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

In the Matter of the Registration of
InTice 10 Perimeter Bait, Reg. No. 73079-6-AA
Request for Determination and Cancellation

DIRECTOR'S DETERMINATION
Docket No. D-09-002

Nisus Corporation, Data Owner
100 Nisus Drive
Rockford, Tennessee 37853

Rockwell Labs, Ltd., Registrant
1512 Taney Street
North Kansas City, Missouri 64116

Statutory Framework

Food and Agricultural Code (FAC) section 12811.5 requires a pesticide registration applicant to offer to pay, and to pay, a share of the cost of data previously submitted by another registrant of a similar product in specified situations. The applicant must share in the cost of data already submitted to the Department to support the previous registration of a similar product when: (1) the data is required to support the registration of the applicant's product and the applicant does not submit its own data to obtain or support registration; (2) the applicant does not have written permission from the owner of data to rely upon the data to support the applicant's product registration; and (3) the applicant is not a party to an arbitration award, data compensation, or data cost-sharing agreement in connection with the federal registration of the applicant's product that covers use of the data to support California registration. There is no obligation under the statute to pay for data first submitted by the data owner to the U.S. Environmental Protection Agency or the Department more than 15 years prior to the date of the applicant's California registration.

The statute provides that the data owner may seek to enforce the cost-sharing obligation of the applicant by bringing an action in any California court of competent jurisdiction or by seeking a determination by the Director that the applicant did not satisfy its obligation and cancellation of the applicant's product. Subsection (d) through (g) of FAC section 12811.5 establishes the process, requirements, and limitations that govern a claim for cost-sharing and the administrative remedy for a failure to comply. The statute sets out a series of sequential steps that must be followed, and allows the diversion of the process to the Director only if there is a refusal by the applicant to proceed to the next step. The process begins with the applicant identifying the owner of the data that support its registration and making an offer to pay. If the applicant cannot identify the owner of the data, the data owner must inform the applicant that it owns the data relied upon within 12 months of the registration of the applicant's product or the obligation is absolved. Negotiation over the amount of cost that must be shared can continue as long as the parties are willing, but at any time after 90 days either party may initiate a binding arbitration proceeding to resolve the issue. The Director only has authority to find that the applicant has failed to meet its obligation under the statute if it fails to make an irrevocable offer to pay, fails or refuses to participate in a proceeding to reach an agreement, or fails to comply

with an order or to pay an award resulting from the proceeding. If the Director determines that an applicant did not meet these obligations under the statute, the director cancels the registration of the applicant. See FAC section 12811.5(f).

Factual and Procedural Background

On November 18, 2008, Rockwell Labs, Ltd. (Rockwell) applied for registration in California of its product InTice 10 Perimeter Bait (InTice 10). The active ingredient in this Rockwell product is boric acid. Rockwell submitted its own acute toxicity studies to meet California's data requirements, and cited to studies it had previously submitted to the Department in support of its previously registered product InTice Granular Bait, EPA Reg. No. 73079-2, to meet California's requirement for efficacy data. The InTice 10 product was registered by the Department on January 7, 2009, without the submission of efficacy data beyond what it had previously submitted in support of the registration of its InTice Granular Bait product cited in its application.

Following its application for federal registration of InTice Granular Bait in January 2002, Rockwell entered into a settlement of an arbitration initiated under the Federal Insecticide, Fungicide, and Rodenticide Act, section 3(c)(1)(F)(iii) to compensate Nisus Corporation (Nisus) for relying on its studies to support the federal registration of its boric products, including InTice 10. According to Rockwell, it agreed to a negotiated settlement amount, but only agreed to the explicit exclusion from the agreement of the use of the data for California registration after Nisus made it clear that an additional amount would be demanded for California use.[1] Rockwell has represented to the Department that it intended to supply its own data to support the California registration of InTice 10, and its application for registration seems to bear witness to that intent. Rockwell's position in this case is that conversations with the Department's registration specialist handling the InTice 10 application led it to believe that it would be informed if the studies it cited and submitted did not respond to all the data requirements to register its product.

The Nisus petition for cancellation of InTice 10 that is the subject of this determination was received concurrently by the Department and Rockwell on January 6, 2010. This was the first notice Rockwell had of the Nisus claim that Rockwell was obligated to pay Nisus for use of its data in connection with the California registration of InTice 10. Nisus failed to give Rockwell prior detailed notice of its claim for data cost-sharing as required by section 6312(d) of Title 3, California Code of Regulations. Perhaps, if this regulation had been complied with, the need for this proceeding could have been avoided. Apparently it was unknown to Nisus that

[1] Given that federal registration is a precondition to California registration, it can be assumed that the intent and logical consequence of the FAC section 12811.5(a)(2) exemption for data that is the subject of an arbitration following federal registration was to encourage the payment issue for use of data in both forums to be resolved at the same time. In this instance, by agreeing to exclude California use from the settlement, it appears that Rockwell decided to handle the California registration in a manner that would avoid the need to negotiate a further payment to Nisus.

Rockwell had submitted its own studies responding to California's acute toxicity data requirements rather than rely on the Nisus data, and had previously provided efficacy studies on all the target pests listed on the InTice 10 label with the sole exception of slugs and snails.[2] Those two target pests were not on the label of the InTice Granular Bait product referenced for efficacy studies in connection Rockwell's InTice 10 application. On February 12, 2010, in connection with label amendments to both the InTice Granular Bait and InTice 10 products, Rockwell submitted its own efficacy studies for slugs and snails. The snail study submitted by Rockwell is dated July 2006 and the slug study submitted it dated June/July 2007, indicating that they were in Rockwell's possession well prior to the submission of the application to the Department for the registration of its Tice 10 product in November 2008.

Analysis and Conclusion

In order to avoid the data-cost sharing obligations in connection with its InTice 10 registration in California, Rockwell had to submit studies for each of California's data requirements. There are facts in the record that support the conclusion that Rockwell intended to meet each of California's data requirements by providing its own studies. By providing data it had in its possession at the time of its application promptly after its omission was brought to its attention, Rockwell has essentially rendered the claim for cancellation moot. It would not be reasonable or equitable to cancel Rockwell's product based upon this inadvertent failure to provide it own studies, studies that it could have provided at the time of its application. This is even more the case when the applicant submitted its own data responding to all the acute toxicity requirements and to the efficacy requirements for nearly all the target pests on the label.

It should be also be noted that the California statute requires only that an applicant share in the cost of the data and does not incur what can be seen as a broader liability implied by the term "data compensation" at the federal level. The later term may arguably include any benefit to applicant resulting from the applicant's ability to obtain registration earlier than otherwise would have been possible, or other "compensable" benefits. In this instance, Rockwell had already incurred the cost of producing its own studies, removing any competitive detriment to Nisus from having Rockwell register its product without having to incur the same upfront expense incurred by Nisus for the efficacy study types Rockwell initially failed to submit.[3] Further, any order of cancellation would likely be followed by an immediate registration given that all the requirements for registration and would be exempt from any data costs-sharing obligations, thus rendering any such cancellation an empty gesture requiring needless bureaucratic paperwork with no countervailing benefit to Nisus.

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[2] Efficacy studies for the listed target pests ants, roaches, silverfish, crickets, and mole crickets were submitted to the Department in connection with Rockwell's InTice Granular Bait product registration and referenced in connection with the InTice 10 application.

[3] It is true that the studies were provided a year after registration. Perspective it given by the fact that, but for the fact that the Department was aware of a similar product already registered, it would have asked for the missing efficacy data and it would have been provided by the applicant Rockwell.

The Nisus request for cancellation is denied.

Judicial Review

Under FAC section 12811.5(h), Nisus 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: 5 April 2010

Mary-Ann Warmerdam, Director
Department of Pesticide Regulation