ILLINOIS POLLUTION CONTROL BOARD
April 10, 1986

IN THE MATTER OF:	)	
	)	
PROPOSAL OF APPLIED BIOCHEMISTS	)	
TO AMEND THE ALGICIDE REGULATIONS	)	R84-4
AT 35 ILL. ADM. CODE 602.103 AND	)	(Deconsolidated
602.110	)	(from R84-19)
	)	

FINAL OPINION AND ORDER OF THE BOARD (by J. Marlin):

This matter comes before the Board upon the filing of a proposal on December 14, 1983 and an amended proposal on January 10, 1984 by Applied Biochemists, Inc. (Applied) to amend 35 Ill. Adm. Code 602.103. This proceeding is being deconsolidated from another proceeding, R84-19. In R84-19, Carus Chemical Company (Carus) had filed a proposal on May 23, 1984 to amend Section 602.103. Both the Applied and Carus proposals were consolidated for hearing by Hearing Officer Order on June 8, 1984 after Board discussion. Merit hearings were held in Springfield, Illinois on July 24, 1984 and in Chicago, Illinois on July 31, 1984. The Illinois Department of Energy and Natural Resources on November 27, 1984 found that an economic impact study was not necessary and stated that "[t]he cost of making a formal study is economically unreasonable in relation to the value of the study to the Board in determining the adverse economic impact of the regulation." (November 27, 1984 Negative Declaration). The Economic and Technical Advisory Committee concurred in this finding on January 23, 1985. A supplemental hearing called by the Board to address informational deficiencies was held May 20, 1985 in DeKalb, Illinois. The participants submitted additional information after hearing. The Illinois Environmental Protection Agency (Agency) submitted comments on October 7, 1985. With those comments, the Agency proposed that not only should Section 602.103 be amended but that Section 602.110 be amended as well by deleting the words "copper sulfate" and adding the words "the algicide."

In its First Notice Opinion and Order dated November 7, 1985, the Board proposed to adopt amendments to 35 Ill. Adm. Code 602.103 and 602.110. First notice of the proposed rules was published at 9 Ill. Reg. 18328 on December 2, 1985. Other than the Administrative Code Unit, no other comments were received during first notice. The second notice period began on January 23, 1986 and terminated on March 10, 1986.

Motion

On March 7, 1986, Applied filed a letter which the Board construes as a motion for reconsideration of the Board's First Notice Opinion and Order and likewise the Second Notice Order.

In re: Algicide Chemicals, R84-4,19 consolidated (November 7, 1985; January 23, 1986). Applied asserts both procedural and substantive error by the Board.

Procedurally, Applied asserts that it did not receive a copy of the Board's First Notice Opinion and Order and first learned of the Board's first notice decision when it received a copy of the Second Notice Order. Applied contacted the hearing officer and asserts that "he acknowledged a possible oversight...."

The hearing officer's attempts to check for receipt of the first notice decision by those on the notice list were inconclusive. The participants, save Applied, all had received copies of the first notice decision. Others on the notice list, who had no regular filing system for Board opinions, could not say whether they had received copies or not. However, in order to prevent any prejudice due to mail system deficiencies, Applied's motion for reconsideration is granted. The Board on its own motion is deconsolidating this from R84-19.

Substantively, Applied reargues the merits of the case and asserts that the record does not show triethanolamine as a risk to human health and that the issue of its mutagenicity and carcinogenicity have been distorted. Applied, however, fails to provide the Board with any new information so as to warrant the Board granting relief to Applied or scheduling another hearing in this matter.

The Board's decisions denying relief to Applied at first and second notice are hereby affirmed. Should Applied wish to pursue registration of its compounds in Illinois it may file another request for regulatory relief. The rationale behind the First Notice Opinion as it pertains to Applied is adopted here and is set forth.

Discussion

The current algicide permit section 602.103 allows the use of only copper sulfate in treating algae problems in bodies of water used as public water supplies. Applied requests that the regulations be modified to allow the use of other products for this purpose. Applied's original proposal would amend the section to include all algicides registered with the USEPA for use in potable water. Its amended proposal narrowed that scope to include only copper sulfate, copper carbonate (malachite), copper monoethanolamine and copper triethanolamine compounds. Applied's two copper ethanolamine products are liquid Cutrine-Plus and granulated Cutrine-Plus. These are registered with the USEPA pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, 7 U.S.C. §136 et seq., 1982) for use in bodies of water that are potable water supply sources. (Reg. No's 8959-10AA and 8959-12AA). They are also registered with the Illinois Department of Agriculture (as of December 28, 1983; Applied Exhibit 20) pursuant to the Illinois Pesticide Act (IPA)

Ill. Rev. Stat. 1985, ch. 5, par. 801 et seq. These are chelated copper compounds which use ethanolamine complexes to keep otherwise insoluble copper carbonate in solution (JR. 30, 31)[1]. This results in a rather uniform copper concentration throughout the water (App. Exhs. 16, 9, 13, 14). The liquid form contains nine percent elemental copper (0.909 lbs./gal Cu). The granulated form contains 3.7 percent active copper material (App. Exh. 14, JR. 15).

The record does not support the proposal to amend sections 602.103 and 602.110 to encompass those potable water supply algicides registered with the USEPA for use in Illinois. In order to incorporate algicides registered with the USEPA pursuant to 40 C.F.R. Part 162 (1984), the Board is statutorily mandated to have on file a list of those chemicals. (Ill. Rev. Stat. 1985, ch. 127, par. 1006.02, 35 Ill. Adm. Code 100.385). The Board attempted to obtain the list of algicides approved for use in potable water supplies from the USEPA. It was not possible to secure a complete listing. The USEPA itself does not have such a listing available for distribution to the public. (Board exhibits 1, 2, 5, 6, 7, and 8 as well as the Hearing Officer Report of March 1, 1985 document the difficulties encountered during the attempt).

The Board notes the USEPA has been mandated by Congress to review all algicides currently registered with it and to reregister those that merit reregistration based on the latest scientific data [7 U.S.C. 136a(g) (P.L. 95-396 eff. 9-30-1978)]. The USEPA has not yet been able to complete this task. There is no evidence in the record to show that the products of Applied have been reregistered (See App. Exh. 1).

Based on the record before it, the Board declines to incorporate all potable water supply algicides registered with the USEPA. It will, however, incorporate individual chemical compounds where the record contains sufficient information to justify such action.

Copper Carbonate (Malachite)

Applied, while proposing copper carbonate as an algicide, provided no information on it. The Agency in its comments stated that because malachite is "insoluble with a solubility factor of 1×10^{-34} and because it does not possess any algicidal properties, it should not be included in the list of acceptable algicides." (Ag. Comments, October 4, 1985). Because of the lack of any data supporting the inclusion of malachite, the Board will not include it as a public water supply algicide.

1 JR. refers to the transcript of the July 1984 hearings which is consecutively paginated. MR. refers to the May 1985 hearing transcript.

Copper Monoethanolamine/Triethanolamine

Both products of Applied contain copper in the form of mixed copper-ethanolamine complexes. Some of the breakdown products of Cutrine-Plus include diethanolamine, monoethanolamine, ammonia, acetic acid, hydroxyacetic acid, glyoxal, glyoxylic acid, oxalic acid, formaldehyde gas and formic acid. Cutrine-Plus is a slight skin irritant and is moderately toxic if swallowed. It is less corrosive than copper sulfate.

Toxicological data show Cutrine-Plus to be "[g]enerally nontoxic to fish and wildlife at recommended dosages," although "trout. . . and certain other sensitive fish species may be adversely affected in very soft water (below 50 ppm of $CaCo_3$)." (App. Exh. 13). Toxicity data for the bluegill sunfish and for the fathead minnow (Pimephales promelas) appear in Exhibits 11 and 17 while data on oral dose, single skin penetration, single inhalation, primary skin irritation and eye injury from animal studies appear in Applied Exhibit 12.

At 45 Fed. Reg. 53478 (August 12, 1980), the USEPA mentions that it was concerned with the presence of 2.1 ppm of N-nitrosodiethanolamine in an original Applied formulation "since 80 percent of known N-nitrosoamine compounds have been shown to be carcinogenic in a variety of species." (App. Exh. 7). The formulation was revised by Applied and now contains less than 1/ppm of N-nitrosodiethanolaminė which represents a risk level acceptable to the USEPA. Id.

Prior to the May 20 hearing, the Board raised the question of the possible mutagenicity and carcinogenicity of triethanolamine (TREA). A scientific paper on that topic by Hoshino and Tanooka was placed in the record (Board Exh. 4). The researchers reported that mice fed on a diet including TREA developed tumors and that TREA in combination with sodium nitrite caused mutations in bacteria.

The Board retained Dr. William Hallenbeck, who has done research involving animal toxicology and human health effects, to evaluate the Tanooka paper. He pointed out that the controls used in the test made it impossible to conclude with certainty that TREA caused the tumors. He also stated that, "a stable and direct, but unidentified, mutagen was found under test conditions which approached normal physiological parameters" (MR. 16 and 17). In answer to a question he replied, "...my overall conclusion about TREA is that at this point you could only go so far as to characterize it as a potential animal carcinogen and, therefore, a potential human carcinogen" (MR. 26). Regarding mutagenicity he pointed out that the Tanooka paper reported a four to five-fold increase in mutagenicity for the combination of TREA and sodium nitrite over sodium nitrite alone. He also stated that sodium nitrite is common in the human diet (MR. 56 and 57).

In response to the Tanooka paper, Applied presented two letters critical of the paper and entered a paper by Inone et. al. which considered the mutagenicity of TREA (Applied Exh. 25). This study found no evidence that TREA by itself was mutagenic. It also suggested further study to determine the exact cause of the tumors reported by Tanooka.

Applied's Exhibit 9 which was introduced at the July 24, 1984 hearing stated:

> In an effort to find any and all available references on chronic data on monoethanolamine and triethanolamine APPLIED BIOCHEMISTS, INC. contacted the environmental and toxicology branches of the ethanolamine manufacturers and suppliers, DOW CHEMICAL, UNION CARBIDE, OLIN CORPORATION, TEXACO INC. and its subsidiary JEFFERSON CHEMICAL. Based on our efforts, there apparently is no chronic data on ethanolamines. However, these contacts yielded significant information and insight into ethanolamines, their biodegradation and toxicology.

No mention was made of the Tanooka paper or of the Inone paper, which were published in 1978 and 1982 respectively. Applied's representative said at hearing that Applied was not informed of the Tanooka paper by the TREA manufacturers and first learned of it in the hearing officer order. He also indicated that the information had not been supplied to the USEPA during the Federal registration process (MR. 69).

Applied Exhibit 10 lists the expected concentration of TREA in treated water as between 0.48 ppm and 2.4 ppm (see MR. 75 for correction). Applied gave no data as to how long TREA persisted in the body of water after treatment and in what concentration (MR. 66).

The USEPA approved Cutrine and Cutrine-Plus for use in public water supplies and the Illinois EPA has recommended that they be approved in Illinois. The Board notes that Federal approval was based largely upon information supplied by Applied, who in turn relied on data provided by TREA suppliers. The Applied products have not yet been reregistered by the USEPA.

The Tanooka paper indicates that TREA is a possible carcinogen. The controls in that study were inadequate to determine whether TREA or TREA in combination with the heated diet, or some other combination of factors caused the reported tumors. Applied's rebuttal of the Tanooka paper failed to dispel the concerns raised. The questions raised can best be addressed by an experiment with proper controls. Regarding mutagenicity, there is reason to believe that TREA in conjunction with sodium nitrite (which is common in the human diet) has mutagenic properties. In the absence of additional substantive data, the

Board believes it is unwise to place this chemical in water supplies which are consumed by the public. The Board has no reason to conclude that the use of Applied's products containing TREA pose a threat in other bodies of water.

The Board finds that Applied has failed to demonstrate that TREA can be applied to public water supplies without posing a threat to the public health. Pursuant to Section 27(b) of the Act, Applied's data indicate that its product is competitive with the approved algicide (JR. 90-99). However, given the uncertainty over potential public health impacts of the product, the Board cannot find that approving Applied's petition will not have an overall adverse economic impact.

ORDER

The March 7, 1986 motion of Applied Biochemists, Inc. for reconsideration of the First Notice Opinion and Order and the Second Notice Order is granted. The Board, however, affirms its decisions at First and Second Notice and denies the requested relief. This docket is hereby closed.

IT IS SO ORDERED.

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above Opinion and Order was adopted on the 10th day of April, 1986, by a vote of 7-0.

Dorothy M. Gunn

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board