

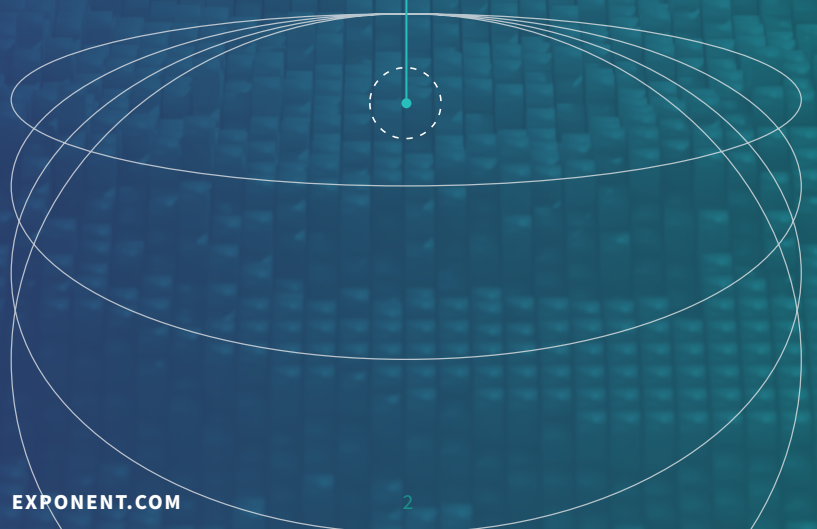


Exponent®



# The Science of Safe & Healthy Food

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# Supporting Clients Across Formulation, Regulatory Compliance, and Safety

In an era of radically-accelerating change, Exponent is the only premium engineering and scientific consulting firm with the depth and breadth of expertise to solve your most profoundly unique, unprecedented, and urgent challenges.

Food and nutritional regulations are imperative when it comes to protecting human health and safety — from cross contamination and E. coli outbreak management to ensuring infant formula safety and school lunch guidelines. Exponent’s scientists are internationally recognized experts in food science, risk assessment, microbiology, chemistry, nutrition, epidemiology, biostatistics, product recall, and can help you overcome a range of regulatory challenges.

## Exponent by The Numbers

90+

Technical Disciplines

30+

Offices Across North America, Europe & Asia

1967

50+ Years of Scientific Excellence

# Navigating Complex Food Safety & Regulatory Issues

The environment in which food companies and their suppliers operate is changing rapidly with growing consumer demand for natural and sustainably sourced food products, more stringent regulations, and increased demand for state-of-the-art food safety systems. Exponent offers a variety of customizable food safety services, from addressing an urgent need for a complete third-party food safety evaluation to ensuring that brands are protected from harmful contaminants and microbes and comply with regulations.

Exponent's scientific and regulatory consultants can conduct vulnerability assessments of regulatory and safety systems, perform safety assessments and compliance audits, and manage due diligence processes from start to finish. We conduct in-plant evaluations for food hazard identification, Good Manufacturing Practice (GMP) compliance, and Hazard Analysis Critical Control Point (HACCP) adequacy.

In addition, we review process and quality systems documentation, validate preventive control technologies, review Food Safety Modernization Act (FSMA) preparedness, and develop process models to verify product safety. Often working with our clients' in-house technical staff, internal counsel, or external law or insurance firms, Exponent provides the scientific, technical, and regulatory capabilities needed for time-sensitive and issue-sensitive work that is critical for business success.

## Regulatory Support

In today's evolving regulatory environment, food and beverage companies, and departments and agencies need experienced advisors who can navigate through complex food and ingredient compliance necessities. Our experts support safety assessments for food and color additives, generally recognized as safe (GRAS) substances, food contact substances, and newly introduced dietary ingredients, and provide dietary intake estimates in the U.S., EU, and other countries to support regulatory submissions and other safety assessments of various food components. In addition to regulatory support on behalf of our clients, our consultants also prepare scientific substantiation for claims related to health, nutrient content, and structure/function.

Whether in a food plant or on a national or international regulatory strategy committee, our scientific and regulatory consultants have the knowledge and experience to efficiently address your most pressing pre- and post-market needs. Our project experience includes foods and beverages, dietary supplements, novel foods, medical foods, infant formula, and bottled water. With a multidisciplinary team including medical, human factors, public health, and nutrition experts, we also have the expanded capability to evaluate consumer behavior, intake and exposures, and adverse reactions.





# Dietary Exposure & Human Health Risk Assessments

When investigating an acute outbreak or emergent concern, there are direct and indirect approaches to dietary risk assessment. Direct methods estimate the intake of the compound of interest in individuals within a population subgroup, while indirect methods combine food consumption data with contaminant concentration data derived from different data sources. Dietary intake of a food component, such as a micronutrient; a food ingredient, such as a food additive; or a contaminant, such as a pesticide residue, is often indirectly estimated based on two parameters: (1) the concentration of the food component, ingredient, or contaminant at the time of consumption and (2) the amount of the food consumed. Whether chemical, microbial, or physical, our consultants can definitively estimate human exposure to a variety of food substances and contaminants using existing integrated models, or construct new models targeted to address your specific questions and concerns.

We offer two assessment types to meet your needs:

## Intake Assessments

Exponent frequently utilizes nationwide surveys such as the CDC's National Health and Nutrition Examination Survey (NHANES), EFSA's comprehensive food consumption database, and the U.K. government's national food consumption surveys for adults, toddlers, and young people, along with food consumption data from several other countries. Proper analysis of the data from these surveys requires the use of specialized statistical methods to adjust for the complex sample designs. Exponent has the tools and experience to help you make sense of these data and routinely uses these data in nutrition and dietary exposure assessments. These assessments can also be used by food companies for market research and product development.

## Chemical/Microbial Dietary Assessments

Evaluating the data to use in dietary exposure assessments and properly interpreting the findings is not always an easy task. Exponent's experienced consultants include both technical and regulatory experts who are knowledgeable in dealing with food composition and consumption, food safety, and nutrition. They use specially designed dietary assessment models to derive estimates of exposure to chemical and microbial contaminants from the diet and have the expertise to design models to address complex scientific questions.



## Process & Production

The best time to discover food safety risks is before they result in contamination. Our assessments can offer you a full understanding of where trouble may be waiting in your supply chain, facilities, equipment, personnel, quality systems, and processes.

Our teams are expert at the application of hazard analysis, preventive controls, and Good Manufacturing Practices (GMP) for food and beverages, dietary supplements, and pet food and animal feed. Our food safety assessments include evaluations of Hazard Analysis Critical Control Points (HACCP) and compliance with relevant regulations such as the Food Drug and Cosmetic Act (FD&C Act), Food Safety Modernization Act (FSMA), Foreign Supplier Verification Plan (FSVP), and several other food safety, traceability, and allergen control programs across the U.S., EU, UK, and other markets.

We also assess compliance with various Global Food Safety Initiative (GFSI) schemes. Exponent can assist with process and equipment design and validation, as well as the development or assessment of sampling and testing approaches for incoming raw materials, in-process quality control, finished products, and microbiological environmental monitoring.

We conduct mock inspections around the world, preparing you for live regulatory visits and helping with responses to regulatory observations, warning letters, and other compliance and enforcement actions.

We prioritize going beyond subjective analysis by conducting both quantitative microbial risk assessments (QMRA) and health hazard evaluations (HHE). This allows us to develop actionable recommendations, grounded in science, to help you work toward minimizing risk to consumers, patients, and your business itself.







## Product Safety & Recall

When lives are on the line and your reputation is in the balance, there's no room for guessing about suspected contamination. Hazards can include chemical, microbiological, physical, and radiological agents. Our experts can provide reliable, science-based evaluations to help you understand:

- What is in the contaminated food, and in what concentrations?
- What are the tolerable levels?
- What are the potential health risks to consumers?
- What can be learned from consumer complaints or adverse event reports?
- What, if anything, should be recalled?
- What is the scope of the recall?
- How should the information be communicated to the government, customers, and public?
- What is the root cause of the problem?
- What corrective actions should be taken to prevent a recurrence?

We can help you every step of the way, from quantifying the problem to conducting incident and foodborne illness outbreak investigations, including advising on epidemiology, supply chain traceback, and intensified sampling, all to aid in identifying the source of the issue and carrying out remediation efforts.

What can we help you solve?

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Exponent<sup>®</sup>

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