ILLINOIS POLLUTION CONTROL BOARD
August 6, 1987

IN THE MATTER OF:	)	
	)	
AMENDMENTS TO 35 ILL. ADM. CODE 211 & 215 ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS FOR SYNTHESIZED PHARMACEUTICAL MANUFACTURING PLANTS.	)	R86-10

PROPOSED RULE. FIRST NOTICE.

ORDER OF THE BOARD (by J.D. Dumelle):

This matter comes before the Board upon a February 26, 1986, proposal for the adoption of amendments to 35 Ill. Adm. Code 211 and 215 filed by the Illinois Environmental Protection Agency (Agency). The proposal was accepted and authorized for hearing by Order of February 26, 1986. On April 23, 1987, the Agency submitted an amended proposal. Hearing was held on June 9, 1987, in Waukegan. The Agency filed a second amended proposal on July 27, 1987. A second hearing is scheduled for August 25, 1987, and additional hearings may be necessary.

However, certain deadlines imposed by the Clean Air Act require that the Board quickly reach a final disposition of this matter. The Board, accordingly, takes its action today to allow that the activities associated with first notice may proceed concurrently with the final submissions of information and comments which the interested entities are expected to make over the next several weeks. In taking this action, the Board believes that whatever the outcome, final disposition of this matter will proceed in as timely a fashion as possible, to the benefit of all concerned. The Board cautions that this action in no way constitutes a determination by the Board on the ultimate merits of the proposed amendments.

The overriding basis of the Agency's proposal is to correct deficiencies in the Illinois State Implementation Plan (SIP) which have been identified by the United States Environmental Protection Agency (USEPA). Section 172 of the Clean Air Act requires the state to impose the use of reasonably available control technology (RACT) on existing sources in non-attainment areas. On May 19, 1978, USEPA gave notice that the SIP must include, at least for major urban areas, enforceable regulations reflecting the application of RACT to those stationary sources for which USEPA has published control techniques guidelines (CTGs) since 1978. In December, 1978, a CTG was published

entitled "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products."

On April 3, 1980, the Agency proposed in R80-5 regulations for the control of volatile organic materials from the manufacture of synthesized pharmaceuticals, together with other regulations generally known as the RACT II categories. On December 30, 1982, the Board adopted the proposed rules, but without provisions for the control of emissions from the manufacture of synthetic pharmaceuticals. On July 11, 1985, USEPA proposed to disapprove Illinois' Part D stationary source control strategy for failure to meet the RACT II control requirements, noting that the synthetic pharmaceutical sources were left unregulated.

To remedy the deficiencies noted in USEPA's proposed disapproval, the Agency filed its proposal of February 26, 1986. The proposal was amended on April 23, 1987, to remove the distinction between "synthesized" pharmaceuticals and non-synthesized pharmaceuticals. Although emission sources used in manufacturing synthesized pharmaceuticals were described in the CTG and those used in non-synthesized pharmaceuticals were not, the Agency found this distinction unimportant from a regulatory standpoint because both kinds of sources produce emissions that are reasonably controlled by similar equipment.

The Agency's second proposed amendment, filed July 27, 1987, responded to concerns addressed at the June 9, 1987, hearing. This proposal incorporates the results of a study undertaken by Mr. Thomas C. Ponder, Jr., of PEI Associates. Mr. Ponder determined that some sources emit more than 15 lbs/day when in operation, but only operate a few days each year. Believing that it would not be cost-effective to require such sources to add controls, Mr. Ponder concluded that an annualization of the 15 lbs/day limit was necessary and appropriate. Based on Mr. Ponder's conclusions, the Agency amended the applicability of the proposed rules to sources emitting volatile organic material in amounts exceeding 2.5 tons/year (i.e., the annual total of a 15 lbs/day limit).

Thus, without rendering any opinion as to the merits of proposed amendments, the Board proposes for First Notice the language contained in the Agency's second amended proposal.

ORDER

The Board hereby proposes the following amendments for first notice publication. The Clerk shall cause first notice publication of these proposed amendments in the Illinois Register.

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE B: AIR POLLUTION
CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER c: EMISSION STANDARDS AND LIMITATIONS FOR STATIONARY SOURCES

PART 211
DEFINITIONS AND GENERAL PROVISIONS

SUBPART A: GENERAL PROVISIONS

Section 211.122 Definitions

"In-Process Tank": A container used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals.

"Pharmaceutical": Any compound or mixture, other than food, used in the prevention, diagnosis, alleviation, treatment or cure of disease in man and animal.

"Production Equipment Exhaust System": A system for collecting and directing into the atmosphere emissions of volatile organic material from reactors, centrifuges and other process emission sources.

"Reactor": A vat, vessel or other device in which chemical reactions take place.

"Surface Condenser": A device which removes a substance from a gas stream by reducing the temperature of the stream, without direct contact between the coolant and the stream.

Volatile Organic Liquid": Any liquid which contains volatile organic material.

"Volatile Organic Material": ~~any organic material which has a vapor pressure of 17.24 kPa (2.5 psia) or greater at 294.3-K (70-F). For purposes of 35 Ill. Adm. Code 215.442 through 215.444, volatile organic material means any organic material which has a vapor pressure of 10.34 kPa (1.5 psia) at 294.3-K (70°F). For purposes of 35 Ill. Adm. Code 215.181 through 215.184, 215.445 through 215.451, 215.204 through 215.209, 215.340 through 215.345, 215.401 through 215.404, 215.461 through 215.464 and 215.601 through 215.603, volatile organic material means any organic material which has a vapor pressure greater than 0.013 kPa (.0019 psia) at 294.3-K (70°F).~~

a) any organic material which participates in atmospheric photochemical reactions or is measured by the applicable reference methods specified under Part 230, Appendix A, unless specifically exempted from this definition.

b) For purposes of this definition, the following are not volatile organic materials:

Methane
Ethane
1,1,1, Trichloroethane
Methylene chloride
Trichlorofluoromethane
Dichlorodifluoromethane
Chlorodifluoromethane
Trifluoromethane
Trichlorotrifluoroethane
Dichlorotetrafluoroethane
Chloropentafluoroethane

(Source: Amended at ___ Ill. Reg. _____, effective _____)

PART 215
ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS

Section 215.102 Testing Methods

a) The total organic material concentrations in an effluent stream shall be measured by a flame ionization detector, or by other methods approved by the Illinois Environmental Protection Agency (Agency) according to the provisions of 35 Ill. Adm. Code 201.

b) Measurement of Vapor Pressures

1) For a single component, the actual vapor pressure shall be obtained from Boublik, T., V. Fried, and E. Hala, the Vapor Pressure of Pure Substances, Elsevier Scientific Publishing Company, New York (1973), Perry's Chemical Engineer's Handbook, McGraw-Hill Book Company (1984), CRC Handbook of Chemistry and Physics, Chemical Rubber Publishing Company (1986-87), Lange's Handbook of Chemistry, John A. Dean, editor, McGraw-Hill Book Company (1985), or as determined by ASTM (American Society of Testing and Materials) Method D-2879-83.

2) For a mixture, the actual vapor pressure shall be taken as either:

i) The lesser of the sum of the actual vapor pressure of each component or each volatile organic material component, as determined above, weighted by its mole fraction, or

ii) If the vapor pressure of the volatile organic material is specified, the sum of the actual vapor pressure of each volatile organic material component as determined above weighted by its mole fraction.

(Source: Amended at ___ Ill. Reg. _____, effective _____)

Section 215.104 Definitions

~~"Volatile Organic Material": Any organic material which has a vapor pressure of 17.24 kPa (2.5 psia) or greater at 294.3-K (70°F). For purposes of this definition, the following are not volatile organic materials:~~

~~Methane~~
~~Ethane~~
~~1,1,1-trichloroethane~~
~~Methylene chloride~~
~~Trichlorofluoromethane~~
~~Dichlorodifluoromethane~~
~~Chlorodifluoromethane~~
~~Trifluoromethane~~
~~Trichlorotrifluoroethane~~
~~Chloropentafluoroethane~~

~~For purposes of the following Sections, volatile organic materials are any organic materials having the corresponding vapor pressures at 294.3-K (70°F):~~

~~Sections~~	~~Vapor Pressure~~	
~~215.181 - 215.184~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.184 - 215.209~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.340 - 215.345~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.401 - 215.408~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.420 - 215.428~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.441 - 215.444~~	~~10.34 kPa~~	~~(1.5 psia)~~
~~215.445 - 215.451~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.461 - 215.464~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.510 - 215.513~~	~~0.013 kPa~~	~~(.0019 psia)~~
~~215.601 - 215.613~~	~~0.013 kPa~~	~~(.0019 psia)~~

(Source: Amended at ___ Ill. Reg. _____, effective _____)

Section 215.105 Incorporations by Reference

The following materials are incorporated by reference:

a) American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103:

1) ASTM D 1644-59 Method A

2) ASTM D 1475-60

3) ASTM D 2369-73

4) ASTM D 2879-83 (Approved 1983)

5) ASTM D 323-82 (Approved 1982)

6) ASTM D 86-82 (Approved 1982)

7) ASTM E 260-73 (Approved 1973), E 168-67 (Reapproved 1977), E 169-63 (Reapproved 1981), E 20 (Approved 1985)

8) ASTM D 97-66

b) Federal Standard 141a, Method 4082.1

c) National Fire Codes, National Fire Prevention Association, Battery March Park, Quincy, Massachusetts 02269 (1979)

d) United States Environmental Protection Agency, Washington, D.C., EPA-450/2-77-026, Appendix A.

e) United States Environmental Protection Agency, Washington, D.C., EPA-450/2-78-051 Appendix A and Appendix B (December 1978).

f) United States Environmental Protection Agency, Washington, D.C., EPA-450/2-78-041, Chapter 7 (1978).

g) Boublik, T., Fried, V., and Hala, E., The Vapor Pressure of Pure Substances, Elsevier Scientific Publishing Company, New York (1973).

h) Perry's Chemical Engineer's Handbook, McGraw-Hill Book Company (1984).

i) CRC Handbook of Chemistry and Physics, Chemical Rubber Publishing Company (1986-87).

j) Lange's Handbook of Chemistry, John A. Dean, editor, McGraw-Hill Book Company (1985).

(Board Note: The incorporations by reference listed above contain no later amendments or editions.)

(Source: Amended at ___ Ill. Reg. _____, effective _____)

SUBPART T: PHARMACEUTICAL MANUFACTURING

Section 215.480 Applicability of Subpart T

a) The rules of this Subpart, except for Sections 215.483 through 215.485, apply to all emission sources of volatile organic material, including but not limited to reactors, distillation units, dryers, storage tanks for volatile organic liquids, equipment for the transfer of volatile organic liquids, filters, crystallizers, washers, laboratory hoods, coating operations, mixing operations and centrifuges used in manufacturing, including packaging, of pharmaceuticals, and emitting more than 6.8 kg/day (15 lbs/day) of volatile organic material and more than 2268 kg/year (2.5 tons/year) of volatile organic material, or, if less than 2.5 tons/year, these sections still apply if emissions from one or more sources exceed 45.4 kg/day (100 lbs/day).

b) Sections 215.483 through 215.485 apply to a plant having one or more emission sources that:

1) are used to manufacture pharmaceuticals; and

2) emit more than 6.8 kg/day (15 lbs/day) of volatile organic material and more than 2268 kg/year (2.5 tons/year) of volatile organic material, or, if less than 2.5 tons/year, these sections still apply if emissions from one or more sources exceed 45.4 kg/day (100 lbs/day).

c) No person shall violate any condition in a permit when the condition results in exclusion of an emission source from this Part 215, Subpart T.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.481 Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers

a) The owner or operator shall control all reactors, distillation units, crystallizers, centrifuges and

vacuum dryers that are used to manufacture pharmaceuticals with surface condensers operated such that the condenser outlet gas temperature does not exceed:

1) 248.2 K (-13°F) when condensing volatile organic material of vapor pressure greater than 40.0 kPa (5.8 psi) at 294.3 K (70°F); or

2) 258.2 K (5°F) when condensing volatile organic material of vapor pressure greater than 20.0 kPa (2.9 psi) at 294.3 K (70°F); or

3) 273.2 K (32°F) when condensing volatile organic material of vapor pressure greater than 10.0 kPa (1.5 psi) at 294.3 K (70°F); or

4) 283.2 K (50°F) when condensing volatile organic material of vapor pressure greater than 7.0 kPa (1.0 psi) at 294.3 K (70); or

5) 298.2 K (77°F) when condensing volatile organic material of vapor pressure greater than 3.45 kPa (0.5 psi) at 294.3 K (70°F).

b) The owner or operator shall enclose all centrifuges used to manufacture pharmaceuticals and that have an exposed volatile organic liquid surface, where the volatile organic material in the volatile organic liquid has a vapor pressure of 3.45 kPa (0.5 psi) or more at 294.3 K (70°F).

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.482 Control of Air Dryers, Production Equipment Exhaust Systems and Filters

a) The owner or operator of an air dryer or production equipment exhaust system used to manufacture pharmaceuticals shall control the emissions of volatile organic material from such emission sources by air pollution control equipment which reduces by 90 percent or more the volatile organic material that would otherwise be emitted into the atmosphere.

b) The owner or operator shall enclose all rotary vacuum filters and other filters used to manufacture pharmaceuticals and that have an exposed volatile organic liquid surface, where the volatile organic material in the volatile organic liquid has a vapor pressure of 3.45 kPa (0.5 psi) or more at 294.3 K (70°F).

(Source: Amended at ___ Ill. Reg. _____, effective _____)

Section 215.483 Material Storage and Transfer

The owner or operator of a pharmaceutical manufacturing plant shall:

a) Provide a vapor balance system or equivalent control system that is at least 90.0 percent effective in reducing volatile organic material emissions from truck or railcar deliveries to storage tanks with capacities equal to or greater than 7.57m^3 (2,000 gallons) that store volatile organic liquids with vapor pressures greater than 28.0 kPa (4.1 psi) at 294.3 K (70°F); and

b) Install pressure/vacuum conservation vents set at 0.2 kPa (0.03 psi) on all storage tanks that store volatile organic liquids with vapor pressures greater than 10 kPa (1.5 psi) at 294.3 K (70°F),unless a more effective control system is used.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.484 In-Process Tanks

The owner or operator shall install covers on all in-process tanks used to manufacture pharmaceuticals and containing a volatile organic liquid at any time. These covers must remain closed, except when production, sampling, maintenance, or inspection procedures require operator access.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.485 Leaks

The owner or operator of a pharmaceutical manufacturing plant shall repair any component from which a leak of volatile organic liquid can be observed. The repair shall be completed as soon as practicable but no later than 15 days after the leak is found unless the leaking component cannot be repaired until the process unit is shut down, and the leaking component must then be repaired before the unit is restarted.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.486 Other Emission Sources

The owner or operator of a washer, laboratory hood, capsule coating operation, mixing operation, or any other process emission source not subject to Section 215.481 through 215.485 of this Subpart, and used to manufacture pharmaceuticals shall control the emissions of volatile organic material from such emission sources by:

a) Air pollution control equipment which reduces by 81 percent or more the volatile organic material that would otherwise be emitted to the atmosphere, or

b) A surface condenser which captures all the volatile organic material which would otherwise be emitted to the atmosphere and which meets the requirements of Section 215.481(a) of this Subpart.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.487 Testing

a) The owner or operator of any volatile organic material emission source subject to this Subpart shall, at his own expense, demonstrate compliance by methods or procedures listed in Section 215.487(c).

b) All tests pursuant to Section 215.487(a) shall be performed in conformance with the procedures set forth in 35 Ill. Adm. Code 283.

c) Test procedures to determine operation and maintenance compliance with this Subpart shall be consistent with EPA-450/2-78-041. Procedures for testing air pollution control equipment to determine compliance with this Subpart shall use Part 230, Appendix A Method 25 (40 CFR 60, Appendix A Method 25).

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.488 Monitors for Air Pollution Control Equipment

a) At a minimum, continuous monitors for the following parameters shall be installed on air pollution control equipment subject to this Subpart:

1) Destruction device combustion temperature;

2) Temperature rise across a catalytic afterburner bed;

3) Breakthrough of volatile organic material on a carbon adsorption unit.

b) Each monitor shall be equipped with a recording device.

c) Each monitor shall be calibrated quarterly.

d) Each monitor shall operate at all times while the associated control equipment is operating.

(Source: Added at ___ Ill. Reg. _____, effective _____)

Section 215.489 Compliance Schedule

a) The owner or operator of an emission source subject to this Subpart, the construction or modification of which has commenced prior to (effective date of rule) must complete on-site construction or installation of the emission control or process equipment, or both, so as to operate in compliance with this Subpart by December 31, 1987.

b) The owner and operator of any emission source subject to this Subpart, the construction or modification of which has not commenced prior to (effective date of rule), shall construct such source so that it will operate in compliance with this Subpart.

(Source: Added at ___ Ill. Reg. _____, effective _____)

IT IS SO ORDERED

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above Proposed Rule, First Notice Order was adopted on the 6th day of August, 1987, by a vote of 6-0.

Dorothy M. Gunn

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board