

JUN 18 1987
11:21 o'clock P.M.
MARCH FONG EU, Secretary of State
By *[Signature]*
Deputy Secretary of State

CALIFORNIA OFFICE OF ADMINISTRATIVE LAW
SACRAMENTO, CALIFORNIA

In re:)	1987 OAL Determination No. 8
Request for Regulatory)	
Determination filed by)	[Docket No. 86-014]
the Swimming Pool)	
Chemical Manufacturers)	June 18, 1987
Association, concerning)	
"California Notice 86-9")	Determination Pursuant to
issued by the Department)	Government Code Section
of Food and Agriculture ¹)	11347.5; Title 1,
)	California Administrative Code
)	Chapter 1, Article 2

Determination by:

[Signature]
 LINDA HURBLE STOCKDALE BREWER, Director
 John D. Smith, Chief Deputy Director/
 General Counsel

Herbert F. Bolz, Coordinating Attorney
 Scott J. Hallabrin, Sr. Staff Counsel
 Rulemaking and Regulatory
 Determinations Unit

SYNOPSIS

The issue presented to the Office of Administrative law was whether the statutory requirement that the Department of Food and Agriculture identify and obtain from pesticide product registrants certain health effects studies has been unlawfully supplemented by the Department.

The Office of Administrative Law has concluded that the Department has imposed requirements in the identification and acquisition of health effects studies which supplement the statute and therefore are invalid and unenforceable until properly adopted as regulations.

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THE ISSUE PRESENTED 2

The Swimming Pool Chemical Manufacturers Association (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 Defect Prevention Act of 1984 (SB 950), California Notice 86-9" (Notice) issued by the California Department of Food and Agriculture (DFA or Department) is a "regulation" as defined in Government Code section 11342, subdivision (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

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THE DECISION 4, 5, 6, 7

- I. The Office of Administrative Law finds that California Notice 86-9 (1) is not a "regulation" as defined in the APA and (2) is not subject to the requirements of the APA insofar as it identifies data gaps that remain unfilled in accordance with Food and Agricultural Code section 13127, subdivision (c), requires return of the Data Gap Response Sheet within 90 days and implies that pesticide registrations would be suspended or revoked for failure to respond to the Notice.

- II. The Office of Administrative Law finds that the following provisions of California Notice 86-9 (1) are subject to the requirements of the APA, (2) are "regulations" as defined in the APA but, (3) between the date of issuance of the Notice and the date of this Determination, were adopted as regulations by DFA and filed with the Secretary of State in accordance with the APA:
 - (a) requiring pesticide registrants who are required to submit data to DFA pursuant to the Birth Defect Prevention Act⁸ to select and submit data according to one of the following options:
 - (1) to generate and submit the required data to DFA;
 - (2) to agree to jointly generate and submit the required data with another party and to provide a copy of the agreement to DFA;
 - (3) to claim that the data requirements are not applicable to the use patterns of the registrant's pesticide products and to provide supporting information to DFA;
 - (4) to submit the data to DFA;
 - (5) to offer to compensate other registrants or suppliers of the data for sharing of the responsibility of generating the data and to provide copies of the offers to DFA;
 - (6) to enter into an agreement to compensate the developer of the required data and to provide a copy of the agreement to DFA;
 - (7) to indicate that another pesticide registrant will submit the required data on behalf of the responding registrant.

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- (b) establishment of a reconsideration process with timetables and requirements for supporting documentation.
- (c) for each active ingredient on the Unit I list, establishment of study categories that have either no data or incomplete data.

III. The Office of Administrative Law finds that the following provisions of California Notice 86-9 (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) categorizing certain pesticide active ingredients into Unit I;⁹
- (b) grouping of certain chemicals and designation of "lead chemicals" for these groups; and¹⁰
- (c) instructing pesticide registrants who are required to submit data to DFA pursuant to the Birth Defect Prevention Act to do the following when notifying DFA of the options they have selected in response to the Notice:
 - (1) when selecting the option to generate and submit the required data, to also submit a progress report on each test every January 1 and July 1 until the data is submitted and to state the protocols by which the data will be generated;
 - (2) when selecting the option to agree and jointly generate and submit the required data with another party, to also provide progress reports to the DFA;
 - (3) when selecting the option to claim that the data requirements are not applicable to the use patterns of the registrant's pesticide products and the claim is under EPA Data Requirements for Pesticide Registration Final Rule, to also provide to DFA six current labels, the registrant's EPA-stamped label, the registrant's letter of acceptance from the EPA and the Confidential Statement of Formula.

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I. AGENCY, AUTHORITY, APPLICABILITY OF APA; BACKGROUND

Agency

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.

Authority¹¹

Food and Agricultural Code section 407 expressly 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."

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

We therefore conclude that DFA has pertinent rulemaking authority.

Applicability of APA to Agency's Quasi-Legislative Enactments

The APA applies to all state agencies, except those "in the judicial or legislative departments."¹² Since DFA is in neither the judicial nor legislative branch of state government, we conclude that APA rulemaking requirements generally apply to DFA.

In any event, 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. . . ."

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"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.]

Background

The requestor, the Swimming Pool Chemical Manufacturers Association, is a not-for-profit mutual benefit corporation, many of whose members have chemical products registered as pesticides with the DFA.¹³ In its Request, the Association states that California Notice 86-9 (excerpts attached as Appendix A) is regulatory in nature.

On March 14, 1986, the Association filed with OAL a Request for Determination similar to the present request. That Request for Determination pertained to a DFA document dated January 31, 1986, and titled "Notice to Pesticide Registrants pertaining to the Birth Defect Prevention Act of 1984, California Notice 86-1."

As is suggested by its title, California Notice 86-1 was issued pursuant to the Birth Defect Prevention Act of 1984 ("the Act").¹⁴ The stated purpose of the Act is to "prevent pesticide induced abortions, birth defects and infertility."¹⁵ Toward this purpose, the Act required, among other things, that DFA compile by July 1, 1985, a list of mandatory health effects studies that it had on file for each pesticide active ingredient¹⁶ in pesticides registered in California.¹⁷ By December 31, 1985, DFA was required, among other things, to provide to the Legislature its assessment as to whether each of these studies was valid, complete and accurate and to further provide a list of data gaps for each pesticide active ingredient in pesticides registered in California.¹⁸

DFA was also required by December 31, 1985, to identify the 200 pesticide active ingredients with (1) the most significant data gaps, (2) the most widespread use and (3) that presented the most hazards to humans. Within 30 days thereafter, DFA was required to notify each registrant of a pesticide product containing any of the 200 identified pesticide active ingredients of the data gap that was required to be filled.¹⁹ California Notice 86-1 was issued by DFA on January 31, 1986, in an effort to satisfy this requirement. The 200 active ingredients deemed most hazardous were placed in a category termed "Unit I".

OAL issued a determination²⁰ (hereafter, the October 1986 determination) in response to the Association's March 1986 Request for Determination concerning California Notice 86-1.

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In that Determination, OAL found that several provisions of California Notice 86-1 were subject to the requirements of the APA and were "regulations" as defined by the APA. These provisions were, therefore, found invalid and unenforceable unless adopted as regulations and filed with the Secretary of State in accordance with the APA. Specifically, OAL's October 1986 determination found California Notice 86-1 to contain the following regulatory provisions:

- (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;
- (i) requiring that certain forms be submitted and that they ~~be completed per specific instructions.~~

California Notice 86-9, the subject of the present request, apparently was DFA's attempt, as required by the Act, to follow-up on California Notice 86-1. Food and Agricultural Code section 13127, subdivision (c)(1) required DFA to determine by September 1, 1986, whether a test had been initiated to fill the data gaps for each of the 200 pesticide active ingredients identified by DFA as of December 31, 1985, and made available to registrants 30 days thereafter. If no test was initiated by September 1, 1986, DFA is empowered to

"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 [of DFA] 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."²¹

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California Notice 86-9 was issued by DFA on September 1, 1986, and did the following:

- (1) pursuant to the statutory deadline set forth in Food and Agricultural Code section 13127, subdivision (c), notified pesticide registrants that DFA's mandatory health effects data base for what is described as the Unit I category of pesticide active ingredients was incomplete;
- (2) included the 200-item Unit I list of pesticide active ingredients;
- (3) identified the study categories for each Unit I active ingredient that have either no data or incomplete data;
- (4) grouped certain chemicals in the Unit I list and designated "lead chemicals" for each group;
- (5) included a multi-part Data Gap Response Sheet (see Appendix A) and instructions for its completion and required pesticide registrants to complete and return the sheet to DFA within 90 days from the date of the Notice;
- (6) included a list of studies submitted to the DFA in response to California Notice No. 86-1, indicated that DFA had not reviewed these studies and indicated that pesticide registrants could, by proper completion of the Data Gap Response Sheet, claim one or more of these studies as fulfilling the applicable data requirement;
- (7) established procedures whereby pesticide registrants could petition DFA for reconsideration of the acceptability of any study; and
- (8) indicated that the continued registration of a registrant's pesticide depended upon a proper response to the Notice.

The Association filed this Request for Determination concerning California Notice 86-9 with OAL on November 14, 1986. DFA responded to the Request for Determination on May 18, 1987. DFA's Response incorporated by reference its Response to the Request for Determination concerning California Notice 86-1. The Response also stated (1) that DFA had recently formally submitted to OAL a proposal that two new provisions be added to the CAC, sections 6194 and 6195 of Title 3 and (2) that the issues raised in this latter Request for Determination were "integrally related" to this regulatory filing. OAL approved DFA's adoption of sections 6194 and 6195 of Title 3 of the CAC; these sections

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were filed with the Secretary of State and made effective June 1, 1987.²² (Sections 6194 and 6195 are attached as Appendix B.)

III. DISCUSSION OF DISPOSITIVE ISSUES

There are two main issues before us:²³

- (1) WHETHER THE CHALLENGED RULE IS A "REGULATION" WITHIN THE MEANING OF THE KEY PROVISION OF GOVERNMENT CODE SECTION 11342.
- (2) WHETHER THE CHALLENGED RULE FALLS WITHIN ANY ESTABLISHED EXCEPTION TO APA REQUIREMENTS.

FIRST, 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, subdivision (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, manual, instruction [or] . . . standard of general application . . . which is a regulation as defined in subdivision (b) of section 11342, unless the guideline, criterion, bulletin, manual, instruction [or] . . . standard of application . . . has been adopted as a regulation and filed with the Secretary of State pursuant to this chapter" [Emphasis added.]

Applying the definition of "regulation" found in Government Code section 11342, subdivision (b) involves a two-part inquiry.

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First, is the informal rule either

- o a rule or standard of general application or
- o a modification or supplement to such a rule?

Second, does the informal rule either

- o implement, interpret, or make specific the law enforced or administered by the Department or
- o govern the agency's procedure?

As set forth in Part I above, California Notice 86-9 contained seven general provisions or requirements. We will discuss each of these provisions or requirements as they relate to the two main issues stated above.²⁴

IV. CONTENTS OF CALIFORNIA NOTICE 86-9

A. Notification to pesticide registrants that DFA's mandatory health effects data base for Unit I pesticide active ingredients is incomplete.

Food and Agricultural Code section 13127, subdivision (c) required DFA to determine by September 1, 1986, whether a test had been initiated to fill the data gaps for each of the 200 pesticide active ingredients identified by December 31, 1985. If no test was initiated by the registrant by September 1, 1986, then DFA was required to

"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 [of DFA] 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."

Title 7 United States Code, section 136a, subdivision (c)(2)(B)(i) requires the Administrator of the Environmental Protection Agency, if he or she determines that additional pesticide data is required, "to notify all existing registrants of the pesticide to which the determination relates...." [Emphasis added.]²⁵

Clearly, DFA is empowered under the provisions of section 13127, subdivision (c) to take action to fill data gaps by notifying registrants of where gaps exist.

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No further implementation, interpretation or specificity is required to enable DFA to undertake such a notification. We conclude, therefore, that this provision of California Notice 86-9 is not a regulation.

B. Establishment of the 200-item Unit I list of pesticide active ingredients

The Unit I list of pesticide active ingredients was established by DFA in response to Food and Agricultural Code section 13127, subdivision (a). That section required DFA to "identify 200 pesticide active ingredients which ...[it]...determines have the most significant data gaps, widespread use, and which are suspected to be hazardous to people...." California Notice 86-1 contained the Unit I list. Notice 86-9 contains the Unit I list and identifies the incomplete study categories²⁶ for each pesticide active ingredient on the list.

The October 1986 determination found that DFA's establishment of the Unit I category as set forth in California Notice 86-1 was a "regulation" as defined in the APA.²⁷

No significant facts arising in the context of Notice 86-9 that would require reversal of our previous conclusion have been brought to our attention; there is ~~thus no basis for modifying our earlier finding.~~

Therefore, we again conclude that the establishment of and reference to the Unit I list of pesticide active ingredients in relation to California Notice 86-9 is a "regulation" as defined in the APA.²⁸

C. Identification of study categories for each Unit I active ingredient that has either no data or incomplete supporting data.

Food and Agricultural Code section 13125, subdivision (c) establishes the study categories for which the required data must be obtained.²⁹ Food and Agricultural Code section 13127, subdivision (a) requires DFA to notify pesticide product registrants of the study categories that have insufficient data. As was discussed in Part IV.A., above, DFA's mere notification about these deficiencies is not regulatory within the terms of the APA.

However, like the establishment of the Unit I list, the establishment of study categories for each pesticide active ingredient on the list that had no data or incomplete data is a "regulation" as defined in the APA. The establishment of these categories is a standard

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applying generally to all registrants of products containing the pesticide active ingredients for which study categories are established. Also, establishing study categories deemed to have insufficient data required interpretation by DFA of the applicable provisions of the Food and Agricultural Code. Food and Agricultural Code section 13225, subdivision (c) identifies the study categories for which the DFA must obtain data,³⁰ and Food and Agricultural section 13125, subdivision (a) only sets forth general requirements that the studies in each category be "valid, complete, and adequate."

Nowhere does the Act set out with specificity the criteria to be applied by DFA in determining whether the data received in a particular study category is sufficient. It follows then that DFA had to establish criteria based upon its expertise (i.e., had to interpret the statute) in order to make these determinations. The establishment of the study categories containing insufficient data is therefore a "regulation" as defined in the APA.³¹

- D. Grouping of certain chemicals in the Unit I list of pesticide active ingredients and designation of "lead chemicals" for each group.

As part of its establishment of the Unit I list of pesticide active ingredients, DFA grouped together on the list certain chemicals and designated "lead chemicals" for each group. The October 1986 determination concluded that this practice, as undertaken in relation to California Notice 86-1, was a "regulation" as defined in the APA.³² As with the establishment of the Unit I list, OAL finds no facts arising in the context of Notice 86-9 that would alter its previous view. Therefore, we again conclude that grouping of chemicals and designation of group "lead chemicals" on the Unit I list in relation to California Notice 86-9 is a "regulation" as defined in the APA.

- E. Inclusion of a Data Gap Response Sheet and instructions for its completion, and requiring pesticide registrants to complete and return the Sheet to DFA within 90 days from the date of issuance of the Notice.

Notice 86-9 includes a pre-printed form known as the Data Gap Response Sheet. This form contains 11 options from which a pesticide registrant can choose in responding to DFA's identification of data gaps for each of the registrant's pesticide products. The form also requires that the registrant complete and return the Sheet to DFA within 90 days from the date of issuance of the Notice. Other portions of the Notice, separate from

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the Sheet, as well as parts of the Sheet itself, contain various instructions for completion of the Sheet. The Data Gap Response Sheet that is part of California Notice 86-9 is virtually identical to the Data Gap Response Sheet issued by DFA as part of California Notice 86-1, except that Notice 86-9 contains the requirements that the Sheet be returned in 90 days and also adds four new options numbered 8 through 11. Instructions for completion of the Sheet that appear in other parts of Notice 86-9 differ from instructions set forth in Notice 86-1.

In the October 1986 determination³³ OAL concluded that Notice 86-1, in requiring completion of the Data Gap Response Sheet and stating instructions for its completion, was a "regulation" as defined in the APA. To the extent that California Notice 86-9 requires completion of a second Data Gap Response Sheet and gives instructions for its completion, it likewise is a "regulation" as defined in the APA. However, we conclude that the requirement that registrants supply data (as opposed to completing the form) within 90 days from the date of issuance of the Notice is not a "regulation" as defined in the APA. The 90-day response requirement is stated in 7 United States Code, section 136a, subdivision (c)(2)(B)(ii)³⁴, and this provision is incorporated into Food and Agricultural Code section 13127, subdivision (c), as quoted above. No further implementation, interpretation or specificity is required to enable DFA to impose such a requirement.

- F. Inclusion of a list of studies submitted to DFA in response to California Notice 86-1, indication that DFA had not reviewed the studies and indication that pesticide registrants could claim one or more of these studies as fulfilling the applicable data requirement.

To the extent that these provisions give instructions for completion of the Data Gap Response Sheet, they are "regulations" as discussed in Part IV.E., above. However, the mere inclusion in the Notice of a list of studies and an indication that DFA has not yet reviewed them does not state a rule of general application or implement, interpret or make specific any law enforced by DFA.

- G. Establishment of procedures whereby pesticide registrants could petition DFA for reconsideration of the acceptability of any study.

Notice 86-9 states that registrants who disagree with DFA's determinations concerning whether or not it will accept studies submitted to fill data gaps can petition DFA for reconsideration. The petition, however, must be

