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INSIGHT

Streamlining pesticide product registration in North America

TSG's regulatory experts looked at how to optimize pesticide product registration to achieve a strategic, cost-effective journey to market in North America. We offer tips for concurrent preparation of applications targeting the US, Canada, and several US states, most notably, California.

Making an early start on this lengthy process is advantageous. It's also a good idea to gather the necessary information for different authorities simultaneously.

Under the United States Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Canadian Pest Control Products Act (PCPA), pesticide products must be registered prior to sale and distribution in the US and Canada. Individual US states and territories also require product registration.

Making an early start on this lengthy process is advantageous. It's also a good idea to gather the necessary information for different authorities simultaneously. Some US states allow their registration process to run alongside that for federal registration via the Environmental Protection Agency (EPA). However, there are benefits to concurrent planning and preparation even when applications are submitted sequentially.

In this article we explain how companies intending to target the US and Canada can plan for the two markets and individual US states at the same time. Aligning preparatory work saves time and reduces the risk of duplicated effort. This is especially true with California where applications involving ecotoxicity data can take more than three years to be processed by the Department of Pesticide Registration (DPR).

Concurrent EPA and California registration

California is the only US state that accepts registration applications before EPA registration is achieved. Taking advantage of this is highly recommended where possible. California's DPR accepts applications before federal registration in five scenarios:

1. Registration of new pesticide products containing new active ingredients.
2. Registration or amendment of Experimental Use Permit pesticide products.
3. Registration of new, or amendment of existing, antimicrobial pesticides intended to control pests that pose a threat to human health.
4. Registration of new, or amendment of existing, 'public health pesticides'.
5. Other scenarios approved by the Pesticide Registration Branch Chief.

This is outlined in more detail in California Notice 2015-03[1].

The benefits of holistic preparation

The EPA, PMRA and US states all require assurance of pesticide products' safety and efficacy. However, the nature of the data that must be submitted with registration applications varies. Acknowledging these variations from the outset enables more streamlined preparation and may influence product development and testing strategies.

Working holistically aids commercialization too. For instance, a company launching a swimming pool algaecide product containing a new active ingredient is likely to want to secure registration in as many locations as possible for a given summer season. For a product of this type (i.e. non-public health) California will require efficacy data to be submitted at the time of application for registration whereas the EPA will not. If the product claims to 'kill' algae, efficacy data will be required for Canada's PMRA as well. Understanding and preparing for this upfront accelerates progress and supports the commercial strategy.

Disinfectant products

It's important to note that Canada and the US have a different outlook on disinfectant products. In the US, they are regulated by the Antimicrobials Division of the EPA's Office of Pesticides Program. However, in Canada they are regulated under Health Canada's Food and Drugs Act because they reduce the transmission of disease. Our dedicated whitepaper Disinfectant registration in Canada:

Finding the right path to market is available here https://www.tsgconsulting.com/news-detail/canada-disinfectant-registration-pathways/

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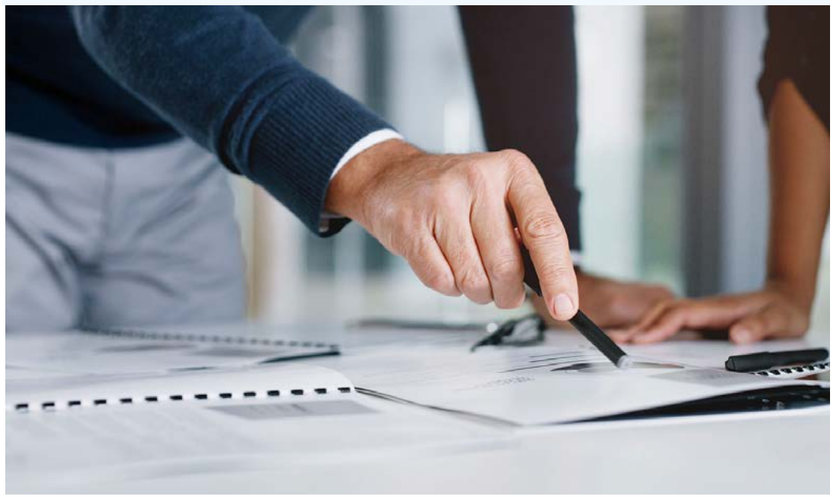
Three factors for a concurrent strategy

The most important factors to consider in a concurrent approach to pesticide product registration are efficacy, chemistry, and labeling. It's also useful to examine the product (see the 'top tips' section). This helps identify specific requirements, hurdles or data gaps that might otherwise stall progress later.

Top tips: questions to ask about pesticide products before registration

It's advisable to conduct a thorough assessment of your product using these questions as a starting point. Additional questions would depend upon the nature of the product and its intended use.

1. Is my product regional? If so, do I have the mechanism in place to control distribution at the state level?
2. Should I register a master label and an end use label in California, or is an end use label sufficient for my product?
3. Do specific requirements of individual US states need to be accounted for, such as those related to groundwater in Arizona or the plant quarantine board in Hawaii?
4. What is the target organism, what is the area of use? What does the product aim to protect or kill?



Efficacy

Within the US, there are discrepancies between what's required at the federal and state level in terms of evidencing efficacy. One noteworthy difference relates to non-public health claims in California. In the US, pesticides are evaluated as either public health or non-public health products. Non-public health products are those that are intended to control odor- and stain-causing bacteria, algae, and other organisms that cause deterioration, spoilage or fouling. Public health products are those that claim to kill or mitigate organisms which are infectious to humans[2].

The EPA requires efficacy data to support any public health claims made on a product's label, such as those relating to sanitization or disinfection. However, data regarding non-public health claims doesn't need to be submitted. This data must be kept on file and made available if the EPA specifically requests it. California's DPR, on the other hand, requires the submission of data to support both types of efficacy claim, and it must be submitted at the time of application. This affects all pesticide product types, from those intended for agricultural use to those that target algae in swimming pools.

Companies often overlook this California requirement when preparing for registrations in a sequential manner. The upshot is unexpected delays and additional costs. Another difference between California and the EPA is California's requirement of volatile organic compound (VOC) data for outdoor agricultural products containing new active ingredients.

In Canada, efficacy data is required for any product that claims to 'kill' or 'repel' its target. However, unlike many US states, the PMRA does not insist that efficacy data is generated under Good Laboratory Practice (GLP) conditions.

Thought should be given to container labels as well. If the product packaging is too small to accommodate necessary, or desirable, information the master label may need to compensate for this.

Chemistry

Canada's PMRA requires any active substance in a pesticide product to come from a registered source, but this is not the case in the US. This is an important distinction to be aware of when planning commercialization strategies in the US and Canada. In some cases, it may be better to go for a more expensive registered source in all markets to avoid potentially having to reformulate for Canada.

Canada also requires that all product chemistry data is developed under GLP conditions. In the US, this only applies to a selection of product chemistry characteristics, such as storage stability and corrosion.

To maximize efficiency and avoid the need to duplicate product testing, it's important to determine whether the commercial strategy will encompass Canada early on. When pursuing registration in Canada, it makes sense to plan for it before developing product chemistry data for the EPA.

Labeling

It pays to consider the wider labeling strategy at the time of master label development for the EPA, since there are significant variations in US state-level demands. Some states require the inclusion of information on the EPA master label that is not necessarily required by the EPA, causing problems if it hasn't been planned for. The EPA reviews the master label (which is primarily a text label with all language, required and optional, which may appear on the market label) or the label affixed to the product at the time of sale. The market label, complete with all colors and graphics, is required by the states but not required by the EPA prior to approval of registration.

One significant example is Maine's requirement that all graphics, including those that don't relate to pesticidal characteristics, are included on the EPA master label. In New York, labels for pesticide products manufactured outside the US must include a US-based phone number, email address or postal address.

Thought should be given to container labels as well. If the product packaging is too small to accommodate necessary, or desirable, information the master label may need to compensate for this. Other elements such as different formats of the company logo (e.g. with or without a tagline) should also be considered and included on the master label as appropriate.

There are still more differences in labeling requirements for Canada. Any product claims must be in French and English and given equal size and prominence. General claims that would not be permissible in the US are allowed in Canada, but precautionary and safety information must be included. It's also important to note that measurements on Canadian labels must be in metric units, not the imperial units used in the US.

Saving time and money

Aligning regulatory strategy with the commercial roadmap may involve more effort upfront, but in many cases, it makes market entry less risky and accelerates commercialization and sale. It also prevents the need to conduct the same efficacy or chemistry tests more than once, or potentially having to reformulate. Your commercial strategy may tackle different markets or states sequentially but taking a concurrent approach to the preparations for product registrations saves time, money and effort.

TSG's regulatory experts and scientists are well-versed in the registration of pesticide products for the US and Canada. We have experience handling the joint review process for pest control products established by Canada's PMRA and the US EPA. Our dedicated state services division also offers specialist expertise and capabilities to streamline state-level registrations.

Find out more about our regulatory services here https://www.tsgconsulting.com/regulation/

References

1. Concurrent submission of pesticide products to the Department of Pesticide Regulation and the U.S. Environmental Protection Agency, https://www.cdpr.ca.gov/docs/registration/canot/2015/ca2015-03.pdf
2. Pesticide Regulation (PR Notice) Notice 2020-[X], Draft List of Pests of Significant Public Health Importance – Revised 2020 https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:c3d8633a-133b-3a89-b2b1-87916ac703b9

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

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