HOT TOPICS - FOOD

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It appears that not a day passes without notice of something happening on the food front, whether with problems in the food itself or new regulations to avoid these same problems.

There are two laws which have been adopted to help resolve the problems, at the same time as complicating things by the complexity of the laws themselves. This paper will treat the Food Safety Modernization Act and the County or Origin Labeling Law. These need to be noticed and monitored because all the regulations have not yet been issued nor have all the lawsuits been resolved.

Much of the information which follows has been obtained from the web sites of the government agencies involved. Web site addresses, as well as a copy of the COOL regulations, are given at the end of this paper.

FOOD SAFETY MODERNIZATION ACT

In 1906, Upton Sinclair's book *The Jungle* shocked many Americans, including President Theodore Roosevelt, with its portrayal of the Chicago slaughter houses. Thus began the involvement of the federal government with our food safety, which continues to this day.

The FDA Food Safety Modernization Act ("FSMA"), one of the most significant changes in our food safety laws in the past 70 years, was signed into law by President Obama on January 4, 2011.

The law increased federal regulation of the food system and increased the U.S. Food and Drug Administration's ("FDA") authority to regulate the food system. The FDA now has the authority to require food companies to recall food under certain circumstances and expanded the FDA's authority to include oversight of specific on-farm agricultural practices.

One new rule sets out standards for produce safety and creates new requirements for certain on-farm practices, which have never been regulated before. The second rule is geared toward preventing food problems in the facilities which process food themselves. The intent is to move from a reactive system to one which aims to prevent problems.

The **Produce Safety Rule ("PSR")** applies to farms that grow, harvest, and hold fresh produce

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that is often consumed raw. If a farm is subject to the PSR, the farm will have to comply with new requirements in the following areas: worker training and health and hygiene; agricultural water; biological soil amendments; domesticated and wild animals; equipment, tools, and buildings.

There are several exemptions from the PSR. First, if over the past three years the farm's food sales average less than $25,000, the farm is not required to comply with the rule at all. The rationale is that these very small farms do not significantly contribute to the food supply and, therefore, do not pose a major threat to the public's health.

Second, if the farm's food sales average less than $500,000 and more than half of the farm's sales are direct to consumer, or to another "qualified end-user" that is defined in the PSR, the farm falls under the "qualified exempt" category. These qualified exempt farms do not have to comply with most portions of the PSR. However, "qualified exempt" farms are still obliged to meet a few requirements. This qualified exemption may be taken away under certain circumstances. If it is taken away, the farm must come into compliance with all provisions of the PSR.

The **Preventive Controls Rule ("PCR")** applies to facilities which manufacture, process, pack or hold human food. *FSMA Proposed Rule for Preventive Controls,* U.S. Dep't of Health & Human Servs., Food & Drug Admin., www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm (last visited 1/17/14).

If a facility is subject to the PCR, the facility must follow the updated current good manufacturing practices and must create a written food safety plan, called the Hazard Analysis and Risk-Based Preventive Controls (HARP-C) plan). This HARP-C plan requires facilities to identify places in their manufacturing and processing activities that might pose a food safety risk, create a plan to prevent those risks, monitor the processes, fix any problems, and keep records of their manufacturing and processing activities. Much of this must be overseen by an individual who has undergone special training in food safety plans or has developed experience through on the job training. Sec 103 of FSMA; 21 U.S.C. § 350(g).

There are modified requirements and exemptions from the PCR for certain facilities. A "qualified facility" exemption that lessens some of the requirements certain facilities must meet. A facility will qualify for this exemption if the facility's annual food sales over the past three years average less than $500,000 and more than half of its sales are direct to consumer (or to another

"qualified end- user" that is defined in the PCR). Facilities which qualify for this exemption must also comply with the current good manufacturing practices. They also must create a modified food safety plan. This exemption may be taken away under certain circumstances, in which case the facility must come into compliance with all provisions of the PCR.

In general, with some exceptions, the new preventive control provisions would apply to facilities that are required to register with FDA under FDA's current food facility registration regulations. Facilities that are required to register include manufacturers, processors, warehouses, storage tanks and grain elevators. FDA may withdraw certain exemptions if it determines it is necessary to protect the public health and prevent or control a foodborne illness outbreak. Activities within the definition of "farm" would not be subject to the proposed rule, and the proposed rule would clarify those activities.

Facilities that do not have to register with FDA, such as farms, retail food establishments, and restaurants, are not subject to the requirements for Hazard Analysis and Risk-based Preventive Controls (HA/PC) in the Proposed Preventive Controls Rule for Human Food.

The proposed hazard analysis and risk-based preventive control requirements are similar to Hazard Analysis and Critical Control Points (HACCP) systems. These were pioneered by the food industry. The FDA already requires their implementation for juice and seafood, which are largely imported. Operators of a facility would be required to understand the hazards that are reasonably likely to occur in their operation and to put in place preventive controls to minimize or prevent the hazards. Although this proposed rule is comparable to the HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.

Each covered facility would be required to prepare and implement a written food safety plan, which would include the following:

1. A **Hazard Analysis** that identifies and evaluates known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility.

2. **Preventive controls**, which would be required to be identified and implemented to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented. Preventive controls would be required to include, as appropriate: (1) process controls, (2) food allergen controls, (3) sanitation controls, and (4) a recall plan. However, the preventive controls required would depend on which, if any, hazards are reasonably likely to occur. It is unlikely that all

possible prevention measures and verification procedures would be applied to all foods at all facilities. FDA believes a supplier approval and verification program is a risk-based and appropriate control to significantly minimize or prevent hazards from raw materials and ingredients that is consistent with current scientific understanding of food safety practices and is seeking comment on such a program.

3. **Monitoring** procedures to provide assurance that preventive controls are consistently performed and records to document the monitoring.

4. **Corrective actions** that would be used if preventive controls are not properly implemented. Facilities would be required to correct problems and minimize the likelihood of reoccurrence, evaluate the food for safety and prevent affected food from entering commerce when necessary. If specific corrective action procedures were not identified for the problem, or if a preventive control were found to be ineffective, the facility would also be required to re-evaluate the food safety plan to determine if modifications are needed.

5. **Verification** activities to ensure that preventive controls are consistently implemented and are effective. Verification activities might include validation that the preventive controls are adequate for their purpose and are effective in controlling the hazard, activities to verify that controls are operating as intended and review of monitoring records. In addition, the proposed rule would require reassessment of the food safety plan at least every three years and at other times as appropriate. FDA recognizes that product and environmental testing programs are science-based verification activities that are commonly accepted in many sectors of the food industry and is seeking comment on these programs. FDA also is asking for comments regarding review of customer and other complaints as part of verification.

6. **Recordkeeping**. Facilities would be required to keep a written food safety plan, including the hazard analysis. They also would be required to keep records of preventive controls, monitoring, corrective actions, and verification.

www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm (last visited 1/17/14)

For imported foods, importers now will be specifically required to have a program to verify that the food products they are bringing into this country are safe. The FDA's new authority under the FSMA includes:

1. **Importer accountability:** Importers are to have an explicit responsibility to verify that their foreign suppliers have adequate controls in place to ensure that the food they produce is safe.

2. **Third-party certification:** There will be a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports.

3. **Certification for high-risk foods:** FDA has the authority to require that imported foods that are at high risk of contamination have a credible third-party certification or other assurance of compliance as a condition of entry into the U.S. The "third party" could be a private company or a governmental entity.

4. Voluntary qualified importer program The FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from program-certified facilities.

5. **Authority to deny entry:** The FDA can refuse entry into the U.S. of food from a foreign facility if the agency is denied inspection access by the facility or the country in which the facility is located.

The FDA has been directed to work with foreign countries and companies to facilitate their exports to the U.S. under the new rules. It has started to do this. They have translated seven different documents about FSMA into 11 languages which include the official languages, in addition to English, of the United Nations (Arabic, Chinese, French, Russian, Spanish) and the six languages which represent the primary countries from which the U. S. imports food (Italy, Japan, Korean, Portugal, Thailand, and India [Hindi]). The FDA has staff doing on-site training and in-country inspections. Where a food producer in China refused to allow an FDA investigator to perform an inspection, the FDA issued an import alert. An import alert can lead to the the product being refused admission in to the U.S. The staff in the FDA's 11 foreign offices have also obtained and shared local information which has resulted into improved identification of products coming into the U.S. which might not meet requisite standards. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm273561.htm (last visited 1/17/14).

Companion provisions are to be found in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) which was signed into law on June 12, 2002. Among other things, it amended Section 801 of the Federal Drug and Cosmetic Act. (21. U.S.C. 381). Section 801(m) created the requirement that FDA receive certain information about imported foods before arrival in the United States. It also provided that an article of food imported or offered for

import is subject to refusal of admission into the United States if adequate prior notice has not been provided to the FDA. Importers and consignees can be debarred from receipt of imported food products. www.fda.gov/regulatoryinformation/legislation/ucm148797.htm (last visited 1/17/14).

COUNTRY OF ORIGIN LABELING

The 2002 Farm Bill, Pub. L. No. 107-171 § 10816, 116 Stat. 134, 533-35, amended the Agricultural Marketing Act of 1946 ("AMS"), 7 U.S.C. §§ 1621-1637b (codified at 7 U.S.C. §§1638-1638d) to require country of origin labeling ("COOL") for shellfish, peanuts, fruits, vegetables, and various meats. (see, gen'ly www.ams.usda.gov)

There have been fights over the requirements since then, including a suit brought by Canada and Mexico in the World Trade Organization ("WTO"). This was resolved in May 2013 when the U.S. Department of Agriculture ("USDA") issued its final rule to bring COOL into compliance with a WTO ruling that found certain requirements to be inconsistent with the WTO agreement on Technical Barriers to Trade but affirmed the right of the United States to label products.

It established labeling requirements of the animal's geographic history, specifically including muscle cut meats of beef, pork, lamb, chicken and goat. All actual or reasonably possible countries of origin must be listed on the origin declaration.

There are exemptions, including: ingredients in processed food; food service establishments such as restaurants, cafeterias, bars.

The final rule modifies the labeling provisions for muscle cut covered commodities to require the origin designations to include information about where each of the production steps (i.e., born, raised, slaughtered) occurred and removes the allowance for commingling of muscle cuts. (7 C.F.R. § 65.300 (e)). Thus, an animal born, raised and slaughtered exclusively in the U.S. will be labeled "born, raised and slaughtered in the U.S.". Other labels might read "born and raised in Canada, slaughtered in the United States" or "born in Mexico, raised and slaughtered in the United States".

COOL covers retailers which purchase at least $230,000 annually of perishable agricultural commodities.

It amends the definition for “retailer” to include any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act (PACA) Retailers must notify their customers of the country of origin of covered commodities. Covered commodities include muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground

goat, and ground pork; wild and farm- raised fish and shellfish; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts.

COOL requires that a "retailer of a covered commodity shall inform consumers, at the final point of sale of the covered commodity to consumers, of the country of origin of the covered commodity". The retailer must provide country of origin labeling to consumers on a clear and visible sign on the commodity itself, the package, the display, or the holding bin at the final point of sale.

Under this final rule, origin designations for muscle cut covered commodities derived from animals slaughtered in the United States are required to specify the production steps of birth, raising, and slaughter of the animal from which the meat is derived that took place in each country listed on the origin designation. In addition, this rule eliminates the allowance for commingling of muscle cut covered commodities of different origins.

However, many imported agricultural products are either exempted from coverage or are deemed to have undergone sufficient additional manufacturing or processing so that they become products of the United States and, therefor, do not require labeling.

The main exceptions to the requirement that all products imported into the United States be marked with that product's country of origin are those products incapable of being marked, items economically prohibitive of being marked, and items on the "J List." The J List is contained in Title 19 Customs Duties, Chapter 1 U.S. Customs and Border Protection, Part 134 Country of Origin Marking, Subpart D Exceptions to Marking Requirements, Section 134.33 J-List exceptions. It includes classes of goods that were imported for five years after 1932 and were not required to indicate their country of origin during that time. Many agricultural products are on the list, including vegetables, fruits, nuts, berries and live or dead animals, fish, and birds. (*see* 19 C.F.R. § 134.33 for the J List exceptions).

RESOURCES

The National Agricultural Law Center: http://nationalaglawcenter.org

FSMA
U. S. Food and Drug Administration: www.fda.gov
- Food Safety Modernization Act (FSMA): www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
- The Law, Rules and Guidance : www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm
- FSMA Progress Reports : www.fda.gov/Food/GuidanceRegulation/FSMA/ucm255893.htm

- *FSMA Proposed Rule for Preventive Controls,* U.S. Dep't of Health & Human Servs., Food & Drug Admin., www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
- Title III -- Protecting Safety and Security of Food and Drug Supply, Subtitle A--Protection of Food Supply: www.fda.gov/RegulatoryInformation/Legislation/ucm155769.htm

COOL
U. S. Department of Agriculture, Agriculture Marketing Service (AMS), Country of Origin Labeling : www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateM&navID=CountryofOriginLabeling&rightNav1=CountryofOriginLabeling&topNav=&leftNav=CommodityAreas&page=CountryOfOriginLabeling&resultType=

7 U.S.C. §1638a. Notice of country of origin

(a) In general

(1) Requirement

Except as provided in subsection (b) of this section, a retailer of a covered commodity shall inform consumers, at the final point of sale of the covered commodity to consumers, of the country of origin of the covered commodity.

(2) Designation of country of origin for beef, lamb, pork, chicken, and goat meat

(A) United States country of origin

A retailer of a covered commodity that is beef, lamb, pork, chicken, or goat meat may designate the covered commodity as exclusively having a United States country of origin only if the covered commodity is derived from an animal that was—

(i) exclusively born, raised, and slaughtered in the United States;

(ii) born and raised in Alaska or Hawaii and transported for a period of not more than 60 days through Canada to the United States and slaughtered in the United States; or

(iii) present in the United States on or before July 15, 2008, and once present in the United States, remained continuously in the United States.

(B) Multiple countries of origin

(i) In general A retailer of a covered commodity that is beef, lamb, pork, chicken, or goat meat that is derived from an animal that is—

(I) not exclusively born, raised, and slaughtered in the United States,

(II) born, raised, or slaughtered in the United States, and

(III) not imported into the United States for immediate slaughter,

may designate the country of origin of such covered commodity as all of the countries in which the animal may have been born, raised, or slaughtered.

(ii) Relation to general requirement Nothing in this subparagraph alters the mandatory requirement to inform consumers of the country of origin of covered commodities under paragraph (1).

(C) Imported for immediate slaughter

A retailer of a covered commodity that is beef, lamb, pork, chicken, or goat meat that is derived from an animal that is imported into the United States for immediate slaughter shall designate the origin of such covered commodity as—

(i) the country from which the animal was imported; and

(ii) the United States.

(D) Foreign country of origin

A retailer of a covered commodity that is beef, lamb, pork, chicken, or goat meat that is derived from an animal that is not born, raised, or slaughtered in the United States shall designate a country other than the United States as the country of origin of such commodity.

(E) Ground beef, pork, lamb, chicken, and goat

The notice of country of origin for ground beef, ground pork, ground lamb, ground chicken, or ground goat shall include—

(i) a list of all countries of origin of such ground beef, ground pork, ground lamb, ground chicken, or ground goat; or

(ii) a list of all reasonably possible countries of origin of such ground beef, ground pork, ground lamb, ground chicken, or ground goat.

(3) Designation of country of origin for fish

(A) In general

A retailer of a covered commodity that is farm-raised fish or wild fish may designate the covered commodity as having a United States country of origin only if the covered commodity—

(i) in the case of farm-raised fish, is hatched, raised, harvested, and processed in the United States; and

(ii) in the case of wild fish, is—

(I) harvested in the United States, a territory of the United States, or a State, or by a vessel that is documented under chapter 121 of title 46 or registered in the United States; and

(II) processed in the United States, a territory of the United States, or a State, including the waters thereof, or aboard a vessel that is documented under chapter 121 of title 46 or registered in the United States.

(B) Designation of wild fish and farm-raised fish

The notice of country of origin for wild fish and farm-raised fish shall distinguish between wild fish and farm-raised fish.

(4) Designation of country of origin for perishable agricultural commodities, ginseng, peanuts, pecans, and macadamia nuts

(A) In general

A retailer of a covered commodity that is a perishable agricultural commodity, ginseng, peanut, pecan, or macadamia nut may designate the covered commodity as having a United States country of origin only if the covered commodity is exclusively produced in the United States.

(B) State, region, locality of the United States

With respect to a covered commodity that is a perishable agricultural commodity, ginseng, peanut, pecan, or macadamia nut produced exclusively in the United States, designation by a retailer of the State, region, or locality of the United States where such commodity was produced shall be sufficient to identify the United States as the country of origin.

(b) Exemption for food service establishments

Subsection (a) of this section shall not apply to a covered commodity if the covered commodity is—

(1) prepared or served in a food service establishment; and

(2)

(A) offered for sale or sold at the food service establishment in normal retail quantities; or

(B) served to consumers at the food service establishment.

(c) Method of notification

(1) In general

The information required by subsection (a) of this section may be provided to consumers by means of a label, stamp, mark, placard, or other clear and visible sign on the covered commodity or on the package, display, holding unit, or bin containing the commodity at the final point of sale to consumers.

(2) Labeled commodities

If the covered commodity is already individually labeled for retail sale regarding country of origin, the retailer shall not be required to provide any additional information to comply with this section.

(d) Audit verification system

(1) In general

The Secretary may conduct an audit of any person that prepares, stores, handles, or distributes a covered commodity for retail sale to verify compliance with this subchapter (including the regulations

promulgated under section 1638c (b) of this title).

(2) Record requirements

(A) In general

A person subject to an audit under paragraph (1) shall provide the Secretary with verification of the country of origin of covered commodities. Records maintained in the course of the normal conduct of the business of such person, including animal health papers, import or customs documents, or producer affidavits, may serve as such verification.

(B) Prohibition on requirement of additional records

The Secretary may not require a person that prepares, stores, handles, or distributes a covered commodity to maintain a record of the country of origin of a covered commodity other than those maintained in the course of the normal conduct of the business of such person.

(e) Information

Any person engaged in the business of supplying a covered commodity to a retailer shall provide information to the retailer indicating the country of origin of the covered commodity.

(f) Certification of origin

(1) Mandatory identification

The Secretary shall not use a mandatory identification system to verify the country of origin of a covered commodity.

(2) Existing certification programs

To certify the country of origin of a covered commodity, the Secretary may use as a model certification programs in existence on May 13, 2002, including—

(A) the carcass grading and certification system carried out under this Act;

(B) the voluntary country of origin beef labeling system carried out under this Act;

(C) voluntary programs established to certify certain premium beef cuts;

(D) the origin verification system established to carry out the child and adult care food program established under section 1766 of title 42; or

(E) the origin verification system established to carry out the market access program under section 5623 of this title.