BEFORE THE DIRECTOR OF THE
DEPARTMENT OF PESTICIDE REGULATION
STATE OF CALIFORNIA

In the Matter of the Registration of
BromMax, Registration Number 63838-3
Request for Determination and Cancellation

DIRECTOR'S DETERMINATION
Docket No. D-07-002

Albemarle Corporation, Data Owner
451 Florida Street
Baton Rouge, Louisiana 70801-1765

Enviro Tech Chemical Services, Inc.
500 Winmoore Way
Modesto, California 95358

Procedural Background

Food & Agricultural Code (FAC) section 12811.5 sets forth a statutory scheme that requires an applicant for a pesticide product registration to pay, in specified situations, a share of the cost incurred by a prior registrant of a similar product for data required to support the registration of that product or to maintain the product's registration. The statute requires that an applicant for the registration of a pesticide product who does not submit its own data to meet a data requirement of the Director, or have written permission from the owner of data already on file with the Department that it may be relied upon to fulfill a data requirement, to make an irrevocable offer to pay the data owner a share of the cost of producing the data provided certain criteria are met. If the parties cannot agree upon the amount of payment within 90 days of the offer, the procedures set out in regulations shall be followed to resolve the issue. (FAC section 12811.5(d).) If the applicant does not make such an offer in compliance with the statute, the data owner can seek a finding of the Director that the applicant failed to comply. (FAC section 12811.5(g).) If the Director determines that the applicant failed to make an offer to pay as required by the statute, she must cancel the applicant's registration. (FAC section 12811.5(f).)

By a letter dated September 11, 2007, Albemarle Corporation (Albemarle) requested that the Director determine whether Enviro Tech Chemical Services, Inc. (Enviro Tech) failed to met its obligation under FAC section 12811.5 to make an irrevocable offer to pay Albemarle in connection with Enviro Tech's application for the registration of the product listed above, and to cancel that product's registration if it was so determined. At the same time, Albemarle set forth the basis of its claim that such an offer should have been made, provided documents to support its position, submitted proof that it had notified the applicant of its claim in two letters dated August 13 and August 29, 2007 (with accompanying attachments), and provided the e-mail response of Enviro Tech. Thus, Albemarle satisfied the prerequisite requirements to make a request for a determination set forth in Title 3, California Code of Regulations (3 CCR) section 6312. Both parties submitted written argument and evidence within 30 days of the notice as provided by the statute. (FAC section 12811(g).) The Director is required to issue a written finding on the claim and resulting consequences 60 days from the statutory deadline for submitting evidence and argument of the data owner's request.

Criteria Requiring Data Cost-Sharing

A data owner can demand payment for a share of the cost of producing data from an applicant only if the data was submitted to the Department after January 1, 1991, and meets certain criteria set forth in FAC section 12811.5(a) or (b). Subsection (a) applies to data meeting a current data requirement of the applicant, and subsection (b) applies to data that met a previous data requirement for a similar product. In this instance, the Albemarle data was submitted to meet a requirement for efficacy data to support the biofilm claim made on the labels of its Stabrom 909 Biocide (Registration Number 3377-55) and Sanibrom 40 CA Biocide (Registration Number 3377-25), a requirement that currently exists to support such claims. No data meeting this requirement was submitted by Enviro Tech to support the registration of its BromMax product that is the subject of this request for determination and cancellation, nor did it obtain permission from Albemarle to use its data. Therefore, if such a claim was made by Enviro Tech, the criteria of FAC section 12811.5(a) apply.

After the initial threshold requirements for data cost-sharing (applicant neither submitted data or obtained permission to use data that was submitted after January 1991) are met, FAC section 12811.5(a) lists three additional criteria that must be satisfied. First, the data for which the claimant seeks cost-sharing must have been required by the Director to in order to obtain, amend, or maintain the registration of a product, including a formal reevaluation request for additional data. Second, the data must not be the subject of an arbitration award, data compensation, or data cost-sharing agreement in connection with the federal registration of the applicant's products. Third, the data that fulfills a current data requirement was not submitted to the Department more than 15 years prior to the application for registration placed in issue by the data owner.

Analysis

In this instance, there seems to be no dispute that the efficacy data submitted by Albemarle to support the biofilm claim in connection with the registration of its products meets all three criteria to qualify for data cost-sharing. The real debate seems to resolve around whether the Albemarle data was needed to support the registration of Enviro Tech's BromMax product. Enviro Tech argues that slime is the equivalent of biofilm, so that the addition of a biofilm claim to the amended BromMax product label that already contained a slime claim required no additional efficacy data. This is incorrect. The Department does distinguish between slime and biofilm, and requires data to support each claim. This is evident from the fact that such data was specifically requested from Albemarle to support the biofilm claim on its product labels. Enviro Tech also argues that the fact that the Albemarle products contain the active ingredients sodium bromide (Sanibrom) and bromide chloride (Stabrom), as opposed to the active ingredients sodium hyprochlorite and sodium bromide in the BromMax product, means that the Albemarle data could not have been used to support the registration of the Enviro Tech product. This is also incorrect. In this instance, all three products are bromine-based and produce the active ingredient hypobromous acid in water, either by dilution or activation with an oxidant, that performs the pesticidal activity. Although not critical to this determination,

there is no claim that this fact is not known to Enviro Tech. Enviro Tech has posted on their Web site an Enviro Tech document that states "all three liquid stabilized bromine products on the market today yield the same active ingredient."[1] In fact, the Department has relied on the same data to support the biofilm claims on both the Albermarle products even though the listed bromine-based active ingredients on those products are different.

Thus, data submitted to support the Albemarle biofilm claim on its bromine-based product could be used to support a biofilm claim on the Enviro Tech BromMax label. The issue then becomes whether there was such a claim on the BromMax label. The first paragraph under large bolded "BromMax ™" on the BromMax label describes the product and the primary claims related to the product use. The product is claimed to be "an effective agent for controlling algae and bacterial slime" in condensing and cooling equipment and "can also be used "to control bacteria and algae slime" in decorative fountains, and certain other industrial systems. The portion of the label titled "Directions For Use" then provides separate directions for six specific use categories. Four of these categories carry the limitation "not for use in California." Claims made under these uses would not have to be supported by data to obtain California registration. One of these non-California use categories, "oil and secondary oil recovery systems, drilling muds and packer fluids," contains the language "it also controls biofilm deposits in downhole formations." This is the only biofilm claim on the label made in connection with a specific use. There is, however, a paragraph following the heading "Basic Guidelines" in the "Directions for Use" section that provides general directions on how to achieve the appropriate bromine levels for the desired control in the various uses. The phrase "or as needed to maintain biofilm or microbial control" does appear in this section. A reasonable interpretation of the use of the word "biofilm" in this section is that it relates to the non-California use. Therefore, the label does not contain a biofilm claim that needs to be supported by data for California registration.

While this determination relates only to the BromMax product listed above, both parties have noted that there is another Enviro Tech bromine-based product under consideration for registration in California, BromMax 7.1 (Registration Number 63838-5). Given that fact, it is incumbent upon the Director to note that the label for BromMax 7.1 contains a direct biofilm claim for uses in California that must be supported by data, either submitted by the applicant or on file with the Department.

Conclusion

The information before the Director establishes that Enviro Tech is not required to make an offer to pay Albemarle for the cost of data under FAC section 12811.5(a) in connection with the registration of BromMax (Registration Number 63838-3).

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[1] This is found at <http://www.stabilizedbromine.com/techinfo/index.asp>, "The Technical Bulletin—UV Exposure."

Judicial Review

Under FAC section 12811.5(h), Albemarle can seek court review of the Director's determination within 30 days of the date of the decision pursuant to section 1094.5 of the Code of Civil Procedure.

Dated: 11/28/07

Mary-Ann Warmerdam, Director
Department of Pesticide Regulation