Complying with California’s Proposition 65: Some Tips for Nutritional Supplement Manufacturers by Paul Damian, PhD, MPH, DABT

Paul Damian is a board certified toxicologist and Principal of Damian Applied Toxicology, LLC (DAT) located in Sacramento, California. Dr. Damian has 30 years of experience evaluating the health and ecological risks of chemicals in the environment and in consumer products. Before founding DAT, Dr. Damian was the National Risk Assessment Practice Leader for Brown and Caldwell and SCS Engineers. His specific practice areas include assessing the human health and/or ecological risks related to: chemical contamination of food and nutritional supplements, Proposition 65 compliance, vapor intrusion/indoor air, and chemical contamination of property. Dr. Damian has a PhD in Toxicology and Pharmacology from the University of California-Davis, a Master of Public Health in Environmental Health from the University of Michigan-Ann Arbor, and a BS in Natural Resources, also from the University of Michigan-Ann Arbor. For more information about Damian Applied Toxicology, LLC please visit the website at www.appliedtox.com or email Dr. Damian at pdamian@appliedtox.com.

California’s Proposition 65 regulations require that manufacturers of consumer products sold in California ensure consumers are not exposed to specific listed chemicals above designated “safe” exposure levels (“Safe Harbor Levels”). Otherwise, the manufacturer must provide a warning notice. Listed chemicals include chemicals that the State of California has determined to be carcinogenic or reproductive/developmental toxins. Any company with 10 or more employees that sells products...
The EU Food Information to Consumers Regulation – Important Changes for US Exporters
By Leonie Evans (née Kirchner)

Editors’ Comment: Leonie Evans (née Kirchner) is a recognized EU food law practitioner. She makes excellent and detailed comments on the EU Food Information rules which become effective in December of this year. US practitioners are advised not to venture into this difficult territory without expert guidance and should always consult an EU practitioner in EU food law matters. Additionally, a US attorney should consider obtaining formal educational credentials in EU Food Law. ~CFW and KLL.

Leonie Kirchner (née Kirchner) is an attorney admitted to practice in Germany. She is an Associate at the law firm Meisterernst Rechtsanwälte in Munich where she works with both domestic and international clients and specialises in food and feed law, intellectual property and competition law. She advises US clients on the marketability of products, label reviews, admission procedures and deals with regulatory objections and competition law disputes. Leonie is Managing Editor of the European Food and Feed Law Review, has published in German and international law journals and has delivered speeches at international food law conferences. Leonie studied law at the University of Passau in Germany and at King’s College London. She completed her legal training in Munich and Sydney specialising in European and international civil law and has gained work experience in international law firms in Germany, Switzerland, Australia and the UK. Email: kirchner@meisterernst.com.

European Union law on food labeling is currently undergoing major legislative changes which are important to U.S. food businesses that export to the European Union (“EU”) or that manufacture in the EU Regulation. No.

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GRAS Concept, Useful and Sensible, is Under Scrutiny
by Eric F. Greenberg

Editor's Comment: Eric Greenberg, is regarded as one of the country's leading authorities on the regulation of food additives and food contact materials and teaches at both Chicago Kent and Michigan State. In this opinion piece, which will help all of us think about GRAS, Eric gives us the benefit of his many years of work in the area and the strategic overview that comes with years of teaching and thinking about the intellectual concepts behind the FDCA and the FDA's approach to the regulation of substances added to or in contact with food. ~CFW.

Eric Greenberg is Principal Attorney with Eric F. Greenberg, P.C., www.ericgreenbergpc.com, a Chicago-based law firm with clients worldwide. Its practice is concentrated in Food and Drug Law and commercial litigation. His firm represents business clients at every level of the food and drug development, production, distribution, and packaging industries. He also is a member of the adjunct faculty of Chicago Kent College of Law, where he teaches Food and Drug Law, and the Michigan State University School of Packaging, where he teaches Packaging Laws and Regulations, and serves as Legal Editor and Columnist for Packaging World magazine. Eric can be reached at greenberg@efg-law.com.

The regulation of the U.S. food supply has long been a paradox: a realm of law and regulation that is relatively obscure and unknown even to many attorneys, while at the same time inevitably touching the lives of every American, every day. It is also, often, the realm of excellent examples of the most basic legal issues and debates.

One such example is the current debate over the system by which some substances are permitted to be used as ingredients in or additives to food. Specifically, there have in recent years been criticisms of the way substances that are

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containing listed chemicals in California is subject to this regulation. The California Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency responsible for administering Proposition 65, with enforcement by the California Attorney General.

Compliance with Proposition 65 is evaluated using health risk assessment methods. Health risk assessment is a subfield of toxicology that focuses on the quantitative evaluation of health risks related to chemical exposure. The health risk assessment methods most commonly used today were originally developed by the United States Environmental Protection Agency (USEPA). In many instances, these original methods have been modified or elaborated to some extent by state agencies, such as OEHHA, to address specific regulatory programs, such as Proposition 65.

Like numerous other consumer products, nutritional supplements (including beverages) are subject to Proposition 65. However, since these products are typically ingested, exposure to a listed chemical has a potential to be much more significant. On the other hand, the discrete, dietary nature of nutritional supplement exposure leads to Proposition 65 exposure assessments that are generally much more straightforward than for non-dietary consumer products. The purpose of this article is to identify the unique aspects of nutritional supplements in the context of Proposition 65 compliance and provide manufacturers of nutritional supplements with several tips for facilitating compliance with Proposition 65.

1. **Provide Crystal Clear Use Instructions on the Product**

   The most fundamental aspect of Proposition 65 compliance is the exposure assessment. This is the calculation of average daily exposure to a listed chemical through the use of the product. For any product, but in particular nutritional supplements, the starting point for this exposure assessment is the product label providing use or dosing instructions. It is essential that these dosing instructions be crystal clear with respect to who can and cannot use the product (e.g. adults only, adults and children, pregnant women?), how much of the product can be taken per day, and for how long the product should be taken over specific periods of time. The clearer the dosing instructions, the more straightforward and supportable the exposure assessment will be.

   Chemical contaminant exposure, and hence the labeler’s Proposition 65 compliance, may differ significantly for an adult or child based on the label instructions. For example, the label may say children should take one tablet per day while an adult may take two tablets per day. If the tablet contains a Proposition 65-listed chemical the adult will receive twice the daily dose that a child will receive. The higher adult dose (expressed in typical Proposition 65 units of mg/day or µg/day) may result in the product labeled as noncompliant for adults but compliant for children at the lower dose. In addition, if a product does not clearly indicate whether or not it may be used by adults or children it may reasonably be assumed, for purposes of litigation, that both consumer groups may be exposed. This opens the door for a Proposition 65 lawsuit as the labels are not compliant for each consumer group. Verifying that the labeling is compliant for both adults and children also increases compliance costs as the manufacturer must show that labeling for both adults and children is in compliance with Proposition 65.

   In most cases, nutritional supplement labels are clear with respect to the daily dosing regimen for the product (e.g. once a day, twice a day, etc.). However, what is not clear on labels in some cases is how long a product may be used over specific periods of time (i.e. the duration of exposure). This is very important information needed to accurately determine compliance because Proposition 65 standards are often based on the average exposure over a long period of time. If a product is specified to be taken twice a day, it can reasonably be assumed that the supplement can be taken indefinitely, and
the average daily exposure can be easily calculated based on two doses per day over a lifetime. However, some dietary supplements involve more complex dosing regimens that effectively constitute a treatment or dosing “cycle”, for example, instructions such as “Take twice a day for one week, then once a day for 4 weeks.” The question then arises as to how often the dosing cycle should/can be repeated over time. This question must be addressed in order to calculate the average daily exposure and determine compliance. If the question is not addressed specifically in the label, assumptions will have to be made in the compliance assessment, the reasonableness of which may be tested in litigation. Health risks due to chemical exposure are typically evaluated based on the exposure pattern occurring over a year, so ideally, the label for supplements with these more complex dosing regimens would specify exactly how often the dosing cycle may be repeated over the course of a year (e.g. once a month, twice a month, etc.). This critical information allows for straightforward and less contentious calculation of the average daily dose based on use of the supplement for one year.

2. Specify a Daily Supplement Intake Limit on the Label

The Proposition 65 Safe Harbor Levels are specified in terms of µg/day. It is therefore important that the nutritional supplement be clear in indicating a daily intake limit for the supplement if it is not obvious from the use information on the label. For most supplements, it is obvious. For example, a label that states “Take one tablet, twice a day.” clearly indicates the maximum recommended daily supplement intake upon which the exposure assessment for a Proposition 65-listed chemical can be based. However, suppose a nutritional supplement beverage simply indicates a serving size with no specific daily intake recommendations, such as for example, “Drink up to two servings daily” or something similar. In the absence of a specified limit on daily intake of the product it could be argued in a Proposition 65 lawsuit that the daily exposure (and hence compliance) is dependent on the number of servings, which are not limited by the product. And while the product may be in compliance based on a single serving per day, it may not be in compliance if two or more servings per day are assumed.

3. Ensure that Adequate Analytical Detection Limits are Used

The Safe Harbor Levels are often very low, in some cases less than 1 µg/day. To evaluate the compliance of a nutritional supplement based on such low levels, low analytical detection limits are required. The detection limits must be low enough to show that predicted exposure to a Proposition 65-listed chemical will actually be below the Safe Harbor Level. If analytical detection limits are too high relative to the relevant Safe Harbor Level it will be impossible to prove that levels of the contaminant are low enough to be in compliance with Proposition 65.

4. Base the Exposure Assessment on Average or Typical User Exposure Assumptions

Recent court decisions regarding Proposition 65 are leaning toward the use of average rather than upper-bound exposure assumptions. Thus, it is becoming increasingly clear that the use of very conservative assumptions regarding use of the product is not necessary to demonstrate compliance. Although it is of course easier to avoid, or short-circuit legal challenges if compliance is clear even when very conservative exposure assumptions are used, the California courts appear to be focusing on the more typical product user rather than the extreme user.

5. Check Your Suppliers of Raw Ingredients!

In some cases manufacturers may inadvertently obtain a supplement ingredient from a supplier that is the source of a Proposition 65-listed chemical. It is essential to independently check raw ingredients from outside suppliers to ensure that all components of the supplement are compliant with Proposition 65. Monitoring programs of raw ingredient suppliers may not address all the chemicals of potential concern (typically metals) or may not use analytical detection limits sufficiently low to detect a potential Proposition 65 issue. Be sure to use adequately low detection limits for this monitoring as discussed above. Seek out alternative suppliers of raw ingredients if quality concerns are not addressed.
6. **Test the Final Product**

Although testing of raw ingredients for Proposition 65-listed chemicals is important in avoiding, or tracking down and mitigating a potential contamination issue, it is most important to test the actual marketed product, as this is ultimately the vehicle through which the consumer may be exposed. It is the concentration of a listed chemical in the final marketed product that serves as the most appropriate basis for the Proposition 65 exposure and compliance assessment. Testing of the final product should be ongoing and should be conducted at least in triplicate samples for each lot or at least for randomly sampled lots.

7. **Test the Final Product Quickly!**

Chemical analysis of a consumer product can take several weeks. However, this is only the first critical step necessary to evaluate compliance with Proposition 65. The actual health risk assessment based on the analytical results may take significant additional time to prepare. On the other hand, a Proposition 65 lawsuit may be initiated at any time. It is therefore recommended to proactively evaluate your products for compliance with Proposition 65 before a lawsuit is initiated.

8. **Monitor Proposition 65 Regulatory Developments**

Additional chemicals are listed under Proposition 65 regularly. In addition, Safe Harbor Levels may be added or revised over time as the toxicological basis for the Safe Harbor Level is updated. These changes may result in a product that was formerly in compliance, now being out of compliance. It is therefore important to monitor changes in the Proposition 65 regulations. This can be done by periodically checking the OEHHA Proposition 65 website (www.oehha.ca.gov/prop65.html), or by subscribing to OEHHA email alerts on this topic via the OEHHA Proposition 65 LISTSERV (go to the OEHHA Proposition 65 website shown above to subscribe).

**Summary**

Nutritional supplements are increasingly the subject of Proposition 65 lawsuits. Unlike many other consumer products, the potential for exposure to a Proposition 65-listed chemical is much greater due to regular dietary exposure. On the plus side, and also unlike other consumer products, exposure assessments for nutritional supplements are in most cases straightforward when the use information is clearly stated on the label. Some other ways in which compliance with Proposition 65 can be facilitated include using average rather than upper-bound exposure assumptions, regularly monitoring raw ingredients and the final consumer product, using adequately low detection limits for monitoring, and tracking Proposition 65 regulatory developments.

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1169/2011 on the provision of food information to consumers (“FIC”) entered into force on December 12, 2011 and will apply for the most part beginning December 13, 2014. This Regulation, which is directly applicable law in all EU member states, replaces Directive 2000/13/EC on the labeling, presentation and advertising of foodstuffs and Directive 90/496/EEC on nutrition labeling for foodstuffs. This article provides an overview of the major changes of EU law on food labeling with a focus on provisions affecting U.S. food businesses in particular. FIC contains provisions on the prohibition of misleading advertising and the prohibition of health-claims related advertising, as well as provisions requiring certain mandatory information to be declared on food labels. The most relevant changes concern nutrition labeling, which becomes obligatory, are the labeling of allergens and so-called “analog products,” country of origin/place of provenance labeling and requirements regarding the font size that must be used on product labeling. New provisions which are particularly important to U.S. food businesses are those on internet-sales. According to the latter provisions, the labels of food products must contain an address of a food business operator responsible for the food information that is located within the EU. This means that an EU address must appear on the label.
1. **Provisions on misleading advertising**

   The general prohibition of misleading advertising is regulated in Art. 7 FIC pertaining to fair information practices. Apart from the provision that food information shall not be misleading and the prohibition of disease-related advertising, which have so far been regulated by Art. 2 Directive 2000/13/EC, this provision also provides that food information must be accurate, clear and easy to understand for the consumer. Under current law, food labeling cannot make claims that the food prevents, treats, or cures a human disease. This principle is very important to note regarding all labeling and advertising of food in the EU. It is part of the main objective of EU food laws that labeling and advertising of food must not mislead the purchaser. In addition, the basic principle of the prohibition against misleading advertising has been memorialized in Art. 7 (1) d FIC, which regulates so-called “analogue products”. These are foodstuffs that are alternative or imitation products and are explicitly regulated now in Art. 7 (1) d FIC which states that “food information shall not be misleading by suggesting, by means of the appearance, description or pictorial representations, the presence of a particular food or ingredient, while in reality a component naturally present or an ingredient normally used in the food has been substituted with a different component or a different ingredient.” Food information must not be misleading by attributing these characteristics to food. For example, this provision applies to convenience foods such as a “pizza mix” containing imitation cheese or any type of processed cheese that does not qualify as true cheese. These are also products that do not consist of one naturally grown piece but have been mechanically put together from alternative components, such as imitation meat or meat substitutes. Further requirements on analog products can be found in Annex VI.4.

2. **Responsibility: Requirement of an EU address**

   FIC contains an explicit provision on responsibility in Art. 8 which states that “the food business operator responsible for the food information shall be the operator under whose name or business name the food is marketed or, if the operator is not established in the Union, the importer into the union market.” Consequently, food labels must contain a European address. In the case of companies that do not have a subsidiary in the EU, the label can bear the address of the importer who brings the product into the EU. This new provision presents challenges for U.S. food business operators who have previously sold their products in the EU using their U.S. address. If U.S. companies do not wish to have an EU establishment – for tax purposes or any other reason – they need to include the address of their importer on the product label. The importer then becomes the person responsible for the declared food information, meaning that the importer is liable for making sure that all food information complies with the respective provisions. The expectation is that the importer will only market products that comply with the new provisions of FIC and all other EU food laws as the importer does not want to bear liability for impermissible food labeling.

3. **Nutrition labeling**

   Until the passage of this regulation, nutrition declaration, which is often presented in the form of a table of nutrients, was voluntary except for products that bear a nutrition claim, a health claim, and for enriched food. Nutrition declaration will be mandatory for all food products beginning December 13, 2016. If a nutrition declaration is provided on a voluntary basis, it must comply with the provisions of FIC beginning on December 13, 2014. The nutrition declaration must include the energy value and the amounts of fats, saturates, carbohydrates, sugars, protein and salt (the so-called “big seven”). There are exceptions for alcoholic beverages and food that is packaged in containers that have a surface area of less than 25 cm². In addition, food supplements and natural mineral waters are exempt from the mandatory nutrition declaration. The content of the mandatory nutrition declaration may be supplemented with a statement of the amounts of mono-unsaturates, polyunsaturates, polyols, starch, fiber and any of the vitamins or minerals listed in Annex XIII and
present in significant amounts. All of the required information must be included in the same field of vision and shall be presented together in a clear format and, where appropriate, in the order of presentation provided for in Annex XV. The nutrients must be expressed per 100 g or per 100 ml. In addition the energy value and the amounts of nutrients may be expressed per portion and/or per consumption unit. Nutrient contents must also be placed in the same field of vision. It is permissible to state the energy value by itself or it is permissible to state the energy value together with the amounts of fat, saturates, sugars and salt. Consequently, it is not permissible to state the amount of one of the other nutrients by itself. This makes cherry picking of favorable ingredients less likely.

4. **Allergies and Food Intolerance**

Substances or products that may cause food allergies or food intolerances, such as gluten, eggs, fish, peanuts, soybeans, milk, certain nuts, celery, mustard etc. (please refer to Annex II for a complete list), must be declared in the list of ingredients of the food, emphasized through a typeset that clearly distinguishes the substance or ingredient from the rest of the list of ingredients (for example, by means of the font, style or background color). Allergy labeling will also be mandatory for non-prepackaged foods or packaged goods at retail, which is another novelty of FIC. The member states may adopt national measures for non-prepackaged food.

5. **Country of Origin Labeling (COOL)**

The declaration of the country of origin or place of provenance on food labels is mandatory where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food. Country of origin labeling will also be mandatory on pork, sheep, goat, and poultry meat listed in Annex XI. Labeling of origin of beef is mandatory already according to Regulation (EU) 1760/2000 which has been adopted as a consequence of the bovine spongiform encephalopathy (also called “BSE” or “mad cow disease”) crises.

6. **Distance Selling and Online Sales**

New rules on online and “distance” selling, which includes all ways of selling products by other means than entering a shop such as by telephone, catalogue and online, provide that all mandatory information for food, except for the date of minimum durability, have to be available before the purchase is concluded. This affects all products sold online. If food is offered in an online shop, which is very common nowadays, all mandatory labeling requirements, such as the name of the food, the list of ingredients, including allergen labeling, the net quantity, storage conditions, the name or business name and the address of the food business operator within the EU, the nutrition declaration etc. have to be included in the product information online. If a food business operator delivers to an EU member state and, therefore, addresses EU consumers with his online offer, the food business operator must comply with this new provision. Therefore, all mandatory food labeling information must be available online when selling food products over the internet into the EU.

7. **Formal requirements**

All mandatory labeling requirements must be printed on the package or on the label of the food in such way as to ensure clear legibility, in characters using a font size where the height of the small letter x is equal or greater than 1.2 mm. In case of packaging or containers, the largest surface of which has an area of less of 80 cm², the height of the font size of the small letter x shall be equal or greater than 0.9 mm. All mandatory labeling requirements must be printed in such a way as to be easily visible, clearly legible and, where appropriate, indelible. They shall be indicated with words and numbers and may additionally be expressed by means of using pictograms and symbols. This provision leads to challenges
for multilingual labels which have to provide all mandatory information, including instruction for use, in all languages used on the label often resulting in space problems.

8. Date of minimum durability

For those who may have gotten the impression that FIC only comes with burdensome requirements, I would lastly like to draw your attention to the requirement of information appearing in the same field of vision. The date of minimum durability (use by date or best before date) no longer must be in the same field of vision with the name of the food, the net quantity of the food and, with respect to beverages containing more than 1.2 % Vol. of alcohol, the actual alcoholic strength by volume. This change might seem minor, but can become relevant for very small labels, on which it can be difficult to fulfill the requirement of the appearance of all these particulars in the same field of vision.

Conclusion

FIC includes many provisions which are stricter than the previous rules on food labeling. However, foods placed on the market or labeled prior to December 13, 2014, which do not comply with the requirements of FIC, may be marketed until the stocks of the foods are exhausted. FIC has a very complex structure with its 59 recitals, 55 articles and 15 annexes. There have been two minor amendments to it already, one on the labeling of gluten and one on foods with added phytosterols, phytosterol esters, phytostanols or phytostanol esters. Furthermore, there is a Q&A on the application of FIC by a working group set up by Commission’s Health and Consumer Directorate and there are national guidelines such as the Guide to Compliance with FIC by the UK government and guidance on the provision of food information to consumers by Food Drink Europe. Even though FIC aims to harmonize EU law on food labeling, provisions are interpreted differently in the individual member states. It remains to be seen how the courts will fill this tremendous piece of legislation with life and help to bring greater clarity to labeling decisions. These future developments regarding the interpretation of FIC by the courts, especially the European Court of Justice and by practitioners as well as academia, must be observed carefully. The complexity of FIC and these developments make it indispensable to always seek competent legal advice when importing food into the EU.

considered “Generally Recognized As Safe,” or GRAS, are handled under the law. The current debate over how to regulate GRAS substances is a good example of the perennial debate between advocates of a free-market philosophy and advocates of reasonable regulatory intervention. One does not have to be a pure free-market ideologue, however, to see the wisdom in leaving the current system, which leaves companies with a great deal of discretion and independence, as it is.

The GRAS concept appears in the law in a context that reflects a free-market approach to food safety. While defining “food additive,” the federal Food, Drug, and Cosmetic Act says that a substance in food will not be considered a food additive if it is generally recognized as safe by relevant scientists, under the intended conditions of its use. If it is not generally recognized as safe, but is safe, its use can be cleared by the U.S. Food and Drug Administration (“FDA”) as an approved food additive, as have thousands of ingredients, packaging components, machinery sanitizers and lubricants, and other substances. Several specialized categories of substances in food, such as pesticide residues, color additives, and substances that have been granted a specific form of grandfathering permission for use called ‘prior sanctions,’ are the subjects of their own specific regulatory clearance programs.

The statute thus makes clear that it is the scientists’ opinion that determines the legal status of a GRAS use of a substance, not the opinion of regulators. It follows that those who put substances in food on the strength of a conclusion that such use is GRAS are not required by law to get FDA’s
approval or concurrence in that conclusion, or even to give FDA notice that they have reached such a conclusion.

So here we have a provision in the food safety law that, almost incidentally, presents us with an exceedingly important concept, the idea that if relevant scientists consider a substance both safe and generally recognized as such, it can be used in food with no regulatory action or involvement before its use. What constitutes sufficient information of GRAS status has received some degree of amplification by FDA regulations and guidance documents (peer-reviewed, scholarly toxicology evaluations are best, for example), but it is still somewhat open-ended, left to the independent judgment of those evaluating substances.

GRAS status can be accurately described in various ways, as the highest status a food component can achieve, as the reason the law permits us to eat many common foodstuffs, and, I would argue, as a free market philosophy embodied in law. This is because, to paraphrase, the GRAS concept in the law says government will not get involved in regulation of substances when there is no good reason for them to do so, and we do not think there is a good reason for them to do so when relevant scientists think the use is both safe and generally recognized to be so by similarly situated scientists. (Alternatively, GRAS status also attaches to a substance if it has been commonly used in food since before January 1, 1958.)

The result is a system in which companies can undertake their own evaluations of the safety of uses of substances, reach a conclusion it is GRAS, and go to market on that legal basis. Companies can, if they choose, voluntarily submit their conclusion to FDA in order to try to get FDA’s confirmation that it ‘has no questions’ about the company’s GRAS conclusion, so that the company then has some FDA acknowledgement for its own comfort and that of its customers.

One’s level of discomfort with the system might vary with one’s tendency to trust or be comfortable with the decisions of commercial companies. Observers in and out of government have listed concerns with this legal framework, even though there does not appear to be evidence of significant safety concerns resulting from it. In 2010, the US Government’s Government Accountability Office (GAO) issued a report that recommended ways to improve FDA's oversight of GRAS determinations, and the PEW Health Group has issued a series of reports about GRAS as well. Further, a consumer advocacy group has more recently filed litigation against FDA challenging its handling of GRAS substances as contrary to the Administrative Procedure Act, and FDA has reportedly begun settlement discussions, though it at first had planned a motion to dismiss the case.

The GAO report recommended:
1. A requirement that any company that conducts a GRAS determination provide FDA with notice, and make it public;
2. Minimizing the potential for conflicts of interest in companies’ GRAS determinations;
3. Monitoring the appropriateness of companies’ GRAS determinations through random audits or some other means, including issuing guidance on how to document GRAS determinations;
4. Finalizing the [1997] FDA proposed rule that governs the voluntary notification program,
5. Conducting reconsiderations of the safety of GRAS substances in a more systematic manner
6. Ensuring the safety of engineered nanomaterials.

The GAO report criticized FDA’s process for reconsidering safety conclusions by pointing to 11 petitions that have been filed seeking reconsideration by FDA of GRAS conclusions – some of which had been pending for years.

The PEW Health Group’s concerns included these:
1. FDA is unaware of a large number of chemical uses in food and, therefore, cannot ensure that
safety decisions regarding these uses were properly made.

2. Food manufacturers are not required to notify FDA of relevant health and safety studies, thereby placing FDA in the difficult position of tracking safety information for more than 10,000 chemicals with limited resources and information.

3. The agency’s expedited approach to reviewing safety decisions since 1995 occurs with little public engagement.

4. FDA may not have the requisite resources and information to identify and prevent potential health problems or to set priorities for systematic reevaluation of safety decisions made during the past half-century.

Are these objections valid? Without attempting to evaluate the accuracy of some of these objections, as other authors have done, we can evaluate the regulatory framework for whether it appears to be fitting in light of the safety issues involved.

First, it is important to remember that, when new safety concerns arise, re-evaluations of GRAS status can occur under the current scheme. In fact, FDA recently initiated such a re-evaluation regarding partially hydrogenated oils which are sources of trans-fats in food.

Partially hydrogenated oils, including partially hydrogenated soybean oil and partially hydrogenated cottonseed oil, are “the primary dietary source of industrially-produced trans fatty acids, or trans fats,” says FDA, and “new scientific evidence” and the findings of various experts leads FDA to conclude that the oils are not generally recognized as safe “for any use in food.” Trans fatty acids or trans fats show up in cookies, other baked goods, shortenings, frostings, stick margarines and other products. FDA explains that “Although all refined edible oils contain some trans fat as an unintentional byproduct of their manufacturing process, trans fats are an integral component of [partially hydrogenated oils] and are purposely produced in these oils to affect the properties of the oil and the characteristics of the food to which they are added.”

If FDA finalizes its tentative conclusion that no uses of such oils are GRAS, then by definition under the law, the oils are food additives when used in food, and users would have to get FDA food additive approval for their uses, but only if they can demonstrate the use is safe.

Admittedly, this proposal to revoke GRAS status is a rare act on FDA’s part, not undertaken since the 1970’s when brominated vegetable oil was the target, but the point here is that the mechanism does exist and can be used to remove substances that once had, but may not any longer enjoy, status as generally recognized as safe.

Second, under the widely respected system of GRAS evaluations operated by the Flavor and Extract Manufacturers Association (“FEMA”), a relatively small number of substances (11 out of 2,600) in use have been the subject of re-evaluations and removals by FEMA from its list of GRAS flavoring substances.

It is hard to argue with the proposition that FDA would be in a better position to evaluate substances in food if it knew about their use as opposed to not knowing about them. Nevertheless, the wisdom of requiring even a seemingly innocuous system requiring companies to give notice of their uses to FDA needs to be weighed against the complexities and burdens it would cause for regulators and companies alike, with due consideration to the perceived safety concerns involved. There simply does not appear to be much evidence that substances in food whose uses are considered GRAS are in fact unsafe in any significant numbers. In fact, this area is, pardon the pun, generally considered safe. When, in 1997, the FDA changed its program from accepting and reviewing GRAS determinations and issuing "affirmations" of the GRAS status of a use, replacing it instead with the GRAS notification program which resulted only in letters confirming that FDA
"has no questions" about a submitter's conclusion that a use is GRAS, the agency made remarks seeming to indicate that the safety of uses of substances perceived to be GRAS was a realm of general safety. 62 FR 18941, 18945.

Even without a premarket role for FDA, there are other motivators for companies to ensure that GRAS are just that – safe. These include civil tort liability should consumers be injured by product, FDA regulatory remedies including seizure of product, injunction against distribution, and criminal prosecution should the agency conclude the food is adulterated, and adverse publicity for the company involved.

Finally, the very idea that FDA-regulated businesses have the primary responsibility for assuring their products' regulatory compliance is a central theme of virtually the entire FDA regulatory scheme, not just the approach to GRAS substances. FDA officials, whether they are inspecting factories, or writing Warning Letters to those they believe have violated the law or regulations, or just discussing the basic framework created by the federal Food, Drug, and Cosmetic Act, are constantly, and correctly, reminding companies that the law places the primary and most important obligation to assure their products' compliance with law and regulations on the company, not on the company’s consultants or suppliers, and certainly not on FDA.

Perhaps its most cogent expression comes from the U.S. Supreme Court’s decision in United States v. Park, 421 U.S. 658 (1975), in which the Court explained a regulated business's legal obligation under the act: “[T]he Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.” That theme, I contend, underlies all aspects of FDA’s regulation of the industries in its purview, because even in situations in which products receive advance, premarket FDA approval (of new drugs, new uses of food additives, or new medical devices, for example), the company retains the ongoing obligation to diligently and consistently assure the product’s compliance in the way it is manufactured, handled and labeled, first time, every time. So it should not be a surprise that GRAS determinations are left to companies to undertake.

The point of the GRAS program is not essentially that FDA is not involved, it is essentially that the company steps up and undertakes responsibility for evaluating the clearance and safety of the food additive GRAS substance it wants to place into food. Some aspects of the program are sure to receive extra attention and perhaps be altered in coming years, but the basic legal framework is sensible and is working well, and should be maintained.

REFERENCES
1. Federal Food, Drug and Cosmetic Act definition of “food additive” Section 201(s) [21 U.S.C. Sec. 321(s)].
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We, the editors of the FCN Committee Newsletter, would like to invite all Committee members to contribute a piece to the Newsletter. Below are some ideas for topics, but please feel free to submit papers based on cases and topics that are currently of interest to you in the areas of food, cosmetics, and nutraceuticals.

- FDA regulation of cosmetics in 2014, 2015, and beyond. What are the regulatory trends and what issues will affect industry in the upcoming year and beyond as FDA takes a greater interest in cosmetic manufacturing practices and imported goods?
- Food, cosmetic, and nutraceuticals advertising. Given some interesting decisions and legal activity in the area of advertising this year, how should clients be advised when crafting advertising for their products?
- The role of third-party auditors in a comprehensive food safety plan and a cost-benefit analysis as well as the relation to insurance and liability issues.
- The relationship between the Article 9 Security Interests of lenders to food companies and FDA’s mandatory recall and administrative detention authority under the FSMA. What are the concerns of counsel for lenders during a serious (Class I or Class II) recall?
- FDA Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition. What does this recently issued guidance document mean for the medical food industry?
- A discussion of FDA’s February 2014 proposal, Draft Approach for Designating High-Risk Foods (Sec. 204 of FSMA).

We anticipate that the Fall issue of the Newsletter will be published in October or November of this year and we request that articles be submitted before then. Articles should be approximately 1,500-2,000 words and formatted with end notes. If you are interested in contributing please email us: Kelly Lightfoot at KLightfoot@fuerstlaw.com and Charley Woodhouse at cfw@regulatory-food-science.com.

Visit the Section of Science & Technology Law: Food, Cosmetics and Nutraceuticals Website!

Visit the site to:
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View our FCN Digests, including current news and events in the areas of food, cosmetics, and nutraceuticals.
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http://apps.americanbar.org/dch/committee.cfm?com=ST103010
Charles F. Woodhouse is an Attorney and Partner, in the law firm of Woodhouse Shanahan PA. Charles is admitted to the Bars of Pennsylvania, Florida, and the District of Columbia. Charles earned his BA at Dartmouth, MBA at Wharton (University of Pennsylvania), JD at Rutgers, and his Graduate Certificate in International Food Law & Regulation and MS Food Safety at Michigan State. His MS Food Safety thesis at MSU received MSU’s 2011 Mather Food Safety Award.

He is Adjunct Professor of Law at MSU College of Law and will be teaching Regulation of US Food Imports for the 2014 Fall Semester in the LLM, MJ, and MS Food Law and Food Sciences programs. His business career includes being a founding shareholder of Marine Harvest International (salmon, shrimp, and other fin-fish aquaculture) and service as its president during its years as a publicly traded company on the American Stock Exchange. Since 1999, Charles has devoted his full time to his law practice which specializes in regulatory matters affecting the seafood and produce industries which together account for nearly 50% of all Food Safety incidents in the USA and the EU. His Food Law Blog may be found at www.food-label-compliance.com and his law firm’s website is www.seafood-and-produce-law.com and he can be contacted by email at cfw@regulatory-food-science.com.

Charles divides his year between Scanno (Aquila) Italy, Atlanta, Georgia, and Cedar Key, Florida. His law practice includes European Union Food Industry Regulatory Compliance with a particular focus on EU Food Labeling Regulation.

Kelly L. Lightfoot is an attorney with the Food, Drug, and Life Sciences Practice Group at Fuerst, Ittleman, David, & Joseph, PL in Miami, Florida. Kelly focuses her practice in the areas of food and drug law, assisting clients with regulatory and legal compliance issues involving the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and other federal, state and local authorities. Kelly is originally from Columbus, Ohio and earned her bachelor’s degree in English from The Ohio State University and received her JD from Cleveland-Marshall College of Law.

Kelly has extensive experience representing clients in various federally regulated industries, including the medical device, food, dietary supplement, cosmetic, veterinary products, over-the-counter drug, and human cells, tissues, and cellular and tissue-based products (HCT/Ps) industries. She has assisted clients with product development, formulation, manufacture, importation and exportation, distribution, and marketing.

Kelly has authored and co-authored articles in various publications on the topics of dietary supplements, conventional foods, veterinary drugs, and medical device regulation. Kelly is also on the Board of Directors of the South Florida chapter of the Organization of Women in International Trade (OWIT). She advises clients on food, supplement, and cosmetic labels and labeling, advertising, social media, formulation, and manufacturing in compliance with FDA and FTC regulations and policies. Kelly can be reached by email at klightfoot@fuerstlaw.com. ♦