in focus

Animal feed and pet food:

Understanding the US federal and state regulatory framework

tsg

a **science group** company

Animal feed, and its pet food subset, is among the most highly regulated of all food products in America. Needing to meet both federal and state requirements, it is often a challenge for manufacturers and other sponsors to navigate the regulations and identify the most appropriate strategy to bring their products to market. In this paper, TSG's Shannon Bryant-Spas, Senior Regulatory Consultant, gives an overview of the US regulatory framework, highlighting the key challenges companies need to overcome.

Collectively, the US animal feed and pet food market is forecast to be worth around USD114.5 billion in 2020.[1] Whether it's small 'mom and pop' stores selling dog and cat treats, or multinational corporations distributing cattle feed, knowing which federal and state pathway to follow is complex. Add to that a lack of a specific regulatory framework for animal supplements, and it's no wonder that companies struggle to define the most appropriate regulatory strategy for their products.

How are animal feed and pet food regulated in the US?

As with many US regulatory structures, there are both federal and state components to the lawful distribution of pet food and animal feed, hereinafter referred to as 'food/feed'.

The US Food & Drug Administration (FDA) is the primary federal agency tasked with regulating food/feed in America.

In addition to federal requirements related to food/feed ingredients and food/feed manufacturing, states have requirements for the labeling and distribution of finished products, which are usually overseen by the State Departments of Agriculture.

This strict regulatory scheme ensures that high quality, safe and nutritionally appropriate foods are available for pets and other animals.

What does animal feed and pet food encompass?

Animal feed encompasses anything that is fed to, or intended to be added to the food or water for any animal. This includes livestock (dairy and beef cattle, sheep, pigs, horses), poultry (chickens and turkeys), aquaculture, zoo animals, exotic animals, wild animals, pets, specialty pets, and so on.

Pet food and specialty pet food are subsets of animal feed. Pet food encompasses food for companion animals – dogs and cats; specialty pet food covers food for other types of household pets such as parrots, hamsters and snakes.

[1] This figure is an estimate based on two sources. The American Pet Products Association (APPA) estimates the US pet food and treats category to be worth USD38.4 billion in 2020 (Americans' Pet Spending Reaches Record-Breaking High: $95.7 Billion (2020) https://www.prnewswire.com/news-releases/americans-pet-spending-reaches-record-breaking-high-95-7-billion-301012852.html). ResearchAndMarkets.com forecasts the US animal feed market to climb to USD76.1 billion in 2020 (United States Animal Feed Market Report 2019: The Market is Forecast to Reach $83.66 Bn in 2024 (2019) https://www.businesswire.com/news/home/20190529005510/en/United-States-Animal-Feed-Market-Report-2019).

Federal regulation

At the federal level, food/feed ingredients are regulated by the Center for Veterinary Medicine (CVM), a branch within the US FDA. Regulation focuses on ingredients rather than finished products; therefore no product registration occurs at this level.

When CVM approves an ingredient, the approval is specific for the animal(s) and use for which the ingredient is appropriate. This is important because what may be a key nutritional element for one animal could be a harmful ingredient for another. Human food ingredients are not automatically acceptable for animals for the same reason – it is common knowledge that chocolate is harmful to dogs, but it is less well known that grapes can cause kidney failure in both dogs and cats.

FDA-approved ingredients

Producers using ingredients that have already received federal approval for their intended use can immediately proceed to state registration of their finished products. Food additives already approved for use in food/feed are listed in Title 21 of the Code of Federal Regulations Part 573 (21 CFR 573). A partial listing of substances that are Generally Recognized as Safe (GRAS) for an intended use are found in 21 CFR 582 and 584. And ingredient definitions approved by the Association of American Feed Control Officials (AAFCO) are included in the AAFCO Official Publication.

Food Safety Modernization Act (FSMA)

Beyond the regulation of ingredients used in food/feed, FDA is responsible for ensuring food/feed safety under the authority of FSMA. Producers must follow strict manufacturing requirements, much like in an environment processing human food. FDA has, and does, issue fines for violations – these fines can be punitive, designed to discourage repeat offense.

Paths for new ingredients and/or uses

Companies that have developed a new food/feed ingredient can take one of three paths forward, depending on whether the new ingredient is considered a food additive or GRAS. Likewise, if a producer wants to use an already-approved ingredient for a new use or species, they must also take the food additive or GRAS route, as appropriate.

Path 1 - Food Additive Petition (FAP)

A food additive is any substance that directly or indirectly becomes a component of a food or affects a food's characteristics. Food additives used in pet food or animal feed are generally intended to supply nutrients, add aroma/flavor, aid stability, or alter a food's characteristics (such as emulsifiers, sequestrants, anti-caking agents, or enzymes). Substances used in the processing, packaging or transporting of food/feed may also be food additives based on indirect or incidental contact with the food/feed.

Approval process – The manufacturer or other sponsor may petition the FDA for approval of a new food additive or for a new use of an already-approved food additive. In the FAP, the manufacturer/sponsor must include data to substantiate that the food additive is safe and accomplishes its intended use under the conditions of use specified in the petition. Completed FAPs are submitted to the CVM.

Pro – Data can be from proprietary sources and studies; and federal government approval will ease the state registration process.

Con – It can take years for the CVM to complete its review.

General information that should be included in a FAP

1. Identity and composition of the additive including manufacturing methods and controls
2. Intended use, use level, and labeling (cautions, warnings, shelf life, directions for use)
3. Data establishing the intended effect (physical, nutritional, or other technical effect)
4. Analytical methods (for the additive and for animal foods containing the additive)
5. Safety evaluation (target animal and human food)
6. Proposed tolerances for the food additive
7. Proposed regulation
8. Environmental assessment

Full details are provided in 21 CFR 571.

Path 2 - Generally Recognized As Safe (GRAS) Determination

Certain substances can be exempt from premarket food additive approval requirements if they are Generally Recognized As Safe (GRAS) by an expert panel. GRAS determinations are specific for a species and usage. Adding new uses or additional species requires additional GRAS determinations.

Approval process – In a GRAS determination, a manufacturer/sponsor is required to assemble publicly available data and information to demonstrate that the ingredient is safe and beneficial for its intended use and species. GRAS determinations can either be self-affirmed (known as Independent Conclusions) or submitted to CVM for review (known as GRAS Notifications). In both cases, the determination is reviewed by an expert panel and must meet the requirements for eligibility as defined in 21 CFR §570.30.

Pro – A GRAS Independent Conclusion can greatly speed up the process because it eliminates the review timelines associated with a regulatory body. A GRAS Notification can remove the uncertainty associated with state registration of a product utilizing novel ingredients.

Con – Many states are wary of the process for Independent Conclusions and will simply not accept the ingredient, which causes them to refuse to register any food/feed that uses the ingredient. In terms of GRAS Notifications, one drawback is the time needed for regulatory review – FDA is required to respond to a GRAS notice within 180 days, but it has the option to extend this timeframe by 90 days on an as-needed basis. At the time of writing this paper, CVM is taking much longer than 180 days to review Notifications.

Path 3 - AAFCO New Ingredient Definition

If a new substance isn't GRAS, an alternative to FAP for some ingredients is the AAFCO New Ingredient Definition route. This route defines the common or usual name, as well as approves the use of the ingredient for specific species and uses. This process is for ingredients that are non-proprietary in nature and have no human health concerns.

AAFCO is composed of state, federal, and international regulatory officials who are responsible for regulating the sale and distribution of food/feed. FDA (via CVM) and AAFCO work together in this area, particularly to establish definitions to describe new feed ingredients.

Approval process – To obtain a new ingredient definition, a company needs to provide the same type of information that would be in a FAP to the AAFCO investigator. AAFCO relies on CVM's expertise in reviewing the safety and efficacy for all new ingredient definitions. Once the AAFCO investigator and CVM have completed their reviews, the definition is assessed by an AAFCO committee, the AAFCO board and finally the AAFCO membership.

Pro – Unlike GRAS Independent Conclusions, this is a state-recognized method for food/feed ingredient approval, which therefore facilitates state registration.

Con – The process can sometimes take several years, like a FAP approval.

State regulation

Once federal requirements have been met, companies need to register their finished products in the states in which they wish to distribute them.

While federal law is supreme, the states maintain regulatory autonomy in that they can regulate in their own interest if they are not in conflict with federal law. This establishes a system in which each state can regulate a single product very differently from another, making nationwide compliance extremely challenging.

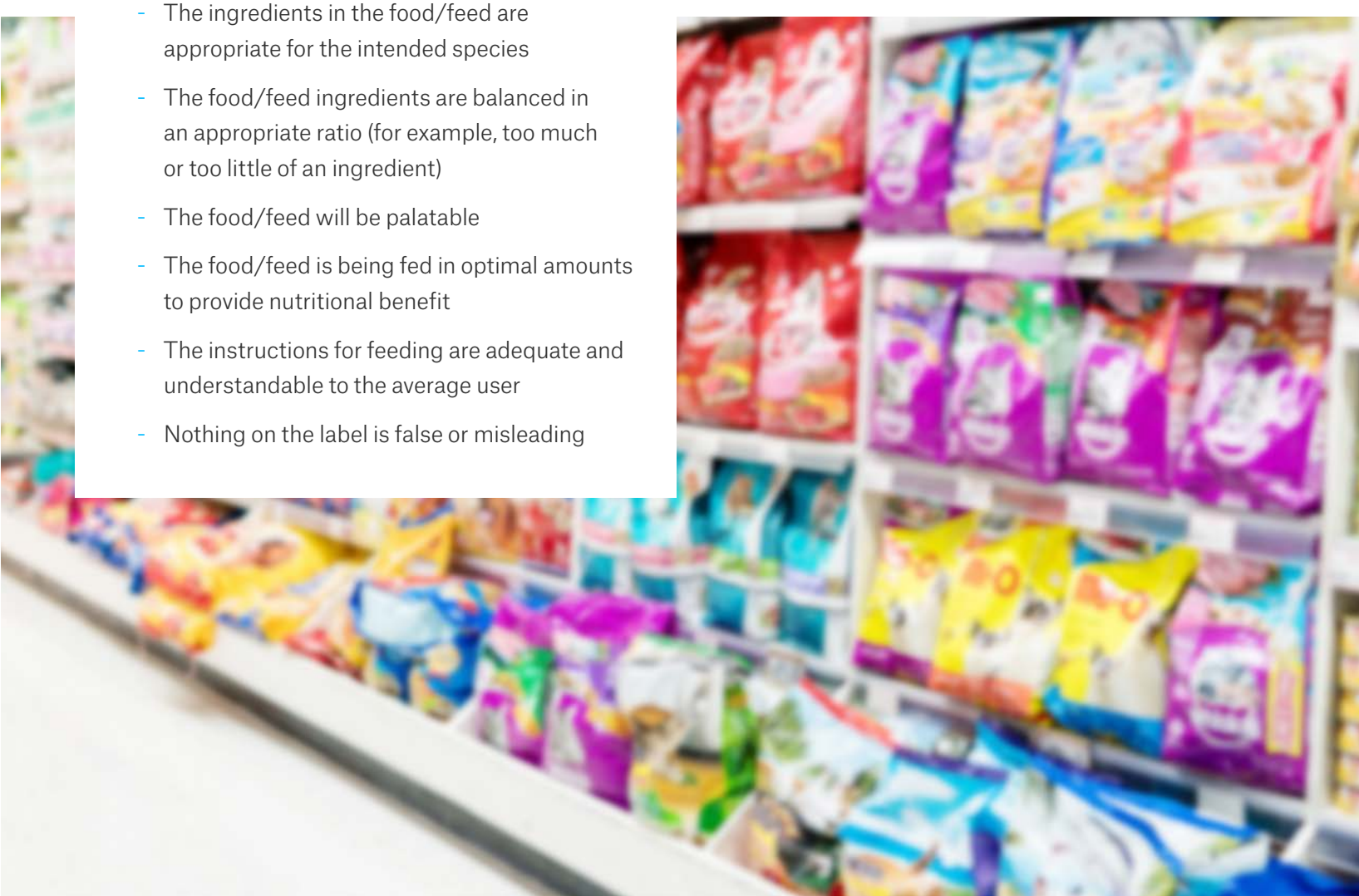
In some states all food/feed products are regulated as animal feed and follow the same rules. In other states, there are separate commercial feed laws and pet food laws, which result in different requirements for these two distinct product types.

The states regulate products as sold, and review formulations and labels to ensure the following:

- The ingredients in the food/feed are appropriate for the intended species
- The food/feed ingredients are balanced in an appropriate ratio (for example, too much or too little of an ingredient)
- The food/feed will be palatable
- The food/feed is being fed in optimal amounts to provide nutritional benefit
- The instructions for feeding are adequate and understandable to the average user
- Nothing on the label is false or misleading

Once these items have been verified, assuming the information was provided in a manner accepted by the reviewing state, a license or certificate of registration is issued that allows for the sale and distribution of the food/feed in that state. Once initial registration is achieved, it must be maintained through routine, often annual, fee payment referred to as renewals. A manufacturer must also notify the states of any changes to their formulations or labels prior to implementing those changes.

In order to achieve full compliance, industry must keep track of 49 sets of rules, all with differing timelines for compliance, different fee structures and different labeling requirements.



Labeling

Labels for animal feed and pet food products are regulated at both the federal and state level.

Federal regulations require ingredients be listed on the product label by their common or usual name in descending order of weight (21 CFR 501.4). A common or usual name is one that accurately identifies or describes the basic nature of the ingredient. FDA-recognized definitions appear in the Official Publication of AAFCO (Compliance Policy Guide 665.100).

Looking to state regulations, food/feed labeling is often the most challenging part of obtaining state registration.

A particular stumbling block is label claims. Forty states may determine that a statement is innocuous, while the remaining states may interpret the same label claim as being false and misleading, halting registration.

Also posing challenges are the labeling requirements for the type of feed, such as balanced and complete feed or supplemental feed, and the intended species. Understanding these particular requirements helps ensure that the necessary information is presented on the label in the correct format.

In spite of the challenges, it is possible to develop a nationally accepted label, which will not only streamline processes, but also reduce costs and the timeline to market. This typically involves understanding the requirements of every state and making sure that the most restrictive elements are incorporated into the label. Evaluation of labeling and marketing claims will also help avoid extensive discussions with state regulators and possibly outright rejection of a registration.

Animal supplements

Vitamins for cats and joint supplements for dogs are a common sight in any US grocery store's pet aisle. However, animal supplements like these are not a recognized product category in the US, and do not have their own regulatory framework. Federal supplement laws do not apply to animals. So depending on a supplement's intended use, products are considered either a food or a drug by the CVM and their ingredients must follow the appropriate federal regulations.

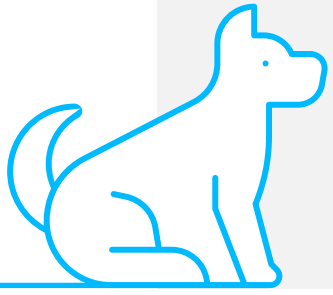
At the state level, supplements for non-food-chain animals are regulated as food/feed. States will enforce regulations against an animal supplement if the label or the marketing crosses over into animal drug territory.

A supplement remains food/feed if it supports the normal function of the body but does not alter or enhance the normal structure or function of the body. If the label claims are written in a way that implies direct benefit, the supplement becomes an animal drug with its own set of federal and state regulatory hurdles. To help illustrate this, a product that claims to make your dog's coat glossy is a drug. Although a glossy coat is an aesthetic effect of the product, the product claims to cause the benefit. On the other hand, if the product claims to support a dog's normal glossy coat, it remains in the food world. Similarly, a product that supports normal joint function is a food, while a product that improves or enhances joint health is considered a drug.

Avoiding violations

As industry grapples with the distinction between a food and a drug, there are several ways in which an animal supplement manufacturer can avoid state and federal violations:

- Pay careful attention to the claims being made in association with the product to ensure they cannot be interpreted as drug claims
- Ensure that the ingredients in the supplement are safe for the animal(s) for which it is intended
- Have proof that the supplement does what it claims to do
- Ensure that the supplement is manufactured in a way that yields a safe product that is consistent batch to batch
- Stay current and alert to any changes made to animal supplement regulations



Keys to overcoming the regulatory challenges

Whilst navigating the federal and state regulations for animal feed and pet food can be complex, it is not insurmountable with the appropriate regulatory guidance and strategic support.

Determining early on what path is appropriate for the ingredient can guide a company's next steps, whether that be conducting a review of existing literature or designing an appropriate safety study. In making this decision, a thorough review of the available data for the ingredient can be a good first step. Often this clearly illuminates the regulatory pathway for the ingredient.

Once an ingredient has been federally approved, key to state registration is taking the time to develop one product label that will be compliant in all states. In addition to streamlining processes and expediting approvals, it will also help reduce costs.

Join us for our free webinar

Animal feed and pet food: Understanding the federal and state regulatory challenges

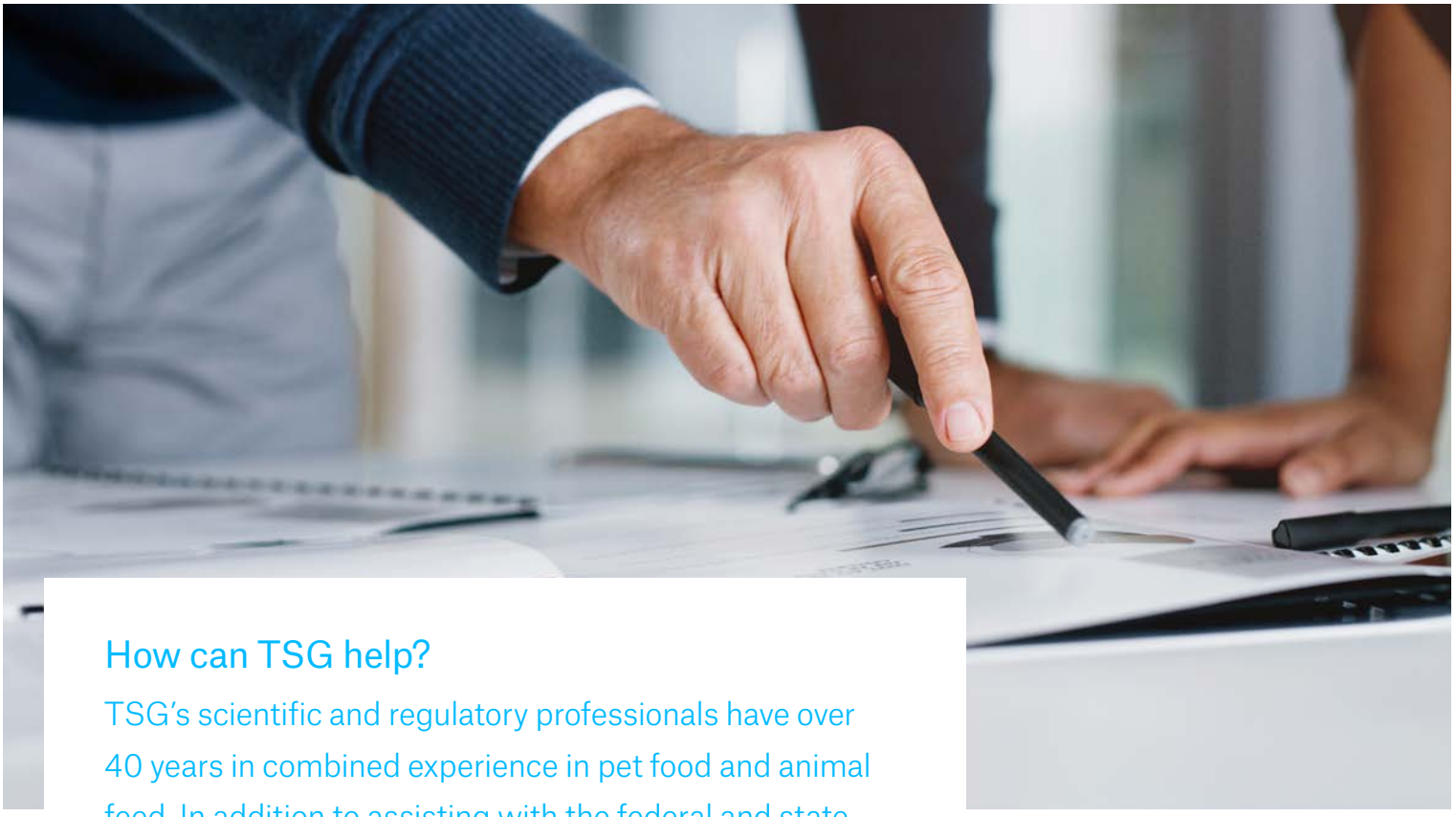
9 September, 2020
08:00 PDT, 11:00 EDT, 16:00 BST

www.tsgconsulting.com/animal-feed-webinar

About the author

Shannon Bryant-Spas, BA
Senior Regulatory Consultant, Team Leader

Shannon specializes in the compliance of products including animal feed and pet food, fertilizers, plant and soil amendments, and organic input materials, at the state level. She is also well-versed in Good Laboratory Practices (GLP) compliance for FDA-regulated studies. With over 20 years of regulatory experience, Shannon oversees product registrations and renewals, develops labels that can be used across all 50 US states and territories, reviews product formulations, assists with tonnage reporting, and evaluates products for organic input eligibility. Shannon has a BA in Chemistry and English from the University of Kansas and is a member of the American Feed Industry Association (AFIA).



How can TSG help?

TSG's scientific and regulatory professionals have over 40 years in combined experience in pet food and animal feed. In addition to assisting with the federal and state registration of these products, we also provide regulatory support and guidance for animal drugs, animal supplements and pesticides intended for use on animals.

Our food/feed services include:

- Assistance with:
  - Food Additive Petitions
  - GRAS Notifications and Independent Conclusions
  - AAFCO New Ingredient Definitions
- Label development and review to ensure compliance with state regulations
- Preparation and submission of new product registrations
- State renewals maintenance and tonnage reporting
- Guidance on regulatory changes that may impact product registration

TSG's clients also benefit from TSG Connect, a platform which provides 24/7 access to the real-time status of all of their registrations in each of the states.

Get in touch for support in bringing your animal feed or pet food product to market.

+1 202 828 8990
info@tsgconsulting.com
www.tsgconsulting.com

About TSG Consulting

TSG Consulting 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 has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

info@tsgconsulting.com

www.tsgconsulting.com

About Science Group plc

Science Group plc (AIM:SAG) is an international, science-led services and product development organization. Its specialist companies, TSG Consulting, Sagentia, Oakland Innovation, OTM Consulting, Leatherhead Food Research and Frontier Smart Technologies, support the product innovation lifecycle, enabling clients to deliver on their investments in R&D.

Science Group's services fall into four broad categories: Applied Science, Product Development, Technology Advisory and Regulatory. These services are combined with vertical market expertise in the Medical, Consumer, Food & Beverage, Industrial, Chemical and Energy sectors. With offices throughout Europe, North America and China/Hong Kong and with over 30 languages written and spoken, Science Group supports a global client base.

info@sciencegroup.com

www.sciencegroup.com

tsg

a **science group** company