

ILLINOIS POLLUTION CONTROL BOARD
January 25, 1990

IN THE MATTER OF:)
)
) R88-14
AMENDMENTS TO 35 ILL. ADM.) (Rulemaking)
CODE 211 AND 215)
(PHARMACEUTICALS))

Proposed Rule. First Notice.

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

This matter comes before the Board upon Abbott Laboratories' Amended Petition for Rulemaking and Motion for Expedited Hearing filed on December 4, 1989. On December 20, 1989, the Board granted Abbott's motion for expedited proceeding insofar as it is practicable in light of the Board's current schedule and workload and directed the hearing officer to schedule hearings. Hearings have been scheduled for March 13 and 28, 1990.

So as to begin the Administrative Procedure Act rulemaking process, the Board today proposes Abbott's amended proposal for first notice. However, the Board takes no position on the merits of the proposal at this time. The Board's action today is taken to effectuate the publication of the proposal in the Illinois Register.

Finally, the Board also decides today that an Economic Impact Study (EcIS) need not be prepared by the Department of Energy and Natural Resources (DENR). The Board makes this determination based upon comments filed by the Agency and by Abbott earlier in this proceeding. The Agency is of the opinion that, in light of the fact that this is a site-specific proposal affecting only one facility and that substantial information is already available from the pharmaceuticals rulemaking (R86-10), preparation of an EcIS would be inappropriate. Abbott also believes that an EcIS need not be prepared, based upon the record developed in R86-10 and its projection of the course of this rulemaking. The Board agrees with Abbott and the Agency on this issue.

As an aside, the Board notes that the timing of this EcIS decision is in no way related to the filing of the amended petition. It is only the result of the unusual history of this particular proceeding that the EcIS decision was not previously made.

ORDER

The Board hereby proposes the following amendments for first notice.

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 B: DEFINITIONS

Section
211.121 Other Definitions
211.122 Definitions

AUTHORITY: Implementing Sections 9 and 10 and authorized by Section 27 of the Environmental Protection Act (Ill. Rev. Stat. 1987, ch. 111½, pars. 1009, 1010 and 1027).

SOURCE: Adopted as Chapter 2: Air Pollution, Rule 201: Definitions, R71-23, 4 PCB 191, filed and effective April 14, 1972; amended in R74-2 and R75-5, 32 PCB 295, at 3 Ill. Reg. 5, p. 777, effective February 3, 1979; amended in R78-3 and 4, 35 PCB 75 and 243, at 3 Ill. Reg. 30, p. 124, effective July 28, 1979; amended in R80-5, at 7 Ill. Reg. 1244, effective January 21, 1983; codified at 7 Ill. Reg. 13590; amended in R82-1 (Docket A) at 10 Ill. Reg. 12624, effective July 7, 1986; amended in R85-21(A) at 11 Ill. Reg. 11747, effective June 29, 1987; amended in R86-34 at 11 Ill. Reg. 12267, effective July 10, 1987; amended in R86-39 at 11 Ill. Reg. 20804, effective December 14, 1987; amended in R82-14 and R86-37 at 12 Ill. Reg. 787, effective December 24, 1987; amended in R86-18 at 12 Ill. Reg. 7284, effective April 8, 1988; amended in R86-10 at 12 Ill. Reg. 7621, effective April 11, 1988; amended in R88-23 at 13 Ill. Reg. 10862, effective June 27, 1989; amended in R88-14 at ____ Ill. Reg. _____, effective _____

SUBPART B: DEFINITIONS

Section 211.122 Definitions

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 of fans and fixed or moveable ducts, pickup points and hooding, for purposes of industrial hygiene or good practice, which collect materials from openings and other operations of reactors, centrifuges, and other process emission sources, which materials are not ducted to the atmosphere through direct vents extending from the interior of the reactor, centrifuge, or process emission source. Laboratory hoods, roof monitors and general building exhausts shall not be considered production equipment exhaust systems.

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

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE B: AIR POLLUTION
CHAPTER I: POLLUTION CONTROL BOARD

SUBCHAPTER c: EMISSIONS STANDARDS AND LIMITATIONS FOR
STATIONARY SOURCES

PART 215
ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS

SUBPART A: GENERAL PROVISIONS

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215.100	Introduction
215.101	Clean-up and Disposal Operations
215.102	Testing Methods
215.103	Abbreviations and Conversion Factors
215.104	Definitions
215.105	Incorporations by Reference
215.106	Afterburners
215.107	Determination of Applicability

SUBPART T: PHARMACEUTICAL MANUFACTURING

Section	
215.480	Applicability of Subpart T
215.481	Control of Reactors, Distillation Units, Crystallizers, Centrifuges and Vacuum Dryers
215.482	Control of Air Dryers, Production Equipment Exhaust Systems and Filters
215.483	Material Storage and Transfer
215.484	In-Process Tanks
215.485	Leaks
215.486	Other Emission Sources
215.487	Testing
215.488	Monitors for Air Pollution Control Equipment
215.489	Compliance Schedule

AUTHORITY: Implementing Section 10 and authorized by Section 27 of the Environmental Protection Act (Ill. Rev. Stat. 1987, ch. 111½ pars. 1010 and 1027).

SOURCE: Adopted as Chapter 2: Air Pollution, Rule 205: Organic Material Emission Standards and Limitations, R71-23, 4 PCB 191, filed and effective April 14, 1972; amended in R77-3, 33 PCB 357, at 3 Ill. Reg. 18, p. 41, effective May 3, 1979; amended in R78-3 and R78-4, 35 PCB 75, at 3 Ill. Reg. 30, p. 124, effective July 28, 1979; amended in R80-5 at 7 Ill. Reg. 1244, effective January 21, 1983; codified at 7 Ill. Reg. 13601; Notice of Corrections at 7 Ill. Reg. 14575; amended in R82-14 at 8 Ill. Reg. 13254, effective July 12, 1984; amended in R83-36 at 9 Ill. Reg. 9114, effective May 30, 1985; amended in R82-14 at 9 Ill. Reg. 13960, effective August 28, 1985; amended in R85-28 at 11 Ill. Reg. 3127, effective February 3, 1987; amended in R82-14 at 11 Ill. Reg. 7296, effective April 3, 1987; amended in R85-21(A) at 11 Ill. Reg. 11770, effective June 29, 1987; recodified in R86-39 at 11 Ill. Reg. 13541; amended in R82-14 and R86-12 at 11 Ill. Reg. 16706, effective September 30, 1987; amended in R85-21(B) at 11 Ill. Reg. 19117, effective

November 9, 1987; amended in R86-36, R86-39, R86-40 at 11 Ill. Reg. 20829, effective December 14, 1987; amended in R82-14 and R86-37 at 12 Ill. Reg. 815, effective December 24, 1987; amended in R86-18 at 12 Ill. Reg. 7311, effective April 8, 1988; amended in R86-10 at 12 Ill. Reg. 7650, effective April 11, 1988; amended in R88-23 at 13 Ill. Reg. 10893, effective June 27, 1989, amended in R88-14 at ___ Ill. Reg. _____, effective _____.

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 determined by ASTM (American Society of Testing and Materials) Method D-2879-83 (Approved 1983), incorporated by reference in Section 215.105, or the vapor pressure may be obtained from a published source such as: Boublik, T., V. Fried and E. Hala, "The Vapor Pressure of Pure Substances," Elsevier Scientific Publishing Co., 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).
 - 2) For a mixture, the actual vapor pressure shall be determined by ASTM (American Society of Testing and Materials) Method D-2879-83 (Approved 1983), incorporated by reference in Section 215.105, or the vapor pressure may be taken as either:
 - A) If the vapor pressure of the volatile organic liquid is specified in the applicable rule, the lesser of the sum of the actual vapor pressure of each component or each volatile organic material component, as determined in accordance with 215.102(b)(1), weighted by its mole fraction excluding water; or
 - B) If the vapor pressure of the organic material or volatile organic material is specified in the applicable rule, the sum of the actual vapor pressure of each such component as determined in accordance with 215.102(b)(1) weighted by its mole fraction, excluding water.

(Source: Amended at 13 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 and air suspension coaters 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 any single source exceed 45.4 kg/day (100 lbs/day) except as to those emission sources subject to the exemptions contained in subsections 215.480(b) and (c).
- b) The following emissions shall be excluded from a determination of what constitutes more than 2268 kg/year (2.5 tons/year) of VOM for the purposes of subsection (a) above: not more than 4535 kg/year (5.0 tons/year) of volatile organic material from each fluid bed drier, or each tunnel drier, or air suspension coaters, and not more than 6803 kg/year (7.5 ton/year) of VOM from each Accelacota. For purposes of this exclusion the 4535 kg/year (5.0 tons/year) limitation on the eight tunnel dryers shall be calculated by adding the total emissions from the eight dryers and dividing by eight. This subsection shall apply only to fluid bed driers; tunnel driers and Accelacotas located in Libertyville Township, Lake County, Illinois, and only when such emissions are not vented to air pollution control equipment.
- c) The following emissions shall be excluded from a determination of what constitutes more than 2268 kg/year (2.5 tons/year) of VOM for the purposes of subsection (a) above: not more than 4535 kg/year (5.0 tons/year) of acetylene from reactor PC842 and not more than 4535 kg/year (5.0 tons/year) of acetone from each of the following: Spectam Centrifuge, Succinate Filter Press, Reactor-Tank 37, Centrifuge Number 4 and Tank 48. This subsection shall apply only to reactor PC842, Spectam Centrifuge, Succinate Filter Press, Reactor-Tank 37, Centrifuge Number 4 and Tank 48 located in Shields Township, Lake County, Illinois.
- d)e) 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).

e)d) 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: Amended at 13 Ill. Reg. _____, effective _____)

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

- a) The owner or operator shall equip all reactors, distillation units, crystallizers, centrifuges and vacuum dryers that are used to manufacture pharmaceuticals with surface condensers, scrubbers, incinerators or carbon adsorbers, operated such that the condenser outlet gas temperature does not exceed:
- 1) If a surface condenser is used, it shall be operated such that the condenser outlet gas temperature does not exceed:
- a)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
 - b)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
 - c)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
 - d)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°F); or
 - e)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).
- 2) If a scrubber, incinerator or carbon adsorber is used it shall be operated in a manner which reduces by 81 percent or more the volatile organic materials that would otherwise be emitted to the atmosphere.
- 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: Amended at 13 Ill. Reg. _____, effective _____)

Section 215.486 Other Emission Sources

The owner or operator of a washer, laboratory hood, capsule pan 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: Amended at 13 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 to the Agency 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 p~~Procedures to determine operation and maintenance compliance with this Subpart shall be consistent with EPA-450/2-78-041, incorporated by reference in Section 215.105. ~~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), material balances, or Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products, Appendix B (EPA-450/2-78-029) herein incorporated by reference.~~

(Source: Amended at 13 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 ~~April 15, 1988~~ June 30, 1990, 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 ~~April 15, 1989~~ December 31, 1991.
- b) The owner and operator of any emission source subject to this Subpart, the construction or modification of which has not commenced prior to ~~April 15, 1988~~ June 30, 1990, shall construct such source so that it will operate in compliance with this Subpart.

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

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 25th day of January, 1990 by a vote of 7-0.

Dorothy M. Gunn
Dorothy M. Gunn, Clerk
Illinois Pollution Control Board