

12/20/92

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of )  
 )  
Farmers Elevator ) Docket No. I.F. & R.-VII-1175C-  
& Supply Co., Inc., ) 92-P  
 )  
Respondent )

ORDER ON CROSS MOTIONS FOR ACCELERATED DECISION

The complaint in this proceeding was issued by the United States Environmental Protection Agency, Region VII on July 14, 1992, pursuant to section 14 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 1361. Respondent, Farmers Elevator and Supply Company, Inc., is charged with selling a misbranded pesticide, in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E). The penalty proposed for the violation is \$5,000.

Specifically, Respondent is alleged to have sold one container of Quick-Phos Aluminum Phosphide Fumigant Pellets ("Quick-Phos" or "product"), a Restricted Use Pesticide, to a person, Mr. James Swaters, on or about February 1, 1991. The product is claimed to be misbranded because the labeling accompanying the product did not

contain directions for use which are necessary for effecting the purpose for which the product is intended, and if complied with, together with any requirements imposed under section [3(d) of FIFRA], are adequate to protect health and the environment.

FIFRA § 2(q)(1)(F). The label of Quick-Phos which accompanied the product states in part:

For retail sale and use only by Certified Applicators for those uses covered by the applicator's certification or persons trained in accordance with the attached product manual working under the direct supervision and in the physical presence of the Certified Applicator on site or on the premises. Read and follow the label and the Quick-Phos product manual which contains complete instructions for the safe use of this pesticide. (C's Exh 4).

According to the complaint, the product manual was not supplied with the container of the product sold to Mr. Swaters at the time of the sale. It is further alleged that placards required to be posted following application were not supplied to Mr. Swaters at the time of sale.<sup>1/</sup>

Respondent answered the complaint by an undated letter from Mr. Jerry Helmick, Manager of Farmers Elevator and Supply Co., which merely requested a hearing. Thereafter, under date of December 18, 1992, present counsel entered an appearance on behalf of Respondent, and filed an amended answer. The answer denied the allegation that the product was misbranded, alleged that the complaint failed to state a claim upon which relief can be granted, and denied the appropriateness of the proposed penalty.<sup>2/</sup> The

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<sup>1/</sup> According to documents in Complainant's prehearing exchange, application of the product to a milo bin at Mr. Swaters' farm resulted in exposure of two persons to fumes from the product, requiring their hospitalization. (Complainant's Prehearing Exchange, Exhs 2, 3, 10.)

<sup>2/</sup> Respondent did not include a motion to amend the answer as required by 40 C.F.R. § 22.15(e). However, no objection having been made by Complainant, to avoid unnecessary delay, the amended answer will be treated as if a motion to amend the answer had been properly filed, and is accepted into the record.

parties have filed prehearing exchange documents in accordance with an order of the ALJ.

Under date of July 15, 1993, Respondent filed a motion for accelerated decision and a supporting memorandum (Motion) pursuant to 40 C.F.R. § 22.20 of the Consolidated Rules of Practice, alleging that no genuine issues of material fact exist and that Respondent is entitled to judgment as a matter of law.<sup>3/</sup> Complainant opposed the Motion, requesting a ruling in its favor and an order assessing the amount of the penalty demanded in the complaint (Cross Motion, July 30, 1993).

Respondent has admitted all elements of the alleged violation except that it denies that the product was misbranded as that term is defined in FIFRA. Respondent claims that the label on the container of Quick-Phos provided sufficient directions for use to meet the standard of section 2(q)(1)(F) of FIFRA. The label provides that at least two trained persons must be present when the product is mixed or applied within a space to be fumigated or during reentry into a fumigated aerated site. Additionally, the label requires inspection and monitoring of the application site, the wearing of dry gloves when handling unpackaged tablets or

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<sup>3/</sup> 40 C.F.R. § 22.20 provides as follows, in pertinent part:

The Presiding Officer, upon motion of any party . . . may at any time render an accelerated decision in favor of the complainant or the respondent as to all or any part of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law, as to all or any part of the proceeding.

pellets, prohibits application of the fumigant in trucks, vans and similar transport vehicles while on public roads or highways, and contains specific admonitions to read and follow the Quick-Phos product manual.<sup>4/</sup>

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<sup>4/</sup> In addition to the portion of the label quoted previously, the label under "Directions For Use" provides:

"It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

The fumigant is a highly hazardous material and may only be used by individuals trained in its proper use. Before using, read and follow all precautions and directions on the label and in the product manual. See Product manual for QUICK-PHOS. Applicator's Manual for complete use directions available from PHOS-FUME CHEMICAL COMPANY, INC., 12700 W St., Overland Park, KS 66210.

At least two trained persons must be present when the product is applied from within a space to be fumigated or during reentry into a fumigated or partially aerated site.

Prior to applying this product, you must inspect the site to be fumigated to determine if it can be made sufficiently gas tight. You should also develop a plan for monitoring (if not done before) how to most efficiently and safely apply the fumigant, emergency procedures, etc. Notify appropriate company employees and provide relevant safety information annually to local officials having jurisdiction (fire department, rescue squad, police, etc.) over the fumigation site.

Follow all local and state regulations. Take or read applicator's manual.

Shipholds, barges, containers on ships, railroad cars and containers shipped piggyback by rail may be fumigated in transit. However, trucks, vans trailers and similar transport vehicles cannot be moved over public roads or highways until the fumigation is completed.

Do not fumigate commodities with this product when commodity temperature is below 40°F (5°C).

Protective Clothing. Wear dry gloves when handling unpackaged tablets or pellets. Wash hands thoroughly after use before smoking or eating.

Respondent argues that the product manual was not required to be attached to the product. Respondent cites the following provision of the regulations:

Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that: (a) (i) if required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide or placed within the outside wrapper or bag.

40 C.F.R. § 156.10(i)(1)(ii). Respondent contends that EPA did not require the product manual to be physically attached to the product.

Respondent argues that the instruction on the label to read and follow the product manual, together with the availability of the manual, including on the label the address of the company producing the manual, satisfies the requirement of section 2(q)(1)(F). That is, the label coupled with the availability of the manual meets the statutory requirement.

Respondent also argues that EPA's failure to require the product manual to be physically attached to the product estops EPA from asserting that the manual must be delivered with the product. Respondent asserts that in registering the product under FIFRA, EPA approved the label on Quick-Phos and did not require physical attachment of the product manual. Respondent claims it relied upon that action to believe that the label was sufficient to meet the standards of FIFRA. According to Respondent, EPA is bound by its approval of the label or labeling, even if it is insufficient, and is estopped from enforcing an alleged defect.

Opposing the Motion, Complainant contends that the seller is responsible for providing all directions for use to the user. The Quick-Phos label did not contain complete directions for use, as evidenced by the manufacturer printing the manual and referring to it on the label. According to Complainant, if part of the instructions for use are put in a manual, the seller is responsible for transmitting the manual with the pesticide at the time of sale. The manufacturer's statement on the label that manuals are available from the product manufacturer does not exempt the seller from its obligation, Complainant argues.

Complainant requests a ruling in its favor on the issue of liability, and requests that the penalty proposed in the complaint be assessed against Respondent.

#### D I S C U S S I O N

The question presented is whether the Quick-Phos label, containing instructions to read the product manual and an address to obtain the manual, meets the requirements for labeling the product with directions for use under FIFRA. Clearly it does not.

Labeling, in general, includes the labels and all written, printed or graphic matter, accompanying the pesticide or to which reference is made in the label or in literature accompanying the pesticide. FIFRA § 2(p)(2)(B).<sup>5/</sup> However, the statute

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<sup>5/</sup> In contrast, the term "label" refers to the "written, printed or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." FIFRA § 2(p)(1). Certain items are required to appear on the label, and others are required to be contained in the labeling.

specifically requires that adequate directions for use be contained in labeling which accompanies the product. Section 2(q)(1)(F) of FIFRA states that "A pesticide is misbranded if . . . the labeling accompanying it does not contain directions for use which are . . . adequate to protect health and the environment."

The federal regulations implementing FIFRA provide in pertinent part as follows:

Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

40 C.F.R § 156.10(i)(1)(ii).

While it does not appear that EPA expressly required that directions for use be securely attached to each package of the pesticide, the label of Quick-Phos refers to "the attached product manual" and there can be no doubt that EPA and the registrant intended that the product manual be attached or at least accompany the product. (C's Prehearing Exchange, Exh 4).

In addition, the label included the following instruction under the heading "Directions For Use":

Before using, read and follow all precautions and directions on the label and in the product manual. See Product manual for QUICK-PHOS. Applicator's Manual for complete use directions available from PHOS-FUME CHEMICAL COMPANY, INC.

(supra note 4). Similarly, the front panel of the Quick-Phos container instructs to "Read and follow the label and the Quick-Phos product manual which contains complete instructions for the safe use of this pesticide." (ante at 2). The directions for use on the label are explicit in acknowledging that only the product manual contains complete directions for use.

Quick-Phos is a registered pesticide, and therefore EPA has determined that its labeling complies with the statutory requirements. FIFRA § 3(c)(5)(B). The product manual, and the assertions on the label that the product manual contains complete instructions for use and is attached to the product were approved by EPA as part of the labeling of Quick-Phos. EPA thus approved the Quick-Phos labeling as including directions for use in the product manual attached to or accompanying the product. A sale of the product without the accompanying product manual is not in conformity with the approved labeling.

Because EPA's approval of the labeling is based on the directions for use being contained in an attached product manual, Respondent's estoppel argument fails. EPA cannot be estopped from enforcing the statutory and regulatory requirement that the directions for use in the product manual accompany the product.

Respondent points out that the label on the product contained some directions for use, but it does not claim that the label alone



(i.e., without obtaining the product manual) contained directions for use which are adequate under the applicable standards. FIFRA § 2(q)(1)(F); see also, 40 C.F.R §§ 156.10(i)(1)(i) and (2). The label on the Quick-Phos container was the only labeling accompanying the product which included directions for use. Because the EPA approved label contemplated that the manual accompany the product, it is clear that the container label did not include adequate directions for use. For example, the label on the container does not appear to include sites of application, target pests, the dosage rate and the frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment, as required by 40 C.F.R. § 156.10(i)(2) (Id.).

Section 12(a)(1)(E) of FIFRA provides that it is a violation for any person to distribute or sell to any person any pesticide which is adulterated or misbranded. It is undisputed that Respondent sold a container of Quick-Phos to Mr. Swaters which did not include the product manual. The labeling accompanying the container did not include adequate directions for use. Therefore the container of Quick-Phos was misbranded as defined in section 2(q) of FIFRA. It is concluded that no genuine issues of material fact exist with respect to the issue of liability, and as a matter of law, Respondent sold a pesticide which was misbranded, which is unlawful according to section 12(a)(1)(E) of FIFRA.

A civil penalty may be assessed for the violation under section 14(a)(1) of FIFRA. Respondent has, however, denied that

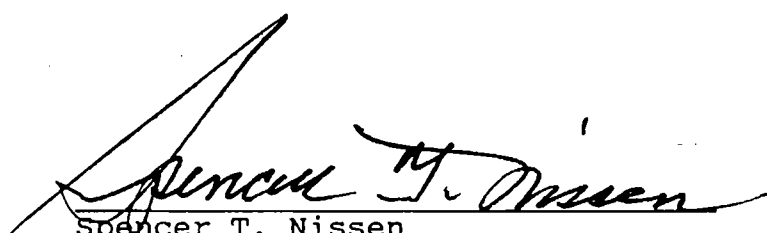
the proposed penalty is appropriate and requested a hearing. The mere fact that the penalty was allegedly calculated in accordance with the FIFRA Enforcement Response Policy may not deprive Respondent of the right to a hearing conferred by FIFRA § 14(a)(3) and the Rules of Practice (40 C.F.R. § 22.15). Complainant's request for an order assessing the penalty demanded in the complaint will be denied.

O R D E R

Respondent's motion for an accelerated decision dismissing the complaint is denied. Complainant's motion for an accelerated decision on the issue of liability is granted. Complainant's motion for an order assessing the amount of the penalty demanded in the complaint is denied.

The amount of the penalty remains at issue and will be determined after further proceedings.

Dated this 26<sup>th</sup> day of October 1994.

  
Spencer T. Nissen  
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the original of this **ORDER ON CROSS MOTIONS FOR ACCELERATED DECISION**, dated October 26, 1994, in re: Farmers Elevator & Supply Co., Inc., Dkt. No. IF&R-VII-1175C-92P, was mailed to the Regional Hearing Clerk, Reg. VII, and a copy was mailed to Respondent and Complainant (see list of addressees).

*Helen F. Handon*

Helen F. Handon  
Legal Staff Assistant

DATE: October 26, 1994

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