

## Food and Food Ingredients

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Wiley is an indispensable Washington, *Chambers USA* recognized firm for food and beverage industry clients navigating a wide range of legal and regulatory complexities – from traditional product formulation, safety, and labeling requirements to cutting-edge issues in alternative protein law such as genetically modified and cell-cultivated food ingredients. We handle matters before the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and related agencies – and our expertise ranges from product conception to food formulation and production to product launch and ongoing marketing.

Drawing on our extensive knowledge across various legal disciplines, we advise clients on the proper and least burdensome pathways to market new human and animal food and dietary ingredients. We assist with food ingredient reviews, food product marketing, food safety and quality control, and food compliance and enforcement. We also help clients ensure regulatory compliance with respect to “clean labeling” and product claims such as healthy, organic, sustainable, GM-free, and grass-fed.

We work with scientific consultants in developing complete submission packages, advise on and manage GRAS panel composition, and assist in responding to FDA inquiries. We have advised clients on pre- and post-market regulatory and legal issues for meat and non-meat foods (including meat and poultry, animal feed/feed ingredients, consumer packaged foods, food additives, GRAS substances, color additives, and dietary supplements/dietary ingredients), as well as the distribution of foods.

Wiley also helps companies achieve regulatory and consumer acceptance of novel healthy sustainable food products – including plant and cell-based alternatives to traditional protein sources.

We also have extensive experience with novel food delivery systems such as restaurant and grocery delivery apps and online “meal kit” services.

Key aspects of our work include:

**Services for food manufacturers, distributors, and marketers:**

- Food ingredient review and approval strategies (human and animal)
- FDA and USDA regulatory compliance
- Labeling, advertising, and promotion

- Enforcement and recalls
- Litigation and administrative advocacy
- Alternative Protein Law

**New food ingredients:**

- Advising on GRAS and GRAS notifications, food additive petitions, food contact notifications, new dietary ingredient notifications, color additive petitions, novel plant varieties consultations, threshold of regulation exemptions
- Reviewing safety dossiers and identify appropriate scientific consultants
- Advising on and assisting with development/management of external scientific review panel
- Liaising with and setting up pre-submission and other meetings with FDA and/or USDA, and assisting with regulatory submissions

**Food product marketing:**

- Advising on packaging and labeling requirements, including USDA label approvals
- Advising on FDA and USDA regulated label claim support and nomenclature issues (e.g., nutrient content claims, health claims, dietary supplement claims, organic, bioengineered disclosure, standard of identity regulations)
- Advising on non-FDA/USDA regulated label claims and non-label promotional activity (e.g., country of origin statements, environmental claims, non-GMO)

**Food safety/quality control:**

- Advising on food current good manufacturing practices and FSMA, including HACCP and HARPC, FSVP, and traceability
- Helping identify GMP/FSMA consultants
- Assisting with prior notifications for imports
- Advising on food facility registration requirements
- Reviewing and advising on food facility reporting requirements

**Compliance and enforcement:**

- Assisting organizations facing enforcement actions, including investigations, inspections, and Warning Letters
- Assisting with recalls, market withdrawals, injunction and seizure actions, and crisis management
- Advising on work to identify effective strategies to deal with counterfeit products and related security concerns

- Helping prepare food facilities for inspections
- Assisting clients facing import detentions and alerts

## Contact Us

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