CR 89-65

State of Wisconsin \ DEPARTMENT OF NATURAL RESOURCES
Carroll D. Besadny, Secretary
Box 7921
Madison, Wisconsin 53707
TELEFAX NO. 608-267-3579
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STATE OF WISCONSIN)
)
DEPARTMENT OF NATURAL RESOURCES)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, Bruce B. Braun, Deputy Secretary of the Department of Natural Resources and custodian of the official records of said Department, do hereby certify that the annexed copy of Natural Resources Board Order No. WW-10-89 was duly approved and adopted by this Department on October 26, 1989. I further certify that said copy has been compared by me with the original on file in this Department and that the same is a true copy thereof, and of the whole of such original.

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Bureau

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department at the Natural Resources Building in the City of Madison, this 1st day of March, 1990.

Bruce B. Braun

Bruce B. Braun, Deputy Secretary

(SEAL)

89-65

ORDER OF THE STATE OF WISCONSIN
NATURAL RESOURCES BOARD
CREATING RULES

IN THE MATTER of creating ch. NR 237 of the Wisconsin Administrative Code pertaining to effluent limitations and pretreatment standards for the pharmaceutical manufacturing industry	WW-10-89

Analysis Prepared by Department of Natural Resources

Statutory authority: ss. 147.035, 147.04, 147.06, 147.07, and 227.11(2)(a), Stats.
Statutes interpreted: ss. 147.035, 147.04, 147.06, and 147.07, Stats.

The Federal Water Pollution Control Act amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical and biological integrity of the Nation's waters" (section 101(a)). To implement the act, the U.S. Environmental Protection Agency issues effluent limitations, pretreatment standards, and new source performance standards for industrial wastewater discharges. The Clean Water Act of 1977 expanded the federal pollution control program by setting different types of effluent limitations: "best practicable technology" (BPT), "best available technology" (BAT), "best conventional technology" (BCT), "new source performance standards" (NSPS), "pretreatment standards for existing sources" (PSES), and "pretreatment standards for new sources" (PSNS). The Clean Water Act stressed control of toxic pollutants, including 65 "priority" pollutants and classes of pollutants from 21 major industries.

The Wisconsin Department of Natural Resources instituted the Wisconsin pollutant discharge elimination system in 1976. This system includes regulating effluent discharges of various industries. The Wisconsin Department of Natural Resources is promulgating ch. NR 237, Wis. Adm. Code, to regulate the pharmaceutical manufacturing industry. The provisions of this chapter are based upon the U.S. Environmental Protection Agency's regulations in 40 C.F.R. Part 439.

The purpose of this rule is to specify effluent limitations for BPT, BAT, BCT, and NSPS for the direct discharge of pollutants to waters of the state and to establish pretreatment standards for the introduction of pollutants to publicly owned treatment works. The effect of the creation of ch. NR 237, Wis. Adm. Code, will be to establish state standards and limitations for industrial wastewater discharges from the pharmaceutical manufacturing industry. The code will reflect changes made by the U.S. Environmental Protection Agency under authority of sections 301, 304, 306, 307, 308, and 501 of the Clean Water Act.

The pharmaceutical manufacturing point source category is characterized by diversity of product, process, plant size, and process stream complexity. The industry has been divided into five subcategories, based upon unit processes: (1) fermentation, (2) extraction, (3) chemical synthesis, (4) mixing, compounding, and formulation, and (5) research. In general, the cleanliness required for pharmacuetical manufacturing results in frequent washdowns and detergents and disinfectants in the wastewater.

Fermentation and chemical synthesis produce the greatest volume of wastewater. Fermentation operations use large quantities of nutrient raw materials such as carbohydrates and proteins. Residues from the organic starting material and mycelia contribute to biological oxygen demand (BOD). In chemical synthesis operations, wastewater is produced by each chemical modification which requires the filling and emptying of batch reactors. These wastewaters contain unreacted raw materials as well as solvents.

Extraction, mixing, compounding, and formulation, and research produce a relatively small volume of wastewater. Biological and natural extraction process have a wide variety of feedstocks, including roots, plant leaves, animal glands, or fungi. These substances contribute to BOD loadings. The wastewater may contain priority pollutants because of the solvents used for extraction. Mixing, compounding, and formulation involves preparing the active ingredients in dosage form for consumption. These activities are often dry processes.

Four federal documents form the basis for 40 CFR Part 439 and ch. NR 237: (1) development document for effluent limitations guidelines and standards for the pharmaceutical manufacturing point source category (USEPA, Washington, D.C., EPA 440/1-83/084, September, 1983); (2) economic analysis of proposed effluent limitations guidelines and standards for the pharmaceutical industry (USEPA, Washington, D.C., EPA 440/2-82/013, November, 1982); (3) development document for final best conventional technology effluent limitations guidelines for the pharmaceutical manufacturing point source category (USEPA, Washington, D.C. EPA 440/1-86/084, December, 1986); and (4) sampling and analysis procedures for screening of industrial effluents for priority pollutants (USEPA, Cincinnati, Ohio, April 1977). Copies of

these documents are available for inspection at the central office of the Wisconsin Department of Natural Resources, 101 south Webster street, Madison, and may be obtained from the National Technical Information Service (NTIS), Springfield, Virginia 22161, (703) 487-4600.

This rule is based upon the text of 40 C.F.R. Part 439 and is identical to the federal regulation for purposes of s. 227.14(1m)(a), Stats. However, changes have been made in the text of the federal regulation to make the rule useful to Wisconsin citizens, industry, and regulating authorities. These changes are consistent with the current state regulatory framework and reflect the conventions of state rule drafting.

The federal regulations are repetitious, so the text has been condensed to form the state rule. The subcategories of the federal rule have been eliminated because the regulations are the same for each subcategory. Where possible, Wisconsin Administrative Code references were substituted in the text for references to the Code of Federal Regulations. Citations in the text to the Code of Federal Regulations may be cross-referenced to corresponding sections of the Wisconsin Administrative Code in the table which has been added at the end of the rule. Several definitions have been added to the state rule. As required by the administrative rules procedures manual, a purpose section has been added. A compliance dates section has been added.

SECTION 1. Chapter NR 237 is created to read:

Chapter NR 237

Pharmaceutical Manufacturing

NR 237.01 Purpose
NR 237.02 Applicability
NR 237.03 General definitions
NR 237.04 Monitoring requirement
NR 237.05 Cyanide
NR 237.06 Dilution
NR 237.07 Compliance dates
NR 237.08 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available
NR 237.09 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable
NR 237.10 New source performance standards
NR 237.11 Pretreatment standards for existing sources
NR 237.12 Pretreatment standards for new sources
NR 237.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology

NR 237.01 PURPOSE. The purpose of this chapter is to establish effluent limitations, performance standards, and pretreatment standards for discharges of process wastes from the pharmaceuticals manufacturing point source category.

NR 237.02 APPLICABILITY. This chapter applies to any facility which manufactures pharmaceuticals by fermentation, extraction, chemical synthesis, or mixing, compounding, and formulation or conducts pharmaceutical research and which discharges or may discharge process wastewater pollutants to waters of the state or introduces or may introduce process wastewater pollutants into a publicly owned treatment works.

NR 237.03 GENERAL DEFINITIONS. In addition to the definitions set forth in ss. NR 205.03, 205.04, and 211.03, the following definitions are applicable to the terms used in this chapter:

(1) "Cyanide destruction unit" means a treatment system specifically designed to remove cyanide.

(2) "Existing source" means any point source, except for a new source as defined in sub. (7), from which pollutants are or may be discharged either into waters of the state or into a publicly owned treatment works.

(3) "Extraction operation" means an operation which produces either biological or natural extraction products, such as blood fractions, vaccines, serums, animal bile derivatives, endocrine products, or medicinal products, such as alkaloids, isolated from botanical drugs and herbs.

(4) "Long term daily average raw waste load" means the average daily mass of a pollutant discharged to the wastewater treatment system over the 12 consecutive month period with the greatest production within the most recent 36 months.

(5) "Maximum 30-day average" means the maximum average of daily values for 30 consecutive days.

(6) "Mixing, compounding, and formulation operation" means an operation which blends, mixes, compounds, or formulates pharmaceutical ingredients into preparations, such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions, for either human or veterinary use.

(7) "New source" means any point source for which construction commenced after November 26, 1982, and from which pollutants are or may be discharged directly to the waters of the state or to a publicly owned treatment works.

NR 237.04 MONITORING REQUIREMENT. Unless otherwise noted, self-monitoring shall be conducted at the final effluent discharge point.

NR 237.05 CYANIDE. (1) Permittees not using or generating cyanide must certify to the control authority that cyanide is neither used nor generated.

(2) DIRECT DISCHARGERS. The following requirements are applicable to any facility which is a direct discharger and which uses or generates cyanide:

(a) If all waste streams containing cyanide are diverted to a cyanide destruction unit and if the effluent from the cyanide destruction unit is discharged to a biological treatment system, self monitoring shall be conducted after cyanide treatment and before dilution with other streams, except as provided in par. (b).

(b) Self monitoring may be conducted at the final effluent discharge point if three adjustments are made:

1. The daily maximum cyanide limitation is multiplied by 0.18;

2. The 30-day maximum cyanide limitation is multiplied by 0.35; and

3. The daily and 30-day maximum cyanide limitations are further adjusted according to the ratio of the flow of the waste streams containing cyanide to the total process wastewater discharge flow.

(c) If all waste streams containing cyanide are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self monitoring shall be conducted at the final effluent discharge point as provided in par. (b).

(3) DISCHARGES TO A PUBLICLY OWNED TREATMENT WORKS. The following requirements are applicable to any facility which discharges to a POTW and which uses or generates cyanide:

(a) If all waste streams containing cyanide are diverted to a cyanide destruction unit, self monitoring shall be conducted after cyanide treatment and before dilution with other streams, except as provided in par. (b).

(b) Self monitoring may be conducted at the final effluent discharge point if the daily and 30-day maximum cyanide standards are adjusted according to the ratio of the flow of the waste streams containing cyanide to the total process wastewater discharge flow.

(c) If all waste streams containing cyanide are not treated, self monitoring shall be conducted at the final effluent discharge point as provided in par. (b).

NR 237.06 DILUTION. Dilution to meet the standards set forth in this chapter may not be practiced.

NR 237.07 COMPLIANCE DATES. (1) Any existing source subject to this chapter which discharges to waters of the state shall achieve:

(a) The effluent limitations representing BPT by July 1, 1977; and

(b) The effluent limitations representing BAT by July 1, 1984.

(2) Any new source subject to this chapter which discharges to waters of the state shall achieve NSPS at the commencement of discharge.

(3) Any existing source subject to this chapter which introduces process wastewater pollutants into a POTW shall achieve PSES by October 27, 1986.

(4) Any new source subject to this chapter which introduces process wastewater pollutants into a POTW shall achieve PSNS at the commencement of discharge.

NR 237.08 EFFLUENT LIMITATIONS REPRESENTING THE DEGREE OF EFFLUENT REDUCTION ATTAINABLE BY THE APPLICATION OF THE BEST PRACTICABLE CONTROL TECHNOLOGY CURRENTLY AVAILABLE. (1) Except as provided in 40 C.F.R. ss. 125.30 to 125.32, any existing source subject to this chapter shall achieve the effluent limitations set forth in subs. (2), (3) and (4) representing the degree of effluent reduction attainable by the application of BPT.

(2) BIOLOGICAL OXYGEN DEMAND AND CHEMICAL OXYGEN DEMAND. (a) Except as provided in par. (c), the limitation for the daily average mass of BOD5 and COD for any calendar month shall be calculated by multiplying the long term daily average raw waste load by a variability factor and the difference between 1 and the required fractional reduction as given in the following table:

Table 1

Pharmaceutical Manufacturing

BPT Effluent Limitations		
Pollutant or pollutant property	Variability factor	Required fractional reduction
BOD5	3.0	0.9
COD	2.2	0.74

(b) The limitations for BOD5 and COD shall be expressed in mass per unit time.

(c) Extraction operations and mixing, compounding, and formulation operations are not required to reduce the maximum 30-day average BOD5 concentration to less than 45 mg/l or reduce the maximum 30-day average COD concentration to less than 220 mg/l.

(d) Exclusions from the raw waste loads. 1. For fermentation operations, calculation of raw waste loads of BOD5 and COD shall exclude any waste load associated with separable mycelia and solvents in those waste loads, except that residual amounts of solvents remaining after solvent recovery, separate disposal, or reuse may be included in the raw waste load. Removal, disposal, and reuse includes physical separation and removal of separable mycelia, recovery of solvents from waste streams, incineration of concentrated solvent waste streams, incineration of tar still bottoms, and broth concentration for disposal other than to the treatment system.

2. For extraction, chemical synthesis, and mixing, compounding, and formulation operations, calculation of raw waste loads of BOD5 and COD shall exclude any waste load associated with solvents in those waste loads, except that residual amounts of solvents remaining after solvent recovery, separate disposal, or reuse may be included in the raw wate load. Removal, disposal, and reuse includes recovery of solvents from waste streams and incineration of concentrated solvent waste streams and incineration of tar still bottoms.

(3) TOTAL SUSPENDED SOLIDS. The TSS BPT effluent limitation shall be calculated by multiplying the BOD5 limitation, as calculated in sub. (2), by 1.7.

(4) CYANIDE AND pH. The following limitations for cyanide and pH apply:

Table 2

Pharmaceutical Manufacturing

BPT Effluent Limitations		
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Pollutant or pollutant property	milligrams per liter	
Cyanide(1)	33.5	9.4
pH	(2)	(2)

(1) This applies only to those plants using or generating cyanide and to discharges not resulting from research.
(2) Within the range of 6.0 to 9.0

NR 237.09 EFFLUENT LIMITATIONS REPRESENTING THE DEGREE OF EFFLUENT REDUCTION ATTAINABLE BY THE APPLICATION OF THE BEST AVAILABLE TECHNOLOGY ECONOMICALLY ACHIEVABLE. (1) Except as provided in 40 C.F.R. ss. 125.30 to 125.32 and sub. (2), any existing source subject to this chapter which uses or generates cyanide shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of BAT:

Table 3

Pharmaceutical Manufacturing

BAT Effluent Limitations		
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Pollutant or pollutant property	milligrams per liter	
Cyanide	33.5	9.4

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

NR 237.10 NEW SOURCE PERFORMANCE STANDARDS. (1) Except as provided in sub. (2), any new source subject to this chapter shall achieve the following standards:

Table 4

Pharmaceutical Manufacturing

	NSPS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Pollutant or pollutant property	milligrams per liter	
Cyanide	33.5	9.4
pH	(1)	(1)

(1) Within the range of 6.0 to 9.0 at all times

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

NR 237.11 PRETREATMENT STANDARDS FOR EXISTING SOURCES. (1) Except as provided in ss. NR 211.13 and 211.14 and sub. (2), any existing source subject to this chapter which introduces pollutants into a POTW and which uses or generates cyanide shall comply with ch. NR 211 and achieve the following PSES:

Table 5

Pharmaceutical Manufacturing

	PSES	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
Pollutant or pollutant property	milligrams per liter	
Cyanide	33.5	9.4

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

NR 237.12 PRETREATMENT STANDARDS FOR NEW SOURCES. (1) Except as provided in s. NR 211.13 and sub. (2), any existing source subject to this chapter which introduces pollutants into a POTW and which uses or generates cyanide shall achieve the standards set forth in s. NR 237.11.

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

NR 237.13 EFFLUENT LIMITATIONS REPRESENTING THE DEGREE OF EFFLUENT REDUCTION ATTAINABLE BY THE APPLICATION OF THE BEST CONVENTIONAL POLLUTANT CONTROL TECHNOLOGY. (1) Except as provided in 40 C.F.R. ss. 125.30 to 125.32 and sub. (2), any existing source subject to this chapter shall achieve the effluent limitations set forth in s. NR 237.09 for BOD5, TSS, and pH.

(2) This section does not apply to discharges resulting from pharmaceutical research at facilities which do not manufacture pharmaceuticals.

NOTE: The Wisconsin administrative code corresponds to the code of federal regulations as cross referenced in the following table:

State Code	Code of Federal Regulations
s. NR 205.03	40 C.F.R. s. 401.11
s. NR 205.04	40 C.F.R. s. 401.11
ch. NR 211	40 C.F.R. Part 403
s. NR 211.03	40 C.F.R. s. 403.3
s. NR 211.13	40 C.F.R. s. 403.7
s. NR 211.14	40 C.F.R. s. 403.13
s. NR 211.15	40 C.F.R. s. 403.12
ch. NR 237	40 C.F.R. Part 439

The foregoing rules were approved and adopted by the State of Wisconsin Natural Resources Board on October 26, 1989.

The rules shall take effect the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22(2) (intro.), Stats.

Dated at Madison, Wisconsin, March 1, 1990.

STATE OF WISCONSIN DEPARTMENT OF NATURAL RESOURCES

SEAL

By Carroll D. Besadny
Carroll D. Besadny, Secretary

State of Wisconsin \ DEPARTMENT OF NATURAL RESOURCES
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March 2, 1990

In reply refer to: 1020

Mr. Gary L. Poulson
Assistant Revisor of Statutes
Suite 702
30 W. Mifflin Street

Dear Mr. Poulson:

Enclosed are two copies, including one certified copy, of State of Wisconsin Natural Resources Board Order No. WW-10-89. These rules were reviewed by the Assembly Committee on Environmental Resources and Utilities and the Senate Committee on Urban Affairs, Environmental Resources, Utilities and Elections pursuant to s. 227.19, Stats. Summaries of the final regulatory flexibility analysis and comments of the legislative review committees are also enclosed.

You will note that this order takes effect following publication. Kindly publish it in the Administrative Code accordingly.

Sincerely,

C. D. Besadny
Secretary

Enc.