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

In the Matter of the Reevaluation of Sulfuryl Fluoride: Request for Determination and Cancellation of Zythor, Reg. No. 81824-1

DIRECTOR'S DETERMINATION
Docket. No. D 13-1

Dow AgroSciences LLC, Data Owner
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

Ensystex II, Inc., Registrant
2175 Village Drive
Fayetteville, North Carolina 28304

Request for Determination

Dow AgroSciences LLC (DAS) has petitioned the Director of the Department of Pesticide Regulation (Department) to cancel the California registration held by Ensystex II, Inc. (Ensystex) for the pesticide product Zythor, Registration Number 81824-1-AA, on the grounds that Ensystex has failed to comply with its obligations under Food and Agricultural Code (FAC) section 12811.5.

Statutory and Regulatory Background

The Legislative intent behind FAC section 12811.5 was to absolve the Department of any responsibility or involvement in resolving issues between applicants and data owners related to data ownership, and encourage parties to take all reasonable steps to resolve their data cost-sharing disputes between themselves before turning to the Director for a determination. (Assem. Bill No. 1011, (2005-2006 Reg. Sess.).)

FAC section 12811.5 requires a pesticide registration applicant to irrevocably offer to pay, and to pay, a share of the cost of producing data previously submitted by another registrant of a similar product in specific situations. A registrant must share in the cost of data already submitted to the Department to support the continued registration of a similar product when the data was required by the Director in order to maintain the continued California registration of a product under a formal reevaluation request for additional information, and the registrant does not submit its own data to support continued registration.

The statute further 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 request cancellation of the applicant's product. Subsections (d) through (g) of FAC section 12811.5 further establish 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 supports its registration and making an offer to pay. 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.

Thus, the Director only has authority to find that the applicant has failed to meet its obligation under the statute if the applicant 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 must cancel the registration of the applicant. (*See* Food & Agr. Code § 12811.5; Cal. Code of Regs., tit. 3, §§ 6310-6314.)

Factual and Procedural Background

On June 25, 2008, under the authority of FAC section 12824 and implementing regulations, the Department issued California Notice 2008-04 entitled, "Notice of Decision to Initiate Reevaluation of Certain Sulfuryl Fluoride Products Intended for Structural Fumigation," to address concerns relating to inhalation exposure by workers, bystanders, and residents to sulfuryl fluoride used in structural fumigations. (DAS Notification of Noncompliance with Food and Agricultural Code Section 12811.5 (DAS 1), Exhibit (Ex.) A.) The reevaluation involved the following three registrants (collectively referred to as "registrants") and pesticide products:

Registrant	Brand Name, Registration Number
Dow AgroSciences LLC	Vikane, Reg. No. 62719-4-ZA
Ensystex II, Inc.	Zythor, Reg. No. 81824-1-AA
Drexel Chemical Company	Drexel Master Fume, Reg. No. 19713-596-AA

Specifically, the Department required the registrants to submit additional data for (1) worker exposure monitoring, including aeration, untarping, and reentry of structures treated at maximum label rates; and (2) residential post-application monitoring, including both instantaneous and continuous air measurements, until measurements are below the level of detection. (*Id.*) During the course of the reevaluation, on October 14, 2009, the Department expanded the data requirements to include monitoring data for multiple-dwelling units to determine if the California Aeration Plan was satisfactory for reducing sulfuryl fluoride levels for larger structures. (DAS 1, Ex. C.)

On July 21, 2008, DAS informed Ensystex that it intended to comply with the Department's reevaluation data requirements solely on its own behalf, and reminded Ensystex of its potential obligations for compensation under FAC section 12811.5 if it chose to rely on DAS'

studies. (DAS 1, Ex. E.) On August 25, 2008, Ensystex informed the Department that it intended to comply with the Department's reevaluation data requirement on its own behalf. On August 26, 2008, DAS also notified the Department that it intended to comply with the Department's reevaluation data requirements solely on its own behalf and that it had notified the other registrants of their potential compensation obligations. (DAS 1, Ex. F.) After failing to complete an adequate study in a time period which was satisfactory to the Department, Ensystex and Drexel Chemical Company (Drexel) informed the Department on January 15, 2013, that they were electing to discontinue efforts to comply with the reevaluation request on their own behalf, and would rely on data generated and submitted by DAS. (DAS 1, Ex. J.) Ensystex also requested the Department to provide it with exact citations to data submitted by DAS for the reevaluation so that Ensystex could determine an appropriate offer. (*Id.*)

On March 13, 2013, the Department issued California Notice 2013-3 entitled, "Notice of Final Decision Concerning Reevaluation of Certain Sulfuryl Fluoride Products Intended for Structural Fumigation." (DAS 1, Ex. D.) The notice stated that based on studies provided by the sulfuryl fluoride registrants, the structural pest control industry developed a new structural aeration plan, called the California Aeration Plan. (*Id.*) The Department found that the California Aeration Plan was sufficiently protective of workers and met the requirements of section 6780(c) of Title 3 of the California Code of Regulations. (*Id.*) As a result, the Department determined that no additional mitigation was necessary and concluded its reevaluation. (*Id.*)

By letter dated April 15, 2013, DAS notified Ensystex of their failure to make an irrevocable offer to pay for data generated and submitted by DAS in response to the Department's reevaluation of sulfuryl fluoride. (DAS 1, Ex. L.) DAS states that Ensystex received this letter on April 16, 2013. (DAS Additional Argument and Evidence in Support of Notification of Noncompliance (DAS 2) at 13.) Ensystex maintains that due to a change of address, it did not receive DAS' April 15, 2013-letter until April 26, 2013. (Ensystex's Response to the DPR Director's Notice to Parties and DAS' Petition for Cancellation (Ensystex) at 3, fn. 2.)

By e-mail dated April 19, 2013, Ensystex informed the Department that although it had originally asked the Department on January 15, 2013, to provide a list of the exact citations to data submitted by DAS for the reevaluation, Ensystex had not received a response from the Department, and was again requesting a list of the relevant citations. (Ensystex, Ex. 2.) On April 22, 2013, the Department provided Ensystex of a list of the following studies: (*Id.*)

DPR Study ID No.	DPR Tracking ID.	Study Title
242458	230168	Sulfuryl Fluoride and Chloropicrin Concentrations in Air During Fumigation, Aeration and Post Clearance of Residential Structures
253882	239864	Sulfuryl Fluoride and Chloropicrin Concentrations in Air During Aeration and Post-Clearance of Residential and Multi-Unit Structures Observed During the Development of the California Aeration Plan

On April 26, 2013, the same day Ensystex asserts they received the DAS April 15-letter informing them of their failure to make an offer to pay, DAS filed their Notification of Noncompliance with Food and Agricultural Code Section 12811.5 and corresponding Petition for Cancellation of California Registration held by Ensystex for the pesticide product Zythor, Registration Number 81824-1-AA, with the Director. (DAS 1.) The petition was simultaneously sent to Ensystex. (*Id.*) By letter dated April 29, 2013, three days after receipt of DAS' April 15-letter notifying them of their failure to make an offer to pay, Ensystex made DAS a formal offer to pay under FAC section 12811.5 for the data submitted by DAS to the Department in support of its reevaluation for sulfuryl fluoride (Ensystex at 4-5; Jacobs Declaration in Support of DAS Petition (Jacobs Decl.) at ¶ 13.)

On April 29, 2013, the Department issued its Notice to Parties in this matter, informing both DAS and Ensystex that they had 30 days to submit evidence and written arguments for the Director to make a determination on DAS' request for determination and cancellation of the pesticide product Zythor. Both parties submitted written evidence and arguments in support of their positions to the Department on May 28, 2013. (*See* DAS 2 and Ensystex.)

The Director's Analysis

The cornerstone issue in this case is whether under FAC section 12811.5, Ensystex made a valid irrevocable offer to pay DAS on April 29, 2013, to share in the cost of producing the data required by the Department's formal reevaluation of sulfuryl fluoride. In its petition to cancel, DAS argues that Ensystex's offer was untimely, and that the integrity of the Department's reevaluation process is in jeopardy if the Department declines to cancel. In response, Ensystex argues that the Department should deny the petition to cancel because Ensystex made the required irrevocable offer to pay on April 29, 2013, shortly after it received notification from DAS of its failure to make an offer. For the reasons that follow, the Director finds that Ensystex made a valid offer to pay under FAC section 12811.5 and denies the petition for cancellation.

A. The Director lacks the authority to cancel under FAC section 12811.5 and implementing regulations because Ensystex made a valid offer to pay.

DAS' main contention in this case is that Ensystex's product registration should be cancelled because Ensystex made an untimely offer to pay under FAC section 12811.5 and its implementing regulations. Specifically, DAS argues that Ensystex was required to make an offer to pay either when it notified the Department that it was relying on DAS' data for the reevaluation; before a petition is filed with the Director; or at least within the ten day "cure period" after a registrant receives notification of noncompliance. (*See* DAS 2 at 15-17.) However, contrary to DAS' assertions, there are no deadlines in statute or regulation for making an offer to pay in the case of a formal reevaluation. As stated above, the Director only has authority to cancel under FAC section 12811.5 if he finds that an applicant or registrant fails to make an offer to pay; refuses to participate in a proceeding to reach an agreement; or fails to comply with an agreement or order to pay an award. Outside of these specific circumstances, the Director lacks the authority to cancel under FAC section 12811.5. In this case, Ensystex met its obligations under the statute by making an offer to pay on April 29, 2013. As a result, the Director lacks the authority to cancel and this petition must be denied.

First, DAS argues that Ensystex's offer to pay was untimely because FAC section 12811.5(d) imposes a "temporal requirement" that an offer to pay be made "upon application to the department," which DAS contends is January 15, 2013, the date Ensystex informed the Department that it had chosen to rely on DAS' data for the reevaluation. (DAS 2 at 15-16.) The statute, however, describes a situation in which an applicant or source makes an application to the Department to register a pesticide product using another's data. (Food & Agr. Code § 12811.5, subd. (d); *Syngenta Crop Protection v. Helliker* (2006) 138 Cal.App.4th 1135, 1159.) Here, all products were already registered with the Department and data was only submitted in response to a reevaluation request for additional information. As a result, there is no relevant date Ensystex made an "application" to the Department. The only requirement imposed by FAC section 12811.5(a), is that an irrevocable offer to pay a share of the cost of producing the data be made to the data owner. Ensystex made this offer to pay on April 29, 2013, and therefore satisfied its obligation under the statute.

Next, DAS argues that Ensystex's offer to pay was untimely because it failed to comply with the ten-day, "cure period" set forth in section 6312(d) of Title 3 of the California Code of Regulations. (DAS 2 at 17.) DAS' interpretation is misguided. Section 6312(d) states that in notifying the Director of a registrant's noncompliance, the data owner must "allow[] the applicant an opportunity of at least ten days to promptly make an offer to pay for the data that serves as a basis of the data owner's claim." (Cal. Code of Regs., tit. 3, § 6312, subd. (d).) It is clear from a plain reading of the regulation that the purpose is to provide a registrant advance notice of their specific noncompliance and give them a final opportunity to make an offer to pay

before the matter is turned over to the Director for a determination. The ten days is not a deadline for Ensystex, but a requirement that DAS must meet before submitting a request to the Director. Further, any other intent to this provision would have logically required a statement of the specific consequence for failing to make an offer within the ten-day period.

Moreover, even under DAS' theory that California law imposes a ten-day deadline for a party to submit an offer to pay, under the facts of this case, Ensystex's offer was timely. Section 6312(d) states that the data owner must "allow[] the applicant *an opportunity* of at least ten days to promptly make an offer to pay." (Cal. Code of Regs., tit. 3, § 6312, subd. (d) (emphasis added).) In order to have *an opportunity,* the ten days must run from the date the registrant *receives* the letter informing them of their failure to comply with FAC section 12811.5. Here, DAS states that it sent a letter dated April 15, 2013, via Federal Express, to Ensystex notifying them of their failure to make an offer to pay. (DAS 1, Ex. L.) DAS also submits evidence that this letter was delivered on April 16, 2013, making the ten day deadline April 26, 2013. (*Id.*) However, in its submission, Ensystex informs the Department that "[b]ecause DAS' April 15, 2013 letter was sent to an old address, Ensystex did not receive DAS' letter until April 26, 2013."[1] (Ensystex at 3, fn. 2.) Based on the date Ensystex says it *received* DAS' letter, the ten day period would have expired on May 6, 2013. Both parties agree that by letter dated April 29, 2013, Ensystex made an irrevocable offer to pay DAS for studies associated with the reevaluation of sulfuryl fluoride. Accordingly, even under DAS' flawed theory regarding the ten-day deadline imposed by California regulations, Ensystex made a timely offer to pay.

Finally, DAS argues that if the Department declines to cancel Zythor, it will demonstrate that there are no real deadlines or consequences for a registrant who fails to make an offer to pay. (DAS 2 at 5, 17.) DAS' argument, however, fails to consider the process outlined in statute and regulation to address noncompliance. (*See* Food & Agr. Code § 12811.5, subd. (g); Cal. Code of Regs., tit. 3, § 6314.) Once a data owner notifies the Director of noncompliance and provides proof that they notified the registrant of its claim, all parties have 30 days from the date they receive the Director's notice to submit written arguments and evidence. (*Id.*) The Director is then required to provide a written finding within 60 days of the deadline for the parties' submission. (*Id.*) As a result, from the point in time in which a party receives notification from the Director to submit evidence and written argument, a data owner would have to wait at the very most, 90 days, to receive a determination from the Director. If the Director determines that the registrant has not met its obligations under FAC section 12811.5, the Director must promptly cancel the registrant's product registration. (Cal. Code of Regs., tit. 3, § 6314.) Therefore,

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1 The Department's own experience supports Ensystex's claim of delayed receipt. The Department's April 29, 2013-Notice to Parties, sent by certified mail to 2709 Breezewood Avenue, Fayetteville, North Carolina, 28302-2587, the same address DAS sent their Notification of Noncompliance, was returned to the Department on May 12, 2013, for the reason that it was "not deliverable as addressed – unable to forward."

contrary to DAS' contention, a registrant who completely fails to comply with the requirements of FAC section 12811.5 faces real deadlines and real consequences.

In sum, the Director only has authority to cancel under FAC section 12811.5 if he finds that an applicant or registrant fails to make an offer to pay; refuses to participate in a proceeding to reach an agreement; or fails to comply with an agreement or order to pay an award. Ensystex made a valid offer to pay DAS on April 29, 2013, for the data associated with the sulfuryl fluoride reevaluation. Accordingly, DAS' petition must be denied.

B. DAS' argument that the Department's failure to cancel the registration of Zythor will jeopardize the integrity of the reevaluation process, is without merit.

DAS contends that Ensystex's failure to submit an offer to pay until after the reevaluation was concluded and a petition to cancel was filed "undermines the system for reevaluation." (DAS 2 at 19.) Specifically, DAS argues that Ensystex's failure to "seriously discuss with other registrants how DPR's data requirements were to be satisfied" before studies were conducted (DAS 2 at 18), and failure to "provide the financial commitment at a time when it is meaningful" (DAS 2 at 20) diminishes the effectiveness of the reevaluation process. However, the logistical problems identified by DAS in their petition are completely irrelevant to the Department's reevaluation process and goals. The Department's sole purpose of placing a pesticide into reevaluation is to obtain additional data to determine the nature or extent of a potential hazard or identify additional mitigation, if appropriate. (Cal. Code of Regs., tit. 3, §§ 6220-6224.) Registrants either comply with the requirements of the reevaluation or FAC section 12811.5, or face the potential cancellation of their product(s). (Food & Agr. Code §§ 12811.5; 12825, subd. (h).) As aptly stated by DAS, "the compulsory nature of the process – when DPR requires all registrants *to participate* or risk cancellation under Section 12825 – is a key factor that makes the reevaluation system work." (DAS 2 at 4 (emphasis added).)

Here, the system worked exactly as it was intended. The Department's risk assessment identified several scenarios where exposure to sulfuryl fluoride was a potential concern and requested registrants to provide additional data or be subject to potential cancellation. (DAS 1, Ex. A.) One month later, DAS informed the other registrants that it intended to comply with the data requirements solely on its own behalf and reminded them of their obligations under FAC section 12811.5 if they chose to rely on DAS' data. (DAS 1, Ex. E.) DAS submitted the required data to the Department and on March 13, 2013, the Department concluded that it had all the necessary information, no additional mitigation was necessary at this time, and closed its reevaluation. (*See* DAS 1, Ex. D.) Subsequent to DAS' notification to its co-registrants of their failure to comply with FAC section 12811.5, both Drexel and Ensystex made the requisite offers to pay a share of the cost of producing the data. (DAS 2, Ex. 1; Ensystex at 4; Jacobs Decl.

at ¶ 13.) Each registrant faced the real threat of cancellation of their individual product if they did not *participate* in the reevaluation process. DAS, Drexel, and Ensystex all *participated* in the reevaluation process; whether it was by submitting their own data or relying on another registrant's data and making the requisite offer to pay. Thus, contrary to DAS' assertions, this case confirms and reinforces the integrity of the reevaluation process.

C. DAS's statutory rights are protected and the intent of FAC section 12811.5 was fulfilled.

As previously stated, the Legislative intent behind FAC section 12811.5 was to eliminate the Department's involvement in data cost sharing disputes and encourage parties to resolve their issues on their own before turning to the Director for a determination. (Assem. Bill No. 1011, (2005-2006 Reg. Sess.).) On April 29, 2013, Ensystex made an offer to pay DAS for a share of the cost of producing the studies required by the sulfuryl fluoride reevaluation. Under California regulations, if, after 90 days from the issuance of Ensystex's irrevocable offer to pay, DAS believes that the negotiations are not fruitful, the remedy is to initiate binding arbitration proceedings. (Cal. Code of Regs., tit. 3, § 6310.) Unless Ensystex refuses to negotiate or participate in an arbitration process initiated by DAS, or refuses to comply with an order or award resulting from those proceedings, the Director has no basis upon which to cancel the registration of Zythor. Accordingly, DAS' request for determination and cancellation is premature. Because Ensystex made a valid offer to pay DAS on April 29, 2013, there is no basis for the Director to cancel Ensystex's registration of Zythor at this time.

Conclusion

Based on the evidence before the Director, the Director denies DAS' request for determination and cancellation.

Judicial Review

Under Food and Agricultural Code, section 12811.5(h), DAS can seek judicial review of the Director's decision within 30 days of the date of the decision under section 1094.5 of the Code of Civil Procedure.

STATE OF CALIFORNIA
DEPARTMENT OF PESTICIDE REGULATION

Dated: JUL 10 2013

By: _____ for
Brian Leahy, Director
Department of Pesticide Regulation