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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
CHAMPON 100% NATURAL PRODUCTS, INC.,	)	DOCKET NO. FIFRA-98-H-13
	)	
RESPONDENT	)	

ORDER GRANTING MOTION FOR ACCELERATED DECISION AS TO LIABILITY

The complaint in this proceeding under Section 14(a)(1) of the Federal Insecticide, Rodenticide and Fungicide Act, as amended, 7 U.S.C. § 136l(a)(1), issued on September 30, 1998, charged Respondent, Champon 100% Natural Products, Inc. (Champon) with two counts of violating Section 12(a)(2)(Q) of the Act in that certifications, which were allegedly submitted to the Agency on June 27, 1996, and August 26, 1996, to the effect that product chemistry studies submitted to support registration of an insect control concentrate known as "Nature's Cide" (EPA Reg. No. 61966-4), conformed to Good Laboratory Practice Standards ("GLPS"), codified at 40 C.F.R. Part 160, were false.(1) Among the ways in which the studies allegedly failed to conform to GLPS were the lack of an approved written protocol clearly indicating the objectives and methods of the studies, the fact that the final report did not contain a description of all circumstances that may have effected the integrity of the studies in that raw data viewed at the laboratory contained analytical results not reported to EPA, and the fact that all data generated during the conduct of the studies were not recorded in ink. For these alleged violations, it was proposed to assess Champon a penalty of $5,000 for each count or a total of $10,000.

Under date of October 21, 1998, Champon served an answer, signed by its President, Mr. Louis Champon, which was apparently delayed in the mail, as it bears the Hearing Clerk's file stamp of November 4, 1998. Among other things, Champon pointed out that the analyses at issue were of the active ingredient Allyl Isothiocyanate, that the analysis was conducted by ADD Testing & Research (ADD), an analytical company used by the food industry, that Allyl Isothiocyanate is from mustard oil

used as a flavoring ingredient in the food industry, that the ADD analysis was conducted prior to the product's registration, that Champon has since submitted to EPA a new analysis by an EPA-approved laboratory, that Champon's background is in the food industry, that Champon had no intention other than to submit to EPA proper analyses of the active ingredients of its product, that Champon has done everything possible to promote a food-grade, safe, biodegradable, effective pesticide, and that Champon had taken all precautions to ensure that the analyses were conducted according to FDA "Good Manufacturing Practice" [standards] of 21 C.F.R. Part 110 applicable to food materials which includes Allyl Isothiocyanate. Champon stated that it was not denying the charges, but denied that [the inaccurate certifications] were submitted purposefully and with full knowledge [of all the facts]. Champon alleged that its total sales were less than $100,000 a year, denied that it had sold any of the product at issue, and stated that it intended to do so [beginning] early next year.(2)

The parties have exchanged prehearing information in accordance with an order of the ALJ. Because financial information submitted by Champon indicated that it belonged in sales Category III (sales of $0 to $300,000) of the Enforcement Response Policy (ERP) rather than in sales Category I (sales over a $1,000,000) as assumed at the time the complaint was issued, Complainant filed a motion on February 19, 1999, to amend the complaint so as to reduce the proposed penalty from $5,000 for each of the two alleged violations of Section 12(a)(2)(Q) to $3,000 and from a total of $10,000 to $6,000. This motion was granted by an order, dated February 25, 1999.

On February 17, 1999, Complainant filed a motion for an accelerated decision as to liability (Motion). The motion recites incorrectly that the complaint charges Champon with two counts of violating FIFRA § 12(a)(2)(Q) for failing to comply with GLPS codified at 40 C.F.R. Part 160. In fact, FIFRA § 12(a)(2)(Q) makes it unlawful "to falsify all or any part of any information relating to the testing of any pesticide.....submitted to the Administrator" and, as indicated above, the gravamen of the offenses is that the certifications, which were allegedly submitted to the Agency on June 27, 1996, and August 26, 1996, to the effect that studies submitted in support of the registration of "Nature's Cide" were conducted in accordance with GLPS, were false.(3) The complaint makes this clear, providing that the violations charged are the submission of false compliance statements (Id. ¶¶ 25 & 45).

Although it appears to be clear that a study was submitted to the Agency on June 27, 1996, and that a study was submitted to the Agency on August 26, 1996, the Statements of Janet L. Anderson, Director Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, dated May 19, 1998, indicate that both submissions were of a study completed by ADD Testing & Research, Inc. on June 12, 1996 (Motion, Exh. 4). Moreover, there is only one fully executed compliance statement in the record, that is, the statement signed by Mr. Champon on June 21, 1996 (Motion Exh. 3). This raises the issue of whether the complaint properly contains two counts, because, as indicated above and as the complaint makes clear, the gravamen of the offenses charged is the submission of false compliance statements. If, in fact, there was only one compliance statement, one count rather than two would be proper.(4)

The motion alleges that Champon's defenses set forth in its answer fail to raise a genuine issue of material fact and that Champon should be found liable for the violations alleged in the complaint and as admitted in its answer. Complainant sets forth the standard for the issuance of an accelerated decision under Rule 22.20 (40 C.F.R. Part 22), i.e., the absence of a genuine issue of material fact and that a party is entitled to judgment as a matter of law as to all or any part of the proceeding (Motion at 1, 2). Complainant points out that a "material" fact is one that may affect the outcome of the litigation and that a dispute concerning a material fact is "genuine" only if there is sufficient evidence from which a reasonable decision maker could rule in favor of the non-moving party, citing, inter alia, Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986); Matsuishita Electrical Industrial Co. v. Zenith Radio Corp., 475 U.S. 574 (1986); and Celotex Corp. v. Catrett, 477 U.S. 317 (1986). Complainant further points out that the rationale of these decisions applying Rule 56 of the Federal Rules of Civil

Procedure concerning summary judgment have been held applicable to motions for accelerated decision and other pleadings under the Consolidated Rules of Practice. Green Thumb Nursery, Inc., FIFRA Appeal No. 95-4a, 6 E.A.D. 782 (EAB, March 6, 1997).

Factually, Complainant emphasizes that Champon has either admitted in its answer or failed to deny that it is a corporation and a person within the meaning of FIFRA, that it is located within the State of Florida, that it submitted the two product chemistry studies at issue in support of the registration of "Nature's Cide" (EPA Reg. No. 61966-4), that it was the sponsor of the studies and that it certified that these studies were performed in accordance with GLPS.[(5)] As support for the allegations that the studies were not conducted in accordance with GLPS, Complainant relies on a Study Audit Report of ADD Testing & Research, Inc., the firm conducting the studies, dated October 23, 1966 (C's Prehearing Exh. 1). Complainant also relies on the statement in Champon's answer that it "...does not deny the charges." (Answer ¶ 22)

Complainant asserts that FIFRA is a strict liability statute and that the matters raised in Champon's answer, recited in the opening paragraphs of this order, are immaterial to whether it violated FIFRA § 12(a)(2)(Q) (Motion at 8-10). Complainant says that it has met all of the requirements for an accelerated decision as to liability in its favor and that its motion should be granted.

Champon has not responded to the motion.

Discussion

On the merits, Champon does not dispute that the product chemistry study or studies submitted to EPA in support of the registration of the product "Nature's Cide" were not conducted in accordance with GLPS in several respects, at least some of which have been detailed above. While Complainant's assertion that FIFRA is a strict liability statute is overly broad in that effect must be given to the language of the specific paragraph of Section 12 which has allegedly been violated,[(6)] there can be little doubt that no showing of intent is necessary to establish a violation of Section 12(a)(2)(Q). This follows from the fact that the words "known," "knowingly," or words of similar import do not appear in Section 12(a)(2)(Q) and from the fact that these words do appear in Sections 12(a)(2)(M) and 12(a)(2)(R), making it clear that where intent is considered a necessary element of a violation, Congress knew how to accomplish that result.

In view of the foregoing, it follows that the defenses raised in Champon's answer are not defenses to the violations alleged in the complaint and that Complainant is entitled to have its motion for a finding of liability granted. This is not to say, however, that these defenses are not relevant to the amount of the penalty, if any. For example, Champon alleges that its background is in the food industry and that because the active ingredient or one of the active ingredients in Nature's Cide is Allyl Isothiocyanate, a component of oil of mustard used in the food industry, it assumed that studies conducted in accordance with standards set forth by the FDA, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (GMS), 21 C.F.R. Part 110, would be adequate. The product chemistry studies at issue were indeed conducted on samples of Allyl Isothiocyanate and Champon's assertion is supported at least in part by the fact that the Good Laboratory Practice Statement, signed by Champon's President on June 21, 1996 (Motion, Exh. 3), contains a printed statement "This study was performed in conformance with the Good Laboratory Practice Standards as outlined in the requirements of 40 CFR Part 160" with the following handwritten addition "and FDA regulations". This is evidence of good faith which tends to support the conclusion that the gravity of the misconduct, if any, was slight.[(7)] Moreover, the principal active ingredient of "Nature's Cide" is Allyl Isothiocyanate, a substance acceptable for use in foodstuffs, and because the Agency has accepted subsequent product chemistry studies by another laboratory, the gravity of the harm or potential harm is also slight. Under these circumstances, it is not apparent that any alleged harm to the regulatory program warrants a substantial penalty. See, e.g., Predex Corporation, FIFRA Appeal No. 97-8 (EAB, May 8, 1998) (butyric acid used in ear tags on lambs

and calves intended to mask their natural odors and make it less likely they would be located by predators).

Order

_Complainant's motion for an accelerated decision as to liability in that Champon violated FIFRA § 12(a)(2)(Q) by submitting a false compliance statement in at least one instance is granted. Whether there were two compliance statements and thus whether two counts are proper is not decided on this record.[(8)] The amount of the penalty, if any, remains at issue and will be decided after a hearing currently scheduled to be held in Delray Beach, Florida on April 20, 1999.

Dated this 18th _day of March 1999.

Original signed by undersigned

_____
Spencer T. Nissen
Administrative Law Judge

1. The Notice of Conditional Registration, dated November 22, 1996 (C's Prehearing Exh. 9), reflects that the name of the product is "Insect Control Concentrate".

2. Although Champon did not expressly request a hearing, the complaint provides that the denial of any material fact or the raising of any affirmative defense will be considered a request for a hearing.

3. The regulation contemplates the submission of studies which were not performed in accordance with GLPS upon the condition that differences between practices used in the studies and GLPS are described in detail (40 C.F.R. § 160.12). The regulation also allows the submission of a statement that the submitter was not the sponsor of the study and does not know whether it was conducted in accordance with GLPS (Id.).

4. It is recognized that an argument could be made that where a single compliance statement refers to, or is submitted in connection with multiple studies, it would be reasonable to consider the compliance statement applicable to each study and, thus in effect, there are as many compliance statements as there are studies.

5. Motion at 5-8. Consolidated Rule 22.15(d) provides that "(f)ailure of respondent to admit, explain, or deny any material factual allegation contained in the complaint constitutes an admission of the allegation." Champon is not represented by counsel and I decline to hold that Champon has admitted that the complaint properly alleges two violations of FIFRA § 12(a)(2)(Q).

6. For example, Section 12(a)(2)(M) makes it unlawful for any person "...to knowingly falsify [inter alia] all or part of any application for registration, application for experimental use permit, ...any records required to be maintained by this subchapter, ..." See Helena Chemical Company, FIFRA Appeal No. 87-3, 3 E.A.D. 26 (CJO, November 16, 1989), on Motion for Reconsideration, 3 E.A.D. 83 (January 24, 1990) (no evidence of intent was necessary to establish that the sale of a restricted use pesticide to a noncertified applicator was a violation of Section 12(a)(2)(F), while inclusion of the word "knowingly" in Section 12(a)(2)(M) made such a showing necessary to establish that falsifying records was a violation of that section). See also Section 12(a)(2)(R) which makes it unlawful for any person to submit to the Administrator data "known" to be false in support of a registration.

7. FIFRA § 14(a)(4) provides that in determining the amount of any penalty, the Administrator shall consider the appropriateness of the penalty to the size of the business of the person charged, the effect [of the penalty] on the person's ability to continue in business, and the gravity of the violation. "Gravity of the violation" is considered from two aspects: gravity of the misconduct and gravity of the harm or potential harm.

8. Complainant is directed to submit a pretrial memorandum on or before April 2, 1999, addressing the issue of whether the second count of the complaint is proper.