

# TECHNOLOGY SCIENCES GROUP INC. (TSG)

Your partner in regulatory compliance  
and scientific strategy



TSG

**TSG provides quality, global scientific and regulatory services to companies that produce and market consumer products, food, cosmetics, electronics, agrochemicals, pharmaceuticals, dietary supplements, traditional chinese medicine products, medical devices, biocides, chemicals, and animal health products. We work with companies, industry groups, trade associations and law firms in the US, Canada, Europe, Asia, Australia, and South America.**

TSG's wide range of scientific expertise includes toxicology, ecotoxicology, environmental fate, efficacy, chemistry, and exposure and risk assessment. We combine innovative approaches, informed and current regulatory analysis, strategic planning, and state-of-the-art scientific knowledge to provide value-added services to our clients.



### **Our services include:**

- ▲ Developing regulatory strategies to fit US and global goals
- ▲ Negotiating with regulatory agencies from requirements through registration
- ▲ Commissioning and monitoring studies and final study reports
- ▲ Preparing applications, including data waiver requests and risk assessments
- ▲ Auditing domestic and foreign contract manufacturers
- ▲ Providing training and consulting services to foreign manufactures for compliance with the US and EU regulatory requirements
- ▲ Conducting due diligence and compliance audits
- ▲ Coordinating product defense and response to government enforcement
- ▲ Preparing expert reports and serving as an expert witness
- ▲ REACH: Assisting companies with European business interests

### **US Federal Regulatory**

TSG provides clients with regulatory strategies and represents clients before the EPA, FDA, CPSC and other agencies.

**FIFRA** - TSG's staff have broad experience in the registration of new active ingredients, agricultural pesticides, biopesticides, antimicrobials and disinfectants, and inert ingredients. Our staff includes former government regulators, industry regulatory experts, and scientists and as such are able to deal with all aspects of pesticide production, research, product development, registration, and product defense. We provide services to individual companies, industry task forces and consortia.

**TSCA** - With over 20 years of compliance expertise on the Toxic Substance Control Act (TSCA), TSG regularly submits new chemical notifications, NOCs, Section 8(e) submissions, and also makes Polymer Exemption eligibility determinations. We conduct compliance audits, offer SOP compliance systems and training, Section 8 reporting, recordkeeping, IUR, and import/export compliance assistance.

**FDA** - TSG provides scientific and regulatory advice in the areas of food, food packaging, human and veterinary drugs, cosmetics, pharmaceuticals, dietary supplements, traditional chinese medicine products, and medical devices.

We can address concerns of the European Food Safety Agency and the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) and can, with the assistance of TSGE, our European affiliate, prepare dossiers and other submissions for the EU.

**Hazardous Chemicals** - TSG offers services for chemical hazard identification and communication that include: classification for supply and transport, DOT, OSHA, ANSI and WHIMS regulations, MSDS authoring and translation, and advice on packaging, labeling, transport, storage and disposal. We also develop hazardous material transportation classifications, ensuring that hazard classifications are consistent and compliant.

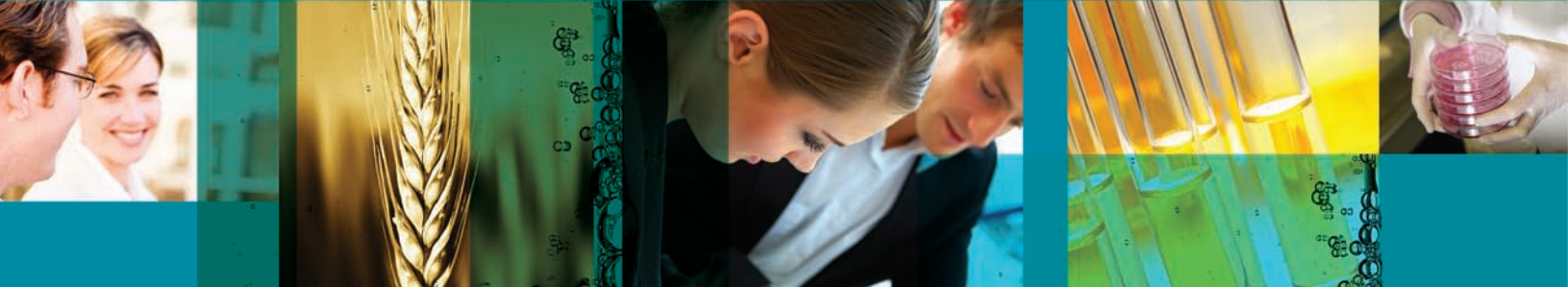
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**INTERNATIONAL LEADERS IN  
REGULATORY COMPLIANCE,  
SCIENTIFIC STRATEGY AND  
CONSULTATION.**

## US State Regulatory

TSG's State Affairs Division is uniquely qualified to provide guidance through the maze of registration and compliance requirements unique to each state and territory. Licenses, registrations, and compliance rules abound for every state, from conventional products to minimum risk alternatives. We provide specific expertise in state regulatory affairs, sound working relationships with state officials, extensive familiarity with scientific approaches that are unique to states, and broad experience in state regulations, policies, practices, enforcement, and laws.

**Prop 65** - TSG's staff have been active in Proposition 65 since its inception, and are therefore experienced at conducting risk assessments and providing underlying documentation to deter litigation. We can assess products under notice of potential litigation, coordinate responses to proposed chemical listings, and negotiate favorable outcomes in litigation under Proposition 65.

**Air and Water** - TSG can assist companies in meeting the complex air and water quality rules as compliance with these requirements requires close tracking of the ever-changing state and regional rules.

**Pesticides** - With 50 states and the attention of the general public on pesticides, the need for defense of products at the state level is expanding. TSG is at the forefront in assisting pesticide companies in defending their products in this tough market.

**Green Chemistry** - Many states are moving into the frontiers of "green" chemistry and environmental procurement rules. State policies and regulations being developed will impact product development and marketability. TSG monitors these efforts and provides guidance on keeping ahead of these evolving policies.

**Fertilizers/Soil Amendments** - State governments, not the federal government, regulate the sale and use of fertilizers and related products such as soil amendments and minerals, creating a maze of labeling and compliance challenges. TSG tracks such regulations and keeps clients aware of requirements in each state.

## International Regulatory

TSG advises clients on international regulatory requirements and on international issues such as NAFTA and prior informed consent (PIC), OECD, FAO, and WHO.

In addition to its offices in the US, TSG has offices in Canada (TSG Canada), and Europe (TSGE and TSGE Iberia). We are active in a number of South Pacific countries, including China, Australia, New Zealand, and Japan.

Through our global regulatory network of subsidiaries, TSG provides up-to-date information on international requirements for registration of pesticides and industrial chemicals, approvals for food, pharmaceuticals, dietary supplements, traditional chinese medicine, and medical devices, and together we bring the latest information on what is necessary for companies to market products world-wide.

**Canada** - TSG Canada and TSG provide clients with regulatory, technical, and

compliance assistance on a broad spectrum of chemical related topics to help companies bring products to the Canadian market. We have developed good working relationships with Canadian regulatory agency staff within PMRA, CFIA, TPD, and Environment Canada and can provide an accurate interpretation of PCPA, F&D, and NSN regulations to better understand the company's' liabilities. Through our technical expertise, we can assist you with the Canadian regulatory system and obtain the required approvals to market and use products in Canada.

**Europe** - Through TSGE, our European affiliate, TSG has extensive experience in European scientific and regulatory issues and can provide clients with a unified approach to product approvals in Europe and North America.

We offer support in the registration and re-registration of products for pesticides,

biopesticides, food contact, feed additives, cosmetics, personal care, animal and human health and can also assist companies in attaining compliance with REACH, the chemicals regulation.

**Asia** - Throughout Asia, TSG assists clients with regulatory matters for pesticides, foods, and chemicals. We coordinate new chemical notifications and pesticide registrations in Asia, including China, Japan, South-East Asia, India, and Pakistan. We also assist clients in sourcing products in Asia by locating, inspecting, and auditing manufacturing facilities, including performing Good Manufacturing Practice audits. We also advise government organizations and industries in Asian Pacific countries regarding US and EU regulatory matters for pesticides, foods, pharmaceuticals, dietary supplements, traditional chinese medicine, medical devices, and chemicals. We provide on-site training and consulting services for compliance with the US and EU regulatory requirements.

## Regulatory Toxicology and Risk Assessment

TSG has senior level, well recognized staff in key disciplines of chemistry and toxicology, with extensive experience in ecological and human health risk assessments. These scientists provide a broad range of technical expertise to support both TSG and client activities in registration, regulatory affairs, and compliance. They are also an important resource in the legal arena providing expert witness and technical support services.

TSG combines a broad range of expertise to evaluate potential health and environmental risks. We provide a complete range of services in all aspects of toxicology including:

- ▲ Mammalian toxicology evaluations
- ▲ Human exposure analysis
- ▲ Human health risk assessments
- ▲ Ecological risk assessment
- ▲ Peer review

TSG can help clients address federal and state requirements, and support good product stewardship. Our board-certified toxicologists routinely estimate potential risk from exposure to pesticides, industrial chemicals, pharmaceutical agents, consumer products, and food ingredients. We make full use of newly emerging methods from the scientific community in developing evaluations and risk assessments.

**Chemistry** - TSG's chemists offer many years of industrial experience in the design, monitoring, and reporting of residue, metabolism, environmental fate, and transport/transfer studies to meet world-wide regulatory requirements. We also offer expertise in selection of methods and review of findings for any project that involves chemical measurements, beginning at the definition phase and continuing through both in-house and contracted sampling, analysis, and reporting.

**Compliance and Litigation Support** - Our consultants can provide support services such as devising scientific and regulatory strategies to support the client's case. We offer a network of regulatory and scientific professionals to act as expert witnesses in a wide variety of subjects necessary to support legal arguments in defense of a chemical tort claim.

**Audits, Compliance and Training** - TSG has extensive expertise in conducting FDA cGMP, FIFRA 6(a)(2), GLP, import, export, label and TSCA compliance audits. We offer services in due diligence, voluntary product audits, and agency-initiated audits and provide in-house TSCA compliance training and also make recommendations for compliance system improvements.

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## Global Reach

TSG provides services on a global basis. We can manage projects small and large in the US, Canada, Asia, Australia, Latin America and Europe.

We are a subsidiary of McKenna Long & Aldridge, LLP, a leading international law firm that provides a broad range of services in the field of environmental law and product regulation, including product liability issues.

TSG Canada provides Canadian regulatory expertise for a wide variety of product-specific programs, including those for disinfectants (DIN), pesticides (PCP), food additives (CFIA), and cosmetics, as well as other regulatory issues.

We are also affiliated with TSGE and TSGE Iberia. TSGE is a European regulatory consulting company providing scientific and registration services to the chemical and associated industries. TSGE has expertise in human health, environmental fate and behavior, ecotoxicology, physical and analytical chemistry, and efficacy. TSGE Iberia, based in Spain extends TSGE's capabilities across Southern Europe providing regulatory advice and services to agrochemical, biocide, and other chemical companies.

