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CALIFORNIA OFFICE OF ADMINISTRATIVE LAW

SACRAMENTO, CALIFORNIA

MARCO ANTONIO EU  
SECRETARY OF STATE  
OF CALIFORNIA

1986 OAL Determination No. 8

[Docket No. 86-004]

October 15, 1986

Determination Pursuant to  
Government Code section  
11347.5; Title 1, California  
Administrative Code, Chapter  
1, Article 2

In re: )  
Request for Regulatory )  
Determination filed by )  
the Swimming Pool Chemical )  
Manufacturers Association, )  
concerning "California )  
Notice 86-1" issued by )  
the Department of Food )  
and Agriculture/1 )

Determination by:



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THE ISSUE PRESENTED/2

The Swimming Pool Chemical Manufacturers Association (SPCMA or Association) has requested the Office of Administrative Law (OAL) to determine whether or not the document titled "Notice to Pesticide Registrants Pertaining to the Birth Defects Prevention Act of 1984; California Notice 86-1" (Notice) issued by the California Department of Food and Agriculture (DFA or Department) is a regulation as defined in Government Code section 11342(b) and is therefore invalid and unenforceable unless adopted as a regulation and filed with the Secretary of State in accordance with the California Administrative Procedure Act (APA)./3

THE DECISION/4, 5, 6

- I . The Office of Administrative Law finds that California Notice 86-1 (1) is not a regulation as defined in the APA and (2) is not subject to the requirements of the APA insofar as it simply notifies registrants that data gaps must be filled in accord with Food and Agricultural Code section 13127.
- II. The Office of Administrative Law finds that the provisions of California Notice 86-1 which interpret, implement or make specific the Birth Defect Prevention Act of 1984/7 or other applicable laws (1) are subject to the requirements of the APA, (2) are regulations as defined in the APA, and are therefore invalid and unenforceable unless adopted as regulations and filed with the Secretary of State in accordance with the APA. These regulatory provisions include the following:
- (a) that registrations of those not responding properly will be subject to "cancellation";
  - (b) all response timetables;
  - (c) specifically how data shall be developed;
  - (d) details of how to share responsibility for developing data;
  - (e) details of how to file claims that data requirements are not applicable;
  - (f) details of how to request registration amendments or voluntary cancellations;
  - (g) categorization of pesticide active ingredients into units I, II, III, and IV;
  - (h) grouping of certain chemicals and designation of "lead chemicals" for these groups; and,
  - (i) requiring that certain forms be submitted and that they be completed per specific instructions.

I. AGENCY AND AUTHORITY; BACKGROUND

The California Department of Food and Agriculture's history may be traced back to the creation in 1880 of the State Board of Viticultural Commissioners. Today, the Department is responsible for administering a wide variety of programs related to agriculture, including pesticide registration.

Food and Agricultural Code section 407 explicitly grants the general power to adopt regulations to the Director of Food and Agriculture:

"The director may adopt such regulations as are reasonably necessary to carry out the provisions of this code which he is directed or authorized to administer or enforce."

Food and Agricultural Code section 14 makes clear that DFA rulemaking is subject to the APA:

"Whenever, pursuant to this code, any state department, officer, board, agency, committee or commission is authorized to adopt rules and regulations, such regulations shall be adopted in accordance with [the APA], to the extent that [the APA] is not specifically in conflict with the express terms of this code which authorize the adoption of such regulations. . . ."

"The authority to adopt any rule, regulation, or rule and regulation which is vested in any state department, officer, board, agency, committee, or commission pursuant to this code includes the authority to amend or repeal the rule, regulation, or rule and regulation." [Emphasis added.]

Express rulemaking authority is also granted by Food and Agricultural Code section 12781 (may adopt regulations reasonably necessary to carry out statutory chapter concerning economic poisons).

In light of the above provisions of law, we conclude that the Department is fully subject to the APA.

The following facts and circumstances have given rise to the present Determination.

The requestor, the Swimming Pool Chemical Manufacturers Association, (hereinafter "the Association"), is "a trade association of manufacturers, packagers and distributors of chemicals for the sanitization and disinfection of swimming pools, spas, hot tubs, waste and potable waters."/8 Many of these chemicals are registered as pesticides with DFA. In its Request, the Association states that California Notice 86-1 is regulatory in nature.

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California Notice 86-1 (excerpts attached as Appendix A) was issued by DFA on January 31, 1986, in response to the Birth Defects Prevention Act of 1984 ("the 1984 Act"); (attached as Appendix B). California Notice 86-1 did the following:

- (1) pursuant to a statutory deadline, notified pesticide registrants that missing health effects studies must be submitted in accord with Food and Agricultural Code section 13127; and
- (2) filled in the gaps in the 1984 Act, by
  - (a) providing that registrations of those not responding properly would be subject to "cancellation";
  - (b) establishing response timetables;
  - (c) specifying how data "shall" be developed;
  - (d) specifying how to share responsibility for developing data;
  - (e) specifying how to file claims that data requirements were not applicable;
  - (f) specifying how to request registration amendments or voluntary cancellation;
  - (g) categorizing pesticide active ingredients into units I, II, III and IV;
  - (h) grouping certain chemicals and designating "lead chemicals" for these groups; and
  - (i) requiring that certain forms be submitted and that they be completed per specific instructions.

Responding to the above "Notice," the Association filed a Request for Determination on March 14, 1986, expressing particular concern over the "cancellation" provision.

In a notice of proposed rulemaking dated June 18, 1986, DFA proposed several new pesticide regulations. A number of these proposed regulatory provisions address objections raised by the Association concerning California Notice 86-1. In its Response, DFA concedes that

"[t]here are indeed important and complex issues associated with the [Birth Defects Prevention Act of 1984]

that should be addressed by regulations [ ] . . . [including] (1) responsibility of registrants to comply with particular data requirements; (2) methods of doing so; (3) joint responsibility of registrants; (4) incorporation of [Federal Insecticide, Fungicide and Rodenticide Act] procedures into California requirements; (5) standards for studies and acceptability of data; and (6) suspension of registrations resulting from failure to provide data."

## II. DISCUSSION OF DISPOSITIVE ISSUES

There are four main issues before us:/9

- (1) WHETHER THE ISSUANCE OF THE CHALLENGED RULE CONSTITUTES AN EXERCISE OF QUASI-LEGISLATIVE POWER BY THE DEPARTMENT.
- (2) WHETHER THE DEPARTMENT'S QUASI-LEGISLATIVE ENACTMENTS ARE GENERALLY SUBJECT TO THE REQUIREMENTS OF THE APA.
- (3) WHETHER THE CHALLENGED RULE IS A REGULATION WITHIN THE MEANING OF THE KEY PROVISION OF GOVERNMENT CODE SECTION 11342.
- (4) WHETHER THE CHALLENGED RULE FALLS WITHIN ANY LEGALLY ESTABLISHED EXCEPTION TO APA REQUIREMENTS.

FIRST, WE INQUIRE WHETHER THE CHALLENGED RULE IS A RESULT OF THE EXERCISE OF THE DEPARTMENT'S QUASI-LEGISLATIVE POWERS./10

The term "quasi-legislative" is not defined in the APA. In determining whether a rule is the result of the exercise of quasi-legislative power, we consider three elements:

- 1) Whether the issuance of the challenged rule constitutes an exercise of "quasi-legislative" power as that term has been judicially defined;
- 2) Whether the state agency in question has been granted pertinent quasi-legislative powers; and
- 3) Whether the rule in question meets the basic definition of "regulation" set out in Government Code section 11342.

Whether the issuance of the challenged rule constitutes an exercise of "quasi-legislative" power as that term has been judicially defined.

According to the California Supreme Court, a quasi-legislative rule is one formulating a general policy oriented toward future decisions,

rather than the application of a rule to the peculiar facts of an individual case./11

Simply applying existing legal requirements to particular situations is not an exercise of quasi-legislative power./12

For instance, a state agency may enforce a self-executing statute-- that is, a statute that clearly and expressly requires certain criteria to be followed--without violating the APA./13

Here, Food and Agricultural Code section 13127(a) required DFA to "not later than [Jan. 31, 1986], . . . notify each registrant . . . of the applicable data gap required to be filled pursuant to this section." Simply notifying registrants on that date of the express statutory requirements concerning data gaps was not inconsistent with Government Code section 11347.5.

In general, if the agency does not add to, interpret, or modify the statute, it may legally inform interested parties in writing of the statute and "its application." Such an enactment is simply "administrative" in nature, rather than "quasi-judicial" or "quasi-legislative."

If, however, the agency makes new law, i.e., supplements or "interprets" a statute or other provision of law, such activity is deemed to be an exercise of quasi-legislative power. Quasi-legislative power is conferred by statute, either expressly or impliedly./14

"In rulemaking, an agency is often free to interpret a statute or another regulation in such a way as to impose an additional requirement on the regulated public. By contrast, in applying a statute or regulation, an agency has much less latitude."/15 [Emphasis added.]

In the matter at hand, DFA--acting pursuant to the 1984 Act--imposed a number of specific requirements on the regulated public, e.g., that registrants must reply to the Notice as instructed or risk "cancellation" of the registration. This "risk of cancellation" provision is clearly a general policy oriented toward future decisions. Further, this provision is not found in the statute: the 1984 Act says nothing about "cancelling" registrations for failure to respond to DFA data-gap notices.

DFA implicitly recognizes the difficulty created by the Notice's "cancellation" provision. In its Response to the Request for Determination, DFA studiously avoids using the Notice's term "cancel":

"The Notice specifies the Director's statutorily required duties, including . . . (5) informs registrants that the Director is required, by statute [no citation], to take action against registrations inadequately supported by reliable data if the data gaps are not filled.

". . . . .

"Certainly, the Director was not required to adopt a regulation to notify registrants in accordance with section 13127 that they will be required by new legislation to fill data gaps and that failure to do so may result in suspension of their registrations. . . ." [Emphasis added.]/16

The Legislative Counsel opinion is equally circumspect:

"The remainder of the notice sets forth the nature of the response required from registrants, methods for meeting data requirements, how to comply with the notice, other courses of action that may be taken, and a data gap response package which includes the aforementioned response sheet." [Emphasis added.]/17

We share DFA's apparent after-the-fact perception that it would have been better had the Notice not used the terms "cancel" or "cancellation." We are, however, obliged to make a determination on the legality of the Notice as it was in fact worded./18

In light of that obligation, we conclude that several features of the Notice meet the judicial definition of "quasi-legislative," notably the "cancellation provision."

There is a crucial difference between the ordinary legal meanings of "cancel" and "suspend." "Cancel" means "to revoke . . . ; to annul or destroy, make void or invalid . . ."/19 By contrast, "suspend" means "[t]o interrupt; . . . to discontinue temporarily, but with an expectation or purpose of resumption."/20 Once cancelled, a registration could presumably only be regained following approval of a newly-prepared application. The need to prepare a new application and await its disposition by DFA might mean that a registrant was effectively out of business. By contrast, under the federal "suspension" process incorporated into Food and Agricultural Code section 13127(c)(1), if a suspended registrant supplies the sought-after data, the agency simply reinstates the registration.

Whether the state agency in question has been granted pertinent quasi-legislative power.

As discussed above in Part I, the Legislature has in three separate statutes expressly granted pertinent quasi-legislative power to DFA./21

Assuming for the sake of argument that the above provisions were not in fact dispositive, we note that under Government Code section 11342.2, rulemaking power may also be impliedly granted by a statute. Thus, we conclude as well that DFA has been impliedly granted pertinent rulemaking power by the 1984 Act.

Whether the rule in question meets the basic definition of "regulation" under Government Code section 11342.

We conclude that California Notice 86-1 meets the definition of "regulation" under Government Code section 11342. This point is discussed below in Part II(3).

In light of our review of the above factors, we conclude

- (1) that the Notice was not quasi-legislative in nature insofar as it simply notified registrants that data gaps must be filled in accord with Food and Agricultural Code section 11327; and
- (2) that the cancellation provision and other specified provisions/22 of the Notice were quasi-legislative in nature.

SECOND, WE INQUIRE WHETHER THE DEPARTMENT'S QUASI-LEGISLATIVE ENACTMENTS ARE GENERALLY SUBJECT TO THE APA.

As discussed in Part I above, Food and Agricultural Code section 14 makes it clear that DFA rulemaking is subject to the APA.

Assuming for the sake of argument that the above provision were not dispositive, we note that the APA applies to all state agencies, except those "in the judicial or legislative department."/23 Since the Department is in neither the judicial nor the legislative "department," there can be no doubt that APA rulemaking requirements generally apply to the Department./24

THIRD, WE INQUIRE WHETHER THE CHALLENGED RULE IS A "REGULATION" WITHIN THE MEANING OF THE KEY PROVISION OF GOVERNMENT CODE SECTION 11342.

In pertinent part, Government Code section 11342(b) defines "regulation" as:

". . . every rule, regulation, order, or standard of general application or the amendment, supplement or revision of any

such rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure . . ." [Emphasis added.]

Government Code section 11347.5, authorizing OAL to determine whether or not agency rules are "regulations," provides in part:

"No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin . . . instruction [or] order . . . which is a regulation as defined in subdivision (b) of section 11342, unless the guideline, criterion, bulletin, . . . instruction [or] order . . . has been adopted as a regulation and filed with the Secretary of State pursuant to this chapter. . . ." [Emphasis added.]

Applying the definition found in Government Code section 11342(b) involves a two-part inquiry:

- (a) is the informal rule either (i) a rule or order of general application or (ii) a modification or supplement to such a rule?
- (b) does the rule being enforced either (i) implement, interpret, or make specific the law enforced or administered by the Department or (ii) govern the Department's procedure?

The answer to both parts of this inquiry is "yes."

For convenience, we will continue to focus our discussion on the "cancellation" provision of California Notice 86-1. Other regulatory provisions will be discussed in notes./25

Before proceeding with our analysis, however, we will explore the background of DFA's pesticide registration monitoring function.

The Food and Agricultural Code charges the Department with registering pesticides, which are referred to in the statute as "economic poisons."/26 In addition to reviewing initial applications for registration, the Department monitors existing registrations. Because the operation of the Department's monitoring function lies at the heart of this Determination, we will discuss this matter in some detail.

Food and Agricultural Code Section 12824 lays out the general objectives of the Department's program to perform "continuous evaluation of all economic poisons actually registered." Food and Agricultural Code section 12825 provides that the Director may, after hearing, cancel any registration if one or more of six listed factors are present:

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"Pursuant to Section 12824, the director may, after hearing, cancel the registration of, or refuse to register, any economic poison:

- (a) Which has demonstrated serious uncontrollable adverse effects either within or outside the agricultural environment.
- (b) The use of which is of less public value or greater detriment to the environment than the benefit received by its use.
- (c) For which there is a reasonably effective and practicable alternate material or procedure which is demonstrably less destructive to the environment.
- (d) Which, when properly used, is detrimental to vegetation, except weeds, to domestic animals, or to the public health and safety.
- (e) Which is of little or no value for the purpose for which it is intended.
- (f) Concerning which any false or misleading statement is made or implied by the registrant or his agent, either verbally or in writing, or in the form of any advertising literature.

In making any such determination, the director may require such practical demonstrations as are necessary as to determine the facts." [Emphasis added.]

Section 12824 states that the Director "may establish specific criteria to evaluate an economic poison with regard to the factors listed in section 12825," i.e., may flesh out these very general factors with more specific regulations.

DFA has indeed adopted regulations implementing these cancellation statutes. Title 3, California Administrative Code (CAC), section 6221, titled "Reevaluation Criteria," provides:

"The director shall also reevaluate a pesticide when the standards as further specified in the Department's Protocol for Pesticide Registration and Evaluation manual have been met. Such standards relate, but are not limited to, the following factors:

- (a) Public or worker health hazard.
- (b) Environmental contamination.
- (c) Pesticide residue overtolerance.
- (d) Fish or wildlife hazard.
- (e) Lack of efficacy.

- (f) Undesirable phytotoxicity.
- (g) Hazardous packaging.
- (h) Inadequate labeling.
- (i) Disruption of the implementation or conduct of pest management.
- (j) Other information suggesting a significant adverse risk.
- (k) Availability of an effect [sic] and feasible alternate material or procedure which is demonstrably less destructive to the environment.
- (l) Discovery that data upon which a registration was issued is false, misleading, or incomplete."

[Emphasis added.]

Two questions arise upon reviewing section 6221. First, what is the significance of the reference to "the Department's Protocol for Pesticide Registration and Evaluation manual"? Second, to which data requirements does the regulation refer?

First, regulatory requirements may not in general be exclusively contained in documents merely mentioned in the CAC. However, the regulation may "incorporate by reference" another document, i.e., a regulation printed in the CAC may make provisions of another document part of that regulation by reference to the other document./27 Section 6221 fails to meet OAL's requirements for incorporation by reference: it does not, for instance, state that the other document is "incorporated by reference"; it does not supply the date of publication or issuance./28

The status of the above noted Evaluation Manual is somewhat clarified in title 3, CAC, section 6160, which provides:

"The Department is revising the Operational Protocol for Pesticide Registration and Evaluation Manual referred to in this Group. Such manual shall become effective only after its revision and adoption pursuant to the provisions of the Administrative Procedures [sic] Act." [Emphasis added.]

Section 6221 provides that reevaluation is triggered by criteria specified in the Manual which "relate . . . to" twelve factors listed in the regulation. Section 6160, by contrast, clearly states that the Manual is not presently "effective." Reading these two regulations together, we conclude--though the matter is not wholly free from doubt--that the Director is authorized by regulation to reevaluate a pesticide registration only when one of the twelve conditions specified in section 6221 applies. We premise this conclusion on the idea that we should to the greatest extent possible give effect to the intent of the drafters of the regulation, despite the subsequent demise of the Manual.

Section 6221 thus authorizes reevaluation if it is discovered that "data upon which a registration was issued is false, misleading, or incomplete." Does the emphasized phrase mean that the Director is thereby empowered to move to cancel registrations not currently supported by "full set[s] of valid mandatory health effect studies"?/29

We conclude that the answer to this question is "no." Section 6221 clearly refers to registration requirements pre-dating the Birth Defects Act of 1984, Food and Agricultural Code, sections 13121-13130, ("the 1984 Act") (attached as Appendix "B").

According to the Department, "[p]resent regulations [allow] registrants to submit summaries of studies which are needed to support the registration of an economic poison." (Emphasis added.)/30 The Department has stated that amendments to present regulations are needed to "allow implementation of . . . Senate Bill 950 [the Birth Defects Prevention Act of 1984] . . . , [which] requires that the Department obtain complete [copies] of all mandatory health effects studies."/31 (Emphasis added.) Indeed, title 3, CAC, sections 6170 and 6172 do make reference to data "summaries." Thus, it would appear that the Department could not under title 3, CAC, section 6221 move to cancel an existing registration on the grounds that absent a full set of health effects studies, the data upon which the registration was originally issued was "incomplete."

We also conclude that the Department could not--absent formal interpretive regulations--properly threaten general cancellation of registrations for failure to fill data gaps under pre-1984 statutory provisions (i.e., Food and Agricultural Code sections 12814 and 12825).

Thus, if the Department had authority to move to "cancel" registrations for failure to fill data gaps, it had this authority solely by virtue of the 1984 Act.

In August 1984, the Legislature passed the Birth Defects Prevention Act of 1984 (SB 950), which required the Department to review its files on all pesticide active ingredients registered in California to determine whether or not the required health effects studies were valid, complete, and adequate. A series of reports to the legislature was required. The Department was in essence required to work toward ensuring that it had on file complete health effect studies for all pesticides registered in California.

The 1984 Act contained two provisions concerning review of existing registrations.

First, the 1984 Act incorporated by reference federal statutory language (attached hereto as Appendix C) empowering the EPA Administrator to move to "suspend" a registration if the registrant

fails to supply additional data within 90 days after receipt of notification from EPA that such data was needed./32 Unless the registrant requests a hearing, the suspension takes effect 30 days after receipt of appropriate notice. However, the registration must be reinstated if the registrant supplies the requested data.

Second, the 1984 Act provided that:

"If the director, after evaluation of the health effects study of an active ingredient, finds that a pesticide product containing the active ingredient presents significant adverse health effects . . . , the director shall take cancellation or suspension action against the product pursuant to section 12825 or 12826."  
[Emphasis added.]/33

Thus, in summary, although "suspensions" were authorized (1) if registrants failed to supply data in timely fashion, or (2) if submitted data revealed significant adverse health effects, nothing in the 1984 Act authorized the Department to "cancel" registrations for failure to fill data gaps.

We note further that the 1984 Act's missing-data suspension provision differs significantly from the earlier-enacted registration suspension provision (Food & Agr. Code section 12826), which authorized the Director to suspend a registration pending a hearing and final decision on cancellation--but only if continued use of the pesticide posed an immediate substantial danger to persons or the environment.

Having examined the background of DFA's pesticide registration monitoring function, we will now proceed to analyze the Notice's cancellation provision in terms of the statutory definition of "regulation."

First, the cancellation provision -- as was indicated above in Part II(1)--is a standard of general application: it applies to all registrants whose registration files do not contain complete health effects data. Also, the cancellation provision modifies or supplements similar provisions

- (1) in the 1984 Act,
- (2) elsewhere in the Food and Agricultural Code,/34 and
- (3) and in DFA regulations./35

Second, the cancellation provision implements, interprets, and makes specific the law enforced by DFA, viz., the 1984 Act, other provisions of the Food and Agricultural Code,/36 and various DFA regulations./37.

Further, the cancellation provision may be viewed as governing the Department's "procedure," insofar as it creates a new ground upon which the Department may notice quasi-judicial administrative hearings intended to lead to cancellation of registrations.

FOURTH, WE INQUIRE WHETHER CALIFORNIA NOTICE 86-1 FALLS WITHIN ANY LEGALLY ESTABLISHED EXCEPTION TO APA REQUIREMENTS.

Rules concerning certain activities of state agencies--for instance, "internal management"--are not subject to the procedural requirements of the APA./38 We conclude that none of the recognized statutory or judicial exceptions (set out in note 38) apply to California Notice 86-1.

The Department, relying largely upon an opinion from the Office of Legislative Counsel, argues that the notice--pursuant to the 1984 Act--is impliedly exempt from APA requirements. The Legislative Counsel opines:

"The contents of California Notice 86-1 would seem, upon first examination, to come within the definition of a regulation governed by the APA. The notice purports to require pesticide registrants to submit data, in a specified manner, so as to fill the data gaps pursuant to the requirements in the act. The notice appears to be a 'rule, regulation, order, or standard . . . adopted by any state agency to implement, interpret, or make specific the law enforced by it . . . ." On closer examination, however, the notices are really nothing more than the name implies, notices of other actions taken by the department and of corresponding actions required to be taken by departments [sic] pursuant to statute.

"Moreover, even if the notices were more than they in fact are, we still think they would not be regulations within the meaning of the APA. In this regard, Section 11346.4 of the Government Code requires that at least 45 days prior to the hearing on the adoption of a regulation, notice of the proposed adoption be published and mailed, as specified. Furthermore, a regulation becomes effective 30 days after filing with the Secretary of State (Sec. 11346.2, Gov. C.). Since subdivision (a) of Section 13127 required the notice to be sent out only 30 days after identifying the pesticide data gaps, it was not possible to comply with both the act and the APA.

"The APA does contain provisions for emergency regulations that become effective upon filing (subd. (d), Sec. 11346.1, Gov. C.). However, emergency regulations are only applicable upon a finding by the adopting agency that the

regulation 'is necessary for the immediate preservation of the public peace, health, and safety or general welfare (subd. (b), Sec. 11346.1, Gov. C.).' In this case, the subject matter relates to health, but the facts giving rise to the administrative action were not unplanned and of an emergency nature. Rather, the duties imposed on the department were specifically set out in the act and were entirely predictable.

"Furthermore, while subdivision (a) of Section 13127 is silent on whether the APA applies, subdivision (c) of that section specifically requires the Director of Food and Agriculture, on or before July 1, 1986, to prescribe procedures for resolving disputes or finding the filling of data gaps, by regulation. 'Where a statute with reference to one subject contains a certain vital word, omission of that word from a similar statute on the same subject is significant to show a different intention (Hennigan v. United Pacific Ins. Co., 53 Cal.App.3d 1, 8).' Thus, by using the term 'regulation' in subdivision (c) of Section 13127, and by omitting that term in subdivisions (a) and (b) of that section, there is an indication that the Legislature did not intend to require the notice provision in subdivision (a) or (b) to come within the APA.

"Therefore, we conclude that the department was not required to adopt California Notice 86-1 as a regulation pursuant to the APA. [Footnote number omitted.]" [Emphasis added.]/39

The footnote to the final quoted sentence of the Legislative Counsel opinion reads:

"We have not considered in this opinion whether the adoption of the list of the 200 pesticide active ingredients with the most significant data gaps under subdivision (a) of Section 13127 or the adoption of the timetables under subdivision (b) of Section 13127 are regulations within the meaning of the APA."/40

This "implied exemption argument" considers neither of the controlling statutes, Government Code section 11346 and Food and Agricultural Code section 14 (quoted above in Part I). When the controlling statutes are considered, it becomes apparent that the above argument is legally untenable. The Legislature has made doubly clear that agencies may not spin implied APA exemptions from non-specific statutory language.

First, let us turn to Government Code section 11346, which provides in part:

"It is the purpose of this article [APA Article 5, "Procedure For Adoption of Regulations"] to establish basic minimum procedural requirements for the adoption, amendment, or repeal of administrative regulations. Except as provided in Section 11346.1, the provisions in this article are applicable to the exercise of any quasi-legislative power conferred by any statute heretofore or hereafter enacted." [Emphasis added.]

Food and Agricultural Code section 14 provides that all DFA regulations shall be adopted pursuant to the APA except where the APA is "specifically in conflict with the express terms of [the Food and Agricultural Code provisions] which authorize the adoption of . . . regulations." (Emphasis added.)

Since there is in the matter at hand no specific conflict between the APA and the express terms of the Food and Agricultural Code, it is clear that the APA fully applies to all exercises of quasi-legislative power conferred by the economic poison portion of the Food and Agricultural Code.

Assuming for the sake of argument that the above statutory provisions were not deemed dispositive on the question of implied APA exemptions, we note the final sentence of Government Code section 11346, which states that APA procedural requirements "shall not be superseded or modified by any subsequent legislation except to the extent that such legislation shall do so expressly." (Emphasis added.) The 1984 Act was enacted subsequent to Government Code section 11346: no express superseding or modifying language is to be found in the later Act.

In an earlier proceeding, we described our basic analytical approach to claims that particular informal rules fall within established exceptions to APA requirements. This narrow construction policy applies with even greater force to claims that particular informal rules are impliedly exempt from APA requirements.

In 1986 OAL Determination No. 5 (Board of Osteopathic Examiners, Docket No. 85-002, August 13, 1986), /41 we stated:

". . . APA exceptions should in general be narrowly construed to further the APA's basic goals--meaningful public participation[/42] and effective judicial review.[/43]

"A statute should be construed with a view toward promoting rather than defeating its general purpose and the policy behind it.[/44]

"As stated by the California Supreme Court, '[i]t is well established that a specific provision should be construed with reference to the entire statutory scheme of which it is a part.' [/45]

"As stated by the California Court of Appeal:

'When a statute contains an exception to a general rule laid down therein, that exception is strictly construed.' [46]

"Finally, in interpreting a statute, it is proper to consider the consequences that will flow from a particular interpretation. [47]

"Each time an APA exception is expansively interpreted, the extent to which the public can shape administrative enactments is diminished; the extent to which reviewing courts can have ready access to the documents associated with such enactments is lessened."

We also reject the "implied exemption" argument for these reasons:

- (1) DFA had time to complete a routine rulemaking;
- (2) In any event, DFA could have filed emergency regulations;
- (3) Mandating adoption of regulations on a particular point does not ipso facto mean that the affected agency is thereby excused from complying with APA requirements on all other points in a statute; and
- (4) The Legislative Counsel opinion carefully avoids discussing one of the least defensible facets of California Notice 86-1.

First, DFA had time to complete a routine (i.e., nonemergency) rulemaking. The 1984 Act was signed by the Governor on August 16, 1984; the deadline to notify registrants was January 31, 1986--DFA had eighteen months within which to adopt any regulations needed to implement the statutory notice requirement.

We note that DFA (a) made extensive non-substantive changes to the registration regulations in July 1985 and (b) released on January 23, 1986, a public notice concerning amendments to one key registration regulation.

Further, we must take exception to the opinion's statement:

"Furthermore, a regulation becomes effective 30 days after filing with the Secretary of State (Section 11346.2, Government Code)."

Government Code section 11346.2 provides in part:

"A regulation or an order of repeal required to be filed with the Secretary of State shall become effective on the 30th day after the date of filing unless:

(a) Otherwise specifically provided by the statute pursuant to which the regulation or order of repeal was adopted, in which event it becomes effective on the day prescribed by such statute.

.....

(d) The agency makes a written request to the office demonstrating good cause for an earlier effective date, in which case the office may prescribe an earlier date. [Emphasis added.]

OAL frequently grants agency requests for early effective dates, if good cause is shown. For instance, OAL granted DFA's May 20, 1986, request for an early effective date concerning an amendment to a pesticide regulation./48 Agencies may also request expedited OAL review, as did DFA in the same May 20, 1986, letter.

DFA was not required to defer needed rulemaking until after the December 31, 1985 report was due. Further, there was no need to defer submitting that report until the last possible moment.

Second, in any event, DFA could have submitted emergency regulations to OAL, finding that the regulations were "necessary for the immediate preservation of the public . . . health and safety."/49 If "specific facts showing the need for immediate action" had been presented as required by the APA, OAL could have approved the emergency regulations./50

Third, we reject DFA's argument that by using the term "regulation" in subdivision (c) of Section 13127, and by omitting that term in subdivisions (a) and (b) of that section, there is an indication that the Legislature did not intend the notice provision in subdivision (a) or (b) to come within the APA. On the contrary, we view section 13127(c)'s language ("director shall, by regulation, prescribe procedures . . .") (emphasis added) as simply stating that adoption of regulations on that particular point was mandatory, in contrast to the discretionary rulemaking language generally pertaining to economic poisons ("director may adopt regulations . . .") (emphasis added)./51

The distinction between mandatory and discretionary grants of rule-making power is a basic concept in administrative law/52; it is highly unusual to equate this distinction with the very different dichotomy between enactments (a) covered by and (b) exempt from the APA.

It is wholly untenable to suggest that any time the Legislature mandates adopting a regulation concerning one particular facet of a statute, it is thereby silently waiving APA public notice and hearing requirements on all other facets of the statute. Government Code section 11346 clearly states (in part) that APA procedural requirements "shall not be superseded or modified by any subsequent Legislation except to the extent such legislation shall do so expressly." (Emphasis added.)

Fourth, the Legislative Counsel opinion totally avoids discussing one of the least defensible facets of California Notice 86-1--the setting of a timetable for filling data gaps on all pesticide active ingredients not deemed worthy of inclusion in the highest-priority group of 200. Food and Agricultural Code section 13127(b) states that DFA "shall adopt" (emphasis added) such a timetable. The statute itself gives no dates. Presumably the Legislature meant the same thing when it used the word "adopt" in both Food and Agricultural Code sections 14 and 13127(b): i.e., promulgation of regulations pursuant to the APA.

### III. CONCLUSIONS

For the reasons set forth above, OAL finds that:

First, California Notice 86-1 (1) is not a regulation as defined in the APA and (2) is not subject to the requirements of the APA insofar as it simply notifies registrants that data gaps must be filled in accord with Food and Agricultural Code section 13127.

Second, the below-listed provisions of California Notice 86-1 (1) are subject to the requirements of the APA, (2) are regulations as defined in the APA, and are therefore, invalid and unenforceable unless adopted as regulations and filed with the Secretary of State in accordance with the APA:

- (a) that registrations of those not responding properly will be subject to "cancellation";
- (b) all response timetables;
- (c) specifically how data shall be developed;
- (d) details of how to share responsibility for developing data;
- (e) details of how to file claims that data requirements are not applicable;
- (f) details of how to request registration amendments or voluntary cancellations;
- (g) categorization of pesticide active ingredients into units I, II, III, and IV;
- (h) grouping of certain chemicals and designation of "lead chemicals" for these groups; and,
- (i) requiring that certain forms be submitted and that they be completed per specific instructions.

## NOTES

1. In this proceeding, the Swimming Pool Chemical Manufacturers Association (Association) was represented by Clifford Kipers, President of the Association; D. J. Wilson, Secretary of the Association; Bill Sossamon; and George Verbryck. The Department was represented by Clare Berryhill, Director; Herbert L. Cohen; and Hans Van Nes.
2. The legal background of the regulatory determination process --including a detailed survey of governing case law--is discussed at length in note 2 to 1986 OAL Determination No. 1 (Board of Chiropractic Examiners, April 9, 1986, Docket No. 85-001), California Administrative Notice Register 86, No. 16-Z, April 18, 1986, pp. B-14--B-16; typewritten version, notes pp. 1-4.
3. We refer to the portion of the APA which concerns rulemaking by state agencies: Chapter 3.5 of Part 1 ("Office of Administrative Law") of Division 3 of Title 2 of the Government Code. Sections 11340 through 11356, Chapters 4 and 5, also part of the APA, concern administrative adjudication rather than rulemaking.
4. As we have indicated elsewhere, an OAL determination concerning a challenged "informal rule" is entitled to great weight in both judicial and adjudicatory administrative proceedings. See 1986 OAL Determination No. 3 (Board of Equalization, May 28, 1986, Docket No. 85-004), California Administrative Notice Register 86, No. 24-Z, June 13, 1986, p. B-22; typewritten version, pp. 7-8; Culligan Water Conditioning of Bellflower, Inc. v. State Board of Equalization (1976) 17 Cal.3d 86, 130 Cal.Rptr. 321. The Legislature's special concern that OAL determinations be given appropriate weight in other proceedings is evidenced by the directive contained in Government Code section 11347.5: "The office's determination shall be published in the California Administrative Notice Register and be made available to . . . the courts." (Emphasis added.) Implementing this directive, this and other determinations are presently being mailed to the clerks of all state and federal courts in California.
5. Eighteen timely comments were received and considered. The following seventeen members of the requesting trade association submitted comments supporting the Request for Determination:

- 1) D. J. Wilson, President, Hasa Chemicals, Inc.
- 2) W. B. Edwards, President, Luseaux Laboratories, Inc.
- 3) William Peter, Redwood Chemical Co., Inc.
- 4) Gary Van Delden, President, APS Industries, Inc.
- 5) G. J. Derthick, Division Manager, Jones Chemicals, Inc.
- 6) Douglas A. Latta, Aqua Clear Pool Chemical Service
- 7) Arthur L. Perea, GPS Industries
- 8) Robert E. Hodgson, Jr., Marketing Manager, Imperial West Chemical Company
- 9) Clifford Kipers, ARM, Vice President Risk Manager, Hill Brothers Chemical Company
- 10) Joe F. Ball, Joe F. Ball Company, Inc.
- 11) Keith Lewis, Ph.D., Technical Director, Leisure Time Chemical Corp.
- 12) Bill M. Sossamon, Director of Quality Control, All Pure Chemical Company
- 13) Michael T. Goldstein, Technical Director, Consumer Products Division, Grow Group, Inc.
- 14) Dana Wm. Somesla, Chief Chemist, Chem Lab Products, Inc.
- 15) Merv Dirkse, Sunset Pools, Inc.
- 16) Albert B. Cord, President, Continental Chemical Company

The Honorable Nicholas C. Petris, Member of the California State Senate, submitted a comment supporting the Department's actions. We are pleased to have received a comment from a member of the Legislature. We hope other legislators will, in the future, also submit comments concerning Requests for Determination of interest to them.

One untimely comment was received from Samantha Schoenfeld, Willard Products, and thus was not considered by OAL.

6. A timely Response to the Request for Determination was received from the Department.
7. Food and Agricultural Code sections 13121-13130.
8. As defined in the public comment submitted by Hill Brothers Chemical Co., signed by Clifford Kipers, ARM Vice President Risk Manager, who is also the President of the Association.
9. See Faulkner v. California Toll Bridge Authority (1953) 40 Cal.2d 317, 324 (points 1 and 3); Winzler & Kelly v. Department of Industrial Relations (1981) 121 Cal.App.3d 120, 174 Cal.Rptr. 744 (points 1, 3 and 4); cases cited in note 2 of 1986 OAL Determination No. 1. A complete reference to this earlier Determination may be found in note 2 to today's Determination.

10. See Government Code section 11346, which provides:

"It is the purpose of this article [Article 5 of Chapter 3.5] to establish basic minimum procedural requirements for the adoption, amendment or repeal of administrative regulations. Except as provided in section 11346.1, the provisions of this article are applicable to the exercise of any quasi-legislative power conferred by any statute heretofore or hereafter enacted, but nothing in this article repeals or diminishes additional requirements imposed by any such statute. The provisions of this article shall not be superseded or modified by any subsequent legislation except to the extent that such legislation shall do so expressly." [Emphasis added.]

11. Pacific Legal Foundation v. California Coastal Commission (1982) 33 Cal.3d 158, 168, 188 Cal.Rptr. 104; as cited in 1986 OAL Determination No. 2 (Coastal Commission, April 30, 1986, Docket No. 85-003), California Administrative Notice Register 86, No. 20-Z, May 16, 1986, p. B-34 and n. 14; typewritten version, p. 7 and n. 14.
12. Bendix Forest Products Corporation v. Division of Occupational Safety and Health (1979) 25 Cal.3d 465, 158 Cal.Rptr. 882.
13. For an example of a self-executing statute, see Government Code section 11349.5.
14. Government Code section 11342.2; title 1, California Administrative Code, section 14(a)(2).
15. 1986 OAL Determination No. 2 (Coastal Commission, April 30, 1986, Docket No. 85-003), California Administrative Notice Register 86, No. 20-Z, May 16, 1986, p. B-35; typewritten version, p. 9.
16. DFA Response to Request for Determination, p. 2.
17. The opinion of the Legislative Counsel of California No. 20528 filed August 15, 1986, entitled Economic Poisons: Notices - #20528, p. 3.
18. Government Code section 11347.5; title 1, California Administrative Code, chapter 1, article 2.
19. Black's Law Dictionary (5th ed. 1979) p. 186, col. 2.

20. Id., p. 1297, col. 1.
21. (a) Food and Agricultural Code section 407;  
(b) Food and Agricultural Code section 14; and  
(c) Food and Agricultural Code section 12781.
22. See note 25, post.
23. Government Code section 11342(a). See Government Code sections 11346; 11343. See also 27 Ops.Cal.Atty.Gen. 56, 59 (1956).
24. See Poschman v. Dumke (1973) 31 Cal.App.3d 932, 943, 107 Cal.Rptr. 596, 609.
25. California Notice 86-1 contains eight other regulatory provisions. These regulatory provisions are listed on the first page of this Determination and in Parts I and III and need not be repeated a fourth time here. Each of the eight provisions meets both prongs of the statutory definition of "regulation." Each of the eight is a straightforward example of an administrative agency conscientiously "filling in the gaps" of a statute that could not realistically be written in sufficient detail to be self-executing.

Brief mention will be made of several particular provisions.

First, response timetables adopted to implement a statute are regulatory. City of San Marcos v. California Highway Commission (1976) 60 Cal.App.3d 383, 405, 131 Cal.Rptr. 804, 818 (deadline to apply for state funds held to be an underground regulation). The 1984 Act prescribes no response timetable for pesticide active ingredients not included in the 200 deemed potentially most hazardous. California Notice 86-1 specified timetables. Such timetables are standards of general application designed to implement and make specific the law enforced by DFA.

Second, in selecting the 200 pesticide active ingredients which were, inter alia, "suspected to be hazardous to people," DFA was interpreting and making specific Food and Agricultural Code section 13127(a).

26. Food and Agricultural Code section 12753 defines "economic poison" as including any of the following:  
  
"(a) Any spray adjuvant.

- (b) Any substance, or mixture of substances which is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any and all insects, fungi, bacteria, weeds, rodents, or predatory animals or any other form of plant or animal life which is, or which the director may declare to be, a pest, which may infest or be detrimental to vegetation, man, animals or households, or be present in any environment whatsoever."
27. Title 1, California Administrative Code, section 20.
28. Id., section 20(c)(4).
29. California Notice 86-1, p. 1, para. 1 (enclosed as Appendix A).
30. California Administrative Notice Register, title 3, Register 86, No. 6-Z, Informative Digest, p. A-3; dated 1-23-86, signed by Rex Magee for the Director of Food and Agriculture.
31. Id., p. A-4.
32. Subparagraph (B) of paragraph (2) of subdivision (c) of section 136a of Title 7 of the United States Codes, as cited in Food and Agricultural Code section 13127(c)(1); attached herein as Appendix C.
33. Food and Agricultural Code section 13129.
34. Food and Agricultural Code section 12824.
35. Title 3, California Administrative Code, section 6221.
36. See note 34, supra.
37. See note 35, supra.
38. The following provisions of law may also permit agencies to avoid the APA's requirements under some circumstances, but do not apply to the case at hand:
- a. Rules relating only to the internal management of the state agency. Government Code section 11342(b).
  - b. Forms prescribed by a state agency or any instructions relating to the use of the form, except where a regulation is required to implement the law under which the form is issued. Government Code section 11342(b).

- c. Rules that "establish[ ] or fix[ ] rates, prices or tariffs." Government Code section 11343(a)(1).
  - d. Rules directed to a specifically named person or group of persons which do not apply generally throughout the state. Government Code section 11343(a)(3).
  - e. Contractual provisions previously agreed to by the complaining party. See Roth v. Department of Veteran Affairs (1980) 110 Cal.App.3d 622, 167 Cal.Rptr. 552.
39. See note 17, supra, pp. 5-6.
40. Id., p. 6, footnote 4.
41. 1986 OAL Determination No. 5 (Board of Osteopathic Examiners, August 13, 1986, Docket No. 85-002), California Administrative Notice Register 86, No. 35-Z, August 29, 1986, p. B-17; typewritten version, p. 10.
42. The significant advantages of public participation in agency rulemaking are noted in NLRB v. Wyman-Gordon Company (1969) 394 U.S. 759, 777-779, 89 S.Ct. 1426, 1436 (Douglas, J., dissenting), quoted in San Diego Nursery Company, Inc. v. ALRB (1979) 100 Cal.App.3d 128, 60 Cal.Rptr. 822, 831:

"The rule-making procedure performs important functions. It gives notice to an entire segment of society of those controls or regimentation that is forthcoming. It gives an opportunity for persons affected to be heard. Recently the proposed Rules of the Federal Highway Administration governing the location and design of freeways, 33 Fed.Reg. 15663, were put down for a hearing; and the Governor of every State appeared or sent an emissary. The result was a revision of the Rules before they were promulgated. 34 Fed.Reg. 727.

"That is not an uncommon experience. Agencies discover that they are not always repositories of ultimate wisdom; they learn from the suggestions of outsiders and often benefit from that advice. See H. Friendly, The Federal Administrative Agencies 45 (1962).

"This is a healthy process that helps make a society viable. The multiplication of agencies and their growing power make them more and more remote from the people affected by what they do and make more likely the arbitrary exercise of their powers. Public airing of

problems through rule making makes the bureaucracy more responsive to public needs and is an important brake on the growth of absolutism in the regime that now governs all of us.

". . .

"Rule making is no cure-all; but it does force important issues into full public display and in that sense makes for more responsible administrative action."

See also 1986 OAL Determination No. 4 (Board of Equalization, June 25, 1986, Docket No. 85-005), California Administrative Notice Register 86, No. 28-Z, July 11, 1986, pp. B-22--B-23, n. 13; typewritten version, pp. 2-4, n. 13 (advantages of public participation in agency rulemaking).

43. See California Optometric Association v. Lackner (1976) 60 Cal.App.3d 500, 510, 131 Cal.Rptr. 744, 751.
44. Fig Garden Park v. Local Agency Formation (1984) 162 Cal.App.3d 336, 343, 208 Cal.Rptr. 474, 478.
45. Bowland v. Municipal Court (1976) 18 Cal.3d 479, 489.
46. Goins v. Board of Pension Commissioners (1979) 96 Cal.App.3d 1005, 1010, 158 Cal.Rptr. 470.
47. See note 44, supra.
48. California Administrative Notice Register, title 3, Register 86, No. 24-Z, Agency Requests for Early Effective Dates, p. B-41.
49. Government Code section 11346.1.
50. Government Code section 11349.6.
51. Food and Agricultural Code section 12781.
52. Title 1, California Administrative Code, section 14.

## DEPARTMENT OF FOOD AND AGRICULTURE

1220 N Street  
Sacramento, CA 95814



January 31, 1986

NOTICE TO PESTICIDE REGISTRANTS PERTAINING TO  
THE BIRTH DEFECTS PREVENTION ACT OF 1984

CALIFORNIA NOTICE 86-1

In accordance with The Birth Defects Prevention Act of 1984, Chapter 669 (SB 950), we are notifying each registrant of the data gaps which are required to be filled for each active ingredient. "Data gap" means that the California Department of Food and Agriculture (CDFA) does not have on file a full set of valid mandatory health effects studies, as defined in Section 13123(b) California Food and Agricultural Code (CFAC). The data required pertain to Chronic Toxicity, Oncogenicity, Reproductive Effect, Teratogenicity, Mutagenicity and Neurotoxicity. The evaluation criteria are validity, completeness, and adequacy.

This Notice requires that registrants of pesticide products in California submit data to meet the requirements of this Act. The enclosed Data Gap Response Package contains Data Gap Response Sheets which must be completed for each pesticide product and submitted by the dates designated in the Response Schedule.

RESPONSE REQUIRED FROM REGISTRANTS

In responding to this Notice, you must inform CDFA of the following:

1. How you will comply with the data requirements set forth in this Notice;  
or
2. Why you believe CDFA should not require you to submit data as specified by this Notice.

IF YOU DO NOT RESPOND TO THIS NOTICE, OR IF YOU DO NOT SATISFY CDFA THAT YOU WILL COMPLY WITH THE REQUIREMENTS OR SHOULD BE EXCUSED FROM DOING SO, THEN THE REGISTRATION(S) OF YOUR PRODUCT(S) WILL BE SUBJECT TO CANCELLATION.

METHODS FOR MEETING DATA REQUIREMENTS

There are two methods by which you may meet the data requirements of this Notice. First, you may make an individual commitment to the Department that you will develop the data. Second, you may make a collective commitment with other registrants or suppliers to share the responsibility of providing data.

COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

Pursuant to the Response Schedule, you must complete and submit a Data Gap Response Sheet for each of your products subject to this Notice. For a product containing more than one active ingredient, a Data Gap Response Sheet is required for each active ingredient. On the response sheet you must state which option(s) you have selected and attach the documents required to support the option(s) chosen. Different options may be chosen for the different data requirements. THE DATA GAP RESPONSE SHEET MAY BE SIMILAR TO THE ENVIRONMENTAL PROTECTION AGENCY'S (EPA'S) DATA CALL-IN SUMMARY SHEET, BUT THERE ARE SIGNIFICANT DIFFERENCES AND IT SHOULD NOT BE CONFUSED WITH EPA'S FORM. DO NOT SUBMIT THIS FORM TO EPA. The response sheet and other enclosures are provided to assist you in responding to this Notice. DO NOT ALTER THE PRINTED MATERIAL.

The Department will monitor compliance with the timetable established pursuant to Section 13127(b) CFAC. If tests are not initiated or completed according to the timetable, the Department will evaluate the need for continued registration of an active ingredient and either propose to cancel registration of products containing that active ingredient or obtain the required test results as provided in Section 13127(c)(1) and (d)(1).

Developing Data--If you choose to develop the required data, you must submit with your response a detailed description of each test, the testing laboratory with whom you are negotiating to conduct the test, and the estimated date of completion. All tests must be conducted in accordance with acceptable standards such as those outlined in EPA's Pesticide Assessment Guidelines, October 1982. Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable provided the OECD recommended standards such as species selection, test duration, and degradate identification (environmental fate) requirements conform to those specified in EPA's Data Requirements for Registration (40 CFR 158). If you choose a protocol which differs from these, you must provide a detailed description of the proposed protocol and your reason for wishing to use it. The Department may not accept the proposed protocol; rejection of the protocol may not be a basis for any extension of time for data submission.

Sharing the Responsibility to Develop Data--If you choose to enter into an agreement to share the responsibility of producing the required data but will not be submitting the data yourself, you must provide the name and address of the registrant or supplier who will submit the data and documentation that an agreement has been formed. Documentation may be your letter offering to join in an agreement and the other party's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms.

OTHER COURSES OF ACTION UNDER THIS NOTICE

There are additional options available in responding to this Notice. You may claim that one or more data requirements do not apply to your product, you may amend your registration to delete the uses to which one or more data requirements apply or you may request voluntary cancellation of your registration.

Claim That Data Requirements are Not Applicable--If the data requirements of this Notice do not apply to your product(s), you will not be required to fill the data gaps. If you claim the data requirements are not applicable to your product(s), you must submit an explanation together with six (6) copies of your current label and a statement of formula for each product. For EPA registered products include current copies of your EPA stamped label, Notice of Registration and/or letter of acceptance, and Confidential Statement of Formula (EPA Form 8570-4). Statements of formula must give the name, percent by weight, and basic manufacturer of each ingredient. If CDFA determines that data are required for your product(s), you must choose a method to fill the data gaps or choose another option to avoid the data requirements.

Request for Amendments or Voluntary Cancellation--You may avoid a requirement of this Notice by eliminating the use(s) of your product(s) to which the requirement applies. To do so you may request either amendment or cancellation of your product registration(s). If you wish to amend your registration(s) to delete the affected uses(s), you must submit six (6) amended labels, and a statement of formula for each product together with a cover letter identifying the deleted use(s). For EPA registered products include current copies of your EPA stamped label, Notice of Registration and/or letter of acceptance, and Confidential Statement of Formula (EPA Form 8570-4). Statements of Formula must give the name, percent by weight, and basic manufacturer of each ingredient. If you wish to voluntarily cancel your registration(s), check Option No. 1 on the Data Gap Response Sheet. Complete a response sheet for each product registration you wish to cancel.

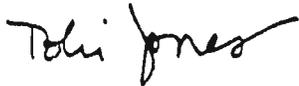
Page 4  
January 31, 1986

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, please contact Rusty Millar at (916) 322-5130. All responses to this Notice must include the required documents and must be addressed to:

SB 950 Data Gap Response  
Pesticide Registration Branch  
California Department of  
Food and Agriculture  
1220 N Street, Room A-447  
Sacramento, California 95814

Sincerely,

A handwritten signature in cursive script that reads "Tobi Jones".

Tobi Jones, Acting Chief  
Pesticide Registration Branch  
(916) 322-5130

Enclosures

DATA GAP RESPONSE PACKAGE

FOR

CALIFORNIA NOTICE 86-1

The data gap response package is provided to assist you with your response to this Notice. This package includes the following:

Data Gap Response Sheet

A response sheet must be completed for each pesticide product. For products containing more than one active ingredient, a response sheet is required for each active ingredient in the product.

Response Schedule (Active Ingredient by Unit)

Active ingredients are divided into four units which include time frames for responding to this Notice.

Data Gaps and Adverse Effects

Data gaps for each active ingredient that were identified from our review of the data on file with CDFA.

Test Titles Reviewed

Titles of the tests that were reviewed to determine what gaps exist in our data base.

Active Ingredients by Company

Companies registered in California for each active ingredient.

Chemical Group List

The chemical groupings for certain active ingredients registered in California.

Certain chemicals have been grouped. For each group, we have designated a chemical for which the data shall be submitted. For example, the dalapon group consists of dalapon, dalapon magnesium salt, and dalapon sodium salt. The chronic data submitted must fill data gaps for dalapon. Since the members of each chemical group are similar, toxicology data available for any of them may be acceptable for the entire group. All registrants with any chemical in these groups are responsible for providing data for the designated active ingredient. Each chemical within a group will be affected by a failure to fill data gaps for the designated lead chemical.

California Department of Food and Agriculture  
 CALIFORNIA DATA GAP RESPONSE SHEET  
 FOR  
 CALIFORNIA NOTICE 86-1

SEND TO: SB 950 Data Gap Response  
 Pesticide Registration Branch  
 California Department of Food and Agriculture  
 1220 N Street, Room A-447  
 Sacramento, California 95814

PESTICIDE REG. NO. \_\_\_\_\_

PRODUCT NAME \_\_\_\_\_

ACTIVE INGREDIENT \_\_\_\_\_

REGISTRANT'S NAME \_\_\_\_\_

BASIC MANUFACTURER OF THE ACTIVE INGREDIENT \_\_\_\_\_

A Data Gap Response Sheet for each product must be filled in and sent to the Department by the date designated in the Response Schedule. For products containing more than one active ingredient, complete a response sheet for each active ingredient in the product. Attach a complete confidential statement of formula for your product (for EPA registered products attach a copy of EPA Form 8570-4) to the response sheet.

OPTION NO.

1.  I request voluntary cancellation of this product's registration. Sign here and return to the above address.

DATE \_\_\_\_\_

SIGNATURE OF AUTHORIZED REPRESENTATIVE \_\_\_\_\_

MAILING ADDRESS: \_\_\_\_\_

TELEPHONE # ( ) \_\_\_\_\_

NAME TYPED OR PRINTED \_\_\_\_\_

You may choose different options for different data requirements, but for each data gap, at least one option must be checked.

Option Nos. 2-7 for filling data gaps	Chronic Feeding		Oncogenicity		Teratogenicity		Reproduction	*Mutagenicity			Neurotoxicity	
	RAT	DOG	RAT	MICE	RAT	RABBIT	RODENT	G	C	D	HEN	
2. I will generate and submit the data for each data requirement I have checked and will submit a progress report on each test every January 1 and July 1 until the data are submitted. These data will be generated according to EPA's Pesticide Assessment Guidelines, October 1982 <input type="checkbox"/> , the OECD protocols <input type="checkbox"/> , or different protocol (copy attached) <input type="checkbox"/> . A complete schedule for submitting data is attached.												
3. I have entered into an agreement with one or more registrants or suppliers to share the responsibility of generating and submitting data and progress reports for each data requirement I have checked. A copy of the agreement is attached and the name and address of the registrant or supplier to submit each test is specified.												
4. I claim that I am not obligated to submit the data required by Notice 86-1 for the checked data requirement box(es) because the use(s) of my registered pesticide product are such that, under the EPA Data Requirements for Pesticide Registration Final Rule, these data requirements do not apply to my product. Attached is an explanation of why my registered pesticide product is not subject to the Requirements together with six (6) current labels, my EPA stamped label and letter of acceptance, and Confidential Statement of Formula.												
5. I enclose a request to amend my registration by deleting one or more of its currently registered uses. Once this amendment is approved, I believe the data requirements in the checked box(es) will not apply to my product.												
6. Studies recently submitted but not listed should fill data gap(s) identified <input type="checkbox"/> . Attached are study title(s) and date(s) of submission.												
7. I have been unsuccessful in entering into any agreement to share the responsibility of generating data with other registrants and suppliers. Attached are copies of the offers I have made and proof of receipt of the offers for the data requirements checked.												

\* G = Gene mutation, C = Chromosome aberration, D = DNA repair

Date \_\_\_\_\_

Signature of Authorized Representative \_\_\_\_\_

Name Typed or Printed \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Telephone Number & Area Code \_\_\_\_\_

CALIFORNIA DEPT OF FOOD & AGRICULTURE  
RESPONSE SCHEDULE

1/31/86

ACTIVE INGREDIENT BY UNIT

PAGE 1

FOR ACTIVE INGREDIENTS IN UNIT I YOUR RESPONSE TO CALIFORNIA  
NOTICE 86-1 IS DUE ON THE DATA GAP RESPONSE SHEET BY 04/01/86  
REQUIRED STUDIES MUST BE INITIATED BY 9/1/86 AND ARE DUE BY 11/1/90

ACEPHATE  
ACROLEIN  
ALACHLOR  
ALDICARB  
ALDRIN  
ALKYL(50%C14,40%C12,10%C16)DIMETHYLBENZYL AMMONIUM CHLORIDE  
ALLETHRIN  
ALUMINUM PHOSPHIDE  
AMITRAZ  
AMITROLE  
ARSENIC PENTOXIDE  
ARSENIC TRIOXIDE  
ASULAM, SODIUM SALT  
✓ ATRAZINE  
AZINPHOS-METHYL  
BARBAN  
BENDIOCARB  
BENOMYL  
✓ BENTAZON, SODIUM SALT  
✓ BORIC ACID  
BROMACIL  
BROMOXYNIL OCTANOATE  
CAPTAFOL  
CAPTAN  
CARBARYL  
CARBOFURAN  
CARBON TETRACHLORIDE  
CARBOXIN  
CHLORAMBEN  
CHLORDANE  
CHLORDIMEFORM  
✓ CHLORFLURENOL, METHYL ESTER  
✓ CHLORINE  
CHLOROBENZILATE  
CHLORONEB  
ORTHO-BENZYL-PARA-CHLOROPHENOL  
CHLOROPICRIN  
CHLOROTHALONIL  
CHLORPYRIFOS  
CHLORSULFURON  
CHLORTHAL-DIMETHYL  
COPPER HYDROXIDE  
COUMAPHOS  
CREOSOTE  
CRYOLITE  
CYANAZINE  
CYCLOATE

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CALIFORNIA DEPT OF FOOD & AGRICULTURE  
RESPONSE SCHEDULE

1/31/86

ACTIVE INGREDIENT BY UNIT

PAGE

5

FOR ACTIVE INGREDIENTS IN UNIT I YOUR RESPONSE TO CALIFORNIA  
NOTICE 86-1 IS DUE ON THE DATA GAP RESPONSE SHEET BY 04/01/86  
REQUIRED STUDIES MUST BE INITIATED BY 9/1/86 AND ARE DUE BY 11/1/90

TRIADIMEFON  
S, S, S-TRIBUTYLPHOSPHOROTRITHIOATE  
TRIBUTYLTIN BENZOATE  
TRIBUTYLTIN OXIDE  
✓ TRICHLOROPHON  
TRICHLORO-S-TRIAZINETRIONE  
TRICLOPYR  
TRIFLURALIN  
TRIFORINE  
VERNOLATE  
VINCLOZOLIN  
ZIRAM

12

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FOR ACTIVE INGREDIENTS IN UNIT II YOUR RESPONSE TO CALIFORNIA  
NOTICE 86-1 IS DUE ON THE DATA GAP RESPONSE SHEET BY 06/01/86

ACETIC ACID  
ACID BLUE 9  
3-ALKOXY(C12-C15)-2-HYDROXYPROPYL TRIMETHYL AMMONIUM CHLORIDE  
ALKYLAMINE HYDROCHLORIDE ALKYL DERIVED FROM COCONUT OIL FATTY ACID  
S  
ALKYLAMINO-3-AMINOPROPANE HYDROXYACETATE ALKYL DERIVED FROM COCONU  
T OIL FATTY ACIDS  
ALKYL(60%C14, 30%C16, 5%C12, 5%C18) DIMETHYL BENZYL AMMONIUM CHLORIDE  
ALKYL (95%C14, 3%C12, 2%C16) DIMETHYL BENZYL AMMONIUM CHLORIDE DIHYD  
RATE  
ALKYL(50%C12, 30%C14, 17%C16, 3%C18) DIMETHYL DICHLOROBENZYL AMMONIUM  
CHLORIDES  
ALKYL(90% C14, 5% C12, 5% C16) DIMETHYL DICHLOROBENZYL AMM ONIUM  
CHLORIDE  
ALKYL(90%C14, 5%C12, 5%C16) DIMETHYL ETHYL AMMONIUM BROMIDE  
ALKYL(50%C12, 30%C14, 17%C16, 3%C18) DIMETHYL ETHYLBENZYL AMMONIUM CHL  
ORIDE  
ALPHA ALKYL(43%C10, 12%C12, 30%C14, 10%C16, 5%C18) POLY(OXYETHYLENE) POL  
Y(OXYPROPYLENE)-I2 COMPLEX  
ALKYL(C12-C15) POLY(OXYPROPYLENE) POLY(OXYETHYLENE); IODINE COMPLEX  
ALKYL(29%C14, 29%C13, 21%C12, 21%C15) POLY(OXYPROPYLENE) POLY(OXE  
THYLENE)-IODINE COMPLEX  
ALKYL-1,3-PROPYLENEDIAMINE ACETATE ALKYL DERIVED FROM COCONUT OIL  
FATTY ACIDS  
ALKYLPYRIDINES, MIXED  
AMMONIUM FLUOSILICATE  
AMMONIUM SULFAMATE  
AMMONIUM TALL OIL FATTY ACID SOAP  
AMMONIUM THIOSULFATE

CALIFORNIA DEPT OF FOOD & AGRICULTURE  
RESPONSE SCHEDULE

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ACTIVE INGREDIENT BY UNIT

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FOR ACTIVE INGREDIENTS IN UNIT III YOUR RESPONSE TO CALIFORNIA  
NOTICE 86-1 IS DUE ON THE DATA GAP RESPONSE SHEET BY 06/01/86

ACETOPHENONE  
ACID YELLOW 23  
ACRIFLAVINE  
AGROBACTERIUM RADIOBACTER  
ALKENYL (75% C18, 25% C16) DIMETHYL AMINE ACETATE  
ALKYL (7% C8, 8% C10, 46% C12, 24% C14, 10% C16, 5% C18) AMINO BETAINE  
✓ N-ALKYL (98% C12, 2% C14) DIMETHYL 1-NAPHTHYL-METHYL AMMONIUM CHLORIDE  
MONOHYDRATE  
N-ALKYL (47% C12, 18% C14, 10% C18, 9% C10, 8% C8, 8% C16) DIPROPOXY-AMIN  
E  
ALKYL (92% C18, 8% C16) -N-ETHYL MORPHOLINIUM ETHYL SULFATE  
ALKYLIMIDAZOLINEMONOCARBOXYLATE, MONOSODIUM SALT  
ALKYL (7% C8, 6.5% C10, 53% C12, 19% C14, 8.5% C16, 6% C18) -1,3-PROPANEDI  
AMINE  
✓ ALKYL (70% C18, 27% C16, 3% C14) TRIMETHYL AMMONIUM CHLORIDE  
ALLYLISOTHIOCYANATE  
AMYL ACETATE  
ANETHOL  
✓ ANIMAL GLAND EXTRACTS  
✓ ASPHALT SOLIDS  
AZOCOSTEROL  
BENZYL ALCOHOL  
BENZYL BENZOATE  
TRANS-1,2-BIS(N-PROPYLSULFONYL) ETHENE  
BOMYL  
✓ BONE OIL  
BRODIFACOU  
BROMADIOLONE  
1,3-BUTYLENE GLYCOL  
CALCIUM THIOSULFATE  
CARBENDAZIM  
CASTOR OIL  
CETYL DIMETHYL ETHYL AMMONIUM BROMIDE  
CHLORDECONE  
CHLORFENVINPHOS  
CHLORHEXIDINE DIACETATE  
✓ CHLORINE DIOXIDE  
CHLORMEQUAT CHLORIDE  
4-CHLORO-2-CYCLOPENTYLPHENOL  
5-CHLORO-2-(2,4-DICHLOROPHENOXY) PHENOL  
CHLOROPHACINONE  
2-CHLORO-4-PHENYLPHENOL  
4-CHLORO-2-PHENYLPHENOL  
4 & 6-CHLORO-2-PHENYLPHENOL  
3-CHLORO-P-TOLUIDINE HYDROCHLORIDE  
4-CHLORO-3,5-XYLENOL  
CITRAL

CALIFORNIA DEPT OF FOOD & AGRICULTURE  
RESPONSE SCHEDULE

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ACTIVE INGREDIENT BY UNIT

PAGE 14

FOR ACTIVE INGREDIENTS IN UNIT III YOUR RESPONSE TO CALIFORNIA  
NOTICE 86-1 IS DUE ON THE DATA GAP RESPONSE SHEET BY 06/01/86

TRIBUTYL TIN METHACRYLATE  
1,1,1-TRICHLOROETHANE  
TRICHLOROMELAMINE  
2,4,5-TRICHLOROPHENOL  
TRICLOCARBAN  
(E)-4-TRIDECEN-1-YL ACETATE  
(Z)-4-TRIDECEN-1-YL ACETATE  
TRIETHANOLAMINE DODECYL BENZENE SULFONATE  
3,4,4-TRIMETHYLOXAZOLIDINE  
TRIPHENYL TIN FLUORIDE  
TRISODIUMNITRILOTRIACETATE  
TYROTHRIN  
WARFARIN  
2,4-XYLENESULFONIC ACID  
2,4-XYLENOL  
ZINC-2-MERCAPTOBENZOTHAZOLE  
ZINC OXIDE  
ZINC 2-PYRIDINETHIOL-1-OXIDE  
1080

600

FOR ACTIVE INGREDIENTS IN UNIT IV YOUR RESPONSE TO CALIFORNIA  
NOTICE 86-1 IS DUE ON THE DATA GAP RESPONSE SHEET BY 08/01/86

ACIFLUORFEN, SODIUM SALT  
ALKENYL (90% C18,10% C16) DIMETHYL ETHYL AMMONIUM BROMIDE  
PARA-ALKYL (C9-C13) BENZENESULFONIC ACID, SODIUM SALT  
ALKYL (50% C14,40% C12,10% C16) DIMETHYL BENZYL AMMONIUM SACCHARIN  
ATE  
AMETRYNE  
AMMONIUM ISOBUTYRATE  
AMMONIUM SULFATE  
ANCYMIDOL  
ANTIMYCIN A  
ANTU  
✓ BACILLUS POPILLIAE  
BAYTHROID  
BIFENOX  
1,4-BIS(BROMOACETOXY)-2-BUTENE  
BITREX  
2-BROMO-4-HYDROXYACETOPHENONE  
1,1, -(2-BUTENYLENE) BIS(3,5,7-TRIAZA-1-AZONIAADAMANTANE  
DE) CHLORI  
BUTOPYRONOXYL  
BUTOXYCARBOXIM  
BUTYL ALCOHOL

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE  
CHEMICAL GROUP LIST

PAGE 1

1/31/86

DATA GAPS ARE TO BE FILLED FOR THE CHEMICAL(S) MARKED "REQUIRED" IN EACH GROUP.  
IF A CHEMICAL IS INDENTED, DATA MAY BE SUBMITTED FOR ANY CHEMICAL  
THAT IS MARKED "REQUIRED" WITHIN THE GROUP.

DATA  
REQUIRED

CHEMICAL NAME

REQUIRED ALKYLAMINO-3-AMINOPROPANE HYDROXYACETATE ALKYL DERIVED  
FROM COCONUT OIL FATTY ACIDS  
ALKYLAMINO-2-AMINOPROPANE MONOACETATE ALKYL DERIVED FROM  
M COCONUT OIL FATTY ACIDS

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REQUIRED ALKYL(50%C14, 40%C12, 10%C16) DIMETHYLBENZYL AMMONIUM CHLO  
RIDE

REQUIRED ALKYL(60%C14, 30%C16, 5%C12, 5%C18) DIMETHYL BENZYL AMMONIU  
M CHLORIDE  
ALKYL(25%C12, 60%C14, 15%C16) DIMETHYL BENZYL AMMONIUM  
CHLORIDE  
ALKYL(47%C12, 18%C14, 10%C18, 10%C16, 15%C8-C10) DIMETHYLBEN  
ZYL AMMONIUM CHLORIDE  
ALKYL(50%C12, 30%C14, 17%C16, 3%C18) DIMETHYL BENZYL AMMONI  
UM CHLORIDE  
ALKYL(58%C14, 28%C16, 14%C12) DIMETHYL BENZYL AMMONIUM CHL  
ORIDE  
ALKYL(61%C12, 23%C14, 11%C16, 5%C8-C10-C18) DIMETHYL BENZY  
L AMMONIUM CHLORIDE  
ALKYL(65%C12, 25%C14, 10%C16) DIMETHYL BENZYL AMMONIUM CHL  
ORIDE  
ALKYL (67% C12, 25% C14, 7% C16, 1% C8, C10, C18) DIMETHYL B  
ENZYL AMMONIUM CHLORIDE  
ALKYL(90%C14, 5%C12, 5%C16) DIMETHYLBENZYL AMMONIUM CHLORI  
DE  
ALKYL (93%C14, 4%C12, 3%C16) DIMETHYL BENZYL AMMONIUM CHL  
ORIDE  
ROCCAL-R, (61/12, 23/C14, 11/C16, 5/C18)  
TETRADECYLDIMETHYLBENZYL AMMONIUM CHLORIDE

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REQUIRED ALKYL(50%C12, 30%C14, 17%C16, 3%C18) DIMETHYL ETHYLBENZYL A  
MMONIUM CHLORIDE  
ALKYL(68%C12, 32%C14) DIMETHYL ETHYLBENZYL AMMONIUM CHLO  
RIDE

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REQUIRED ALKYL-1,3-PROPYLENEDIAMINE ACETATE ALKYL DERIVED FROM C  
OCONUT OIL FATTY ACIDS  
ALKYL-1,3-PROPYLENEDIAMINE ALKYL DERIVED FROM COCONUT O  
ILFATTY ACIDS  
ALKYL-1,3-PROPYLENE DIAMINE ADIPATE ALKYL DERIVED FROM  
COCONUT OIL FATTY ACIDS

APPENDIX B

§ 12999.5

FOOD AND AGRICULTURAL CODE

- (2) Any party may, at the time of filing the appeal or within 10 days thereafter, present written evidence and a written argument to the director.
  - (3) The director may grant oral arguments upon application made at the time written arguments are filed.
  - (4) If an application to present an oral argument is granted, written notice of the time and place for the oral argument shall be given at least 10 days before the date set therefor. The times may be altered by mutual agreement.
  - (5) The director shall decide the appeal on any oral or written argument, briefs, and evidence that he or she has received.
  - (6) The director shall render a written decision within 45 days of the date of appeal or within 15 days of the date of oral arguments.
  - (7) On an appeal pursuant to this section, the director may sustain, modify by reducing the amount of the fine levied, or reverse the decision of the commissioner. A copy of the director's decision shall be delivered or mailed to the appellant and the commissioner.
  - (8) Review of the decision of the director may be sought by the appellant pursuant to Section 1094.5 of the Code of Civil Procedure.
- (d) This section shall become operative on October 1, 1986.

Added Stats 1985 ch 943 § 3.

Note—Stats 1985 ch 943 provides:

SEC. 4. The director shall adopt regulations to serve as guidelines, on or before October 1, 1986, specifying the types of violations for which fines may be levied and the amounts of the fines that may be assessed pursuant to Section 12999.5 of the Food and Agricultural Code. The amounts of the fines shall be related to the seriousness of the violation and the potential for harm to public health or worker safety. These regulations shall also provide that the person fined be notified of the fine prior to its imposition. Authority to levy civil penalty in lieu of civil prosecution: §§ 11892, 12997.

ARTICLE 14

Birth Defect Prevention

[Added by Stats 1984 ch 669 § 1.]

- § 13121. Citation of article
- § 13122. Purpose
- § 13123. Definitions
- § 13123.5. Manner of conducting health effects studies
- § 13124. Report to Legislature
- § 13125. Report as to active pesticide ingredients registered in California
- § 13126. Conditional registration or licensing; Prohibition
- § 13127. Filling data gaps on pesticide active ingredients; Timetable; Compliance; Exemptions
- § 13128. Purchase of registered pesticide for formulation into end use product; Safety data
- § 13129. Cancellation or suspension action; Access to health effects studies
- § 13130. Severability clause

§ 13121. Citation of article

This article shall be known and may be cited as the Birth Defect Prevention Act of 1984.

Added Stats 1984 ch 669 § 1.

§ 13122. Purpose

It is the purpose of the Legislature in enacting this chapter to prevent pesticide induced abortions, birth defects, and infertility.

Added Stats 1984 ch 669 § 1.

### § 13123. Definitions

For purposes of this chapter, the following definitions apply:

- (a) "Adverse reproductive effect" means a statistically significant adverse effect on parental reproductive performance and the growth and development of offspring, including gonadal function, conception, and parturition; abortions; birth defects; stillbirths; and resorptions.
- (b) "Data gap" means that the department does not have on file a full set of valid mandatory health effects studies.
- (c) "Mandatory health effects study" means adverse reproductive effect, chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, and teratogenicity studies required for full registration or licensing of pesticides in California, as of July 1, 1983.
- (d) "Teratogenic" means the property of a substance or mixture of substances to produce or induce functional deviations or developmental anomalies, not heritable, in or on an animal embryo or fetus.
- (e) "Mutagenic effect" means the property of a substance or mixture of substances to induce changes in the genetic complement of either somatic or germinal tissue in subsequent generations.
- (f) "Chronic toxicity" means the property of a substance or mixture of substances to cause adverse effects in an organism upon repeated or continuous exposure over a period of at least one-half the lifetime of that organism.
- (g) "Oncogenic" means the property of a substance or a mixture of substances to produce or induce benign or malignant tumor formations in living animals.
- (h) "Neurotoxic effect" means any adverse effect on the nervous system such as delayed-onset locomotor ataxia resulting from single administration of the test substance, repeated once if necessary.

Added Stats 1984 ch 669 § 1.

#### § 13123.5. Manner of conducting health effects studies

To the extent feasible, health effects studies shall be conducted in accordance with standards and protocols established pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 135 et seq.).

Added Stats 1984 ch 669 § 1.

### § 13124. Report to Legislature

The department shall report all of the following to the Legislature:

- (a) By April 1, 1985, a list of pesticide active ingredients currently registered in California.
- (b) By April 1, 1985, a list of the department's mandatory health effects study requirements for full registration of pesticides in California as of July 1, 1983.
- (c) By July 1, 1985, a list of mandatory health effects studies on file at the department for each pesticide active ingredient.

Added Stats 1984 ch 669 § 1

§ 13125. Report as to active pesticide ingredients registered in California  
 Not later than December 31, 1985, the department shall report the following information for each active pesticide ingredient presently registered in California:

- (a) The department's determination of whether each of the studies specified in Section 13124 is valid, complete, and adequate. This determination shall be based on a thorough evaluation of the studies, but does not require an onsite audit of the laboratory that produced the study.
- (b) A list of data gaps for each active pesticide ingredient.
- (c) The department's determination of whether each study shows adverse reproductive effects, chronic toxicity, mutagenic effects, neurotoxic effects, oncogenic effects, or teratogenic effects.
- (d) For each active pesticide ingredient for which an effect described in subdivision (c) has been shown, or a data gap exists, a list of the amount sold in California during 1985, and whether this active ingredient is sold for home or agricultural use.
- (e) If all of the data cannot be acquired by the department by the reporting deadline established by this section, the department shall report the data available, and provide a supplemental report with the remaining data by April 1, 1986.

Added Stats 1984 ch 669 § 1.

§ 13126. Conditional registration or licensing; Prohibition

No new active pesticide ingredient shall be conditionally registered or licensed when any of the mandatory health effects studies, as defined in subdivision (c) of Section 13123, is missing, incomplete, or of questionable validity unless the registration is based on previous consultation with the State Director of Health Services and the Director of Industrial Relations.

Added Stats 1984 ch 669 § 1.

§ 13127. Filling data gaps on pesticide active ingredients; Timetable; Compliance; Exemptions

- (a) Not later than December 31, 1985, the department shall identify 200 pesticide active ingredients which the department determines have the most significant data gaps, widespread use, and which are suspected to be hazardous to people. Not later than 30 days after the report issued pursuant to Section 13125, the department shall notify each registrant of a pesticide product containing any of the identified 200 pesticide active ingredients of the applicable data gap required to be filled pursuant to this section.
- (b) Not later than December 31, 1985, the department shall also adopt a timetable for the filling of all data gaps on all pesticide active ingredients, other than those identified by the department pursuant to subdivision (a), which are currently registered or licensed in California. The department shall notify registrants of the applicable data gaps and the scheduled time to initiate and complete studies as provided in the timetable.
- (c) (1) Not later than September 1, 1986, the department shall determine whether a test has been initiated to fill each of the data gaps for each pesticide active ingredient identified in subdivision (a). If no test has been initiated, the department shall fill data gaps in accordance with procedures provided in subparagraph (B) of paragraph (2) of subdivision (c) of Section

136a of Title 7 of the United States Code. In order to carry out this section, the director has the same authority to require information from registrants of active pesticide ingredients that the administrator of the Environmental Protection Agency has pursuant to subparagraph (B) of paragraph (2) of subdivision (c) of Section 136a of Title 7 of the United States Code. On or before July 1, 1986, the director shall, by regulation, prescribe procedures for resolving disputes or funding the filling of data gaps. The procedures may include mediation and arbitration. The arbitration procedures, insofar as practical, shall be consistent with the federal act, or otherwise shall be in accordance with the commercial arbitration rules established by the American Arbitration Association. The procedures shall be established so as to resolve any dispute within the timetable established in subdivision (a) of Section 13127.

(2) The department shall also obtain the data which is identified in subdivision (b), according to the timetable and procedures specified in this section.

(d) (1) Not later than March 1, 1987, the director shall again determine whether tests have been initiated to fill each of the data gaps for each pesticide active ingredient identified in subdivision (a). If the tests have not been initiated or if, having been initiated, the tests are not completed within a reasonable time not to exceed four years, the director shall obtain the required test results. The director may utilize assessments charged to those registrants of the active ingredient for which the data gaps exist in amounts necessary to cover the department's expenses in filling the data gaps. Any assessments shall be made pursuant to Section 12824 of the Food and Agricultural Code. The director may also request an appropriation to be used in combination with assessments to obtain the required test results. The director shall initiate the tests as soon as possible, and the tests shall be completed within a reasonable time, not to exceed four years after initiation. The director shall furnish not less than 30 days' public notice of any proposed action under this section, stating the reasons therefor and allowing public comment thereon. Copies of this notice and final decision shall be provided to the appropriate committees of the Legislature

(2) The director shall monitor compliance with the timetable established pursuant to subdivision (b) of Section 13127. If the director determines that tests are not initiated or completed according to the timetable, the director shall obtain the required test results as provided in paragraph (1).

(e) (1) This section does not apply to any product which the director determines has limited use or that substantial economic hardship would result to users due to unavailability of the product and there is not significant exposure to the public or workers and the product is otherwise in compliance with federal law.

(2) The director may not, pursuant to this subdivision, exempt all pesticide products containing the same pesticide active ingredient unless it is determined that the pesticide active ingredient has only limited use, there is insignificant exposure to workers or the public, and the products are otherwise in compliance with federal law. Any exemption issued pursuant to this paragraph shall expire at the end of three years after it is issued.

(f) (1) Whenever the director exercises the authority provided in paragraph (1) of subdivision (e), he or she shall give public notice of the action stating the reasons for exempting the pesticide product from the data requirements of this article. Copies of this notice shall be provided to the appropriate policy committees of the Legislature.

(2) Whenever the director acts pursuant to paragraph (2) of subdivision (e), the director shall furnish not less than 30 days' public notice of the proposed action, stating the reasons for exempting the pesticide product from the data requirements of this article and allowing public comment thereon. Copies of the notice and the final decision shall be provided to the appropriate policy committees of the Legislature.

Added Stats 1984 ch 669 § 1.

**§ 13128. Purchase of registered pesticide for formulation into end use product; Safety data**

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate the purchased pesticide into an end use product shall be required to submit or cite data pertaining to the safety of the purchased product or to offer to pay reasonable compensation for the use of any such data.

Added Stats 1984 ch 669 § 1.

**§ 13129. Cancellation or suspension action; Access to health effects studies**

(a) If the director, after evaluation of the health effects study of an active ingredient, finds that a pesticide product containing the active ingredient presents significant adverse health effects, including reproduction, birth defects, or infertility abnormalities, the director shall take cancellation or suspension action against the product pursuant to Section 12825 or 12826.

(b) The State Director of Health Services shall have access to mandatory health effects studies and other health effects studies on file at the Department of Food and Agriculture, and may, based upon the determination of the State Director of Health Services, provide advice, consultation, and recommendations concerning the risks to human health associated with exposure to the substances tested.

Added Stats 1984 ch 669 § 1.

**§ 13130. Severability clause**

If any provision of this article or the application thereof to any person or circumstances is held invalid, this invalidity shall not affect other provisions or applications of the article which can be given effect without the invalid provision or application, and to this end the provisions of this article are severable.

Added Stats 1984 ch 669 § 1.

ARTICLE 15

The Pesticide Contamination Prevention Act

[Added by Stats 1985 ch 1298 § 1.]

- § 13141. Legislative findings and declaration
- § 13142. Definitions
- § 13143. Information required to be submitted by registrants
- § 13144. Establishment and revision of numerical values; Reports as to economic poisons registered for agricultural use
- § 13145. Fines for groundwater protection data gaps; Review of disputes. List of poisons with potential to pollute

as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data;

(E) the complete formula of the pesticide; and

(F) a request that the pesticide be classified for general use, for restricted use, or for both.

(2)(A) Data in support of registration.—The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses shall make

such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

(B) Additional data to support existing registration.—

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified com-

plaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title: *Provided*, That the only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of subsection (c)(1)(D) of this

section. Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(C) **Simplified procedures.**—Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) **Exemption.**—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

(i) submit or cite data pertaining to the safety of such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(3) **Time for acting with respect to application.**—The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of his determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(4) **Notice of application.**—The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) **Approval of registration.**—The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d) of this section—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material require to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.