

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

PROPOSED CHANGES IN THE REGULATIONS

PROTECTION OF TRADE SECRETS

CALIFORNIA CODE OF REGULATIONS
TITLE 3. FOOD AND AGRICULTURE
DIVISION 4. PLANT INDUSTRY
CHAPTER 1. CHEMISTRY
SUBCHAPTER 1. FERTILIZING MATERIALS
ARTICLE 1. STANDARDS AND LABELING

Amend Section 2300 to Read:

2300 Fertilizing Materials – General Provisions. (Continued)

- (k) The manufacturer of fertilizing materials shall provide information regarding a product's composition to the Secretary:
- (1) For fertilizing materials requiring registration, information regarding the product's composition shall accompany the Fertilizing Material Registration Application.
 - (2) For registered fertilizing materials, the manufacturer shall notify the Secretary of any changes in the information on file regarding the product's composition within 30 days of the change.
 - (3) For fertilizing materials that do not require registration, the manufacturer shall provide information regarding the product's composition upon request by the Secretary.
 - (4) For all fertilizing materials, the manufacturer may reference previously submitted information in compliance with subsections (k)(1), (k)(2) and (k)(3) but only with permission from the manufacturer who submitted the original information.
 - (5) For all fertilizing materials whose production process allows for alternative inert ingredients, a list of alternative inert ingredients may be submitted when providing the Secretary information regarding composition as required by subsections (k)(1), (k)(2) and (k)(3).
- (l) The manufacturer shall submit the following information on the composition of fertilizing materials:
- (1) The name of each active and inactive ingredient and its concentration in percentage by weight. The ingredient shall be identified using its chemical or substance name according to the Chemical Abstract Society (CAS) nomenclature (including the CAS Registry Number) or its common, generally recognized name. For products whose net content is expressed by volume on its label, the ingredients' concentration information may be submitted based on volume as long as the approximate bulk density information is also included.
 - (2) When the information submitted in accordance to subsection (l)(1) is not sufficient to verify the safety or efficacy, the Secretary may require the manufacturer to provide additional ingredient information including but not limited to:

- (a) The purpose of each ingredient, active or inactive.
- (b) The source of each ingredient, including the manufacturer's and/or distributor's contact information and country of origin.
- (c) The Material Safety Data Sheet (MSDS) if applicable, or any other technical information in support of safety.
- (d) The physical or chemical characteristic of each ingredient.
- (e) A description of the manufacturing process.
- (f) The impurities associated with each ingredient. The term "impurity" means any substance in the fertilizing material other than an active ingredient or an inert ingredient, including but not limited to non-reactive ingredients, side-reaction products, contaminants, and degradation products.
- (g) A valid analytical method for each ingredient where applicable.

Note:

Authority cited: Sections 407, 14501, 14502, 14601, 14631 and 14641 of the Food and Agricultural Code

Reference cited: Sections 14601, 14631 of the Food and Agricultural Code

Adopt Section 2300.1 to read:

Section 2300.1 Definitions.

- (a) The term "trade secret" means any data and/or information that discloses:
 - (1) The manufacturing or quality control processes, manufacturing facility or equipment
 - (2) The identity or percentage quantity of any deliberately added ingredients other than active ingredients.
 - (3) Any business practice that is otherwise considered as trade secrets under California Government Code Section 6254.7(d).

All information concerning efficacy, including but not limited to the objectives, methodology, results, or significance of any test or experiment performed on or with a fertilizing material, and any information concerning the effects of such fertilizing material's action on the environment or human or animal health, shall not be considered "trade secrets."
- (b) The term "active ingredient" means any agent responsible for the intended beneficial purpose, including but not limited to: provide primary plant nutrients, secondary nutrients or micronutrients; correct soil conditions through chemical and biological affects; enhance plant's growth, vigor, quality or size through chemical, biochemical, or biological change; or amends the soil through physical or chemical means.
- (c) The term "inert ingredient" means a substance, other than an active ingredient, which is intentionally included in a fertilizing material product.

Note:

Authority cited: Section 407 and 14502 of the Food and Agricultural Code, Section 6250 of the Government Code

Reference cited: Sections 14601, 14631 of the Food and Agricultural Code, Section 6254.7 of the Government Code

Adopt Section 2300.2 to read:

2300.2 Procedures for Claiming Protection of Trade Secrets

To assert a claim of confidentiality, a manufacturer must clearly identify any information which he claims is entitled to be considered as trade secrets.

(a) Any data and information claimed by the manufacturer to be trade secrets under Section 2300.1(a) of the California Code of Regulations shall be submitted in accordance to the following procedures:

- (1) Any items of information which, in the manufacturer's opinion, should be considered as trade secrets as defined in Section 2300.1(a), shall be removed from the body of information and submitted in a separate, confidential attachment marked with "Trade Secrets" on its cover page. The manufacturer waives the claim for consideration as trade secret for any item that remains in the body of information.
- (2) A reference number shall be assigned to each item that is to be considered as a trade secret in the confidential attachment; the corresponding reference number shall be placed in the body of the submitted information where the item was removed.
- (3) The page number(s) and the number of the line from where the trade secret item was removed along with the applicability of the definition of a trade secret (Section 2300.1(a)) shall be included for each trade secret claim in the confidential appendix.

(b) Statements of confidentiality shall accompany all submissions of information. The statement shall be accompanied by the name, title, signature of the manufacturer or his properly designated agent, and the date of signature.

- (1) If claiming confidentiality, the following statement of confidentiality shall be submitted: "Information claimed confidential on the basis of its falling within the scope of the trade secret definition in Section 2300.1(a), has been removed to a confidential appendix, and is cited by cross-reference number in the body of the submitted information."
- (2) If no claim of confidentiality is being made for the information/data submitted, or if no such information is contained in the submitted information, the following statement of confidentiality shall be submitted: "No claim of confidentiality is made for any information contained in this study on the basis of its falling under the definition of trade secret in Section 2300.1 (a)."

Note:

Authority cited: Section 407 and 14502 of the Food and Agricultural Code, Section 6250 of the Government Code

Reference cited: Sections 14601, 14631 of the Food and Agricultural Code, and Section 6254.7 of the Government Code

Adopt Section 2300.3 to read:

Section 2300.3 Conditions of Confidentiality

Information considered as trade secrets and therefore confidential will be withheld from public disclosure unless the Secretary has determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

- (a) Designating information as trade secrets by the manufacturer does not automatically qualify them as trade secrets and therefore subject to confidentiality. Upon receipt of a public records act request; a compulsory judicial process; or a regulatory or investigative demand by a legislative branch, executive branch or other state or federal agency, the Secretary will determine the validity of trade secret claims. If the Secretary determines that the information designated as a trade secret is, in fact a trade secret, that information will be treated as such and will be held in confidence, unless the Secretary is ordered to release it.
- (b) If the Secretary determines that information designated by the manufacturer as trade secrets does not qualify as such and proposes to release it for inspection or, if the protection of the trade secret is made the subject of a judicial or administrative proceeding, the Secretary shall notify the manufacturer in writing, to the address provided by the manufacturer as stated on the license application, unless such notification is legally prohibited. The Secretary shall not thereafter release for inspection any designated information until 10 days after mailing notice to the manufacturer. During this period, the manufacturer may institute an action in an appropriate venue for judgment as to whether such information is subject to protection.
- (c) The Secretary will not make public without first notifying the manufacturer, if permitted by law, information which in the Secretary's judgment, contains or relates to trade secrets obtained from a manufacturer as privileged or confidential, except as follows:
 - (1) When necessary, information relating to a product's composition obtained by authorization of this chapter may be revealed to any federal or state agency for purpose of consultation.
 - (2) If necessary, for the purpose of carrying out the enforcement activities the fertilizer inspection program, subject to the notification provision of subsection (b) of this section.
 - (3) If required, in the public interest in order to respond to an emergency that threatens public health or safety or the environment.
 - (4) When otherwise compelled by law, or executive or legislative branch request.
 - (5) In regards to items in subsections (c)(3) and (c)(4), the Secretary shall first provide notice to the manufacturer of the request for information, if permitted by law, unless an immediate, urgent release is required.

Note:

Authority cited: Section 407 and 14502 of the Food and Agricultural Code, Section 6250 of the Government Code

Reference cited: Section 6254.7 of the Government Code