Chapter 7

Pesticide Product Registration

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In this chapter This chapter contains the following sections.

General Registration Requirements

Interprets FAC sections 12753 and 12811; 3 CCR sections 6147 and 6301

Introduction	This section provides county field staff with a general overview of pesticide registration requirements so they are equipped to make general determinations about the applicability of registration requirements to the products they encounter in the field.
Interpretation	County personnel who encounter suspected unregistered pesticide products during field activities are expected to document readily available relevant evidence and forward it to DPR via the EBL assigned to their county for evaluation and investigation by DPR's Product Compliance Branch. Generally, it is illegal to manufacture, deliver, or sell (collectively referred to as "distribute") any substance that makes pesticidal claims or is represented to be an essential ingredient necessary to make a pesticide unless it is registered by U.S. EPA and DPR (<i>FAC section 12993</i>). It is also illegal to use an unregistered pesticide. <i>FAC section 12995</i> prohibits, with some exceptions found in <i>3 CCR sections 6147 and 6301</i> , the use of a pesticide that is not registered. The purpose of the registration process is to evaluate a pesticide for suitability and efficacy under California conditions. The law requires that a pesticide manufacturer or importer register a product before it is offered for sale in California. The law also specifies the registrant is in violation if it ships the product after the registration has expired. Exceptions to the Registration Requirement: (1) Attractants – Food products (which do not contain an active pesticide ingredient) used to attract pests are exempt [<i>3 CCR section 6147(a)(3)</i>]. Products intended to be used with a pesticide, such as syrup baits, adjuvants (<i>FAC section 12758</i>) or as pesticides themselves (i.e., pheromones), require registration.

General Registration Requirements, Continued

Interpretation (2) Minimum risk products [FIFRA section 25(b)] – Both federal and State (continued) laws exempt certain pesticide products from the requirement to obtain registration, provided they meet certain criteria. These products have been granted exemption from registration because they do not pose an unreasonable risk to public health or the environment. These products are still pesticides and subject to most other provisions. At a minimum, all products must meet the following requirements: List all the active ingredient(s) by name and percentage (by weight) on the label. To qualify for an exemption as a minimum risk pesticide, each active ingredient in the pesticide product must be listed in 40 CFR part 152.25(f)(1). The approved list of active ingredients can also be found in 3 CCR section 6147(a)(5). List all inert ingredients by name on the label. All inert ingredients • must be on U.S. EPA's most current Minimal Risk FIFRA Section 25(b) Inert Ingredients list (formerly List 4A). These two lists are not interchangeable. The total percentage by weight must equal 100%. • The label must not contain false or misleading statements defined in 40 CFR part 156.10(a)(5)(i) through (viii). Additionally, products must also meet a series of exemption • conditions described in 40 CFR part 152.25 and 3CCR section 6147. NOTE: Section 6147 exempts manufacturers, importers, and dealers (distributors) of certain [FIFRA section 25(b)] products from the registration and registration-related requirements of the regulations. Distributors of section 25(b) products are not required to obtain a certificate of registration before a pesticide is offered for sale. There is nothing in section 6147 that implies that such products are not pesticides. However, requirements based on the need for "registered" labeling cannot be enforced against them since there is no "registered" labeling. Although not specifically listed as an exemption in 3 CCR section 6301, DPR considers these products exempt from the provisions of FAC section 12995 by virtue of their inclusion in section 6147. FAC sections 12971 and 12973 and 3 CCR section 6602 would not apply since one element required for a violation of these sections relates to

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"registered" labeling.

General Registration Requirements, Continued

Interpretation (continued)	Other law and regulation sections do apply to those who recommend, sell or use these products:
	 Those who recommend, sell or apply these products are subject to the licensing requirements of FAC Division 6. A CAC could require a permit for these pesticides pursuant to FAC section 14006.6. They are subject to tolerance requirements on food or feed commodities. Pesticide use records are necessary for other regulatory purposes and would apply to these products. However, pesticide use reports (3 CCR sections 6625-6627 will not be required at this time (See the <i>PUR</i> chapter in Volume 1 of the Compendium). Only regulations required PPE, not labeling requirements, can be enforced.
	(3) Previously Registered Products – A dealer or broker who acquired a pesticide product in California while the product was properly registered may lawfully sell and deliver the product for two years after the last date of registration. If acquired by an end-user while legally registered or within two years after the last date of registration, these products may be possessed and used indefinitely. This exemption does not apply to the registrant. A registrant

used indefinitely. This exemption does not apply to the registrant. A registrant may not sell or distribute any pesticide that is not currently registered (3 CCR section 6301).

Recommendations may be made and restricted permits may be issued for the use of these products. However, a pesticide cannot lawfully be sold or used, or a permit issued contrary to any U.S. EPA or DPR cancellation or suspension order pertaining to use.

Contact your regional pesticide enforcement office or Enforcement Branch Liaison for any questions you may have regarding these policies.

Fertilizing Material/Livestock Drug vs. Pesticide

Interprets FAC section 12811

Interpretation The California Department of Food and Agriculture (CDFA) has regulatory authority over fertilizing materials and livestock drugs sold in California. In order to be legally sold as a fertilizer compound or livestock drug, the product must be registered as a fertilizing material or livestock drug with CDFA.

Manufacturers sometimes attempt to evade DPR pesticide registration and other regulatory requirements by registering the substance with CDFA as a fertilizing material or livestock drug. U.S. EPA and FDA have established an MOU (memorandum of understanding) to clarify overlap between livestock drugs and pesticides (see *Agricultural and Non-Agricultural Pesticide Use* in Chapter 1 for a discussion of this exemption). DPR follows this MOU.

An analysis of the FAC uncovered nothing that would preclude the registration of a substance by both DPR and CDFA. In other words, registration as a fertilizing material does not preclude requiring registration as a pesticide for specific identified uses where a pesticide effect can be documented. CDFA has acknowledged that DPR may regulate some uses of a fertilizing material as a pesticide.

Specific Pesticide Use Determinations

Interprets FAC sections 12811 and 12995

About this section	This section discusses: nitrogen compounds (fertilizer or plant growth regulator), phosphorous (fertilizing material or fungicide), elemental sulfur (fertilizing material or fungicide), and sulfur dioxide.
Nitrogen com	pounds (fertilizer or plant growth regulator)
Purpose	This interprets and clarifies current DPR application of FAC sections 12811, 12995, and other provisions of the FAC to the use of certain nitrogen-based fertilizer compounds such as Calcium Ammonium Nitrate (CAN-17), Urea Ammonium Nitrogen (UAN), Calcium Nitrate, and other similar materials applied post-dormant to plants to influence bud break. DPR acknowledges the position taken by U.S. EPA and has little choice but to interpret state pesticide law in a manner consistent with U.S. EPA's position insofar as that is possible.
Background	 "Aqueous hydrogen cyanamide solution derived from calcium cyanamide and water" was registered in the 1980's as a plant growth regulator (PGR) at both the State and federal levels for its desirable effect on bud break; it remains registered at the present time. Subsequently, the agricultural industry found that other sources of nitrogen would provide similar beneficial effects when used in this manner on other crops, such as kiwis and cherries, in addition to grapes. A registration package, including all of the required data, was submitted to U.S. EPA for registration. In response, U.S. EPA made the determination that this was a non-pesticide use in an August 21, 2003 letter. U.S. EPA further notified the applicants that making PGR claims for these nitrogen-based fertilizer products would be a violation of FIFRA.

U.S. EPA conclusion	U. S. EPA's finding was that "When these nitrogen-based fertilizer compounds are applied directly to trees and vines during a post-dormant phase, or "quiescence," the result is a uniform bud break, a physicochemical process caused by increased turgor pressures in tissues, provided necessary environmental conditions are present. None of these fertilizer compounds would cause a plant to break dormancy, a physiological process that responds to environmental stimuli and hormonal changes within the plant or to related chemicals known as PGRs. These nitrogen-based fertilizer compounds used post-dormant on trees, shrubs, and vines to ensure uniform bud break are not pesticides."
U.S. EPA basis for conclusion	U.S. EPA presented six points to justify their decision to classify these uses as non-pesticides:
	 The major factors controlling breaking of dormancy are photoperiod and temperature. Typical application rates of nitrogen-based fertilizer compounds are greater than any plant hormone concentrations needed to evoke a plant response. The time lapse between application and bud-break is too great to be considered a PGR effect. There is no data to demonstrate that these nitrogen-based fertilizer compounds act by a mode of action similar to PGRs in the breaking of dormancy. Bud break is not the signal of breaking of dormancy. Nitrogen-based fertilizer compounds are common fertilizing materials.
DPR position	As a result of these actions, California agriculture can use these nitrogen-based fertilizer compounds that are registered as fertilizing materials with CDFA during the post-dormant season to enhance uniform bud break, provided the labeling or advertising does not include express pesticide (PGR) claims.
Regulating fertilizing materials	Since CDFA has regulatory authority over fertilizing materials sold in California, in order to be legally sold as a nitrogen-based fertilizer compound, the product must be registered as a fertilizing material with CDFA. Labeling and advertising must not include any specific PGR claims.

Phosphorous (fertilizing material or fungicide)

DPR position DPR's position is that phosphorous acid materials applied directly into (injection) or to (foliar) plants or applied as a soil drench at rates that provide little or no nutritional benefit to the plant are being applied for their pesticide value regardless of the product's status as a registered fertilizing material with CDFA. Because of this intent, these products must be registered as a pesticide with DPR. It is not necessary that the manufacturer make specific pesticide claims for the product when these specific use patterns are on labeling. The pesticide benefits and intent of this use pattern are well known and understood by all involved.

CDFA: no credible data to support nutritional claims

CDFA has informed us that it has no credible data on file to support nutritional claims for application of phosphorous acid directly to or into the plant. Various phosphate compounds can be applied as foliar fertilizers. This would be a form of phosphorus available to the plant with little or no pesticide benefit.

Phosphorous acid, when applied to soil, slowly converts to phosphate, the only nutritionally active form of phosphorous. Soil application is the appropriate method for use of phosphorous acid as a nutrient. This would be an acceptable non-pesticide use. However, soil application rates that provide significant amounts of phosphate are far above the soil application rates commonly recommended for pesticide effect. Generally, soil application at these low rates per acre would be considered to be primarily for pesticide intent.

There are currently several phosphorous acid products registered as pesticides with the U.S. EPA and DPR. The labeling for these products has use directions that are consistent with the use patterns described above.

Over the years, DPR has been consistent in its interpretation of when phosphorous acid becomes a pesticide. Two specific cases have involved its use on avocados to control phytophthora and its use on oak trees to control sudden oak death.

Labeling When you encounter phosphorous acid products with labeling that includes direct application on or into the plant, or soil application rates significantly below fertilizer rates per acre, gather product labeling and any additional information you can obtain about how the product is marketed or presented to the grower. For example, reducing or substituting for applications of fungicides or other phosphorous acid products, other "indirect" pesticide benefits, timing of applications, technical bulletins, research results, other oral claims, etc. Product compliance (registration) issues should be forwarded to the EBL assigned to your county for follow-up action against the manufacturer and/or distributor. Enforcement action may be taken against users who persist in this use violation pursuant to *FAC section 12995*.

Elemental sulfur (fertilizing material or fungicide)

DPR interpretation of elemental sulfur materials	DPR's interpretation of the law is that the application of elemental sulfur materials directly to or "over the top" of plants in leaf are presumed to be a pesticide (fungicide) use. Elemental sulfur products, with labeling that suggests this use, must be registered as a pesticide, regardless of the product's status as a registered fertilizing material with CDFA. It is not necessary that the manufacturer make specific pesticide claims for the product; the pesticidal benefits and intent of this use are well known and understood.
DPR review of literature	DPR's scientific review of available literature indicates that plants take up and utilize sulfur in the sulfate form - SO_4 . Elemental sulfur must be oxidized to sulfate to be made available to the plant. This process takes place in the soil and is accomplished by soil microbes. Available references, including the <i>Western Fertilizer Handbook</i> , make no mention of plants using elemental sulfur directly, nor the conversion of elemental sulfur to sulfate in or on the plant itself. Thus, the application of elemental sulfur to foliage is not going to provide any significant amount of nutritionally available sulfur to the plant. The sulfur must go through the soil first.
	On the other hand, sulfur applied to leaves has several direct pesticidal benefits for disease and mite control. Registered sulfur pesticide product labeling has a vast array of crops listed. The conclusion is that the only benefit gained from the foliar application of elemental sulfur is a pesticidal benefit, not a nutritional one.
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Non-pesticide use of sulfur	Soil application is the appropriate method for use of elemental sulfur as a nutrient. This would be an acceptable non-pesticide use. Sulfur and sulfate also have soil amendment properties, e.g., lowering pH in alkaline soils and improving structure in sodic soils if applied with calcium, etc. Various mineral sulfate compounds can be applied as foliar fertilizers. This would be an available form of sulfur to the plant, with little to no pesticidal benefit.
Product labeling	When you encounter elemental sulfur products with labeling that includes foliar use, gather product labeling and any additional information you can obtain about how the product is marketed or presented to the grower. For example, reducing or substituting for applications of fungicides or other registered sulfur products, other "indirect" pesticidal benefits, timing of applications (e.g., starting applications early when canes are 6" - 8" long), technical bulletins, research results, other oral claims, etc. Product compliance (registration) issues should be referred to the EBL assigned to your county for follow-up action against the manufacturer and/or distributor. Enforcement action may be taken against growers who persist in this use violation pursuant to FAC section 12995.

Sulfur dioxide

Sulfur dioxide (wine fermentation or equipment disinfection)	Sulfur dioxide (SO_2) is a product that has multiple uses in the wine industry. According to the University of California, one of the primary uses is as an antioxidant to prevent off-odors and discoloration. This use is considered non-pesticidal. SO_2 is also used as a commodity fumigant to prevent bacterial or mold spoilage of grapes and as a container disinfectant. The primary issue is the use of SO_2 as a disinfectant. SO_2 has been registered as a pesticide active ingredient since 1961.
	Wooden barrels and tanks have porous surfaces that allow mold, yeast, and bacteria to accumulate and can eventually spoil the wine when it contacts the contaminated barrels. To prevent this, SO_2 is introduced into the barrel or tank along with water, killing the mold, yeast, and bacteria. This meets the federal and state definition of a pesticide and therefore is a pesticidal use and a concern for DPR and CACs. Registered pesticide products must be used for this purpose.

Sulfur dioxide (wine fermentation or equipment disinfection) (continued) When you encounter SO_2 products with labeling that includes disinfectant use, gather product labeling and any additional information you can obtain about how the product is marketed or presented to the winery. Product compliance (registration) issues should be referred to the EBL assigned to your county for follow-up action against the manufacturer and/or distributor. Enforcement action may be taken against wineries who persist in this use violation pursuant to FAC section 12995.

Unregistered Pesticide Products -- Use

Interprets FAC section 12995; 3 CCR sections 6147 and 6301

Interpretation It is unlawful for persons to mix and apply, for pesticidal purposes, materials that were prepared from unregistered materials (e.g., an unregistered bordeaux mixture made from copper sulfate and hydrated lime that is subsequently used as a fungicide). It is a violation of *FAC section 12995* to possess and use unregistered materials intended for pest control purposes, except as specifically exempted in 3 CCR sections 6147 and 6301. Often, this occurs as an inadvertent violation by well-intentioned persons who may often be looking for a "greener" method of pest control or simply as a way to save money by using a cheaper source of pest control material. Where evidence shows this to be the case and no commercial food use or significant adverse impacts have occurred, a first time violation may be handled with a cease and desist order and a notice of violation. However, where it appears that it is a knowledgeable violation, an enforcement action may be warranted.

The role of the product manufacturer should also be evaluated. It is particularly important to collect any advertising, sales invoices, or other literature that can be used as evidence of their intent to have their product used as a pesticide. These cases should be routed through the EBL assigned to your county for forwarding to DPR's Product Compliance Branch.

Unregistered or Misbranded Products -- Sales

Interprets FAC section 12811

Interpretation Complaints of illegal sales tactics or misrepresentation of products by firms should be documented and submitted to DPR's Product Compliance Branch through your EBL so that appropriate enforcement steps by State or federal agencies can be taken.

Information needed in a statement from the purchaser documenting the reported complaint includes the following, if available:

- Name of complainant or other party;
- Salesperson's name and company represented, address;
- Name of product offered for sale or sold, date, etc.;
- Type of claims made by salesperson or advertising;
- Invoice or truck line or carrier by which product delivered;
- Other information (date of call, time of call, price per gallon, farmer's statement, etc.).