in focus

FIFRA 25(b) exempt pesticides

Regulatory perspectives and challenges in the United States

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a **science group** company

As consumers look for alternatives to conventional pesticides, a category of pesticide products considered to be minimum risk pesticides is gaining in popularity. From herbal insect repellant bracelets to citronella candles, we are seeing more of these types of products on the market in the USA.

However, while the United States Environmental Protection Agency (EPA) has exempted minimum risk pesticides from federal registration, many states do require them to be registered, wherein lies the challenge.

This paper outlines the key challenges of state registration so that producers can anticipate and prepare for them early in the product's lifecycle.

The US EPA has exempted certain pesticides that pose little to no risk to man or the environment from federal registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These pesticides are known as FIFRA 25(b) exempt, or minimum risk, pesticides. From no review time or fees at the federal level to a greatly reduced and less costly data set, the benefits of exemption from federal registration are easy to understand. However, this does not mean that minimum risk pesticides are without their regulatory challenges, as we will find out in this paper.

A pesticide must meet six criteria to qualify for exemption from federal registration:

1. The formula's active ingredient(s) must be on EPA's approved list
2. The formula's inert ingredients must be on one of several EPA lists
3. The product label must list all the product's ingredients, both active and inert
4. The label may not make claims to mitigate organisms that pose a threat to human health and, while claims to mitigate insects or mammals that vector disease are allowable, the specific diseases that may be vectored may not be stated on the label
5. The company name and address must appear on the label
6. The label may not contain any false or misleading statements

US EPA has identified six criteria that products must meet to qualify as a FIFRA 25(b) exempt pesticide.

Why do FIFRA 25(b) exempt pesticides prove so challenging?

A lack of federal oversight of minimum risk pesticides is the main driver behind the challenging registration environment.

Intuitively, one might assume that if all one needs to do to be compliant is to follow six rules, then the process should be simple. However, approximately 40 states do not exempt 25(b) products from state registration. Therefore, interpretations inherent in the approval of any pesticide are not being made by one federal authority, but rather by 40 different states. While each state's regulations are written differently, every state is mandated to ensure that products entering their state pose no unacceptable risk. This sets up a system that, by its very nature, will be inconsistent, particularly as not every state will have the same interpretation of risk.

For many registrants, controlling product distribution at the state level is exceedingly difficult and, to ensure compliance, approval in all the registering states can become a hurdle for market entry.

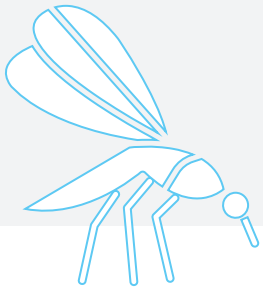
Three key challenges

State-to-state variation in the registration process causes significant obstacles for companies looking to obtain state registration for their 25(b) product.

Efficacy data concerns, false and misleading claims and a lack of a singular form for conveying the product formula are the three main inconsistencies that cause challenges.

1. Efficacy data concerns

a. Each state requiring registration of a 25b product decides what, if any, efficacy data needs to be submitted in the application. For example, states have differing opinions as to what makes an efficacy study robust enough to support registration, and this interpretation is constantly evolving. Consequently, there is no one set of rules to follow when generating this data, which leads to uncertainty as to the acceptability of test results. To further convolute the issue, some state regulators feel that public health claims of any type, including claims for disease transmitting pests like ticks, mosquitoes and rodents, should be prohibited from 25(b) labels completely. This feeling is, in part, due to the lack of federal oversight regarding the minimum performance criteria needed to be protective of human health.



b. Efficacy data for inert ingredients is also new and emerging in the state registration process. In order to be deemed as an inert ingredient, some states will require that the ingredient does not contribute to the efficacy of the product. The crux of the issue is that some of the inert ingredients on the 25(b) inert ingredient list are also used in FIFRA registered pesticide products as active ingredients. States have expressed concern that some of these inert ingredients may actually be contributing to the efficacy of the product. Regardless of whether the ingredient is on the EPA inert listing for 25(b)s, some regulators believe that the ingredients should be listed as active ingredients. This raises a few concerns. Firstly, there is the inherent disconnect with how federal regulation is written and how the product will be registered in the states; namely a state accepted label that lists a federal inert ingredient as an active ingredient. Secondly, states may require proof that the inert ingredient is truly inert. That proof takes the form of efficacy data with and without the inert ingredient. If the product's efficacy suffers a decrease when testing without the inert ingredient, the inert ingredient must be listed as an active ingredient. This additional efficacy data requirement is costly to the registrant and slows the forward path to market.

2. False and misleading claims

For a traditional pesticide registered at the federal level, false and misleading claims are removed from labeling prior to registration in the states. For 25(b) products, each of the registering states interprets what constitutes a false and misleading claim. The variability in these interpretations can cause the state registration process to start and stop multiple times prior to all state registrations being achieved. Take the example of a 25(b) label that has been sent to all registering states. Registrants could face the scenario where the label has already been approved in 20 states, then the 21st state decides that claim A is false and requires revision. The claim is reworded, and this revised label must now be re-reviewed by all the states that have already approved it. Additionally, this label must be swapped out in the states which are still processing the registration. And, just when these frustrating and time-consuming tasks have been completed, another state decides that claim B is misleading and must be removed. The cycle starts all over again.

3. Lack of a single form for conveying the formula of a product

Each pesticide registered at the federal level uses the Confidential Statement of Formula (CSF) form to provide the pesticide's ingredient makeup. This CSF form has been in use for decades and all its intricacies have been worked through during that time. For 25(b) products, there is a 'universal' form that states may voluntarily accept; however, even when this universal form is used, some of the fields are interpreted differently by the states. This makes it difficult and, in some instances, impossible to generate one 'formula statement' that will be accepted in all the states that require this disclosure.

Will the regulatory process for FIFRA 25(b) exempt pesticides change?

Although much of the regulatory community is calling for change, only time will tell. One avenue for change could be federal oversight for these products. Given the principle that products in this category pose little to no threat to man or the environment, it could be considered an injudicious use of EPA's time to require that these products go through the entire registration process as it exists today. An alternative could be the development of a 'lighter' registration process, with shortened review times being driven by reduced data sets. To be of use, this registration process would need to include a review of the areas of variability that exist currently. US EPA, like many of the state agencies that regulate pesticides, are short on resources and increasing the universe of what must be reviewed is not palatable to many.

Another avenue for change could take the form of the states developing universal registration processes and criteria that remove variability from the current system; movement in this direction has already started. Operating under the auspices of the Association of American Pesticide Control Officials (AAPCO), the FIFRA 25(b) Working Group is taking steps to insert some uniformity in the way these registrations are handled.

FIFRA 25(b) Working Group Mission

"...to facilitate the collaboration of states and industry in order to share information, provide guidance, foster label consistency, and reduce the duplication of efforts in the review and registration of Minimum Risk Pesticide products."

How can TSG help?

TSG has significant experience with minimum risk pesticides and can guide you through the current regulatory processes at the state level. We have helped many clients attain 25(b) registrations and we interact routinely with state regulators and understand the intricacies of the process. This constant communication allows our consultants to stay abreast of changes in the 25(b) process in real time. Additionally, TSG is actively involved in AAPCO's FIFRA 25(b) working group, which allows us to not only monitor for changes, but also represent our clients' interests and help steer decisions being made.

TSG's service offerings include:

- Strategy development at the outset of a project, designed to ease the approval process in the states
- Interpretation of the six EPA exemption criteria as they relate to your product, with a basis in how we feel the various states will make these interpretations
- Assistance with label review and label development to achieve compliance in the states and minimize the number of label versions needed
- Review of efficacy data to identify acceptable claims for labeling and other marketing materials
- Preparation and submission of registrations on your behalf and interaction with the state regulators throughout the registration process

To learn more about how TSG can demystify the 25(b) process and assist you in obtaining the registrations your business needs, please reach out to us at:

info@tsgconsulting.com
+1 202 828 8990

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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 the USA, Canada, France, Germany, Spain and the UK. TSG is a Science Group (London listed) company.

info@tsgconsulting.com

www.tsgconsulting.com

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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

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