NOTE FROM THE CHAIRS

As the world gets smaller, supply chains are getting longer, and more complicated. Much of the food we eat is imported, a trend that has been accelerating. But even as supplies are increasingly drawn from more and more distant places, consumers and retailers are insisting on greater information about food sources and processing: the growing "clean label" movement demands food that is "all natural," non-GMO, minimally processed, etc. We therefore begin the Newsletter with John Johnson's primer on FDA's authority to control the importation of foods (and other FDA-regulated products), followed by Charley Woodhouse's in-depth analysis of how the demands of the clean-label movement are complicating efforts to track sources, maintain quality control, and verify label claims.

Cosmetics have long been only lightly regulated, at least in comparison to foods and medical product. This may be changing. Our last article, from Dr. Annette Santamaria, tracks a bipartisan bill that may prove to be as significant to cosmetics safety (and safety regulations) as FSMA has been for foods.

Jonathan Berman, John Fuson

When Looks are All that Matter: A Primer about FDA’s Enforcement Authority over Imported Products

By John Johnson III, Esq.

FDA commonly stresses that it regulates approximately 25 cents of every dollar through its regulation of food, drugs, medical devices, cosmetics, dietary supplements, animal food and drugs, and tobacco products.¹ These commodities are increasingly imported into the United States or at least they rely on imported raw materials. Such statistics that are commonly shared about imports: (1) 80% of Active Pharmaceutical Ingredients (APIs),² (2) 94% of seafood,³ 50% of fresh fruit and 20% fresh vegetables,⁴ and 50% of medical devices⁵—and these numbers are old. Against this backdrop, the public and Congress have expressed concern that FDA is unable to ensure the compliance of these imported products.⁶ Despite all of this, there is a lot of misunderstanding about FDA's authority to inspect and refuse imported products, and how FDA implements its authority. This leads to some unfair criticism of the Agency, and failure to appreciate the strength of FDA's authority. For example in essence, FDA can issue an embargo against some imported products without needing to go to court or even undergo notice and comment rulemaking.⁷ To alleviate this confusion, the following provides a primer about the basic structure and approach that FDA takes to reviewing commodities for compliance while they are being imported.

CONTINUED ON PAGE 4
This article will: (1) highlight the impact of the Clean Label Movement on US and EU markets for processed foods; (2) discuss the Food Technology implications of Clean Label for Processing, Additives, Food Contact Materials, and Shelf-Life of foods; (3) present a 21st Century Supply-Chain logistics model for the Clean Label era; and (4) familiarize Food Lawyers with the implications of Clean Label for Supply-Chain liability, indemnification, and insurance.

Food Scientists and Food Industry Executives know that the fastest growing sector is “Clean Label”. Andrew Winston, writing in *Harvard Business Review* addresses “…the relentless shift to transparency and what many call the ‘clean label’ movement. In the food world, a clean label focuses on having fewer ingredients that are very clear about their origins, and recognizable (e.g., ‘cream’ versus ‘microparticulated whey protein concentrate.’)”

Keith Nunes, writing in *Food Business News* estimates the Clean Label Food category at $165 Billion (US $62 Billion and EU $103 Billion) in 2015 sales and defines Clean Label as “…all natural, no artificial additives, no artificial colors, no artificial preservatives, no artificial flavors, no artificial sweeteners, G.M.O. free, B.P.A. free and no monosodium glutamate.”

Thus by 2015 Clean Label had reached nearly 10% of Total Annual US Retail Grocery Sales and a significantly higher percentage when adjusted for Processed Foods categories.

Nothing could be more emblematic of the Clean Label Movement than the Panera Bread “No-No List” and the Whole Foods “Unacceptable Ingredients List” which ban those companies’ suppliers from using over 100 commonly used Food Additives.

Food Scientists, led by the Institute of Food Technologists have been quick to respond to the demand for Clean Label Foods. Lu Ann Williams, writing in *Food Technology* comments:

“Clean labeling has moved beyond being a trend and is now regarded as more or less standard in the food industry, with consumers demanding shorter and more recognizable ingredients lists and manufacturers responding by increasingly highlighting the naturalness and origins of their products. With growing concerns over the lack of a definition of natural, however, there is a need for more clarity and specificity, with consumers, retailers, industry, and regulators all driving the demand for more transparency in food labeling.”

Notwithstanding Williams’ comment, FDA has already given us a reasonable working definition for Natural, albeit not issued as a regulation. “FDA has considered the term ‘natural’ to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food.”

The details of the Food Technology and Food Engineering advances that drive the processing changes that are required by Clean Label are beyond the scope of this article. However, Food Lawyers should be aware that significant manufacturing changes are required by the reduction of shelf-life caused by the elimination of many commonly used Food Additives. Food Technologists must be nimble when these common additives are banned, without notice, comment, or appeal by private buyers such as Panera and Whole Foods who are well ahead of regulators in imposing changes upon the food manufacturing industry. Three important trends will affect the food industry in the coming decade: (1) the movement to “minimal processing”; (2) the continuing growth of ESL (Extended Shelf Life) Foods; and (3) the increased use of active, intelligent, and responsive food packaging to extend shelf-life. (For readers who want to learn more about ESL, minimal processing, and enhanced shelf-life the Balasubramanian article cited in End Note 9 is an excellent beginning.)

Food Lawyers must understand that the relationship between market trends and Food Technology will necessitate changes in modern Supply-Chain logistics. Fortunately the drafters of the Food Safety Modernization Act (“FSMA”) have been prescient in addressing the compliance and liability issues presented by 21st Century Logististics. The most important of USFDA’s Food Safety Modernization Act Final Rules, the Risk-Based Preventative Controls Rule provides considerable flexibility to Manufacturers, Distributors, and End-Users in the structures of evolving Food-Supply Chain models that will guide future FDA compliance monitoring. The ABA in its publications has addressed some of the implications of these new Supply-Chain Models and the accompanying Risk-Management challenges. Articles by Vince Keane and Rebecca Cross have explored Supply-Chain Indemnification and Insurance. Two articles by Woodhouse have introduced FSMA liability considerations and have discussed Logistics Supply-Chains in relation to the Sanitary Transportation FSMA Rule.

In the era of Clean Label and minimally-processed ESL Foods, the technical information links between Manufacturers (and their Ingredient, Additive, and Packaging Suppliers) and the End-Users (Retail Grocery and Food Service Sector) will need to be strengthened. Thus, new Supply-Chain Models are already evolving to connect the technical staffs all the way down the Supply-Chain. Minimal Processing entails reduced use of traditional Thermal Processing preservation technologies and reduced use of Food Additives. This means that pathogen “Kill-Steps” will be moved down the Supply-Chain by agreement between Suppliers and First Receivers. An example would be the use of High-Pressure Sterilization or Irradiation (Kill-Steps) by a downstream...
The Personal Care Products Safety Act (PCPSA) was introduced into the Senate on April 20, 2015 by Senator Dianne Feinstein (D-Calif) and Senator Susan Collins (R-Maine). The Bill is expected to be introduced again in the 115th Congress by Senators Feinstein and Collins and would amend the Federal Food, Drug, and Cosmetic Act to require cosmetics companies to register their facilities with the Food and Drug Administration (FDA) and to submit cosmetic ingredient statements to the FDA that include the amounts of a cosmetic's ingredients. In addition, cosmetic companies must pay a facility registration fee based on their annual gross sales of cosmetics. The bill also states that if the FDA determines that a cosmetic has a reasonable probability of causing serious adverse health consequences, it may prohibit the cosmetic's distribution by suspending the cosmetic ingredient statement. The Bill specifies that the FDA must review the safety of at least five cosmetic ingredients each year, and it may establish conditions for safe use of an ingredient, including a limit on the amount of the ingredient or a requirement for a warning label. The initial five ingredients include methylene glycol/formaldehyde (used in hair-smoothing treatments), lead acetate (a color additive in hair dyes), propyl paraben (a preservative in many liquid cosmetics like shampoo, conditioner, and lotions), diazolidinyl urea (a preservative often found in shampoos, conditioners, and deodorants), and quaternium-15 (a preservative frequently found in skin creams and cleansers). Of these five chemicals, four are already restricted for use in cosmetics and personal care products with concentration limits set by the European Union (EU) and lead acetate is banned in the EU. A committee will be formed to advise the FDA on ingredient safety assessments and the FDA could require specific labeling and warnings for products that contain ingredients not suitable for the entire population. A cosmetic cannot be sold if it contains an ingredient that is not safe, not safe under the recommended conditions of use, or not safe in the amount present in the cosmetic.

Any cosmetics manufacturer with less than $100,000 in gross annual revenue (three year average) would be exempt from compliance with the bill. The PCPSA would make it mandatory to register and pay registration fees for cosmetics manufacturers and fee amounts will be dependent on the annual gross revenue of the business. For example, the bill provides a cap on the fee amount for small businesses with $500,000 to $2,500,000 in annual gross revenues. Businesses with greater than $100,000 and less than $500,000 in annual gross revenue would be exempt from fees, but would still need to register. Electronic filings will be required to comply with the registration, ingredient statements, and adverse event reporting. The registration information would include the facility name, physical address, business trading names, nature of the business, emergency contact information, and a statement that the FDA will be permitted to inspect the facility. Manufacturers would be required to file annual ingredient statements, which will include the facility's identification number tied to their registration, the facility's name, the product's name, and the product's full ingredient list (with a range of percentages of each ingredient), name and contact information of the person filing the statement, and any additional required information. This information would become a part of public record, with the exemption that registered facilities with residential addresses would not have their location disclosed publicly.

In addition, the bill requires the FDA to develop and implement actual good manufacturing practices (GMPs) definitions that will become mandatory for all cosmetic and personal care product manufacturers. Small businesses will be given two years to comply, rather than 180 days given to larger manufacturers. Extensive adverse event reporting would become mandatory, including individual reports and an annual report summarizing all adverse events. Product recalls would fall under FDA jurisdiction, and the agency would be given authority to inspect records and order recalls if a voluntary request for recall is not upheld. The bill also recommends more extensive labeling requirements, including ingredients not appropriate for children or for professional use only. Furthermore, internet websites must include the product labeling that appears on packaging.

To date, there has been one Hearing on the Bill before the Senate Health, Education, Labor and Pensions (HELP) Committee on September 22, 2016. Senator Collins testified and additional individuals that testified at the hearing included: 1) Beth Jonas,
FDA's Legal Authority on the Border

FDA's authority comes from the Food, Drug, and Cosmetic Act of 1938, which replaced the Pure Food and Drug Act of 1906. For products being offered for import into the United States, the Congress granted FDA the power to hold an administrative hearing and determine whether a product offered for import may be imported or not—note once released into domestic commerce, FDA no longer has its import authority and must rely on its domestic power. This import administrative hearing is parallel to FDA acting in rem against a product in court under Section 304—in particular FDA is alleging that the product is violative; FDA is not proceeding against an individual.

In particular, FDA's authority to hold this administratively review and refuse imported articles comes from Section 801(a) of the Act. This Section is an excellent example of poor legal draftsmanship as it consists of one massive paragraph made up of eleven sentences that uses approximate 850 words. This poor construction occurred in part because the 1938 Act largely copied the language from the 1906 Act. Then since 1938, the Congress kept cramming more words into a bloated paragraph rather than clean-up the language when it added new requirements.

Throughout all of these many words, the statute establishes quite a simple system. FDA has the authority to examine any imported regulated product and the owner or consignee has the right to introduce testimony as to the product's compliance. If based on FDA's examination or otherwise the product appears to violate the Act, then FDA shall refuse its importation. However, prior to refusal, the importer may petition FDA to relabel or otherwise recondition the product, and it will be released if the reconditioning is successful. Yet, if the owner or consignee does not recondition the violative product, then FDA will refuse it and the product must be destroyed or exported within 90 days from the refusal.

In the regulations, FDA further illuminated the administrative hearing process. When FDA decides to sample a product, the owner or consignee will receive notice and they must hold the product until they receive the results. If the product is in compliance, then FDA will pay for the samples and it may be released into commerce after being released by FDA. If not in compliance, then FDA will start the process to issue an import refusal. Beyond the examination, FDA encapsulated the right of the owner or consignee to introduce testimony by creating an informal hearing structure. In particular, once FDA concludes that it appears that a product "may be subject to refusal of admission," then FDA will "detain" the product and give the owner or consignee written notice stating the reason why FDA asserts the product maybe subject to import refusal. With this notice, FDA provides the time and location for the hearing, but this can be changed. This "detention" is generally a metaphorical detention as the importer will usually have custody of the product as Customs will have conditionally released the product.

Implementing this Framework:

The statute and the regulations provide the basic framework, but there remain many issues that FDA resolved in practice. These include: (1) must FDA sample the product in order to detain it, (2) who has the burden of proof, what is the evidentiary standard, and is it reviewable by a court, and (3) are there other tools FDA can use against imported product. Admittedly, these are but a few of the many issues, but some of the most critical.

Must FDA Sample the Product to Detain It?

The statute indicates that FDA shall refuse a product "based upon the examination or otherwise." FDA has interpreted the "or otherwise" language to mean that it can issue an import refusal based upon evidence gathered outside of examining an individual shipment. FDA's reliance on the "or otherwise" language is largely manifest in FDA's import alert system. An import alert is an internal Agency directive that a product that matches which is described in an import alert may be subject to "detention without physical examination." In other words, FDA will automatically detain a shipment of a product based upon previously collected evidence indicating the product's non-compliance. There several different types of import alerts: (1) those limited to a specific product from a specific manufacturer (the most common), (2) those limited to a product from any manufacturer within a given country, unless exempt (referred to as "countrywide" alert), and (3) those for a given product, regardless of manufacturer or country of production.

In most cases, an import alert ultimately serves to shift the burden of proof. For FDA to refuse an imported product, it must persuade itself that the product appears to violate the Act. When subject to an import alert, FDA in essence is referring to evidence collected outside of the individual shipment at question to say that this current one appears subject to import refusal. At this point, the importer can collect evidence (usually in the form of third-party testing) to demonstrate to FDA that the product is in fact in compliance. If the testing demonstrates compliance, then FDA will release the shipment.

For example, FDA tested a previous shipment of tuna fish and detected Salmonella (thereby making the product appear to violate Section 402(a)(1) by containing a poisonous or deleterious substance that may render it injurious to health). When a later shipment of tuna fish arrives from the same manufacturer, FDA may detain it without physical examination. At this point the importer generally has two options: (1) test the product and provide evidence it does not contain Salmonella, or (2) take an import refusal.
This process of detention without physical examination continues in definitely until either (1) the manufacturer or importer petitions FDA to remove the product from import alert (or exempt it), or (2) FDA deletes the import alert completely because the Agency believes it is no longer sustainable (this usually only happens for countrywide alerts). If a facility hopes that FDA will remove the product/facility from an import alert sua sponte, they will be waiting a long time—indefinitely. FDA issued the first import alerts in 1974, and according to the public data, there are some facilities still on import alert since the 1980s.

Who has the Burden and What is Burden:

It is commonly said that the importer and foreign manufacturer are obligated to ensure the compliance of their product. While this is true (and is also true for domestic product), it does not mean that a product is subject to import refusal unless the importer satisfy FDA's desires for any evidence that demonstrates compliance. Rather FDA has the burden of proof to obtain evidence to support the standard that the product "appears" to violate the Act.

By its very name (the appearance standard), this burden is low and usually easy for FDA to meet. The Agency simply needs some evidence to support the conclusion that it looks like the product is not in compliance—some logical relationship between the evidence and the charge made against the product. While these import hearings are subject to judicial review under the Administrative Procedure Act, the courts apply a highly deferential analysis to the Agency and will only overturn an import hearing if the Agency was arbitrary and capricious. In the report ed cases, FDA has a strong record for their decisions being upheld.

What are Other Tools:

For imported products, FDA still possesses all of its other enforcement tools, which may be necessary given some of the limitations of Section 801(a) of the Act. To appreciate Section 801(a)'s limited capabilities, the Act's enforcement tools need to be placed into context. Essentially, the Act's enforcement provisions have two separate purposes: (1) keep adulterated or misbranded products out of commerce, which is accomplished through seizure, and punish either civilly or criminally those associated with adulterated or misbranded products, which is accomplished through court proceedings. Section 801(a) is simply an administrative alternative for imported products that FDA can rely upon in place of seeking judicial seizure.

With that in mind, there are several limitations to Section 801(a). First, it does not provide FDA with seizure authority despite being the import alternative to judicial seizure. For imports, Customs commonly conditionally releases the imported product while FDA contemplates its compliance. This means that the importer has custody over the product, thereby creating a risk of the importer either intentionally or mistakenly distributes it. To minimize this risk, the importer only obtains custody of the product after posting a bond. If the importer fails to comply with its obligations, then it can be issued a claim for liquidated damages, which is three times the value of the product, up to the value of the bond. If FDA is concerned about that risk, then it must work with Customs proactively to not have the product conditionally released, or to have the importer return it to Customs' custody.

Once a product is subject to import refusal, like a court proceeding, it can be either destroyed or reconditioned (fixed) (although the reconditioning process must take place before the refusal). Product prohibited from commerce under Section 801(a) can be exported, unlike those condemned under Section 304. This creates the risk that someone will export the apparently volatile product and attempt to reimport it in hope of slipping past FDA. Thus if FDA wants to seize an article to ensure that it does not enter into commerce, it must either ask U.S. Customs and Border Protection to use its authority under the Tariff Action of 1930, or it must seek judicial seizure under Section 304 of the FDCA.

Second, it is not a prohibited act itself to attempt to import a product that is later refused entry into the United States. Thus to punish someone who performs this action, FDA must bring a judicial action under Chapter 3 of the FDCA and prove by a preponderance of the evidence (civil) or beyond a reasonable doubt (criminal) that the importer committed a prohibited act, such as introducing into interstate commerce an adulterated or misbranded product. Thus FDA must possess greater quantity and quality of evidence beyond what it collected to issue the import refusal.

This being said, if the importer seeks to reimport a product previously subject to FDA import refusal, the food is adulterated if the owner or consignee does not affirmatively establish the food's compliance. Then as a condition of import, the owner or consignee must declare to FDA if the food was previously refused admission. Thus if an importer seeks to evade FDA and reimport refused food, then it is easier to prosecute the individual as FDA is not having to establish that the food is adulterated or misbranded under the traditional means. Rather FDA is only having to establish the identity of the food and the behavior of the importer at question—an easier proposition.

Concluding Thoughts:

Although these import hearings are informal and common (FDA performs thousands every year), they should not be confused with FDA's better known enforcement tools: 483 Inspection Observations, Untitled Letters, and Warning Letters. Those tools are all advisory and the recipient is under no obligation to respond to them. An import detention hearing is in fact a hearing, and failure to respond will result in import refusal that will not generally be overturned—much like a default judgment. Furthermore, based on FDA's ability to use "other" evidence, FDA may use the refusal from one past shipment to justify stopping future shipments.

Thus as supply-chains continue to rely more on imported finished goods or components, it is essential to understand FDA's authority on the border and how the Agency implements its power. Otherwise, someone will find themselves with no product or at least delays—either option represents commercial harm to the importer and its customers.
customer to reduce the flavor-degradation of traditional Thermal Processing at the Supplier level.

The traditional conceptualization of the Supply-Chain is illustrated in Chart I where the Importer or Domestic Manufacturer is the sole source of “information” regarding the product. But in the Clean Label era, the complexities of modern Supply-Chain Models involve multiple “players” and the assignment, by mutual agreement, of Food Safety Compliance Responsibilities to those parties that are most able to control such Food Safety Risks. A Food Scientist at a US food manufacturer is no longer willing to pass scientific questions through a non-scientist at a US food importer—she needs to interact directly with an overseas supplier of Ingredients, Additives, or Food Contact Materials (“FCMs”).

An analysis of the requirements on the FSMA Final Rule on Risk-Based Preventative Controls (“RBPCs”) is beyond the scope of this article. However, we are fortunate that FDA’s discussion of the Supply-Chain provisions is contained in a relatively compact 27-pages within the massive (261 pages in Federal Register) document as this discussion will assist in understanding the relatively sparse wording of the new 21 CFR Part 117 provisions for Supply-Chain Programs.18, 19 (For further background on the RPBC Rule Audits and Certifications, interested readers may wish to review the several PowerPoint Presentations available on the author’s Blog.)20

The provisions of 21 CFR Part 117 Subpart G are illustrated in Charts I and II which highlight the differences between Traditional Concepts of the Supply-Chain and more modern 21st Century Supply-Chains used in global commerce. These Supply-Chain concepts can apply to both international and domestic scenarios with the only possible “missing player” in the domestic scenario being US Customs in the event that there are no foreign sourced ingredients, additives, or FCMs in the product. Listed below are the Section titles of 21 CFR Part 117 Subpart G—Supply-Chain Programs:

CONTINUED ON PAGE 7

© 2017, Charles F. Woodhouse

FSMA = Food Safety Modernization Act

TRADITIONAL MANUFACTURER-IMPORTER RELATIONSHIP

Suppliers - Ingredients, Additives, Food Contact Materials

Overseas Manufacturer "initiates shipment" (Alternatively shipper may be separate entity)

Technical Information - Ingredients, Additives, Food Contact Materials

Risk-Based Preventative Controls Plan

Sanitary Transportation Plan

See FDA Discussion of "Qualified Individual" (QI) 80 FR 56070-72 and 21 CFR 117.180

Preparation and subsequent periodic review and analysis must be supervised by QI. Name of QI and educational qualifications must be disclosed.

US IMPORTER "causes transaction"
(Importer may take physical delivery or instruct House-to-House delivery directly to Inland Customer)

Importer Sanitary Transportation Plan

Importer’s Risk-Based Preventative Controls Plan

ADDITIONAL DOCUMENTATION
1. Intentional Adulteration Prevention Plan
2. Recall Plan
3. Contamination & Recall Insurance with Third-party Rider
4. Product Liability Insurance

Importer’s Foreign Supplier Verification Plan

Third-Party Certification of “Process”

Movement of Goods

Documentation Flow

Importer’s Recall Indemnification obligations as defined in Vendor Agreement

Domestic US Customer

Supply-Chain Guarantees

Indemnification Rights

© 2017, Charles F. Woodhouse

FSMA = Food Safety Modernization Act
FOOD LAWYERS FACE CHALLENGES

continued from page 6

- Requirement to establish and implement a supply-chain program. §117.405
- General requirements applicable to a supply-chain program. §117.410
- Responsibilities of the receiving facility. §117.415
- Using approved suppliers. §117.420
- Determining appropriate supplier verification activities (including determining the frequency of conducting the activity). §117.425
- Conducting supplier verification activities for raw materials and other ingredients. §117.430
- Onsite audit. §117.435
- Records documenting the supply-chain program. §117.475

Chart II illustrates the concept, as in the example on page 6, that the Domestic Manufacturer or First Receiver of an imported product may waive direct responsibility for a Food Safety RBPC which is beyond its direct control. However, the entity that waives responsibility for a Preventative Control must employ a robust Supplier Verification System and be diligent in maintaining documentation of waivers, guarantees, and indemnification agreements with parties "upstream" in the Supply-Chain. An additional consideration is that major buyers in the Retail Grocery and Food Service sectors have shown little inclination to modify their Vendor Agreements to accept waivers. Thus, if your client is only one step upstream from the Retail Grocer, then the "buck stops" with your client who will be financially responsible for all Recall Costs including indemnification under the Vendor Agreement with the Retail Grocer or Food Service operator.

The challenge to Food Lawyers is to understand that the new Clean Label and ESL environment is characterized by a much higher degree of technical (Food Science and Technology) requirements and by much greater direct involvement by the US Retail Grocery Industry. This extends all the way up the Supply Chain as Retail Grocers and Restaurant Chains move out well ahead of regulators in the elimination of food ingredients that are "unacceptable" to informed post-consumer millennials. Thus all documentation and Risk-Management practices must be reevaluated and reconceptualized.

To serve food industry clients Food Lawyers must begin by first understanding these fundamental changes in America's food production and distribution systems.

Charles F. Woodhouse, Esq., BA Dartmouth, MBA Wharton, JD Rutgers, and MS Food Safety Michigan State, is a principal at Woodhouse Shanahan PA, a Professional Member of the Institute of Food Technologists, and was a founding shareholder of Marine Harvest International serving as its president until its purchase by European Investors in 1995. He is currently earning his second food technology related MS (Packaging—Materials Science & Engineering) at Michigan State with research agenda "Regulation of Use of Nanomaterials in Food Contact Substances". His Blog on scientific issues affecting the US and EU Food Business is at: www.food-label-compliance.com
MANUFACTURER-IMPORTER RELATIONSHIP; 21ST CENTURY LOGISTICS UNDER FSMA

**MANUFACTURER'S DOCUMENTATION**
1. Risk-Based Preventative Controls Plan
2. Intentional Adulteration Plan
3. Sanitary Transportation Plan
4. Technical Information: Ingredients, Additives, Food Contact Materials, ESL Preservation Technologies
5. Downstream Continuing Guarantee to First-Receiver
6. Third-Party Certifications

**FIRST-RECEIVER'S DOCUMENTATION**
1. Risk-Based Preventative Controls Plan
2. Recall Plan
3. Intentional Adulteration Plan
4. Sanitary Transportation Plan
5. Food Safety Responsibility Waivers with Agent (Broker)
6. Upstream Continuing Guarantees
7. Technical Information from Manufacturer, and Suppliers of Ingredients, Additives and FCMs

**INSURANCE CONSIDERATIONS FOR FIRST RECEIVER**
1. Risk-Management Analysis of Indemnification provisions in Vendor Agreements
2. Product Liability Insurance ACORD Certificates
3. Contamination & Recall Insurance (C&R)
4. Third-party Liability Rider to C&R
5. Analysis of Subrogation Obligations to Insurance Carriers
6. Evaluation of Tort Liability Risk associated with specific products
7. Protection of Privilege in litigation

**OVERSEAS MANUFACTURER**
Advances in Preservation and Aseptic Packaging Technologies for ESL Foods require End-User Coordination

**AGENT (BROKER)**
- FSMA envisions 21st Century Logistics Solutions
- Facilitator (Agent) may or may not serve as Importer of Record
- Agent may disclaim Food Safety Responsibility in whole or part

**FIRST-RECEIVER IN USA**
- Receives Product in House-to-House International Shipment
- May be either US Manufacturer or only Importer/Distributor
- May or may not be US Customs Importer of Record
- May accept Food Safety Responsibility in whole or part by agreement with Agent (Broker)

**US RETAIL GROCERY OR FOOD SERVICE DISTRIBUTION CUSTOMER**
Vendor Agreements include Guarantee and Indemnification terms and ACORD Certificate of First-Receiver's Product Liability Insurance

**DOCUMENTS**
- Ingredient Suppliers
- Processing Technologies for ESL Foods
- Additives Suppliers
- Advanced Additives for ESL and Aseptic Foods
- Food Contact Materials Suppliers
- Packaging Polymer Converter
- Active, Intelligent & Responsive Packaging

**CONTINUING GUARANTEES**
- Advances in Preservation and Aseptic Packaging Technologies for ESL Foods require End-User Coordination
- Technical Information required by USFDA, USDA, EPA, USCBP

FSMA = Food Safety Modernization Act

© 2017, Charles F. Woodhouse
CURRENT STATUS OF THE PERSONAL CARE PRODUCTS
continued from page 3

Ph.D., Chief Scientist for the Personal Care Products Council (PCPC), which represents approximately 600 large, medium and small sized manufacturers and distributors of personal care products; 2) Wilma Bergfeld, M.D., Chair of the Cosmetic Ingredient Review (CIR) Expert Panel and a consultant and member of the FDA’s Dermatology and Ophthalmology Advisory Committee since 1973; 3) Scott Faber, Senior Vice President for Government Affairs at the Environmental Working Group (EWG), which has been evaluating the safety of personal care product chemicals for more than a decade; and 4) Curran Dandurand, Chief Executive Officer of Jack Black LLC., a marketer of personal care products for men.

Senator Collins testified on the need to update the nation’s nearly 80-year-old law to ensure the safety of personal care products and she urged the Committee to advance the Personal Care Products Safety Act, which she introduced with Senator Feinstein. Senator Collins cited a case of a nine-year-old girl who lost all her hair after using a WEN hair product. She further stated that the company had received more than 21,000 consumer reports of harmful effects, while the FDA had received 127 reports at the time the agency announced that it would investigate claims of hair loss, hair breakage, balding, itching, and rashes. She further stated that the number had since grown to more than 1,000 reports, but the personal care products company is not required to report adverse events to the FDA. She elaborated on some of the details about the Act and concluded, “By modernizing the oversight of personal care products that are used so widely by the American public, consumers will be better informed and protected.”

Dr. Jonas of the PCPC testified that: (1) cosmetics and personal care products are among the safest product categories regulated by the FDA; (2) consumer and product safety are top priorities in the industry; (3) cosmetic safety assessments are thorough and address numerous health questions, including, the potential for cancer, reproductive harm, allergic reactions, and how an ingredient is cleared if it goes through the body; and (4) companies’ post market surveillance of the consumer experience acts to affirm product safety. She further stated that the PCPC supports independent programs to review product and ingredient safety, such as the Cosmetic Ingredient Review (CIR) Expert Panel, which defines safe ranges for ingredients used in products. The CIR Expert Panel, which meets in public in Washington, D.C. four times a year, is an independent, non-profit body of world-renowned physicians and scientists who examine and assess cosmetic ingredient safety data in an open, public manner. Dr. Jonas stated that the PCPC supports the goals contained in the bill and that despite the strong safety record in the industry, a comprehensive national program is needed to assure uniform regulation of cosmetics throughout the country and to prevent an unworkable patchwork of differing state requirements across the nation.

Dr. Bergfeld testified that the CIR thoroughly reviews and assesses the safety of ingredients used in cosmetics in an open and expert manner, and publishes the results in peer-reviewed literature. Dr. Bergfeld assured the committee that the CIR and its review process are independent and that the CIR solicits public comment at all stages of a multi-review process. Furthermore, if the scientific literature contains insufficient information or if the information submitted is not sufficient to make a safety determination, the CIR requests that industry and other interested parties undertake studies to address these insufficiencies, or to provide previously unpublished data. Dr. Bergfeld gave the CIR’s support to the congressional efforts to modernize the regulatory structure and to ensure the FDA has the appropriate funding, resources and administrative authority to continue to provide effective oversight of the cosmetics industry.

Mr. Faber testified that while most cosmetic chemicals likely pose little or no risk to human health, exposure to some chemicals used in cosmetics and other personal care products has been linked to serious health problems, including cancer and reproductive harm. He further noted that, in addition to risks to consumers, hair and nail salon workers are especially susceptible to cosmetic chemical exposures. He stated that the FDA has little authority to review or restrict chemicals in cosmetics and under current law the FDA can only restrict chemicals that render the product “adulterated,” for which the FDA has only banned or restricted nine ingredients under this authority. Mr. Faber agreed that Congress must create a modern regulatory program for cosmetics and other personal care products, as proposed in the PCPSA.

Mr. Dandurand stressed that the science establishing ingredient safety varies from state to state, and that a consistent national standard would improve the existing regulatory framework. He expressed his support for: 1) mandatory registration of all U.S. and foreign manufacturing facilities that import products into the U.S. market; 2) requiring all manufacturers to file ingredient statements for all products they manufacture; and 3) requiring all manufacturers, both domestic and international, to follow good manufacturing practices, as established by the FDA.

The act is bipartisan and is broadly supported by industry and consumer groups and if the act becomes law, cosmetics companies will face increased regulatory and financial burdens and some companies will need to hire regulatory professionals.

Annette B. Santamaria, PhD, MPH, DABT is the Director of Toxicology and Food Safety for Rimkus Consulting Group in their headquarters located in Houston, Texas. She is a board-certified toxicologist with over 25 years of multidisciplinary experience critically evaluating a broad range of toxicological, epidemiological, and clinical studies, conducting exposure and human health risk assessments, and communicating results to clients and governmental agencies.
Senator Feinstein sent a letter to the FDA on September 26, 2016 requesting information from the FDA about their current regulatory authority over cosmetics and personal care products. The FDA responded in a letter dated October 5, 2016 and stated that the administration supports stronger safety rules for personal care products. FDA further stated that they do not know the concentration of ingredients used in personal care products and does not have the authority to require companies to submit these safety studies during an inspection, but they do have the ability to recall products that pose a serious health risk. The bill was not enacted in 2016 and it will likely be reintroduced in 2017. A similar proposal is making its way through the House of Representatives. The bill has been supported by several companies, including Johnson & Johnson, Procter & Gamble, Revlon, L’Oréal, Estée Lauder, and Unilever, and trade associations (e.g., Personal Care Products Council) and nongovernmental organizations (e.g., Environmental Working Group). If it becomes law, the act will be the most significant change in FDA cosmetics regulation in over 70 years. The act is bipartisan and is broadly supported by industry and consumer groups and if the act becomes law, cosmetics companies will face increased regulatory and financial burdens and some companies will need to hire regulatory professionals. Companies will also need to: 1) implement changes to conform to the act to ensure that they timely and properly register facilities with the FDA and submit cosmetic ingredient statements; 2) develop expertise in GMPs, make sure their manufacturing processes conform to the FDA’s GMPs and become adept at handling FDA inspections and audits; 3) Companies will also need to track and timely pay fees, review their product labels to ensure that they are FDA compliant; 4) implement adverse event reporting and monitor ingredients to ensure that they remain classified as safe for use; and, 5) put recall protocols in place in the event that a recall is required by the FDA.

Endnotes

FOOD LAWYERS FACE CHALLENGE

6 Williams, Lu Ann, Formulating Clean Label Products, Food Technology, December 2016.
7 This definition may be found on the USFDA Website at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm45690.htm
8 Note that “shelf-life” as used here is the polymer science definition that has little relation to the more commonly understood “Best if Used By” and similar concepts.
13 USFDA, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, Final Rule, 80 Federal Register 55908, September 17, 2015.
17 Woodhouse, Charles, FSMA Final Rules on Sanitary Transportation of Human and Animal Food Pose Special Challenges for Food Importers, Food Cosmetics & Nutraceuticals news, Spring 2016.
18 USFDA, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, Final Rule, 80 Federal Register 55908, at pp. 56093-56120, September 17, 2015.
20 See, generally, ”Getting from HACCP to HARPC” and “Third-Party Certification” posting date January 1, 2017 at www.food-label-compliance.com
WHEN LOOKS ARE ALL THAT MATTER


7 See, e.g., Import Alert 16-120 (detention without physical examination for fish/fish products processors not in compliance with seafood HACCP), available at http://www.accessdata.fda.gov/cms_ia/importalert_25.html (although not mentioned in the public guidance, once a facility has been placed on the alert, FDA will not generally find persuasive any evidence to demonstrate that the product is in compliance and therefore should not be refused); Import Alert 66-40 (dentetion without physical examination of drugs from frims which have not met drug GMPs), available at http://www.accessdata.fda.gov/cms_ia/importalert_189.html (like Import Alert 16-120, the guidance makes no mention that it is essentially impossible to obtain the release of an individual shipment once the facility is on the alert).

8 FDCA, Section 801(a); Pure Food and Drug Act, Section 11.

9 FDCA, Section 801(a).

10 FDCA, Section 801(a).

11 21 C.F.R. 1.90.

12 21 C.F.R. 1.91.

13 21 C.F.R. 1.94(a).

14 FDCA, Section 801(a).

15 FDA, Regulatory Procedures Manual, Chapter 9, Section 9-6.

16 Id.


18 RPM, Chapter 9, Section 9-6.

19 See, e.g., Sugarman v. Forbragd, 405. F.2d 1189 (9th Cir. 1969) (holding that an FDA refusal was not arbitrary and capricious).

20 FDCA, Section 304; Pure Food and Drug Act, 1906 Act.

21 FDCA, Section 303.

22 19 C.F.R. 113.62(m)(1).

23 19 C.F.R. 141.113(c).


26 FDCA, Section 402(h).

27 FDCA, Section 801(m)(1).

28 Compare FDCA, Section 301(a) (prohibiting the introduction into interstate commerce of an adulterated food, which requires proving the ) with Section 301(prohibiting importing or offering for import a food that violates Section 801(m), which requires notifying FDA that a food was previously refused importation).

29 As it relates to harm, the courts have thus far held that a claim for damages under the Federal Tort Claim Act (28 U.S.C. Part 171) is barred because the decision to investigate a product is discretionary. See, e.g., Fisher. Bros. Sales v. United States, 46 F.3d 279 (3rd Cir. 1995).

CURRENT STATUS OF THE PERSONAL CARE PRODUCTS


6 Ibid