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PRESS RELEASE

TSG Consulting publishes guidance for developing an inert petition strategy for pesticide products

WASHINGTON DC – April 29, 2019: The inert petition process for pesticide products can be lengthy and expensive. A comprehensive understanding of the process, potential pitfalls and strategies for reducing data generation requirements can shorten the prep time before a petition is submitted and may reduce application costs, say regulatory and scientific experts [TSG Consulting](#).

To help companies navigate the inert petition process, TSG has published a free paper – [Developing an inert petition strategy: five key considerations](#).

Inert ingredients are those components intentionally added to pesticide formulations which do not impart pesticidal activity, for example emulsifiers, stabilizers, surfactants, diluents, colorants, and fragrances. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the US Environmental Protection Agency (EPA) requires that inert ingredients are approved for use in pesticide products before it will approve those product formulations for sale and distribution in the US. It is therefore important for registrants to identify inert ingredients early, understand their approval status, and consider the impacts of an inert petition on any anticipated regulatory timeline.

The five key considerations in developing an inert petition strategy are:

1. **Do I need inert approval?** – If the inert ingredient hasn't already been approved by EPA, or is not approved for the desired use (non-food use, food use, or use as a fragrance) and there are no viable alternate ingredients, then an applicant must submit a petition to EPA.
2. **Inerts are regulated under the Pesticide Registration Enhancement Act of 2019 (PRIA 4)** – There are sixteen PRIA 4 fee categories under which an inert petition may be regulated. Fees can be significant and decision review times can range from three to 24 months, depending on the category. It is important to build these into budgets and timelines.

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3. **Petitions for food-use inert ingredients** – If an inert is intended for food-use, applicants must submit a petition to EPA which includes: a Notice of Filing summarizing the request for a tolerance or exemption from a tolerance, the proposed use, and a summary of all the supporting data.
4. **Trade name ingredients** – Manufacturers of inert ingredients or mixtures must submit the full compositional information and trade name of the ingredient or mixture to EPA for addition to the List of Trade Name Inert Ingredients database. The database will only show the approval status and not disclose the composition of that ingredient, providing protection under Confidential Business Information.
5. **Approach the petition process with an open mind** – Registrants should consider methods beyond data generation to satisfy data requirements, understand the use of the ingredient in other jurisdictions and engage with the EPA early to obtain feedback.

The paper's author, Abigail Wacek, Senior Regulatory Consultant at TSG Consulting, explains: "Inert ingredients are just as important in product formulations as their active counterparts. However, they are not always given the focus they deserve. As the US Environmental Protection Agency (EPA) must approve the inert ingredient first, the petition can become a limiting factor in the pesticide registration process. Prior planning and strategic thinking can pave the path towards successful approval of a new or amended inert ingredient."

Developing an inert petition strategy: five key considerations is available to download at:

<https://www.tsgconsulting.com/advisory/developing-an-inert-petition-strategy-five-key-considerations>

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About TSG Consulting

TSG provides companies with high-quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance.

TSG Consulting is a Science Group company. Science Group provides independent advisory and leading-edge product development services focused on science and technology initiatives. It has offices in Europe and North America, two UK-based dedicated R&D innovation centres and more than 400 employees. Other Science Group companies include Sagentia, Oakland Innovation, OTM Consulting & Leatherhead Food Research.

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About Science Group

Science Group plc (AIM:SAG) is an international consulting services group supporting the product innovation lifecycle to enable our clients to deliver on their investments in R&D. Our services fall into four broad categories: Applied Science, Product Development, Technology Advisory and Regulatory. These services are combined with vertical market expertise in Medical, Food & Beverage, Industrial, Chemical, Energy and Consumer sectors. With offices throughout Europe and North America and over 30 languages written and spoken, Science Group supports a global client base.

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