

AMENDED IN ASSEMBLY MARCH 27, 2006

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 2648

Introduced by Assembly Member Matthews

February 24, 2006

An act to amend Sections 12811.5 and 12836.6 of the Food and Agricultural Code, relating to pesticides.

LEGISLATIVE COUNSEL'S DIGEST

AB 2648, as amended, Matthews. Pesticides.

Existing law authorizes the Director of the Department of Pesticide Regulation to rely upon any evaluations of previously submitted data with respect to an application for registration, an amendment to a registration, or to maintain a registration of a registered pesticide if certain criteria are met including that the applicant either obtain written permission from the owner to rely on the data or irrevocably offer to pay the owner a share of the cost of producing the data, as specified.

This bill would make technical clarifying amendments to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 12811.5 of the Food and Agricultural
- 2 Code is amended to read:
- 3 12811.5. The director may rely upon any evaluations of
- 4 previously submitted data to determine whether to accept an

1 application for registration of a new pesticide product, an
2 amendment to the registration of a registered pesticide product,
3 or to maintain the registration of a registered pesticide product
4 regardless of the ownership of the data previously evaluated.
5 However, effective January 1, 2006, applicants will be subject to
6 the following provisions:

7 (a) If an applicant for registration of a pesticide product, or an
8 amendment to the registration of a registered pesticide product,
9 including a registrant that desires to maintain its registration of a
10 registered pesticide product after the director makes a formal
11 reevaluation request for additional data, does not submit its own
12 data to fulfill a current data requirement imposed by the director
13 and relies upon data that the applicant does not own or have
14 written permission to rely upon that was submitted to the director
15 by another entity after January 1, 1991, and meets the three
16 criteria set forth in this subdivision, the applicant must either (i)
17 obtain written permission from the data owner to rely on the data,
18 (ii) formulate or obtain its product from a source that has data
19 authorization from the data owner, or a source that complies with
20 subdivision (c), or (iii) if the data meets the criteria set forth in
21 paragraphs (1), (2), and (3), irrevocably offer to pay the data
22 owner a share of the cost of producing the data and comply with
23 the provisions of subdivision (d). The director may rely upon
24 data submitted prior to January 1, 1991, or that does not meet the
25 criteria set forth in paragraphs (1), (2), and (3) to support any
26 application or comply with any formal reevaluation request for
27 additional data, without permission from the data owner. An
28 offer to pay, and a payment pursuant to that offer, shall only be
29 required as to data not submitted by the applicant that meets the
30 criteria set forth in paragraphs (1), (2), and (3). To be eligible for
31 cost sharing pursuant to this subdivision, the data must meet all
32 of the following requirements:

33 (1) The data was required by the director in order to obtain,
34 amend, or maintain the data owner's California registration or
35 registrations for uses covered by the application, amendment, or
36 formal reevaluation request for additional data.

37 (2) There has been no arbitration award, data compensation, or
38 data cost-sharing agreement pertaining to data supporting the
39 product at the federal level pursuant to Section 3(c)(1) (F)(iii) or
40 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide

1 Act (7 U.S.C. Sec. ~~136a(c)(1)(F)(iii)~~ *136a(c)(1)(F)(iii)* or
2 *136a(c)(2)(B)*), or, if an award or agreement exists, the use of
3 data in California was excluded from compensation or cost
4 sharing on its face.

5 (3) The data that fulfills a current requirement was submitted
6 to the United States Environmental Protection Agency or the
7 department no more than 15 years prior to the date of the
8 applicant's California registration, application, or amendment or
9 the formal reevaluation request for additional data to which the
10 registrant's reliance responds, provided that as to data submitted
11 to the department as of August 1, 2005, in support of the first
12 registration of a product, the applicable period shall be 17 years
13 from the date of submission to the United States Environmental
14 Protection Agency.

15 (b) If the director previously imposed a specific documented
16 data requirement after January 1, 1991, to obtain, amend, or
17 maintain the California registration of a pesticide product
18 substantially similar to the applicant's product and that data
19 requirement is not currently imposed in California for
20 registration, amendment, or maintenance of the applicant's
21 product, the applicant is further obligated to submit data to meet
22 the requirement, obtain written permission from an owner of the
23 data to rely upon the data, formulate or obtain its product from a
24 source that has authorization from the data owner to rely upon
25 the data or from a source that complies with subdivision (c), or, if
26 the data meets the criteria set forth in paragraphs (1), (2), and (3),
27 irrevocably offer to pay the data owner a share in the cost of
28 producing the data and comply with the provisions of subdivision
29 (c). An offer to pay, and a payment pursuant to that offer, shall
30 only be required as to data not submitted by the applicant that
31 meets the criteria set forth in paragraphs (1), (2), and (3). To be
32 eligible for cost sharing pursuant to this subdivision, the data
33 must meet all of the following requirements:

34 (1) The data met a specific, documented requirement of the
35 director to obtain, amend, or maintain the California registration
36 of the data owner's pesticide product for a use covered by the
37 applicant's application or amendment.

38 (2) There has been no arbitration award, data compensation, or
39 data cost-sharing agreement pertaining to data supporting the
40 product at the federal level pursuant to Section 3(c)(1)(F)(iii) or

1 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide
2 Act (7 U.S.C. Sec. ~~136a(c)(i)(F)(iii)~~ *136a(c)(1)(F)(iii)* or
3 136a(c)(2)(B)), or, if an award or agreement exists, the use of the
4 data in California was excluded from compensation or cost
5 sharing on its face.

6 (3) The data was submitted to the U.S. Environmental
7 Protection Agency or Department of Pesticide Regulation by the
8 data owner after January 1, 1991, and no more than 15 years
9 prior to the date of the applicant's California application for
10 registration or amendment or the response to a formal specific
11 document data requirement to which the registrant's reliance
12 responds, provided that as to data submitted to the department as
13 of August 1, 2005, in support of the first registration of a product,
14 the applicable period shall be 17 years from the date of
15 submission to the U.S. Environmental Protection Agency.

16 (c) An applicant may formulate its product from a source that
17 does not have data authorization provided that source has
18 submitted data to support the product or makes or has made an
19 irrevocable offer to pay the data owner a share of the cost of
20 producing the data required pursuant to subdivision (a) or (b) for
21 the applicant's product and complies with or has made payment
22 in accordance with the provisions of subdivision (d). In the event
23 that the source has already reached a data compensation or
24 cost-sharing agreement or there has been an arbitration award
25 under the Federal Insecticide, Fungicide, and Rodenticide Act
26 (commencing at 7 U.S.C. Sec. 136) that excludes the right to rely
27 on the data to satisfy the California requirement on its face, the
28 source must make or have made a new irrevocable offer to pay a
29 share of the cost of producing that data to support the applicant's
30 product in California and comply with the provisions of
31 subdivision (d).

32 (d) If an applicant is required to offer to pay a share in the cost
33 of producing the data pursuant to subdivision (a) or (b), or if a
34 source of product makes an offer pursuant to subdivision (c), the
35 applicant or source must submit to the data owner upon
36 application to the department an irrevocable offer to pay the data
37 owner a share in the cost of producing the data and to comply
38 with regulations promulgated under this subdivision to determine
39 the amount and terms, if the parties cannot agree. If a data owner
40 for which cost sharing is required under subdivision (a) or (b)

1 cannot be identified from information readily available to the
2 applicant, the applicant's obligation under subdivision (a) or (b)
3 will be absolved if the data owner does not identify himself or
4 herself to the applicant within 12 months after registration of the
5 pesticide product. If within 12 months of registration, the data
6 owner identifies himself or herself to the applicant and the
7 applicant has not already made an irrevocable offer to pay to the
8 data owner, or the applicant's source of product has not made an
9 offer pursuant to subdivision (c), the applicant must do so
10 promptly. In either event, the specific terms and amount of
11 payments to be made shall be fixed by agreement between the
12 applicant and the data owner, but determination of those amounts
13 and terms shall not delay approval of the applicant's application.

14 If agreement cannot be reached about the terms and amount of
15 payment required by this section at any time more than 90 days
16 after issuance of an irrevocable offer to pay, either the applicant,
17 source or data owner may initiate, or with the consent of all
18 parties, join a proceeding under the Federal Insecticide,
19 Fungicide, and Rodenticide Act (commencing at 7 U.S.C. Sec.
20 136), pursuant to regulations promulgated by the director
21 pursuant to this statute. The purpose of this proceeding shall be
22 to determine the amount due under this section. The director shall
23 promulgate those regulations as emergency regulations within 60
24 days of the enactment of the bill that enacts this section. The
25 regulations shall provide all of the following:

26 (1) Allow the proceeding authorized by this subdivision, upon
27 mutual agreement of the parties, to be consolidated with dispute
28 resolution under the Federal Insecticide Fungicide and
29 Rodenticide Act (commencing at 7 U.S.C. Sec. 136).

30 (2) Require that the decisionmaker consider, among other
31 factors, that the data owner's exclusive right to sell the pesticide
32 resulted in the data owner recovering all or part of the costs of
33 generating the data.

34 (3) Require that the parties to the proceeding share equally in
35 the payment of the expenses thereof.

36 (e) If a data owner fails to participate in a procedure for
37 reaching an agreement or in a proceeding as required by
38 subdivision (d), or fails to comply with the terms of an agreement
39 or decision conducted under subdivision (d), then that data owner

1 forfeits his or her right to cost recovery as a result of the use of
2 the data at issue.

3 (f) If the director finds that an applicant has failed to make an
4 offer to pay as required under subdivision (a) or (b), or if its
5 source of product has failed to make an offer pursuant to
6 subdivision (c), or if an applicant or its source of product has
7 failed to participate in a proceeding for reaching an agreement, or
8 has refused to participate in a proceeding pursuant to subdivision
9 (d), or has failed to comply with an agreement or to comply with
10 an order, or to pay an award resulting from that proceeding, the
11 director shall cancel the registration of the pesticide product in
12 support of which the data was used in accordance with the
13 provisions of subdivision (g), notwithstanding the provisions of
14 Section 12825.

15 (g) If the applicant subject to subdivision (a) or (b) fails to
16 comply with the provisions of this article, the data owner shall
17 notify the director of the specific provision of noncompliance and
18 provide proof of notification to the applicant of its claim of
19 noncompliance. All parties shall have 30 days from the date of
20 receipt of notification by the director to submit written evidence
21 or arguments to the director regarding the claim and any defenses
22 thereto. The director shall provide a written finding within 60
23 days of the deadline for submission as to the claim and the
24 resulting consequences.

25 (h) No hearing or live testimony shall be conducted under
26 subdivision (g) and this proceeding shall not be used as
27 mechanism to prevent or delay the registration or payment for
28 cost sharing as determined by this article. The finding of the
29 director shall be final and conclusive, except that any party
30 aggrieved by such a finding may seek review within 30 days of
31 the finding pursuant to Section 1094.5 of the Code of Civil
32 Procedure.

33 (i) In lieu of seeking a determination by the director and
34 cancellation of the registration pursuant to subdivision (f), the
35 data owner may bring an action in any California court of
36 competent jurisdiction against the applicant to enforce the
37 obligations of that party set forth in the provisions of this section.

38 (j) No cost sharing as provided in subdivisions (a), (b), and (c)
39 shall be required to support an application for annual renewal of
40 a pesticide product registration, provided this provision shall not

1 authorize renewal of a product registered prior to the effective
2 date of this section if that registration is declared to have been
3 unlawfully issued by a court of competent jurisdiction.

4 (k) The Department of Pesticide Regulation shall make
5 available in the public domain its index of data submitted in
6 support of registration applications, the ownership of that data,
7 and the date it was submitted to California.

8 SEC. 2. Section 12836.6 of the Food and Agricultural Code is
9 amended to read:

10 12836.6. The director shall, with the assistance of the
11 Legislative Analyst, conduct a study to consider more carefully
12 the consequences of data-sharing agreements required under
13 Section 12811.5 and the volume of high-hazard pesticides sold in
14 California. The report shall be submitted to the Legislature no
15 later than December 31, 2008.

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