residues in foodstuffs, and, as of 2007, it has 380 pesticides lists. In comparison with 2006 year's 370, it increases 10 items. If an MRL is established in the Food Code for a given agricultural chemical, other tolerance levels including CODEX are not accepted. However, agricultural chemicals not established in the Food Code, CODEX standard is applicable. RDA under MAF is responsible for the registration of pesticides, and all pesticides used in Korea should be registered with RDA. Lastly, MOE is responsible for testing pesticide levels in water, soil and agricultural products.

(6) Others

- StarLink Free Certification: Since KFDA detected StarLink Protein in the U.S. shipment, the imported corn-based food products were required to arrive with a StarLink-free certification issued by the exporting country. For U.S. corn shipment, such certification should be issued by the USDA, Grain Inspection, Packers, and Stockyards Administration (GIPSA), or an accredited lab, to minimize potential problems during inspection clearance. Regardless, the sales contract

must specify the terms for pre-shipment tests. For processed food containing corn as an ingredient, certification can be met with a letter, statement, or certificate issued by the manufacturer or the exporter stating the raw corn ingredient was “StarLink-free.”

3. China

Several China’s exports were rejected for failing to meet stringent standards in Japan, Europe, and other countries, and it revealed a gap between Chinese and international food safety standards. In response to recent food safety developments, the Standardization Administration of China (SAC) announced, in 2007, plans to revise up to 4,000 of China's food safety standards, particularly in the areas of food additives, dairy, meat and eggs, and fisheries. Up to the end of 2006, China has 634 mandatory food safety standards and a further 1,331 standards are recommended for adoption. SAC also aims to revise an additional 1,141 national standards, which deal with quality factors, and 1,322 industry standards which are intended for business operations. China intends to complete this work by 2010. It has not been determined if SAC’s commitments will also extend to the hundreds of safety and quality standards maintained by the Ministry of Agriculture, Ministry of Health, and the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ). To date, China has notified to the WTO only 101 sanitary and phytosanitary measures.⁷¹

⁷¹ 2007 USDA GAIN Rep. CH7066,
http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

(1) Governing major laws⁷²

Under the Peoples Republic of China Foreign Trade Law, import and export are permitted freely, although there may be some quotas or tariff rate quotas. The imported foods must conform to state hygiene standards and hygiene management measures and must be inspected by the hygiene supervision and inspection authorities at the entry ports prior to customs clearance. The importing units are required to provide inspection reports and relevant information on the pesticides, additives, and fumigants used in the exporting countries. Where there are no state hygiene standards, the importing units must provide a hygiene appraisal issued by the health departments or authorities of the exporting countries.

(2) Labeling Requirements⁷³

In 2006, The AQSIQ announced “Adjustment of Import/Export Food and Cosmetic Label Examination System.” This Announcement eliminated the need for a separate preliminary examination and approval used imported and exported foods. Also, it states that, “up until October 1, 2006, labels used on imported food that do not comply with China’s labeling requirement can be changed to bring them into compliance. However, now, any imported foods that used labels that do not comply with the relevant labeling laws will be disposed”⁷⁴

⁷² Michael T. Roberts, *Introduction to Food Law in the People’s Republic of China*, (2007), <http://www.nationalaglawcenter.Org>

⁷³ 2004 USDA GAIN Rep. CH4026, http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

⁷⁴ 2006 USDA GAIN Rep. CH6020, pt.2, http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

According to the General Standard of Labeling for Pre-packaged Foods (GB7718-2003) which China notified to WTO, in the Article 4. 4-5, the contents of label cannot use the language or character which may lead to misconception or confusion among consumers. In Article 5, it defines the mandatory labeling contents as followings: food name; list of ingredients (all ingredients shall be identified with their designated names except sweeteners, preservatives, coloring); ingredient amount; net content and drip-dried material (solid) content (if it contains both solid and liquid materials); product standard coding (if product standards that the enterprise adopts have specified the quality grade of the food); etc.⁷⁵ Items of voluntary labeling are batch number, serving instruction, and calorie and nutrient; however, these are likely to be changed to the extent to match with other Asian countries.

(4) Food Additives⁷⁶

The inspection and Quarantine Authorities (CIQ's) announced the list of 124 products used for human food, animal food additives to strengthen the surveillance of import and export inspection. For examples, maple sugar & maple syrup of the 124 lists was once under the import inspection; but, not a export inspection. However, now, it is under the both inspections. Many of Vitamins and their derivatives were not under any inspection; but, now, it is under the both import and export inspection.

(5) Pesticides and Other Contaminants

⁷⁵ The some requirements which are common in the above 2 countries are omitted.

⁷⁶ 2007 USDA GAIN Rep. CH7036,
http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

The MOH and the SAC issued a notional standard on Maximum Levels of Contaminants in Food in 2005. This standard combines and replaces previous thirteen hygienic standards for chemical contaminants. Most standard requirements for these are adjusted to comply with Codex Alimentarius Committee standards.⁷⁷

(6) Others

- Certification⁷⁸: In 2003, AQSIQ and the Certification and Accreditation Administration of the People's Republic of China (CNCA) jointly implemented a new system of compulsory certification—the Compulsory Product Certification System (CPCS). Under this system, “any enterprise that wishes to import commodities listed in the First Catalogue of Products Subject to Compulsory Certification must obtain a China Compulsory Certification certificate and purchase corresponding “CCC” marks for the imported commodities from the CNCA before goods can be marketed, imported, or used for any commercial purposes.”

4. Taiwan⁷⁹

(1) Governing major laws

The Department of Health (DOH) is the statutory body responsible for the management of food safety, and it promulgated “The Law Governing Food Sanitation”, together with its enforcement rules and standards. Among its commissions, the Ministry of Economic Affairs(MOEA) inspects

⁷⁷ 2007 USDA GAIN Rep. CH7066, pt. 9,
http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

⁷⁸ 2007 USDA GAIN Rep. CH7079,
http://fas.usda.gov/agx/ship_doc_req/foreign_import_req.asp

⁷⁹ 2007 USDA GAIN Rep. TW7033

imported foods at the port of entry by the Bureau of Standards, Metrology and Inspection(BSMI). The Bureau of Animal and Plant Health Inspection and Quarantine(BAPHIQ) of the Council of Agriculture inspects fresh produce, meats, and pet food. The food safety inspection of processed foods focuses on labeling, food hygiene and food additives. Bioengineered corn and soybeans, and certain processed foods made from them, are subject to specific regulations.

(2) Labeling Requirements

Under the Act Governing Food Sanitation, the labeling must be in Chinese language (since 2002, affix in government-approved logistics centers prior to Customs clearance is allowed).

- Mandatory: Generally, product name; name, weight, volume or quantity of the contents; name of food additives; name, telephone number, and detailed address of manufacturer and importer; expiration date (date of manufacture, shelf life, and conditions of storage may also be used, if required by the health authorities). For frozen food, types of frozen foods; method and conditions of storage; cooking instructions if the products require cooking or are not ready-to-eat are additionally required.

- Optional: Regarding the regulation on Nutrition Labeling for Packaged Food, the following information should be added at a conspicuous place on the container of the product: (1) items of labeling(the heading “Nutrition labeling”); content of energy; content of protein, fat, carbohydrate(dietary fiber) and sodium contained; content of other nutrients declared in the nutrition claim; content of other nutrients labeled by the producer voluntarily;...(4) Each nutrient may further be expressed in percentage of Daily Value of Nutrient Intake; (5) Rules for rounding –off: expressed in not more than three significant figures and each serving, content of energy,

protein, fat, carbohydrate and sodium shall be expressed in an integer or to the first place of decimal; in 2007, trans fatty requirement is added.

(3) Packaging and Container Regulations

There are no legal requirements stipulating specific packaging materials or sizes to be used for processed foods. The Environmental Protection Administration (EPA) is the statutory body responsible for the removal, disposal and recycling of waste, including packaging or containers for food products. According to the Article 15 of the Waste Disposal Act, manufacturers or importers shall be responsible for the recycling, disposal and removal of an article, or its package or container, which is likely to cause serious pollution to the environment after consumption or use.

(4) Food Additives

Imported processed food products that contain artificial food additives are subject to strict tolerance levels and acceptable use requirements as prescribed by Taiwan's Department of Health (DOH). The BSMI of the Ministry of Economic Affairs(MOFA) inspect imported foods at the port of entry. Foreign suppliers or their Taiwan importers may apply to DOH for approval of new-to-Taiwan food additives. Once applied by submitting required information, the DOH will then evaluate the acceptability of these ingredients and make a formal determination within four to six months. The DOH will only consider accepting and/or adding new-to-Taiwan food ingredients to its "Scope and Application Standards of Food Additives."

(5) Pesticides and Other Contaminants

Taiwan has its' own MRLs, and many pesticides used in the U.S. have not been assigned Taiwan MRLs. The default MRL for a compound where a MRL has not been established is the smallest detectible amount which is effectively zero. Violation of the standard generally results in the recall of the product. Provisional MRLs have been established for some fruit and vegetable crop-compound combinations; but provisional MRLs are not longer being granted. This is in spite of a backlog of almost 1,500 MRLs that are waiting to be established. Nevertheless, as Taiwan's pesticide MRLs are different from those established by the U.S. or Codex, exporters may want to apply for Taiwan MRLs for chemicals used in the production of their products. The fact that an application is on file may be helpful if a problem arises.

(6) Others

Phytosanitary Certificates: Basically, Taiwan only accepts government certifications. For some limited cases, certification issued by organizations or agencies accredited or authorized by the government are accepted. Private industry certificates are not accepted. Imports of U.S. fruits or vegetables require phytosanitary certificates issued by USDA/APHIS. Since 2002, Taiwan has only accepted the Federal Phytosanitary Certificate issued by the U.S. Federal Government. Certificate issued by state quarantine offices are no longer accepted.

6. ASEAN (Association of South-East Nations)⁸⁰

The member countries of ASEAN are Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam. ASEAN cooperation in the

⁸⁰ <http://www.aseansec.org/4921.htm>

agriculture sector started early 1968 in order to cooperate in food production and supply. Currently, it broadened its area into the food security, food handling, crops, livestock, agricultural training and extension, etc. The basic objective of the cooperation in Food area is to formulate and implement regional cooperation activities to enhance the international competitiveness of ASEAN's food, as well as further strengthen the food security arrangement. For that objective, not only ASEAN member themselves, but also together with China, South Korea, and Japan, have continuously collaborated. Establishing Food Safety Network website⁸¹ to provide useful food safety information, implementing the initiative on ASEAN GMO Testing Network, developing training modules to educate farmers, and establishing certain ASEAN Guidelines (General Guidelines on the Preparation and Handling of Halal Food; Guidelines on the Risk Assessment of Agriculture related GMOs; A Harmonized Regulation on Food Irradiation) are the fruits from the cooperation.

They do not have a unified food safety regulation like Europe yet; therefore, U.S. exporters should look at each country's own regulation in order to export foods. But, the more they cooperate, the more they are likely to have a similar regulation. Although similar regulations will help the U.S. exporters to understand how to prepare for the food export to ASEAN members, we cannot say that it will also help the U.S. exporters to sell more foods to them.⁸²

II. Securing Food Safety in order to disrupt free trade?

⁸¹ www.aseanfoodsafetynetwork.net

⁸² 2003 USDA GAIN Rep. TH3077

Agriculture business is different from other business such as travel business or industrial business. It is related to foods, which human cannot survive without it. Therefore, each country is entitled to have some way to secure its domestic agricultural business. Furthermore, currently, the importance of foods resources has been a world-wide issue, and it is natural for each government to fear from lack of foods resources in a coming future and to try to prevent the disaster.

Now, more farmers leave their farms because they cannot make any benefit from agriculture, and this phenomenon is more serious in poorer countries. Rich countries usually support their farmers and keep their agricultural business. In this situation where we have not resolved the doubt whether or not free trade on agriculture is beneficial or right, enforcing free trade principle into agriculture area could cause disastrous results. That is, arguing free trade in agriculture would be a weapon to accomplish a new imperialism by powerful countries. Also, this rash application of trade liberalization into agriculture has caused each country to use food safety regulations as a shield. However, this shield may be effective when it is made with richer sources.

Now, Asia countries have been making lots of changes to their food safety regulations. Their changes are largely modeled on Japanese or Korean regulations. Therefore, unless one can clearly point out that the modeled country's regulation is nothing but disrupting trade, the change to have more strict rules may not be challenged. Furthermore, many of Asian countries such as China and some ASEAN, their food safety has been under the general international standard, and those current changes are to enhance food safety standard to the extent to match the general standard. Those changes must be secured as long as having a rational basis.

Surely, there are some problematic points such as unreasonable delay by improper import procedures; product-by-product basis rejection; or overly limiting certificate system like in Taiwan. Those improper procedures not only interferes the import but also harms domestic market. Therefore, some Asian countries have tried to simplify the import procedures. For example, Japan simplifies certain import procedures with the following system: the exemption of the import notification for salts, copra, oil and fat, crude sugar, uncertified alcohol, molasses, rapeseed, etc; advance approval of imported foods and related products; inspection results by public inspection organizations in other countries; planned import system; continuous import of same items; advance notification system.⁸³

One of the most challenged import regulations is a positive list system such as Japan and Korea's approved additives lists. It is challenged because the list does not contain a item which export country has or because it is too restrictive in comparison with the international standard like CODEX. However, many countries operate this positive system, and, by the application of approval, adding new items is highly possible. As long as scientifically safe items are entitled to be approved in a reasonable time limit, the positive system looks like a good method to secure food safety.

Deciding whether or not a specific food safety regulation is to distort trade is a difficult and time-consuming work because it costs expensive money to prove and also is related to politics, rather than business itself. It is clear that an agricultural business will be critical to the survival of countries in the future. The earlier we know and prepare like Joseph did in old Egypt, the better position we will have.

⁸³ Jiyong Park, Improvements in Operational Administrative System of Imported Foods, 104 (Yonsei Univ. eds., 2006) (2006), <http://rnd.kfda.go.kr/documentReport/documentReportResult.do>

Africa

Introduction

Africa as a trading bloc exhibits similar concerns regarding food safety regulations as other trading blocs – namely, labeling, nutrition information, contaminants, and packaging. However requirements under these topics are generally less stringent compared to those of other wealthier regions. As a result, regulations sometimes reference laws from other countries or international standards such as the Codex Alimentarius.

Africa does not yet have a harmonized set of food safety guidelines. Individual food safety codes must be inspected on a country-by-country basis when considering export of a prepared food product to an African nation. Accessing the food safety codes for some countries can be difficult, and in some cases research may yield varying or contradictory results. The information below represents food safety regulations applicable to prepared food imports for South Africa and Nigeria, two countries which provide reliable sources of legislation information and presently import such products.

South Africa

From 2005-06, the United States exported to South Africa \$202 million in agricultural products, a large amount of which was specifically in prepared foods.⁸⁴ South Africa's

⁸⁴ USDA Foreign Agricultural Service, *Republic of South Africa Exporter Guide*, Annual Report, 2006, GAIN Report SF6037 (October 3, 2006).

Foodstuffs, Cosmetics and Disinfectants Act, 1972, governs the sale and distribution of food products.⁸⁵

General Requirements

Information on the label must be printed in at least one official language of South Africa.⁸⁶ The label must contain the product's name⁸⁷, the name and address of the manufacturer, packer, seller, or importer⁸⁸, instructions for use⁸⁹, the list of ingredients⁹⁰, and special storage conditions for the product⁹¹. In addition, the label must declare its net contents in the metric system.⁹²

The product must also be marked with its country of origin⁹³, batch identification information⁹⁴, and either a "Best-before", "Sell-by", or "Use-by" date⁹⁵.

⁸⁵ South Africa Foodstuffs, Cosmetics and Disinfectants Act (1972), Act No. 54 of 1972, Regs. Relating to Labeling and Advertising of Foodstuffs.

⁸⁶ Id. at § 5(a).

⁸⁷ Id. at § (a).

⁸⁸ Id. at § 8(b).

⁸⁹ Id. at § 8(c).

⁹⁰ Id. at § 8(d).

⁹¹ Id. at paragraph 8(e).

⁹² Id. at § 9.

⁹³ Id. at § 11.

⁹⁴ Id. at § 12.

⁹⁵ Id at § 13.

Nutrition Information

Providing nutritional information is voluntary; however, if it is provided on the product's label, then it must be scientifically substantiated.⁹⁶

Additives

Food additives shall be named on the package and indicate the applicable shelf-life of the additives.⁹⁷

Contaminants and GMOs

The Act is silent regarding prohibited pesticides and contaminants. However, should a product make a claim of being free from pesticides, contaminants⁹⁸, or genetic modification⁹⁹, then that claim is subject to verification.

Packaging Guidelines

With regard to packaging, the Act only proscribes that a prepackaged food product with a visible exterior area of less than 2000mm² may be exempted from labeling requirements except for the name of the product.¹⁰⁰

⁹⁶ Id. at § 4.

⁹⁷ Id. at § 36.

⁹⁸ Id. at § 82.

⁹⁹ Id. at § 83.

¹⁰⁰ Id. at § 35.

Nigeria

The National Agency for Food and Drug Administration and Control (NAFDAC) is the Government of Nigeria's regulatory body responsible for food product manufacturing, importation, advertisement and distribution in Nigeria. Its laws pertaining to all food imported, advertised, sold, or distributed in Nigeria are codified in GON Decree 19 of 1993, as amended by Decree 20 of 1999.¹⁰¹

The following is a summary of NAFDAC's regulations for imported prepared foods as prepared by the USDA Foreign Agricultural Service.¹⁰²

General Requirements – the Minimum Labeling Requirements for U.S. Food Imports

If a prepared food product from the U.S. bears a standard label, only these requirements must be met¹⁰³:

Labeling should be in English. If it is in another language, an English translation must be shown on the label or package insert (where applicable).

A product's brand name or common name must appear in bold letters.

A complete "location" address of the manufacturer showing country of origin must be provided on the product label.

¹⁰¹ NAFDAC Nigeria, *Food – General Guidelines*, <http://www.nafdacnigeria.org/food.html>.

¹⁰² USDA Foreign Agricultural Service, *Nigeria Food and Agricultural Import Regulations and Standards*, Country Report, GAIN Report NI5015 (August 1, 2005).

¹⁰³ *Id.* at p.3.

The production "batch" number, date of manufacture and best use before/expiry date.

Ingredients must be listed by their common names in order of their prominence by weight unless the food is "standardized," in which case the label must include only those ingredients, which the standard makes optional.

Food additives and colors must be declared on the label. Spices, flavors and colors may be listed as such, without naming the specific material, but any artificial color or flavor should be identified as such.

Guidelines for Prepackaged Foods¹⁰⁴

In addition to the other guidelines provided in this section, NAFDAC provides additional rules specifically regarding prepackaged foods.¹⁰⁵

No person may sell a prepackaged food unless a label has been affixed thereto.

A prepackaged food label must not be presented in a manner, which is false, deceptive or likely to create an erroneous impression regarding its character, quality, quantity and origin.

A complete list of ingredients used in preparing the food item will be declared on the label in a descending order of their proportion.

¹⁰⁴ Id. at p. 7.

¹⁰⁵ According to the USDA report, violation of rules governing prepackaged food may temporarily or permanently prohibit its importation, distribution, sale, or use, and may also result in fines. (Ibid.).

A date of minimum durability must be identified on the label along with any special storage conditions.

Prepackaged food items that are treated with ionizing radiation must be so declared and the nature of the ionizing radiation will be stated on the label.

Nutrition Information¹⁰⁶

The standard U.S. nutritional fact panel is acceptable by NAFDAC.

Any nutritional claim must be justified on the product's label. Nutritional labeling is mandatory for any prepackaged food item for which the manufacturer makes a nutrition or dietary claim.

Foods for special dietary uses with claims of disease prevention, treatment, mitigation, cure or diagnosis must comply with NAFDAC's guidelines for registration of drugs and be registered as medicinal products. Labels must contain directions for safe usage.

Additional nutritional labeling information is voluntary.

Additives¹⁰⁷

NAFDAC employs the food additive and contaminant regulations of the Codex Alimentarius Commission in its assessment of food safety. The regulations focus primarily on the control of non-nutritive sweeteners.¹⁰⁸

¹⁰⁶ Id. at p. 4.

¹⁰⁷ Ibid.

No person may manufacture, import, advertise, sell or present any food item or beverage containing a non-nutritive sweetener for human consumption unless the product is "specified for special dietary usage."¹⁰⁹

Non-nutritive sweeteners, including saccharin and cyclamates, may be used in low-calorie, dietary foods/beverages but are not permitted in any food or beverage to be consumed by infants or children.

Contaminants and GMOs¹¹⁰

NAFDAC also applies the pesticide residue and mycotoxin standards of the Codex Alimentarius Commission in its assessment of food safety. All food products must have a certificate of analysis, which demonstrates to NAFDAC's satisfaction that the item is free of pesticide and radioactive contaminants in addition to other quality parameters. NAFDAC reserves the right to subject any domestic or imported product to its own analysis to determine freedom of contamination.¹¹¹

Packaging Guidelines

¹⁰⁸ According to the USDA report, violation of the NAFDAC's additive regulations will result in a \$1000 fine and/or 1 year in prison. (Ibid.).

¹⁰⁹ Ibid.

¹¹⁰ Id. at p. 5.

¹¹¹ The USDA reports that imported foods are subject to inspection at the port of entry and point of sale by NAFDAC officials. Contaminated foods may be seized and destroyed, and persons responsible for the violation may face prosecution. (Ibid.)

NAFDAC regulations do not specify packaging restrictions or requirements such as packaging materials. However, the USDA reports a packaging preference by Nigerian importers high-value food products of smaller size that are packaged for one-time use; products that can be shipped in bulk and re-packaged locally; and perishable food products processed or packaged for extended shelf-life without refrigeration.¹¹²

Conclusion

Relative to the countries of wealthier trading blocs, South Africa and Nigeria have less stringent food safety laws concerning the labeling of nutrition, additive, and contaminant information. Other African nations with growing markets for imported prepared food products have similar regulations to those of South Africa and Nigeria, subject to some language and regional particularities. Individual country food safety regulations should always be reviewed in order to ascertain specific requirements.

Besides avoiding costs associated with conforming to rigorous regulation requirements, U.S. exporters of prepared food products may find other advantages to trade with some African countries. According to reports conducted by the USDA on Senegal, Ghana, Cote d'Ivoire, and Kenya, there is a growing demand for U.S. imports of prepared food as the overall population and middle-class of these nations increase.¹¹³ Preference for U.S. products due to a perception

¹¹² Id. at p. 4.

¹¹³ See USDA Foreign Agricultural Service GAIN Reports: *Senegal Market Development Reports*, Best Market Prospects, 2007, Report SG7021 (October 9, 2007); *Ghana Exporter Guide*, 2007, Report GH7005 (October 5, 2007); *Cote D'Ivoire Exporter Guide*, 2004, GAIN

of high-quality by African consumers also contributes to an attractive market advantage. Among the most frequently mentioned prepared, or “high value” food prospects are rice in consumer pack, processed fruits and vegetables, sauces and condiments, and breakfast cereals.¹¹⁴

Among the challenges to trade are an overall lower per capita income in many African nations, higher freight costs compared to those from EU or Asia, and lack of direct shipping routes to parts of West Africa. Political volatility also is a risk in some countries.¹¹⁵

Australia & New Zealand

In Australia and New Zealand, most food safety regulations have been harmonized under a comprehensive set of rules entitled the Australia New Zealand Food Standard Code, also known as the Joint Standards Code. Regulations pertaining to labeling, nutrition information requirements, and additives information are thus uniform for both countries.¹¹⁶ The major difference in New Zealand’s food safety regulations is that country of origin labeling is voluntary.

As a whole, the Standard is highly specific and farther-reaching relative to regulations in other regions. Australia and New Zealand’s rules on nutrition and additives, among other areas, exemplify the governments’ emphasis on scientifically corroborated conclusions, social concerns regarding healthful and organic products, and trade policy.

Report IV4014 (October 28, 2007); and, *Kenya Exporter Guide*, 2006, GAIN Report KE6010 (November 11, 2006).

¹¹⁴ Ibid.

¹¹⁵ Ibid.

¹¹⁶ Food Standards Australia New Zealand, *Australia New Zealand Food Standards Code*, <http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm>.

General Requirements

The Standard precisely sets out what information must be labeled on food products.

The label of a prepared food product must provide a name and, if necessary, a description of the food contained.¹¹⁷

The label must be written in English as at least one of the languages represented¹¹⁸, and it must be printed legibly¹¹⁹ and presented without obstruction to the reader¹²⁰.

Lot identification information must be included on the label.¹²¹

The label must also provide the business name and Australia or New Zealand address of the product's supplier, which, under the definitions of the Code includes importers, packers, manufacturers, and vendors.¹²²

All ingredients must be listed by their common name.

Certain foods, ingredients, and additives must be included on the product label accompanied by a warning or advisory statement specified under the Code.¹²³ For

¹¹⁷ Australia New Zealand Food Standards Code, Standard 1.2.2, cl. 1.

¹¹⁸ *Id.* at Standard 1.2.9, cl. 2(2).

¹¹⁹ *Id.* at cl. 3.

¹²⁰ *Id.* at Editor's Note to cl. 2(1).

¹²¹ *Id.* at cl. 2.

¹²² *Id.* at cl. 3.

¹²³ *Id.*, Standard 1.2.3., cl. 1.

example, products which contain guarana or extracts of guarana must also state that the product contains caffeine.¹²⁴

Depending on the type of food and intended use, the product must provide a “baked-for date”, “baked-on date”, “best-before date”, or “use-by date”.¹²⁵

Directions for use and storage must be included on the label where such information is required to protect the health and safety of the consumer.¹²⁶

The label must indicate where the product was made or produced, or where the product was made, manufactured, or packaged for retail sale and indicate whether it was made from imported and/or local ingredients, as appropriate.¹²⁷

For products containing pork, fish, fresh vegetables, and/or fresh fruit, the label must indicate either the country or countries of origin of the foods, or that the product is comprised of a mix of local and imported foods.¹²⁸

New Zealand – Country of origin labeling is voluntary.¹²⁹

Nutrition Information

Providing a nutrition panel is mandatory on all packaged food items unless specifically exempted in the Standard.

¹²⁴ Id. at Table to cl. 2.

¹²⁵ Id. at Standard 1.2.5.

¹²⁶ Id. at Standard 1.2.6.

¹²⁷ Id. at Standard 1.2.11, cl. 2(1).

¹²⁸ Id. at cl. 2(2).

¹²⁹ For reasons of trade policy and because country of origin information is not directly related to food safety, among other reasons, New Zealand makes country of origin voluntary. See the New Zealand Food Safety Authority website, “Country of Origin Labeling,” at <http://www.nzfsa.govt.nz/consumers/food-safety-topics/country-of-origin/index.htm>.

Nutrition information must be provided on the package of a prepared food item and list, in the metric system, the number of servings contained therein¹³⁰, the average quantity of food contained in a serving¹³¹, and the unit quantity of the food¹³².

The package must also provide the energy content of the food in kilojoules or in both kilojoules and calories, for both a serving of the food and the unit quantity.¹³³

The package must provide the average quantity, expressed in grams of, protein, fat, saturated fat, carbohydrate and sugars, in a serving of the food and in a unit quantity of the food.¹³⁴

The sodium content in both a serving of the food and in the unit quantity of the food must be included among the nutrition information.¹³⁵

If a nutrition claim is made on the package, then any substantiating nutrients or biologically active substances must be provided in the appropriate metric measurement.¹³⁶

Additives

The Joint Standards Code provides highly specific guidelines for additives, establishing maximum levels of particular substances.

¹³⁰ Id. at Standard 1.2.8. cl. 5(1)(a).

¹³¹ Id. at cl. 5(1)(b).

¹³² Id. at cl. 5(1)(c).

¹³³ Id. at cl. 5(1)(d).

¹³⁴ Id. at cl. 5(1)(e).

¹³⁵ Id. at cl. 5(1)(f).

¹³⁶ Id. at cl. 5(1)(g).

Additives are defined in the Standard as any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve a technological function¹³⁷ expressly permitted under the Standard, such as thickening or anti-caking.¹³⁸

Additives may be used in prepared food products only as permitted under the Standard.¹³⁹

Additives must be listed in the product's ingredient list, and if the additive is specifically classified under the Code, then it must be listed in accordance with the Code description.¹⁴⁰

If used as part of the product, flavouring must be included in the ingredients list.¹⁴¹

Certain additives specified by the Code must be accompanied by an appropriate warning or advisory.¹⁴²

Vitamins and minerals may be added to prepared food products only as permitted under the Standard.¹⁴³

Processing aids that may be used in the production of the food are limited to substances listed in the Standard.¹⁴⁴

¹³⁷ Id. at Standard 1.3.1, Statement of Purpose.

¹³⁸ Id. at Schedule 5.

¹³⁹ Id. at Standard 1.3.1, Statement of Purpose.

¹⁴⁰ Id. Standard 1.2.4, cl. 8

¹⁴¹ Id. at cl. 8(6).

¹⁴² Id., Standard 1.2.3., cl. 1.

¹⁴³ Id. at Standard 1.3.2.

Contaminants and GMOs

The Standard establishes a maximum level for certain food-based contaminants that may pose a public health risk.¹⁴⁵ Regarding genetically modified foods, the Standard requires food businesses along the supply chain to be cognizant of their products containing genetically modified food or ingredients.

Foods produced using gene technology must be assessed before sale and use, and all genetically modified food and ingredients must be labeled if they contain a novel DNA or a novel protein, or if they have altered characteristics in the final food product.¹⁴⁶

Food businesses such as manufacturers, packers, importers and, where appropriate, retailers should take all reasonable steps to find out if a product contains genetically modified food or ingredients, if the gene technology used is approved, and what labeling is required to inform the reader.¹⁴⁷

Packaging Guidelines

¹⁴⁴ Id. at Standard 1.3.3.

¹⁴⁵ Id. at Standard 1.4.1.

¹⁴⁶ Ibid.

¹⁴⁷ Id. at Standard 1.5.2, User Guide, see Food Standards Australia New Zealand Website, *User Guide, Labeling Genetically Modified Food*, at <http://www.foodstandards.gov.au/thecode/assistanceforindustry/userguides/labellinggeneticallymodifiedfooduserguide/index.cfm>

Both Australia and New Zealand refrain from specifying particular packaging materials that must be used. As long as the materials do not pose a threat of contamination to the food or to the health and safety of the consumer, any packaging material may be used.¹⁴⁸

Both countries place responsibility of manufacturers and retailers to ensure packaging materials are in accordance with all relevant safety regulations, and adhere to relevant U.S. FDA standards and European Union directives regarding use of plastic materials.¹⁴⁹

Conclusion

Australia and New Zealand has largely harmonized its food safety regulations, and is continually amending legislation to become increasingly harmonized. Some trade-based distinctions are still in place as motivated by political policy, such as New Zealand's policy on country of origin labeling.

There are numerous advantages to exporting prepared food products to Australia and New Zealand. Due to size limitations, Australia and New Zealand also have a limited production capacity for agricultural production. As a result there is a demand for food products that must be

¹⁴⁸ Id. at Standard 1.4.3; and, New Zealand Food Act 1981, § 9(4)(c).

¹⁴⁹ See Food Standards Australia New Zealand Website, *Bisphenol A (BPA) and food packaging*, at <http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2008/bisphenolabpaandfood3898.cfm>; and, New Zealand Food Safety Authority website, *Food Packaging Materials*, at http://www.nzfsa.govt.nz/labelling-composition/publications/regulation-of-food-in-nz/index.htm#P96_11791.

met with imports. In addition, U.S. products generally enjoy a reputation for high quality products in this region.¹⁵⁰

Some disadvantages include manufacturing expenses associated with altering packaging of products to conform to the Standard. In addition, shipping related costs may also be a deterrent to trade.

AMERICAS

American food producers and exporters must be aware of various issues regarding the exportation of prepared food products to other parts of the Americas including North, Central, and South America, and the Caribbean Islands. Issues concerning the importation of prepared food include labeling, country of origin marking, restrictions on certain food additives for preservation, and packaging. American food producers and exporters must be aware of other rules concerning exportation from the United States as discussed in previous sections.

NORTH AMERICA

CANADA

The Canadian Food Inspection Agency regulates the imports of food products.¹⁵¹ Not only does it determine which types of fresh fruits, vegetables, and meats can enter the country, but it also examines processed products prior to importation. To import into Canada, processed foods must be sound, wholesome, fit for human consumption, manufactured from sound raw

¹⁵⁰ Western United States Trade Association, *A Guide to Exporting Food to Australia* (October 2004), at www.ota.com/pics/documents/Australiareport.pdf.

¹⁵¹ Canadian Food Inspection Agency at <http://www.inspection.gc.ca/english/fssa/impe.shtml> (last visited August 1, 2008).

materials, and packed under sanitary conditions.¹⁵² Furthermore, they must be of a minimum grade or standard of identity, be packaged in prescribed containers, and be correctly labeled with nutritional information, country of origin markings, and any added preservative markings.¹⁵³

Grading

The Processed Products Regulations are the rules governing the importation of prepared food products into Canada.¹⁵⁴ The rules require that all processed foods being imported meet the minimum grade standard set for Canadian domestic foods. There may be up to three grades that can be given food products that are imported and sold in original containers.¹⁵⁵ These include Fancy Grade, Choice Grade, and Standard Grade. The minimum grade that products must meet is Canada Standard.¹⁵⁶ The grading represents the quality permitted to be imported into Canada. Each food product will have a minimum grade requirement to be met. For example, vegetable soups, spaghetti in tomato sauce, and other items containing vegetable products of some kind must meet the minimum Standard Grade before it can be imported into Canada.¹⁵⁷ Canned and

¹⁵² Canadian Food Inspection Agency, <http://www.inspection.gc.ca/english/fssa/protra/cdnreque.shtml> [last visited July 23, 2008].

¹⁵³ *Id.*

¹⁵⁴ Canadian Food Inspection Agency, *Import Requirements: Minimum Grade*, at <http://www.inspection.gc.ca/english/fssa/protra/cdnreque.shtml#a6> (last visited July 31, 2008)[hereinafter *Import Requirements*].

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ Processed Products Regulations Part VIII IMPORTS, at http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.291/bo-ga:l_VIII/en#anchorbo-ga:l_VIII.

frozen fruits and vegetables are also required to be given a minimum grade.¹⁵⁸ The grading is the quality of the vegetable or fruit product at the time of canning, freezing, or production. The minimum will have information on the freshness, ripeness, and the size of the fruits and vegetables prior to canning, freezing, or production of the final product.¹⁵⁹ For example, to achieve the Standard Grade for fruits and vegetables, they must possess a normal flavor and aroma associated with that particular fruit or vegetable, they must be of just normal color, they must be free of their core and peel, and be free of major defects like bruising and insect injury prior to processing.¹⁶⁰ On the other hand, to meet the fancy standard, the flavors must be very good, the fruit or vegetable must be well ripened, good in color and condition, and if cutting is required prior to canning, or freezing, the cuts must be even and uniform.¹⁶¹

There are some products included in the Processed Products Regulations that do not have grades established for them. In these cases, “standards of identity” have been created where common name for the composition is used.¹⁶² These products include jams, jellies, mixed frozen vegetables and fruit, canned pineapples, bean sprouts for chop suey, tomato sauces, canned bean

¹⁵⁸ Processed Products Regulations Part I.1(3), available at http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.291/bo-ga:l_I_1/en#anchorbo-ga:l_I_1.

¹⁵⁹ *Id.* See generally, Part I.1 Table 1.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

products like baked beans, vegetarian beans and the like, pickles, relishes, chutneys, fruit nectars, and different fruit juices.¹⁶³

Labeling Requirements

Processed products entering Canada must have specific items listed on the labels. Labels must show the where food was processed and packed; what kinds of foods are packaged and how they are packaged (i.e. in water or syrup); whether any additives were added to the final product; and the origin of the food products.¹⁶⁴ Part IV of the Processed Products Regulations lists how different food items are to be labeled.¹⁶⁵ Labeling must include:

“the full name and address of the operator or, where the containers were packed for a first dealer, an indication that the product was packed for or distributed by the first dealer, together with the full name and address of the first dealer;

the common name of the food product legibly and conspicuously declared, and when the name consists of more than one word, each word shall be clearly and prominently displayed on the label;

in the English version the word “Brand” immediately below or in the French version the word “Marque”

immediately above the brand or trade name if it is a geographical location or some other descriptive name;

¹⁶³ Processed Products Regulations Schedule II *Standards of Identity for Specified*, available at <http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.291/sc:2/en#anchorsc:2>.

¹⁶⁴ *Id.* at Part IV available at http://laws.justice.gc.ca/en/showdoc/cr/C.R.C.-c.291/bo-ga:l_IV/en#anchorbo-ga:l_IV.

¹⁶⁵ *Id.*

the true and correct variety, if the variety of fruit or vegetable is named on the label;

the true and correct grade name for the product;

the correct size number or the optional word designation on vegetable products that are size graded according to these Regulations;

the words “solid pack”, if the product is a solid pack from which there is little or no free liquid;

the words “heavy pack”, if the product is packed to contain the maximum drained weight that processing will permit;

the words “in water”, if the product is packed in water;

the words “with pectin” in letters not less than 1/8 inch in height on containers over 10 ounces and not less than 3/32 inch in height on containers under 10 ounces in lettering readily discernible and prominently displayed immediately below the name of the jam, jelly or marmalade to which pectin has been added;

the words “Seville”, “Extra Bitter” or “Bitter” if the product is an orange marmalade made from Seville, or similar bitter varieties of oranges;

the words “whole”, “cut”, “whole vertical pack”, “asparagus style”, “french style” or “french cut” to describe the style of pack if the product is canned or frozen green or wax beans;

the words “tips removed” or “without tips” clearly and prominently displayed immediately below the name of the product if the product is Canada Choice Grade Asparagus cuts or cuttings packed without tips;

the words “cream style”, “vacuum pack”, “brine pack”, “packed in brine” or “packed in liquid”, as the case may be, if the product is canned corn;

the words “contents — per cent slack filled” or “contents — per cent short weight”, if the container is slack filled or contains less than the minimum net and drained weight prescribed by these Regulations;

and a code mark indicating clearly the establishment where the product was packed and the date of packing if the product is a canned fruit or vegetable for which grades are established in these Regulations...¹⁶⁶

Additionally, labels must include the nutritional information including the vitamins the processed foods contain and whether any extra additives were added to the final products prior to packaging. For example, a label must have the amounts and daily values of vitamins. Furthermore, if vitamins have been added similar to an additive then the label must state “Vitamin added,” or “Vitaminized” and it must state the exact vitamins added.¹⁶⁷ This type of information is vital to each and every package in order to avoid consumer deception and increase consumer awareness of the food consumed.

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

Country of Origin Marking Under NAFTA

The United States entered into the North American Free Trade Agreement (“NAFTA”) that was implemented in 1994.¹⁶⁸ The free trade agreement was meant to eliminate trade barriers between the United States, Canada, and Mexico with respect to products made in the each country for export into the other countries.¹⁶⁹ Under NAFTA, country of origin rules are quite different. American exporters must be aware of these rules in order to be in compliance with Canadian marking rules.

Where food products are imported, the label shall state clearly and conspicuously the country where the product was packed, in type as prescribed in section 1 of Schedule V, either as part of the name and address of the foreign operator or as a separate declaration indicating the origin of the product.¹⁷⁰ Under the NAFTA rules of origin, so long as the food products are made of material from the United States, the country of origin will be the United States and the food product will be exported to Canada duty free.¹⁷¹ However, the rules gain importance where the final processed food product contains material not originating in the United States or Mexico. In that situation, the final product will originate in the United States so long as the material

¹⁶⁸ See United States Department of Agriculture Foreign Agricultural Service, *North American Free Trade Agreement (NAFTA)*, available at <http://www.fas.usda.gov/itp/Policy/NAFTA/nafta.asp> [hereinafter NAFTA Rules].

¹⁶⁹ *Id.*; See North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.-U.S., 32 ILM 289 & 605 (1993).

¹⁷⁰ Processed Products Regulations *supra* note 14.

¹⁷¹ NAFTA Rules *supra* note 18.

undergoes a substantial transformation into a new product.¹⁷² In other words, minor assembly of the foreign originating material in the United States will not qualify for NAFTA treatment. Many agricultural products even contain less than 3% of non-originating materials may not qualify for NAFTA treatment.¹⁷³

MEXICO

The United States exports many processed food products to Mexico.¹⁷⁴ Much like Canada, Mexico's regulations are similar. The rules of origin for marking purposes are exactly the same under NAFTA.¹⁷⁵ Processed food labeling and environmental impacts are the key factors that may hinder growth in exports of processed foods to Mexico.¹⁷⁶

Labeling

Processed foods being imported into Mexico requires labeling of certain information. Product labeling for food safety purposes only developed in Mexico after the passage of

¹⁷² See North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.-U.S., 32 ILM 289 & 605 (1993) Annex 401 Specific Rules of Origin, available at <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/nafta-alena/ann-401-03.aspx?lang=eng> <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/nafta-alena/ann-401-03.aspx?lang=eng>.

¹⁷³ *Id.*

¹⁷⁴ Foreign Affairs and International Trade Canada, *Doing Business in Mexico: Imports*, at <http://www.infoexport.gc.ca/ie-en/DisplayDocument.jsp?did=24197>.

¹⁷⁵ NAFTA Rules *supra* note 18.

¹⁷⁶ See Carlos Zertuche, Lourdes Guzman & Luis Chaez, *Mexico Exporter Guide Annual 2005*, USDA Foreign Agriculture Gain Report MX5316 (Dec. 2005) [hereinafter Zertuche].

NAFTA.¹⁷⁷ Until recently, Mexico mainly imported raw materials for the production of processed foods from the United States. However, the Mexican population has witnessed a change in age and work force.¹⁷⁸ The majority of the population is younger than 25 and more women have entered the work force. Therefore, more processed food is being imported, but imports of finished food products makes up a small percentage of imported food. Because processing is much more expensive in the United States than Mexico, and the Mexican population is price conscious, processed food is difficult to import.¹⁷⁹

The labeling standards mirror those of the United States, however all labels are required to be published in Spanish to avoid consumer deception.¹⁸⁰ The Government of Mexico regulates products through Normas Oficiales Mexicanos (“NOMs”).¹⁸¹ These standards are the official mandatory standards governing imported consumer goods. The rules can be issued by The Mexican Ministry of Health which regulates the importation of processed food products and beverages.¹⁸² Labeling standards apply to additives and pesticides as well and norms established by the United States and the World Trade Organization are strictly followed.¹⁸³

¹⁷⁷ *Don't Get Frozen Out of the Growing Mexican Foods Market*, Ag Exporter (Jan. 1995) at http://findarticles.com/p/articles/mi_m3723/is_n1_v7/ai_16424617/pg_2?tag=artBody;col1.

¹⁷⁸ Zertuche *supra* note 26 at 2-4.

¹⁷⁹ *Id.*

¹⁸⁰ Agri-Food Trade Service, *Mexico Export Preparedness Guide Exporting Agriculture and Agri-Food Products to Mexico* at http://www.atn-riae.agr.ca/latin/4138002_e.htm.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

CARIBBEAN

TRINIDAD¹⁸⁴

Trinidad like many of the other Caribbean nations do not have many rules and regulations governing the importation of processed foods. Regulations mainly mirror that of the United States and Europe. The Food and Drug Act of Trinidad does list some important rules concerning product labeling, country of origin marking, and additive and pesticide information.

Labeling

Labeling of food products is governed by the Food & Drug Act and requirements are established in Chapter 30:01, Part II, Section 16 of the Food and Drug regulations.¹⁸⁵ A key requirement is that all products be labeled in English. Multilingual labels are acceptable as long as English is one of the languages included on the label.¹⁸⁶ In such cases, the English portion need not appear on the main panel. Standard U.S. labels are acceptable and are generally viewed as containing more information than what is required by Trinidad & Tobago standards. The information required on all food product labels include:

“Main panel:

¹⁸⁴ Most of the Caribbean countries adhere to the same rules of importation of food products, however most of the information readily available focused on Trinidad. Therefore this paper also focuses on Trinidad, but the region in general has the much of the same rules.

¹⁸⁵ Omar Gonzalez, *Trinidad and Tobago FAIRS Country Report 2007*, USDA Foreign Agricultural Service Gain Report TD7001, 3, available at <http://www.cbato.fas.usda.gov/TD7001.doc>.

¹⁸⁶ *Id.* at 3-4.

1. Brand name or trade name of the product.
2. Common name of the product (the name by which the food is generally known).
3. Net contents of the package in terms of weight, volume or number. If a liquid packaged with the food product is to be consumed with the food, the drained weight of the food should be stated. Net weight is not required if the quantity of food is less than 56 grams or 56 ml.

Any panel, except the bottom:

4. A complete list of ingredients in descending order of proportion by weight or percentage.
5. Name and address of the manufacturer, packer, etc.”¹⁸⁷

Nutritional labeling rules mirror those of the United States.¹⁸⁸

Rules of Origin Marking

Many U.S. products state the manufacturer’s city and state only. As is the case in many other countries, Trinidad & Tobago health authorities require the country of origin to be

¹⁸⁷ *Id.*

¹⁸⁸ Gonzalez *supra* note 29 at 4.

explicitly stated as part of the address.¹⁸⁹ Therefore, either "USA" must be added to the address or the label must contain statements such as "Product of USA" or "Made in USA" in order to clearly identify the product's origin.¹⁹⁰ In cases where non-U.S. products are packed and shipped by U.S. companies, the true country of origin must be specified so that the label is not considered misleading.¹⁹¹

Additives and Pesticides

The Trinidadian Ministry of Health has no specific regulations for food additives or pesticides. Therefore, it does not maintain a positive or a negative list of additives.¹⁹² As a general rule, health officials rely on international Codex Alimentarius standards in determining whether to accept or reject additives and pesticides.¹⁹³ Codex, also known as the "food code," is a set of scientifically-based and globally-recognized standards, codes of practice, guidelines and recommendations for food products.¹⁹⁴ Health officials also rely on European and U.S. standards for additive and pesticide restrictions.¹⁹⁵

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² Gonzalez *supra* note 29 at 5.

¹⁹³ *Id.*

¹⁹⁴ *Id.* At 5-6

¹⁹⁵ *Id.*

SOUTH AMERICA

BRAZIL

The importation of processed food and beverages into Brazil is regulated and enforced by different governmental agencies including the Ministry of Health, the Ministry of Environment, the Ministry of Development Industry and Foreign Trade, and the Ministry of Justice.¹⁹⁶ Many rules governing the importation of prepared food into Brazil are similar to those in force in the United States.¹⁹⁷ However, there are key differences American exporters should know.

Labeling

Brazilian consumer protections laws require that all domestic and imported foods and beverages be labeled with “correct, precise, clear, and easily readable information about the food product in Portuguese.”¹⁹⁸ The most important labeling information required are expiration dates and shelf life dates.¹⁹⁹ Furthermore, foreign labels found on processed meat, dairy and seafood products must be registered and approved by the Brazilian regulatory agencies prior to importation.²⁰⁰

Plant Inspections

¹⁹⁶ Fabiana Fonseca, *Brazil: Food and Agricultural Import Regulations and Standards*, USDA Foreign Agricultural Service GAIN Report BR6011, 8-11 (July 2006).

¹⁹⁷ *Id.* at 11-12.

¹⁹⁸ *Id.* at 11.

¹⁹⁹ *Id.* (stating that the Brazilian importer is held liable for any health risks associated with incorrect dates on labels of imported food products).

²⁰⁰ Fonseca *supra* note 46 at 11.

The second major regulation implemented for the enforcement of food safety in Brazil is the requirement that meat, dairy, and seafood processing plants be inspected.²⁰¹ At this time, Brazil has approved the Food Safety and Inspection Service for inspection of U.S. meat processing plants.²⁰² Those products inspected by the U.S. agency will be permitted to be imported into Brazil.²⁰³ The dairy processing plants in the United States that export to Brazil must be inspected by the Agricultural Marketing Services or the Food and Drug Administration prior to export.²⁰⁴

ARGENTINA

Like many of the other countries in the Americas, Argentina's rules regarding the importation of processed food products has been modeled after the United States.²⁰⁵ The National Service of Agricultural Food Health and Quality ("SENASA") is the agency that governs, regulates, and implements legislation involving the importation of prepared food products in Argentina.²⁰⁶ With regard to labeling, Argentina accepts labels generated in the United States under U.S. law with the major requirement being that the labels be in Spanish.²⁰⁷

²⁰¹ *Id.* at 13.

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ See generally Francisco Pirovano, *Argentina: Food and Agricultural Import Regulations and Standards 2006*, USDA Foreign Agricultural Service GAIN Report (Otc. 2006) available at <http://www.fas.usda.gov/gainfiles/200610/146249128.pdf>.

²⁰⁶ *Id.* at 4.

²⁰⁷ *Id.* at 5.

Labels indicating “organic products” must come from a country whose organic standards have been evaluated by SENASA and found to be equivalent to the Argentine regulations on organic production which includes inspection by Argentine certifying agencies.²⁰⁸ In other words those products claimed to be organic must be certified by agencies in Argentina prior to exportation.

CONCLUSION

The countries that make up the Americas have many similar rules governing the importation of prepared food products. Many of the countries have used the United States along with the World Trade Organization to develop and implement regulations regarding food packaging, labeling, rules of origin, and additive and pesticide use. Only particular countries have extra rules that differ from the United States as discussed above. These differences should be noted by American food producers and exporters prior to exporting final products to these countries. For the most part, the Caribbean nations and some South American countries including Brazil and Argentina do not have many regulations governing the importation of food processing. The rules that do exist have been taken from the United States and implemented. The few differences that existed had been highlighted above. Some have reasoned that these countries continue to import agricultural raw materials rather than processed products. Nevertheless, U.S. exporters should be aware of the differences in regulations.

²⁰⁸ *Id.*