

# Manufacturing and Materials Restrictions

## Product Manufacturing

Wiley has significant experience assisting clients who manufacture consumer products and the materials and substances contained in them. Our experience extends from providing regulatory advice, to defending clients in enforcement actions, and assisting with the regulatory aspects of transactions involving the sale and transfer of manufacturing facilities and related assets. We have particular expertise in the manufacturing processes for chemicals, pesticides, food (including pet foods), drugs, medical devices, household products, biotechnology products, consumer electronics, and batteries. Our expertise covers a wide range of regulatory requirements applicable to these product sectors, including U.S. Food and Drug Administration (FDA) Good Manufacturing Practice (GMP) standards, the Toxic Substances Control Act (TSCA) requirements, the Occupational Safety and Health Administration (OSHA) worker safety standards and recordkeeping requirements, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) manufacturing and packaging requirements, the Emergency Planning and Community Right-to-Know Act (EPCRA) reporting and recordkeeping requirements, hazardous waste disposal and recycling requirements under the Resource Conservation and Recovery Act (RCRA), and Clean Air Act (CAA) requirements relating to ozone depleting substances and phased emissions compliance programs, among others. We have a long track record of successfully representing manufacturing clients before the U.S. Environmental Protection Agency (EPA), OSHA, the U.S. Department of Agriculture, (USDA), and FDA in matters involving inspections, records requests, and enforcement proceedings.

## Materials Restrictions

Our work also extends to advising clients regarding regulatory regimes, voluntary sustainability standards and certification programs that govern the use of certain materials, and substances that are contained in consumer products and/or used in manufacturing. In particular, we have experience providing counsel to clients regarding California's Proposition 65 program and various state "green chemistry" regulations. We also advise clients on chemical and materials restrictions established within the supply chain through corporate policies aimed at sustainability, including those of large retailers aimed at evaluating particular ingredients and substances of concern for phaseout and removal from consumer products.

## Representative Experience

- Assisting major chemical manufacturer with internal compliance review and design of regulatory compliance programs under TSCA.

- Routinely representing pesticide manufacturers in regulatory compliance and enforcement matters before EPA.
- Serving as on-site regulatory compliance officer for major agricultural chemical manufacturer while client undertook major internal compliance review and corrective action program.
- Conducting regulatory compliance review at numerous toll manufacturing sites for client involved in manufacture of pesticides and chemical substances.
- Providing strategic advice to client regarding proposed listing of chemical substance under California Prop 65.
- Advising major consumer product manufacturing client regarding intellectual property and confidentiality issues arising from product composition and chemistry reporting obligations.

## Contact Us

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