Vireo Advisors, LLC

Obtaining a Biocide Registration for an Advanced Material

So you think you've got something to beat COVID-19, Influenza or other pandemic-causing organisms?

Some advanced materials are being evaluated to mitigate the impacts of COVID-19 and other pathogens such as influenza, SARS, MRSA etc. These pathogens include viruses, bacteria and fungi, which are included in a group known as microbes. The intent of some anticipated applications of advanced materials is to kill or control these pathogens. If this is true for you, then…

This means you have created an antimicrobial pesticide

Among many of the potential uses for advanced materials is as antimicrobial pesticides, sometimes referred to as **biocides**. This is one of the three classes of pesticides considered by US EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The other two classes (Biopesticides and Conventional pesticides) will not be discussed here. Not all microbes are pathogens. Pathogens are distinguished from other microbes in that they are known to cause diseases such as those caused by COVID-19 and the flu virus. Due to the impact they can have on public health, chemicals used to control pathogens get special attention in the pesticide registration process.

You need to prove your product is effective against each target organism

There are many types of pathogens and individual biocides are not always effective on all types. Therefore, testing is required to prove that a biocide is effective against each targeted pathogen. For example, the testing required to demonstrate the efficacy of a biocide against COVID-19 needs to be done even if efficacy has already been demonstrated against influenza virus. Actually, COVID-19 is a special case, however, because **COVID-19 virus is not available to perform testing to submit for regulatory requirements due to the novelty of this virus.** For this reason, the US EPA enacted a 'hierarchy-based' policy that if a company's product has been found to be effective against harder-to-kill viruses or similar viruses, it is likely to kill a virus like COVID-19.

All components have to be evaluated and approved (e.g. actives, inerts, solvents)

Pesticide products are often mixtures of more than one chemical. The most important component of a pesticide product is the one that controls the pathogen and it is called the Active Ingredient (AI). Some products have more than one AI. It is also often the case that the concentration of the AI is low compared to the other ingredients. The other ingredients that are needed to make the use of the AI possible but that are not involved in actually controlling the target pathogen are called Inert Ingredients (Inerts). Inerts include solvents, adjuvants, coloring agents, perfumes and the like. When a pesticide product is evaluated during the registration process their impacts on safety and efficacy are considered and must be found to be acceptable in order for a registration to be granted.

For example, if a product was intended to be sprayed onto surfaces to kill COVID-19 virus, but contained an ingredient that was highly toxic to humans and animals who would touch the surface after treatment the product, it might not be approved.

Key registration documents and Confidential Business Information (CSF, product chemistry, product label)

Any company wishing to sell its own pesticide product must obtain a federal registration for its own product or become a supplemental registrant for a product that is already federally registered. The registration process for a pesticide varies depending on the product. A typical registration dossier for a new pesticide or pesticide product includes some of the following information.

- ***Product Chemistry*** lists all ingredients, explains why each is needed and provides required safety information. Some safety information can be included as appendices such as Safety Data Sheets and toxicology studies. Efficacy data is also included.
- ***Confidential Statement of Formula*** (CSF) lists the composition of the product including the allowable specification limits for each component as defined by the registration requirements. The limits are set by the regulations, not the manufacturer. The manufacturer's limit can fall within the regulatory range but not exceed it.
- ***Proposed Product Label*** includes information about the target organism(s) and directions on how to use the product in way that assures the efficacy. For example, some products when sprayed onto a surface must stay on a surface for an extended period (*e.g.* 5 minutes) before being wiped off. All pesticide labels have as the first statement "It is a violation of Federal law to use this product in a way different from that described on this label".

Possible outcomes of the registration process

The outcome of your registration process might be "Registered", "Temporarily Registered with Pending Submission of Additional Information", "Registered on an Emergency Basis" or "Not Allowed".

Post-registration notice

FIFRA 6(a)(2) requires that if new information becomes available during the development of a pesticide product or after a product is registered that alleges or demonstrates an impact on safety that a notice must be sent to US EPA.

PRIA costs and timelines

The costs and timelines involved in obtaining a federal registration depends on many factors such as the proposed uses of the product, the formulation of the product and how the data requirements will be addressed. This document assumes that your advanced material will be considered to be a new active ingredient as an antimicrobial pesticide.

Fees and anticipated review periods can be found via this link:
https://www.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients

More general information about fees and timelines can be found here:
https://www.epa.gov/pria-fees/fy-2020-2021-fee-schedule-registration-applications#antimicrobials

Pre-notice consultation with EPA

Pre-notice consultations with US EPA can be helpful. Before and during the registration process, you can discuss the details of a potential product with EPA and the information EPA will ultimately require. There are not fixed data requirements for each pesticide product since each is unique in composition, in the target organisms and in how it is to be used. Data will be required based on these factors so talking with EPA in advance can speed the registration process.

Consider using a skilled third party to help

The registration process is complicated and involves many details. Consider using a skilled third-party service provider to help on registration process would save your time and money, if you don't have the experience.

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