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UNDERSTANDING PESTICIDE REGULATION

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Any company wishing to sell a pesticide product must obtain a federal registration for its own product; or become a supplemental registrant (also known as a supplemental distributor or a sub-registrant) for a product that is already federally registered. Before submitting a registration request to EPA, the company must obtain a company number.

In order to determine how to register a pesticide, a business must first understand the regulations that define pesticides and pesticide use and determine whether a product is a pesticide or device under FIFRA. The primary federal law that governs how EPA oversees pesticide use in the United States is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which has been amended by the Food Quality Protection Act of 1996 (FQPA) and by the Pesticide Registration Improvement Act of 2003 (PRIA).

PRIA was reauthorized by the Pesticide Registration Improvement Extension Act of 2012. The FQPA strengthened the safety criteria in the Federal Food, Drug, and Cosmetic Act (FFDCA), which is the statute under which EPA regulates pesticide use on food crops. EPA evaluates pesticides intended for use on food or animal feed crops and if EPA determines that use of the product would result in residues of chemicals in or on food/feed items, EPA may decide not to register the product under FIFRA.

EPA may decide to register the product if it determines that the chemical residues are "safe" under the FFDCA (there is "a reasonable certainty of no harm" from the exposure to the residue in food). EPA can establish a "tolerance," (a maximum permissible pesticide residue on a particular food/feed commodity) or it may establish an exemption from the requirement of a tolerance, which would allow *any* amount of a pesticide residue to remain in or on food or feed, if it determines that the residue will still meet the FFDCA safety standard.

Anyone who plans to sell or distribute a product in the United States that is intended to control a pest or regulate plant growth is subject to pesticide laws and regulations. The term “pesticide” means: “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest;” and “any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant;” and “any nitrogen stabilizer.” FIFRA section 2(u), 40 CFR section 152.15. In order to be regulated by FIFRA, a person must “intend” to use a chemical as a pesticide

State of California’s Implementation of DPR Risk Management Strategy

In the state of California, the approval and denial of new pesticide registration – and the cancellation of an existing registration – is the responsibility of the Department of Pesticide Regulation (DPR). Enforcement and compliance of pesticide regulations occurs at the county level by the County Agricultural Commission (CAC).]

The DPR is tasked with minimizing or prohibiting the use of dangerous pesticides that have harmful effects on human health and the environment, are not beneficial for their stated purpose, or are otherwise misrepresented. To accomplish this task, the DPR conducts a thorough program of pesticide risk assessment and risk management.

Certain pesticides may pose an unacceptable risk to human health and the environment – even when used for intended purposes. The risk management process requires the DPR to identify and potentially implement a feasible plan of action to ensure that the pesticide achieves

acceptable risk standards. As an initial matter, to ensure that your pesticides meets acceptable standards in the state, you should first consult with experienced California chemical lawyers.

No Economic Analysis

The DPR's risk management does not involve an economic analysis, nor does the DPR consider potential economic benefits in their approval, denial, or cancellation of pesticide registration.

Selection of a risk management strategy is based primarily on technical data indicating that implementation will lead to a risk reduction to acceptable levels while maintaining the efficacy of the pesticide. These considerations are then balanced with the feasibility of compliance and enforcement in real-world scenarios.

Risk Management Strategy Implementation

Risk management is fundamental to the DPR's decision-making process in approving, denying, or cancelling a pesticide registration. If a pesticide poses an unacceptable risk to human health and the environment, then the DPR's risk managers may consider several strategic implementations for mitigation of such risk.

The following is a non-exhaustive list of potential strategy implementations for risk management.

Pesticide labeling revisions

Per federal law, the Environmental Protection Agency (EPA) has exclusive authority over pesticide label language. As such, California's DPR cannot demand alterations on pesticide label language. To get around these limitations, the DPR often cooperates with the EPA and the pesticide registrant to ensure that certain state standards are met during the drafting process. If the pesticide is already registered, then the DPR may request (but cannot force) the registrant to revise the language with the support of the EPA.

In the event that a pesticide registrant has not acquired or does not comply with their EPA-approved label, then the DPR is authorized to deny registration.

Permitting limitations

Alternatively, the DPR can designate a pesticide a California-restricted material. When a pesticide has been designated as such, only specific, trained persons (with special permits issued by the county agricultural commissioners) can purchase and use the pesticide. The DPR may draft additional controls governing pesticide use into the permit, which the county agricultural commissioners will subsequently implement in a manner that suits local application of the pesticide.

Stricter state law controls

The DPR has the authority to further restrict pesticide use by adopting pesticide controls that are more stringent than the applicable federal controls. They can impose controls on the timing of pesticide use, frequency of such use, geographical and site limitations, buffer zones for the protection of human and animal health, among others. For example, in 2015, the DPR set regulation of the pesticide chloropicrin higher than the EPA. California farmers are limited to an application of chloropicrin on forty acres per day. The pesticide has caused coughing fits, irritated eyes, and headaches

In the event that no feasible options exist for mitigating the pesticide's risk to acceptable levels, then the DPR are entitled to deny the proposed registration, or even to cancel an existing registration.

New Risk Assessment Regulations

On March 17, 2016, the EPA's Office of Pesticide Programs (OPP) announced that it had developed alternative tools for improving the quality of its risk assessment and risk management decisions on pesticides. The tools were developed to help implement the OPP's strategic initiative for Adopting 21st Century Science Methodologies and to help minimize animal testing. As part of the initiative, one final guidance document and one draft guidance document was published.

Alternative approaches to traditional In Vivo acute toxicity studies

In this final guidance document, the use of alternative methods for acute toxicity testing is expanded upon and a stepwise process for evaluating and implementing alternative testing methods (for acute oral, dermal, and inhalation toxicity, in addition to irritation and sensitization – commonly referred to as "six pack studies") is described.

The OPP hopes that this alternative testing approach will allow for the assessment of a broader range of potentially more human-relevant adverse effects. Certainly, through the evaluation process, the EPA will determine whether the alternative methods meet the OPP's regulatory needs.

If there is a reasonably reliable correlation between the different test methods, then this will raise concerns about existing pesticide registrations. The OPP recognizes that if the alternative methods demonstrate significant differences, then it is possible that existing registrants will have to report data to the EPA using the new, alternative testing methods, and could affect registration decisions and prompt labeling amendments.

Draft guidance waiving acute dermal toxicity tests

The draft guidance published by the OPP (and opened to comments) advised waiving all acute lethality dermal studies for formulated pesticide products, after the OPP assessed the utility of acute dermal toxicity studies for formulations in pesticide labeling for end-use products.

Impact to California Chemical Industry of New Risk Assessment Regulations

California pesticide registrants could be affected in the long-term. If existing registrants do not comply with new labeling amendment requirements requested by the EPA – based on risk assessment data derived from these alternative methodologies –the DPR may deny registration at the state level. It is imperative that registrants get ahead of the issue and work collaboratively with DPR and EPA to ensure the