

9/26/75

ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE REGIONAL ADMINISTRATOR

In re
Calgon Corporation,
Respondent } I.F. & R. Docket No. VII-102C

ACCELERATED INITIAL DECISION^{1/}
of
Frederick W. Denniston
Administrative Law Judge

By Complaint, dated April 1, 1975, the Chief of the Pesticides Branch, EPA Region VII, alleges that Calgon Corporation has violated the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (86 Stat. 973; 7 U.S.C. 136) (FIFRA herein), in connection with a shipment of SYN-SOL CLEANER-SANITIZER, from St. Louis, Mo. to Newark, N.J., on August 8, 1974.

Following a denial of the allegations by Calgon Corporation, and a prehearing exchange of evidence, a hearing was held in St. Louis, Mo., on September 9, 1975.

At the hearing, Calgon Corporation was represented by Jack R. Mennis, Senior Attorney, of Pittsburgh, Pa., and the Complainant, by James Vieregg and Daniel J. Shiel, of Kansas City, Mo.

By letter dated August 12, 1975, the Presiding Officer requested Complainant to file a brief on the question of whether a Technical

^{1/} Exceptions may be filed by the parties pursuant to 40 CFR 168.51 of the Rules.

Bulletin must physically accompany a shipping container. Such a brief was filed on September 2, 1975 and Calgon replied on September 9, 1975.

At the hearing, Calgon moved for the issuance of an Accelerated Decision under 40 CFR 168.37 of the Rules. The Motion, which was taken under advisement, is hereby granted pursuant to 168.37(a)(2).

A brief date of October 13, 1975, was specified with replies due on October 23, 1975. In view of the issuance of this Accelerated Decision such need not be filed but the parties may file exceptions pursuant to 40 CFR 168.51(a).

FINDINGS OF FACT

The following facts were stipulated:

1. Respondent had gross sales (total business revenues from all business operations) for the prior fiscal year which exceeded \$1,000,000.00.
2. Respondent is the registrant for the pesticide, SYN-SOL CLEANER-SANITIZER, which bears EPA Registration No. 2914-33.
3. The approved registered label affixed to the pesticide, SYN-SOL CLEANER-SANITIZER, contains the language "SEE TECHNICAL BULLETIN FOR USE DIRECTIONS."
4. The Technical Bulletin referred to on the approved registered label was accepted on April 30, 1969, under FIFRA.
5. Respondent on August 8, 1974, shipped (one) three hundred fifty pound drum of the pesticide, SYN-SOL CLEANER-SANITIZER, from St. Louis, Missouri, to American Bakeries Company, Newark, New Jersey.

6. The above referenced pesticide did not have affixed to it a Technical Bulletin bearing directions for use, during shipment on the above-referenced shipment.

7. A Technical Bulletin accepted in accordance with registration, bearing use directions for the above-referenced pesticide, was received by American Bakeries Company, Newark, N.J., on or about August 27, 1974.

Additional facts disclosed of record are:

8. American Bakeries received the shipment of the drum on August 14, 1974. Its representative, John Taylor, testified that on or about August 6, 1974, he requested a copy of the Technical Bulletin from the sales representative, but did not receive it until August 27, 1974. While first contending a portion of the August 14 shipment was used prior to receipt of the Bulletin, Taylor later expressed uncertainty.

9. The sales representative of Calgon/testified that the Technical Bulletin for SYN-SOL, had been supplied to Taylor in connection with previous orders which had been placed in July 1972 and May 1973 and positively identified July 18, 1972 as the date the first one had been given and another in July 1974. Taylor, while uncertain as to whether he previously had a Technical Bulletin and acknowledging it is possible, stated he did not have one in his possession in August 1974. From the standpoint of the demeanor of the witnesses, each appeared sincere in their beliefs and Taylor conceded Parks may have previously supplied the

Technical Bulletin prior to August 27, 1974 and he may have been unable to find it.

10. In view of the certainty of Parks' testimony and of the uncertainty of Taylor's, it must be concluded that Taylor had received a Technical Bulletin at least once prior to August 27, 1974.

CONCLUSIONS

The record is silent as to why EPA approved a separate document containing directions for use, herein for convenience referred to as a Technical Bulletin, although not so designated on its face. The so-called Technical Bulletin is a single page 8 1/2" x 11", the same size as the label itself. Being used on a large drum containing in excess of 300 lbs. of dry powder, there is ample space for adhering the Bulletin as well as the label to the surface. Moreover, in approving the Bulletin, EPA specified no conditions as to its display or use and no regulation has been cited which does so.

It is understandable that a Technical Bulletin in the form of a pamphlet or consisting of many pages, could not readily be affixed to a large drum with any certainty of its safe arrival after shipment. But no justifiable reason appears for the separation of label and use instructions in this case. It is noted that in February 1975, Respondent submitted a revision of the label to combine them into a single document, and this was approved by EPA.

The label in question prominently displayed in large letters, the statement "See Technical Bulletin for use Directions." While there is conflicting testimony as to whether John Taylor of American Bakeries, the receiver of the shipment, had received a Technical Bulletin in connection with earlier purchases of SYN-SOL in 1972 and 1973, it is clear that upon receiving the shipment here in question on August 14, 1974, Taylor was aware of the need for the Technical Bulletin, requested it of the manufacturer, and at least partially withheld use of the product until he received it 13 days later. While this may be poor customer relations, the question here is whether any statute or regulations were violated.

In its Special Hearing Brief on the subject, Complainant contends that "If a product's label incorporates use directions by reference to another document and the consumer has not been provided such document prior to or concurrent with receipt of such product, the product is also misbranded." (Brief, p. 10). But the EPA regulations do not so state and no source for this contention is offered.

The only pronouncements of EPA on this subject appear to be the interpretations embraced in 40 CFR Part 162. Section 162.105(d) specifies that directions for use shall appear on the labeling, which "includes the label which is affixed to the product plus all printed or graphic matter which accompanies the product at any time. Directions for use may appear on the label or on accompanying leaflets or circulars."

The precise meaning of "accompanies" or "accompanying" is not stated. It is noted however, that the same regulation provides an exception with respect to "well known economic poisons which are sold in containers of . . . 50 pounds or more of a solid intended primarily for use after dilution" provided "there is readily available general knowledge of the composition methods of use, and effectiveness of the product." Moreover, Section 162.108(d), an interpretation with respect to labels for large containers, such as the drum here involved, provides an almost identical exemption from the directions for use requirement on "well known economic poisons which are sold in containers of . . . 50 pounds or more of a solid intended primarily for use after dilution." Witness Taylor described SYN-SOL as a chlorine type sanitizer and that these have been well known for many years.

Complainant's testimony did not direct itself to whether Sec. 162.105 (c)(1), 162.105(c)(2), or 167.108(d)(2) applied in this case, but there is nothing in the testimony to indicate the product here is not a "well-known" economic poison. Even if it be assumed those exemptions do not apply, however, there is no provision in the regulations or in the specific approval as to how the Technical Bulletin which EPA had approved for a separated use, should "accompany" the shipment of the product. A 300 pound or larger drum must be shipped by freight or its equivalent, whereas the single-page, letter-sized bulletin would necessarily move by mail or other means and could not, in its separated form, physically accompany the drum.

The absence of articulation of the meaning of "accompanying" in the EPA regulations is particularly significant in the light of Kordel v. United States, 335 U.S. 345 (1948), and United States v. Urbuteit, 335 U.S. 355 (1948), which hold, in effect, that it is immaterial whether the description of uses directly follows a shipment. It is true, no doubt, that EPA could by general regulation, or in the approval of a separate document, as here, specify precise conditions as to the display or availability of the document. But EPA has not done so, and by approving a separate Technical Bulletin without specifying how it should be brought to the attention of users, itself created an anomaly as to the meaning of "accompanying" since it could not mean a physical accompaniment. To attempt to create a requirement incapable of fulfillment, by retroactive adoption of an interpretation not heretofore announced and in a punitive action would be Draconian in the extreme.

Parenthetically, it should be noted that Complainant offered testimony indicating the economic damage or potential dangers to a user inherent in the absence of adequate directions for use of SYN-SOL. But a number of these dangers are not dealt with in the directions for use approved by EPA and, at best, can only be inferred.

For the foregoing reasons, the Complaint is DISMISSED.

Frederick W. Denniston

Frederick W. Denniston
Administrative Law Judge

September 26, 1975