

INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION
Title 3. California Code of Regulations
Amend Section 6400
Expanding Carbaryl Designation as a Restricted Material

This is the Initial Statement of Reasons required by Government Code section 11346.2 and the public report specified in section 6110 of Title 3, California Code of Regulations (3 CCR). Section 6110 meets the requirements of Title 14, CCR section 15252 and Public Resources Code section 21080.5 pertaining to state regulatory programs certified under the California Environmental Quality Act.

SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM
ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to amend 3 CCR subsections 6400(c) and (e). The pesticide regulatory program activities affected by the proposal are those pertaining to pesticide chemicals designated as state-restricted materials. Pesticide products containing the active ingredient carbaryl are designated as California restricted materials, with some exemptions. The proposed action will make all carbaryl products California restricted materials, with the exception of baits labeled only for agricultural use.

SPECIFIC PURPOSE AND FACTUAL BASIS

DPR protects human health and the environment by regulating pesticide sales and use and by promoting reduced-risk pest management. DPR's oversight includes product evaluation and registration; statewide licensing of commercial and private pesticide applicators, pest control businesses, dealers, and advisers; environmental monitoring; and residue testing of fresh produce. This statutory scheme is set forth primarily in Food and Agricultural Code (FAC) Divisions 6 and 7.

Pesticides are registered and licensed for use and sale with the U.S. Environmental Protection Agency (U.S. EPA) prior to being registered in California. DPR's preregistration evaluation is in addition to U.S. EPA's evaluation. Before a pesticide is registered, both agencies require data on a product's toxicology and chemistry to evaluate how it behaves in the environment; its effectiveness against target pests and hazards it poses to non-target organisms; its effect on fish and wildlife; and its degree of worker and bystander exposure.

Carbaryl is a broad spectrum, carbamate insecticide that inhibits acetylcholinesterase in the nervous system of targeted insects. It is used in both agricultural and non-agricultural (including residential) settings for control of numerous insects and is effective through either ingestion or absorption through bodily contact. Carbaryl products are available in granule (including bait), liquid concentrate, liquid ready-to-use, and dust ready-to-use formulations.

Carbaryl products labeled for most agricultural uses are designated as California restricted materials under 3 CCR section 6400, with several exemptions. Under subsection 6400(c),

carbaryl products are exempted from designation as California restricted materials if they meet all of the following criteria: (1) formulated as a dust, packaged in containers greater than 25 pounds, and labeled for outdoor use; (2) carbaryl is the only active ingredient; and (3) labeled only for one or more of the following uses: home use, structural pest control, industrial use, institutional use, and use by public agency vector control districts pursuant to section 116180 of the Health and Safety Code. Subsection 6400(e) further exempts other formulations of carbaryl from designation as restricted materials, including: (1) products formulated as a bait; or (2) labeled only for one or more of the following uses: use directly on livestock or poultry, home use, structural pest control, industrial use, institutional use, or use by public agency vector control districts.

In accordance with FAC section 14015, restricted materials can only be possessed or used by, or under the direct supervision of, a certified private applicator or a certified commercial applicator. 3 CCR section 6000 defines certified commercial applicator to include a person holding a valid structural pest control operator or field representative license issued by the Structural Pest Control Board. In California, a person is certified by taking and passing an examination to demonstrate they have the knowledge and proficiency required to use restricted materials, and by maintaining their certification through continuing education courses. Generally, the purchase, possession, and use of a restricted material are allowed only under a permit issued by a local county agricultural commissioner (CAC).

DPR publishes risk characterization documents (RCDs) for pesticide active ingredients to evaluate the extent and likelihood of adverse health effects on humans who may be exposed to a particular amount of a pesticide. As part of an RCD, a margin of exposure (MOE) value is calculated for each human exposure scenario to determine non-cancer risk. To calculate the MOE, the highest dose level in a study that caused no adverse or toxic effect (i.e., the no observable effect level [NOEL]) is divided by the dose level to which a human may be exposed. For carbaryl, an MOE of 100 or more is considered protective of human health. In 2014, DPR's RCD for carbaryl identified several exposure scenarios of concern (i.e., MOEs were less than 100), including scenarios exempted from the restricted materials designation in subsections 6400(c) and (e).

In developing the proposed regulations, DPR presented the concepts for the proposed regulations to the California Department of Food and Agriculture (CDFA), registrants of home use carbaryl products, the Vector-Borne Disease Section at the California Department of Public Health, and the Mosquito and Vector Control Association of California.

California Use Patterns

Carbaryl is applied as a foliar treatment to a variety of agricultural commodities for control of insect pests. It is also used in and around homes for control of insect garden pests. Currently, 18 products containing carbaryl are registered for use in California. Among these products, 7 already have restricted use designations and require a permit to purchase, possess, and apply. The remaining 11 products are exempt from this designation under subsections 6400(c) or (e). Since 2006, an average of 6,500 pounds of carbaryl has been applied to non-agricultural sites every year according to DPR's Pesticide Use Report (PUR) data. The five highest non-

agricultural use sites are landscape maintenance, structural pest control, regulatory pest control (e.g., pest control for quarantine purposes), research commodity, and rights-of-way. However, PUR does not include data from carbaryl products used by homeowners. Approximately 29 percent of the total carbaryl products sold between 2014 and 2016 were labeled for home use.

Human Health Concerns

The carbaryl RCD identified several exposure scenarios of concern in which MOEs were less than 100. These scenarios include residential and bystander exposure during residential application of home use carbaryl products via dust application equipment (e.g., shaker container); residential adult and toddler exposure via reentry onto turf treated with carbaryl products; and residential toddler exposure via hand-to-mouth transfer, object-to-mouth transfer, and soil ingestion. The identified exposure scenarios indicate acute health risks via both dermal and inhalation exposure pathways. However, uses associated with these scenarios are exempted from current restricted material use requirements for carbaryl in subsections 6400(c) and (e). Backpack applications were also an identified exposure scenario of concern. However there are no products currently registered that allow backpack applications for home use products.

DPR's Pesticide Illness Surveillance Program collects and evaluates physician-reported known or suspected illnesses resulting from pesticide exposure. Between 2006 and 2015, the most recent ten-year period of data available, 36 carbaryl exposure cases from 32 separate exposure events were reported. Of these, 30 cases from 26 exposure events were associated with non-agricultural use applications. The most common routes of exposure for non-agricultural use of carbaryl were via ingestion (10 cases) and residue, i.e., chemical that remains in the environment following a pesticide application (7 cases). Symptoms of ingestion can include nausea, vomiting, burning sensation in the throat, and diarrhea. Symptoms of residue exposure can include nasal irritation, skin irritation, sneezing, dizziness, headaches, and shortness of breath. The routes of carbaryl exposure associated with reported illnesses (i.e., ingestion and residue) correlate to the residential and bystander exposure scenarios identified in the RCD.

Proposal for Restricting Additional Uses

FAC sections 14004.5 and 14005 authorize the Director to adopt a list of restricted materials based upon criteria including danger of impairment of public health; hazards to applicators, farmworkers, domestic animals, and crops from direct application or drift; hazards related to persistent residues in the soil resulting in the contamination of air, waterways, estuaries, or lakes; or hazards to subsequent crops. A California-restricted material can only be sold in stores that have a DPR-issued dealer license authorizing the sale of restricted materials, and can only be purchased by certified applicators and, if purchasers are not structural pest control applicators, those with a restricted materials permit issued by the CAC.

The carbaryl RCD identified exposures of concern associated with the following scenarios: residential handler exposure during application of home use carbaryl products via backpack or dust application equipment; residential adult and toddler exposure via reentry onto turf treated with carbaryl products; and residential toddler exposure via hand-to-mouth transfer, object-to-mouth transfer, or soil ingestion. Therefore, DPR proposes to amend subsections 6400(c) and (e)

to make all carbaryl products that could lead to residential and bystander exposure when applied in and around residences California restricted materials.

This proposed action will further limit the purchase and use of all carbaryl products to only certified applicators from a DPR-licensed pest control dealer, and will require a restricted materials permit for application of all products containing carbaryl, except when formulated as a bait and labeled only for the production of agricultural plant commodities.

DPR proposes to delete carbaryl from subsection 6400(c)(2), thus removing the exemption for carbaryl products formulated as a dust and packaged in containers of more than 25 pounds from being designated as a restricted material. The carbaryl RCD indicated a low aggregate MOE for the residential exposure scenario in the loading and application of dust formulations of carbaryl. By removing carbaryl exemptions listed in subsection 6400(c)(2), inhalation and dermal exposure risks for residents and bystanders would be reduced or eliminated when products containing carbaryl are applied in and around homes; industrial sites, such as restaurants and retail nurseries; institutional sites, such as schools and hospitals; or when it is applied for vector control. Such products would need to be applied by a certified applicator who is trained to be aware of the precautions and dangers related to use of the product.

DPR also proposes to narrow the exemptions in 6400(e) to just bait formulations labeled only for agricultural use. Most of the current, unrestricted products containing carbaryl are sold for home use only and are in a bait form that can be used on lawns. By making these non-agricultural baits California restricted materials, the risk of adults and toddlers being exposed to carbaryl-treated turf is reduced since these products will not be available for homeowners and other untrained individuals in such areas and will be used only by a certified applicator who is trained to be aware of reentry restrictions for carbaryl-treated turf.

By making products labeled for home use, structural pest control, or institutional use California restricted materials, the potential for residential and bystander exposure will be reduced for scenarios such as reentry onto carbaryl-treated turf; loading and application by non-supervised applicators (such as homeowners or residents) of carbaryl products using a dust formulation; and residential toddler exposure via hand-to-mouth transfer, object-to-mouth transfer, or soil ingestion. As carbaryl products would only be applied by trained and certified applicators, exposures from these scenarios will either be completely eliminated or significantly lowered.

This proposed action will also make products labeled for use on livestock or poultry, industrial use, or use by public agency vector control districts California restricted materials, since there are no currently registered carbaryl products labeled for these uses. If a new use for livestock, poultry, industrial sites, or vector control is submitted to DPR, product evaluation would be completed to determine if the product can be used safely.

By making all carbaryl products California restricted materials (except baits labeled only for agricultural use), carbaryl products can only be sold to, purchased by, possessed by, and used by persons holding a restricted materials permit issued by their local CAC (with the exception of structural pest control operators who will not be required to obtain a permit pursuant to FAC section 14006.6). The permit requirement provides an effective way for CACs to oversee the use

of carbaryl by all other certified applicators. This permit system is unique to California and allows for more specific restrictions, in addition to state restrictions, to be put in place based on site-specific characteristics to address issues that may vary based on site.

In addition to eliminating direct general consumer use of carbaryl, designating most carbaryl products as California-restricted materials will allow DPR to collect critical information to help fulfill its responsibility to continuously evaluate the impact of carbaryl use and take additional steps to mitigate exposure, if necessary. General consumers have no obligation to report pesticide use. However, certified applicators that use carbaryl under a permit or apply products used for the production of an agricultural commodity and applicators licensed by the Structural Pest Control Board must report use as required by Business and Professions Code section 8505.17. Such reports, to the extent that they indicate who, where, and in what amount these products are being used, could inform decisions to further mitigate any reported adverse impacts.

CONSULTATION WITH OTHER AGENCIES

DPR consulted with the California Department of Food and Agriculture during the development of the text of proposed regulations, as specified in FAC section 11454, and the Memorandum of Understanding updated on January 15, 2019, that was developed per FAC section 11454.2.

DPR also consulted with the Health Canada Pest Management Regulatory Agency and the California Department of Public Health Services.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION [GOVERNMENT CODE SECTION 11346.2(b)(4)]

DPR has not identified any feasible alternatives to the proposed regulatory action that would lessen any possible adverse economic impacts, including any impacts on small businesses, and invites the submission of suggested alternatives.

ECONOMIC IMPACT OF BUSINESSES [GOVERNMENT CODE SECTION 11346.2(b)(5)(A)]

The proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The adoption of these regulations will make most carbaryl products California restricted materials. Consequently, homeowners would no longer be able to purchase carbaryl products, but may purchase alternative products. Pesticide registrants (manufacturers) currently selling carbaryl products for home use also sell other pesticide products. In this scenario, although some businesses may lose revenue due to restrictions on carbaryl, they will be able to recuperate revenue by selling alternatives to carbaryl.

The cost of alternative products compared to carbaryl products may be 50 percent or 100 percent higher. In both scenarios, the sales revenue of businesses selling carbaryl or its alternatives

increases due to the regulation. If the cost of alternative products is double that of carbaryl products, it is estimated that sales revenue annually would increase by \$524,326 for businesses currently selling carbaryl products for home use. However, taking into consideration that this impact is on the entire retail sector dealing with pesticides for home use, the magnitude of this impact might be considered small compared to total economic activities in California. As a result, the proposed regulations should not have a significant statewide adverse economic impact directly affecting businesses.

The document relied upon to make this determination is the “Economic Impact Analysis for Rulemaking Expanding Carbaryl Designation as a Restricted Material.” This document is listed in the “Documents Relied Upon” section of this initial statement of reasons and is available from DPR.

ECONOMIC IMPACT ASSESSMENT PURSUANT TO SECTION 11346.3(b)

Creation or Elimination of Jobs within the State of California: DPR has determined that the proposed action would create, but not eliminate any jobs in California. When homeowners do not have access to carbaryl products, they may buy alternative products or contract with commercial applicators to apply carbaryl. The replacement of carbaryl products with alternative products can increase the number of employees of the businesses currently selling carbaryl products for home use. When the cost of alternative products is higher than the cost of carbaryl products, an additional 1.9-3.9 jobs would be created (Asci, Konduru, & Yamazaki, 2019). The creation of these jobs is not only due to higher revenues for businesses selling carbaryl products, but also due to the multiplier effects that increase revenues for California’s economy.

Creation of New Businesses or the Elimination of Existing Businesses within the State of California: DPR has determined that this proposed regulatory action is unlikely to result in the creation of new businesses or the elimination of existing businesses. It would not impact pesticide registrants (manufacturers) currently selling carbaryl products for home use because these businesses also sell other pesticide products. Although some businesses may lose revenue due to restrictions on carbaryl, they will be able to recuperate revenue by selling alternative products.

The Expansion of Businesses Currently Doing Business within the State of California: When homeowners no longer have access to carbaryl products, they may choose to buy alternative products or contract with commercial applicators to apply carbaryl. As a result, there is the potential that this proposed regulatory action could create more business for businesses selling alternative products and for pest control businesses within the State of California.

The Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: Eliminating most current exemptions to the restricted materials designation for carbaryl would ensure that only trained applicators are utilizing these products, reducing the likelihood of unintended exposures to homeowners and children, and residential handlers who currently use carbaryl.

IDENTIFICATION OF ANY SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THE PROPOSAL

DPR's review of the proposed action showed that no significant adverse effect to California's environment can reasonably be expected to occur from implementing the proposal. Therefore, no alternatives or mitigation measures are proposed to lessen any significant adverse effects on the environment.

EFFORTS TO AVOID CONFLICT OR DUPLICATION OF FEDERAL REGULATIONS

The proposed action does not conflict with or duplicate federal regulations because there are no federal regulations contained in the Code of Federal Regulations that address this issue.

DOCUMENTS RELIED UPON

1. Beauvais, Sheryl. Human Exposure Assessment Document for Carbaryl. Worker Health and Safety Branch, DPR. November 5, 2014.
2. Bi, Jianlong, J, et al. Emulsifiable Concentrate Alternatives Analysis. University of California Cooperative Extension. California Department of Food and Agriculture. March 2011, Revised March 2012.
3. Carbaryl Final Work Plan Registration Review. U.S. Environmental Protection Agency. February 2011.
4. Rubin, Andrew L. Carbaryl (1-naphthyl methylcarbamate), Occupational and Bystander Risk Characterization Document. Medical Toxicology Branch, DPR. June 23, 2014.
5. Zeiss, Michael. Carbaryl Mitigation Scoping Document. Worker Health and Safety Branch, DPR. August 28, 2015.
6. Zeiss, Michael. Critical Uses of Carbaryl within California. Worker Health and Safety Branch, DPR. June 13, 2016.
7. Asci, Serhat, Konduru, Srini, and Yamazaki, Fumiko. Economic Impact Analysis for Rulemaking Expanding Carbaryl Designation as a Restricted Material. Fresno State. March 13, 2019.