DEPARTMENT OF FOOD AND AGRICULTURE
PROPOSED CHANGES IN THE REGULATIONS

Title 3. California Code of Regulations
Division 4: Plant Industry
Chapter 1. Chemistry
Subchapter 1. Fertilizing Materials
Article 1. Standards and Labeling

FINAL STATEMENT OF REASONS

UPDATE OF INITIAL STATEMENT OF REASONS

In agreement with OAL, the following modifications were made to the initial proposed regulation changes. Section 2300.3 was modified for the sake of clarity and necessity. It was determined that it was not necessary to describe the different circumstances in which the Secretary may release trade secret information. All requests for Trade Secret information will be considered on a case-by-case basis. The Secretary will abide by applicable procedures set by existing government code and proposed regulations if approved. The Authorities and References in the proposed regulation changes were modified for accuracy and format.

No public hearing was held.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD

COMMENT 0001-01:
Commenter is in support of requiring the valid analytical methods from the manufacturer.

Response: None

COMMENTS 0002-01, 0004-02, 0004-09, 0004-10, 0008-03:
Trade Secret definition is unclear to the submitter, conflicts with CGC 6254.7 and California Uniform Trade Secrets Act, Civil Code Section 3426.1(d).

Response: The purpose of the proposed regulation changes is to establish a definition of “Trade Secret” as it applies to fertilizing materials and is in harmony with CGC 6254.7

COMMENTS: 0002-02, 0006-01, 0007-01, 0008-01, 0018-01
No valid purpose for requiring the formula. The disclosures required exceed the need to determine the hazard. Firms could not comply with the disclosure of the formula requirement.

Response: The Department has determined that formula information will help confirm that the claimed mode of action is solely due to the components identified in the derivation statement on the label. Environmental and human safety can be better evaluated if all the ingredients and their concentrations are known.

COMMENTS 0002-03, 0004-08, 0005-02, 0005-04, 0010-04:
There is a lack of authority to collect trade secret information.

Response: Sections 14601 and 14631 gives CDFA the authority to require what may be considered as trade secret information and does not conflict with Economic Espionage Act of 1996. The Secretary would request additional information only as needed.

COMMENTS 0002-04, 0003-01, 0004-07, 0005-01, 0005-05, 0006-02, 0008-02, 0008-04, 0013-01, 0014-01, 0015-02, 0018-04, 0019-01:
There is a lack of adequate protection ensuring the confidentiality of trade secret information. Completely fails to define what measures CDFA will take to secure the protected information from disclosure. There is nothing in the regulations that interprets CDFA authority to deny release of trade secrets if the material is the subject of a Public Records Act request. They should be comparable to other regulations that provide adequate protection of confidential information.

Response: Section 2300.2 as proposed will provide the process by which manufacturers may request information to be identified as trade secrets. Section 2300.3 as proposed describes the circumstances of trade secrets protection. If this regulation is implemented, the Department shall adopt internal procedures to ensure that trade secret information is only released consistent with these provisions.

COMMENTS 0003-02, 0005-07, 0015-01:
Designating information as trade secrets is time consuming and adds expense to the registration process. The registration process already takes a lot of time.

Response: Designation of trade secret information while somewhat time consuming is considered a normal practice for other regulated industries and is necessary in order to provide protection from the unwanted release of confidential information. Obtaining trade secret information described in the proposed regulation will enable the Department to evaluate product efficacy and determine the risk to public health and the environment. Cost for designating trade secret information is offset by the costs incurred in protection of trade secret information litigation.

COMMENT 0003-03:
Trade secret information could be divulged to CDFA only in the event of an emergency and only if the substances are toxic.

Response: This alternative is not viable because it would not provide CDFA the opportunity to review the ingredients and their concentration as they relate to safety and efficacy. Additionally, the Department could encounter delays if required to

subsequently obtain this information from product manufacturers in response to an emergency.

COMMENT 0004-01:
"Country of Origin" information is not necessary.

Response: The Department only requires country of origin information if necessary to verify the safety and/or efficacy of the product.

COMMENT 0004-03:
In Section 2300.3 Condition of Confidentiality, the term "unreasonable" is a subjective term and causes the meaning of this section to be vague.

Response: Section 2300.3 as proposed, empowers the Secretary to make appropriate determinations as to when trade secret disclosure is necessary to protect against an unreasonable risk to injury to health or the environment based upon best available information.

COMMENT 0004-04:
Definition of trade secrets includes anything involved in bringing a product to market as long as: 1. Knowledge is limited within the commercial concern; 2. The knowledge gives an advantage to the commercial concern; and 3. The competition of the commercial concern does not know or does not use this knowledge.

Response: While this comment generally has merit, the department is proposing specific language that is most suitable for the registration of fertilizer products. Similar language is included in the Trade Secret definition in CGC Section 6254.7 and is referenced in proposed regulation, Section 2300.1(a)(3).

COMMENT 0004-05:
If the registration is denied, then the information should be destroyed or returned to the applicant.

Response: This suggestion is not viable. The Department believes that it is necessary to retain such information because it requires information to support the decision to deny registration.

COMMENTS 0004-05 0008-09, 0011-03, 0018-05, 0019-04:
10 days upon notification to respond to notification that a PRA request was made of information marked as trade secrets is not sufficient time to account for delivery delays, arranging for legal counsel, etc. Suggested length of time: 30 days, 30-45 days

Response: The requirement for manufacturer to respond within 10 days of notice as stated in proposed regulation Section 2300.3 is necessary in order for the Department to comply with Section 6253 Public Records Act.

COMMENT 0004-06:
Recommendation: CDFA should release trade secret information to only agencies with similar protection of trade secret provisions.

Response: While recognizing the legitimate concern of this commenter, the Department instead should be guided by the nature of the efficacy or public health and safety issues when deciding when to release trade secret information.

COMMENT 0005-03:
The commenter objects to identifying inactive ingredients because they are not measurable in the final product and do not support the claims of the product.

Response: For ingredients that undergo a process and results in a product different than its ingredients, the manufacturer should identify the process to the Secretary. Inactive ingredients will be reviewed for appropriateness and evaluated to verify the status of the ingredient (active or inactive).

COMMENT 0005-04:
Notifying the Secretary of changes in the composition within 30 days would be a never-ending process.

Response: Changes in the composition would not always trigger notification. Section 2300(k)(5) as proposed would allow the identification of alternative inert ingredients at the time of registration. Changes in the active ingredients would require a new registration.

COMMENTS 0005-06, 0018-02:
Efficacy and safety can be proven through repeated results better than the submission of facts and list of claims in support of efficacy. Efficacy requirements could be used to financially burden one company and not another.

Response: Efficacy and occasionally safety data are already required for products whose claims are not supported by the ingredients found in the derivation statement. While the financial burden to develop and provide efficacy data may be challenging, such data is necessary in order to provide a level of assurance to the consumer. Administration of this requirement is not meant to burden or favor a specific firm.

COMMENTS 0006-03, 0018-07:
The commenter recommends that the proposed regulations not be adopted.

Response: The recommendation has been considered and dismissed for reasons stated in the Initial Statement of Reasons.

COMMENTS 0008-01, 0008-13, 0013-02, 0018-06:

Manufacturers could not afford expensive research an analysis that would be required to determine the exact composition of their products and effectiveness. Developing efficacy data can be expensive and additionally burdens the smaller companies.

Response: The regulatory requirement does not singularly focus on small firms. Providing efficacy data for questionable claims is required of all firms manufacturing or distributing fertilizer materials. The firm has an option to remove the questionable claim and hence no additional efficacy data for this claim is required.

COMMENT 0008-06:
The commenter objects to the statement that CDFA would release information when ordered and without explanation of who has the authority to make such an order.

Response: Section 2300.3(a) as proposed describes the circumstances and compulsory processes by which the Department may be ordered to release trade secret information.

COMMENT 0008-07:
Exceptions for allowing the release of trade secret information are vague.

Response: As proposed in Section 2300.3, this section describes the circumstances by which information, trade secret or not, will be released upon request. This section is sufficiently clear and yet flexible enough for implementation.

COMMENT 0008-08:
The term "Consultation" is not clear as proposed in Section 2300.3(c)(1). Manufacturer should be provided the option to withdraw from action that triggers the consultation as an alternative.

Response: The Department believes such consultation is necessary in order to enable multiple departments, agencies and jurisdictions to respond to issues of efficacy, public health and safety, and environmental protection.

COMMENT 0008-10:
As a public agency, CDFA should not get involved in the business of storing trade secrets and deciding when protected trade secrets can be revealed and to whom.

Response: The Department believes that it is necessary to obtain the information described in the regulation with limitations upon disclosure for the reasons set forth in the Initial Statement of Reasons.

COMMENT 0008-11:
The commenter recommends that Sections 2300.2(a)-(c) should be amended to provide the conditions under which CDFA may specifically request that a manufacturer disclose additional information during an investigation or alleged misbranding.

Response: This recommendation had been considered but was found not to be a viable alternative to best address the reasons presented in the Initial Statement of Reasons.

COMMENTS 0008-12, 0009-01, 0010-02:
The commenter recommends that the proposed regulation changes require a list of ingredients instead of the formulation.

Response: Disclosure of the formula is necessary as ingredients whether inert or active may be either safe and/or effective or neither depending upon its concentrations found in the fertilizing material. Therefore requiring ingredient concentration information is necessary.

COMMENTS 0010-01, 0011-02:
The commenter recommends that manufacturers should be required to provide information only upon request for products requiring registration as required for products not requiring registration.

Response: This recommendation if adopted would keep the status quo. The Secretary already requests trade secret information to evaluate safety and efficacy.

COMMENT 0010-03:
Manufacturers should not be required to disclose sources or ingredient manufacturer's name, unless testing indicates a high concentration of heavy metals or other discrepancy from label derivation statement.

Response: As proposed in Section 2300(l)(2), disclosure of ingredient sources is not required unless there is reason to believe that there is a safety issue or is necessary to substantiate claims or to evaluate safety and/or efficacy.

COMMENT 0010-05:
What are the criteria used by the Secretary to determine trade secret status? The manufacturer should have the right to withdraw information, registration or product from the market so that the information does not become public.

Response: The criteria to determine trade secret status is from the California Government Code Section 6254.7. The Department has considered this request but finds it infeasible because of the need to retain documentation of decisions related to registration of fertilizing materials.

COMMENTS 0011-01, 0017-01:
The commenter suggests that the CDFA not require the disclosure of ingredient information for ingredients that are already registered with the California Department of Pesticide Registration.

Response: The Department sees some value in this suggestion. The Department will monitor this issue in order to evaluate whether future rulemaking is necessary.

COMMENT 0014-02:
Consider the cost of the regulations to the state and industry.

Response: The economic assessment will be conducted as required by the Administrative Procedures Act.

COMMENT 0015-03:
Manufacturers may adjust their formula based upon the information needed and/or disclosed.

Response: A change in active ingredients requires that the manufacturer submit a new registration. As mentioned before the Department must retain records related to previous registrations to document its decisions. Therefore, changing the formula after the submitting the registration application will not remove the original formula information from trade secret files.

COMMENTS 0019-01, 0018-03:
The commenter recommends that the Department regulate bulk fertilizer similarly to ensure an equal playing field.

Response: Bulk fertilizer information is required on an as-needed basis. Bulk fertilizers used for agricultural purposes may vary from truckload to truckload. Therefore, the Department has determined that the registration of these bulk products would be unreasonable. However, the Department intends to monitor the issue and will initiate rulemaking to include bulk products if the circumstances merit it.

COMMENT 0016-02:
The commenter recommends that the Department recognize that alternative fillers may be used depending upon the location of the manufacturer.

Response: Section 2300(k)(5) as proposed, allows the manufacturer to list alternative inert ingredients and their concentrations.

COMMENT 0019-03:
The commenter recommends that the proposed regulations target only fertilizers claimed as appropriate for organic production rather than all fertilizers.

Response: As stated in the Initial Statement of Reasons, the Department believes that provisions related to the disclosure and possible release of trade secrets is necessary for reasons unrelated to the production of organic fertilizer. The proposed regulations while includes organic fertilizers packaged for home and garden use, it does not single them out. All specialty fertilizers would be required to comply with the proposed regulation if adopted.

COMMENT 0019-02:
Under the proposed regulations it is clear that the Secretary can release trade secret information after a ten-day notice to the manufacturer.

Response: This is an inaccurate characterization of the regulation. As proposed in Section 2300.3, upon receipt of a 10-day notice, the manufacturer may pursue judicial remedies to prevent the release of information.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC

Comment 1001-01, 1002-01:
This section (2300.3) should specifically define the precise circumstances when disclosure of confidential and sensitive information is required to protect health or the environment. While other California agencies have addressed the submission of confidential information by using specific regulatory language, no such regulatory language is evident in this proposed amendment.

Response: While the Department appreciates the legitimate concern of the commenter, all requests for Trade Secret information will be considered on a case-by-case basis. The Secretary will abide by applicable procedures set by existing government code and proposed regulations if approved. In any case, the Department will make every reasonable attempt to notify the manufacturer of the Department's intent in a timely manner.

AUTHORITY

Section 401 of the California Food and Agricultural Code declares that the California Department of Food and Agriculture shall promote and protect the agricultural industry of California. Section 407 declares that the Secretary may adopt such regulations as are reasonably necessary to carry out the provisions of the Food and Agricultural Code which he is directed or authorized to administer or enforce.

The Department of Food and Agriculture concurs with the above comments and finds that the proposed regulation changes are necessary to provide consumers with a level of assurance that fertilizing materials when used as directed are safe and effective and will have a positive impact on the agricultural industry**.**

ALTERNATIVES

The Department has determined that no alternative considered by the Department would be more effective in carrying out the purpose for which these regulations are proposed or would be as effective as and less burdensome to affected private persons than the proposed regulations.

LOCAL MANDATE DETERMINATION

The proposed regulations do not impose any mandate on local agencies or school districts.