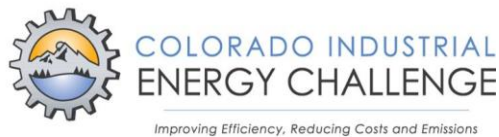




CORDENPHARMA COLORADO

ENVIRONMENTAL PROGRAMS STATUS REPORT

June 4, 2020



Introduction

Status Report History and Purpose

The annual Environmental Programs Status Report (Status Report), which was first issued in 1998, is part of the voluntary pollution prevention program at CordenPharma Colorado. The Status Report serves as an update to the City of Boulder and Boulder County on the current status and results of CordenPharma Colorado's pollution prevention activities. The Status Report also meets the requirements of City of Boulder municipal code 10-7.7-8(a)(1). The goal is to provide our stakeholders and the general public with an understanding of CordenPharma Colorado's environmental footprint. The Status Report also demonstrates CordenPharma Colorado's commitment to continuous improvement in our operations, both benefitting the patients who depend on the medicines CordenPharma Colorado produces and also protecting the environment. As always, a copy of the latest Environmental Programs Status Report is available for general public review on our website, www.cordenpharma.com/facilities/colorado.

Status Report Summary

In 2019, CordenPharma Colorado increased the production of bulk pharmaceuticals and pharmaceutical intermediates by 6 percent from 2018. As a result, there were negative trends in several environmental figures that directly correlate to production rates. However, because of the different environmental impacts of each process, some environmental figures reflect positive trends due to changes in the mix of products produced as well as pollution prevention efforts.

From 2018 to 2019, total bulk liquid sent offsite increased by 40 percent, however, the percentage sent offsite for the beneficial purposes of recycling or energy recovery improved from 72 percent to 92 percent. Additional changes from 2018 to 2019 include an 8 percent increase in energy usage and a 25 percent increase in volatile organic compound emissions. Details can be found in the Summary Tables, beginning on page 12.

Status Report Outline

The remainder of this Status Report includes the following sections:

- **2019 Activity Background**
- **Environmental Compliance and Regulatory Status Changes**
- **Pollution Prevention Goals and Objectives**
- **2019 Summary Tables**

2019 Activity Background

This section of the Environmental Programs Status Report details the production and technical development activities at CordenPharma Colorado and the voluntary environmental performance programs in which the company participates.

Production Activities Summary

CordenPharma Colorado is a member of the CordenPharma Group. The CordenPharma Group includes a network of international companies that manufacture bulk intermediates, active ingredients, and final prescription and over-the-counter medicines.

The current focus of CordenPharma Colorado's activities is the contract production of therapeutic peptides, highly active compounds, and complex small molecules. CordenPharma Colorado sends the compounds it produces to other manufacturing sites for formulation into finished pharmaceutical products. As a multi-purpose facility that can handle small and large scale production, the medicinal compounds that CordenPharma Colorado manufactures frequently change in response to market demand and the development of new therapeutic innovations.

Technical Development Activities

CordenPharma Colorado's technical development activities include designing of manufacturing processes for intermediates and APIs that produce high purity medicinal compounds, while optimizing cost, reliability and safety. These same development activities also have environmental benefits:

- Improving the inherent safety of our manufacturing processes often entails the discovery and development of chemical synthesis routes that minimize or eliminate the use of environmentally undesirable materials.
- The improved synthesis routes that CordenPharma Colorado scientists design also can help avoid high pressure and high temperature process conditions, with both safety benefits and energy savings.
- Starting with the simplest materials as building blocks for our products and improving the efficiency of our manufacturing processes minimizes the demand for raw materials.
- Maximizing the ability of our existing equipment to manufacture pharmaceutical products minimizes the need to construct and operate new facilities.

CordenPharma Colorado's technical development facilities include both laboratories for process research and pilot scale production facilities for manufacturing drug compounds in the quantities necessary for approval by regulatory agencies, to supply the clinical trials for new drugs, and to demonstrate new manufacturing processes.

Voluntary Environmental Performance Programs

CordenPharma Colorado participates in a variety of federal, state, local, and industry-wide initiatives that set challenging pollution prevention standards. The following are the pollution prevention programs in which CordenPharma Colorado currently participates:

City of Boulder Pollution Prevention Program

CordenPharma Colorado has been a voluntary participant in the City of Boulder's Pollution Prevention Program since its inception. Participation in the Pollution Prevention Program began with the development of a "Pollution Prevention Master Plan and Statement of Commitments" and the setting of specific pollution reduction goals. CordenPharma Colorado tracks the success of its environmental initiatives as a founding participant in the Pollution Prevention Program through this annual report to the City of Boulder, now titled "Environmental Programs Status Report."

Colorado Environmental Leadership Recognition

The State of Colorado's Environmental Leadership certification recognizes companies that voluntarily perform above and beyond existing mandated environmental regulations. Environmental Leaders like CordenPharma Colorado must have a comprehensive and operational environmental management system and a pollution prevention plan that commits the company to a program of continuous environmental improvement. In its letter announcing the Environmental Leadership certification, the Colorado Department of Public Health and Environment thanked CordenPharma Colorado for the "effort and dedication" it brings to environmental issues. Under the Environmental Leadership program, CordenPharma Colorado has participated in statewide pollution prevention workshops and mentoring programs. Since 2003, CordenPharma Colorado has held the highest environmental honor that the State of Colorado bestows, the title of "Gold Level" Environmental Leader.

ISO 14001 Certification

CordenPharma Colorado obtained certification under the ISO 14001 standard in 2006 and has maintained the certification since that time. CordenPharma Colorado earned and maintains its ISO 14001 certification through a comprehensive independent audit of the company's environmental, health, safety, and security management system.

Colorado Industrial Energy Challenge

In 2010, CordenPharma Colorado became a Charter Member of the Colorado Industrial Energy Challenge (CIEC) program. CIEC is a voluntary program sponsored by the Colorado Energy Office (CEO) and the U.S. Department of Energy (DOE). The program challenges industrial firms to set energy efficiency goals and to demonstrate progress towards achieving their goals. CordenPharma Colorado was awarded an "Excellence in Energy Efficiency" award in 2012, and again in 2017, for its energy reduction efforts.

Volunteer Work with Boulder County Parks and Open Space

CordenPharma Colorado has been supporting Boulder County Open Space (BCOS) since 2009. Each year, CordenPharma Colorado employees, along with their friends and families, volunteer to spend a day or two working to maintain and improve various open spaces. Employees have built fences, repaired trails, collected native seeds, fixed bridges, restored burned slash pile areas, removed infected trees, and worked on whatever else might be needed.

Environmental Compliance or Regulatory Status Changes

There was no change in CordenPharma Colorado's compliance or regulatory status in 2019.

Pollution Prevention Goals and Objectives

CordenPharma Colorado is committed to pursuing pollution prevention goals associated with our energy reduction, process waste minimization, and other pollution prevention efforts. This section details the progress CordenPharma Colorado made in 2019 towards these three goal categories, including specific program achievements and plans for further action in 2020 and 2021.

Energy Reduction Goals

Due to recent increases in energy demand driven by facility improvements and growth of the business, energy reduction has been a challenge. From 2018 to 2019, the company increased onsite energy consumption by 8 percent. In addition to business growth and bringing additional HVAC units online, these numbers were also impacted by cooler weather in 2019 compared to 2018, with the winter months averaging 2.2°F cooler. However, energy consumption at CordenPharma Colorado has decreased 14 percent since 2005 when the company's original energy goals were set.

CordenPharma Colorado continues to identify, evaluate, and implement energy reduction measures. A number of initiatives have been completed over the last ten years that were highly effective. The following recent objectives are underway to continue to support energy reduction both on and off site:

Objective 1a: Implement a new standard for lighting in office and manufacturing buildings, where LED lights will be used in new installations. This will result in lower energy consumption.

Achievement: CordenPharma Colorado has implemented the new lighting standard and over the last several years has installed many LED lights for specific applications to collect data on performance and functionality. In 2019, in the office areas, the T-8 lighting system replacement program progressed. A keystone Smart Drive LED system is being utilized that allows direct replacement into ballasted systems. Assuming 25 percent utilization, this saves 20 kilowatt-hour per year per bulb. This allows the changeover to continue with minimal disruption to the office areas. In 2019, 1129 units were purchased, which annualized saves approximately 23,000 KWH of electricity per year.

Objective 1b: A new larger lyophilizer is being installed to expand production capability. Rather than installing a new independent chiller unit to cool the lyophilizer, a new dedicated pipe will be installed from the existing cooling tower to the new lyophilizer to provide energy efficient cooling. This will eliminate the need for a new 95 ton chiller.

Achievement: Complete. This unit was installed in 2019. Annualized savings are approximately 21,000 KWH of electricity per year.

Objective 1c: To meet production needs, one manufacturing area in Plant 3 is being converted to conform to ISO 8 cleanroom standards. In this area, CordenPharma Colorado will replace an existing HVAC unit. Overall capacity will increase with dual units due to implementation of the ISO 8 cleanroom standards and replacement of swamp cooling with Dx cooling. To mitigate the effect of this capacity increase, the dual replacement air conditioning units will be controlled by Variable Frequency Drives (VFD) and will utilize multiple service modes to allow reduced usage during non-active production periods. Additionally, LED lighting will be installed, and active pressure control will be installed to ensure that sufficient but not excess conditioned air is utilized.

Achievement: Complete. This project was commissioned in 2019. Annualized savings are approximately 1,400 KWH of electricity and 200 decatherms natural gas per year.

Objective 1d: Improve the production efficiency of the existing pressure swing adsorption (PSA) nitrogen generators by replacing and upgrading the Carbon Molecular Sieve media. These units supply nitrogen for manufacturing equipment, primarily for flammability control. If PSA nitrogen is not available, it is necessary to make-up the difference by vaporizing cryogenic nitrogen purchased from an outside supplier.

Achievement: Complete. Upgrade was completed in 2019, increasing nitrogen production by 70 percent with no increase in power demand at the CordenPharma Colorado facility. This results in less cryogenic nitrogen being purchased and therefore an overall lower global energy requirement for the nitrogen generation processes on-site, although direct energy savings are not located at the facility. Annualized savings are approximately 426,000 KWH.

Process Waste Minimization Goals

CordenPharma Colorado strives to reduce the solvent waste and air emissions its pharmaceutical manufacturing processes generate. The company achieves these goals by modifying manufacturing processes to reduce the need for production material, recycling materials for re-use, controlling air emissions, and many other process waste minimization efforts. Over the years, CordenPharma Colorado has successfully reduced the process waste from many manufacturing steps. The following specific objectives were identified to further advance these efforts in 2019 and 2020.

Objective 2a: Eliminate the use of holding drums in the chromatography steps of a manufacturing process by instead storing the intermediate products in a vessel between steps. This will eliminate the waste of approximately 90 drums per batch and also reduce the air emissions generated from charging the material to drums and then back into a vessel.

Achievement: Complete. The process improvements were implemented in 2019.

Objective 2b: Evaluate three solvent waste streams in a specific manufacturing process for on-site recycle. Heptane, MTBE, and ethyl acetate, which are used in a manufacturing process, will be evaluated for recycling feasibility and implemented if possible.

Achievement: Laboratory studies and engineering evaluations have been completed. Ethyl acetate is likely a viable solvent recycle operation for this process, and the recovery will be demonstrated in 2020. MTBE and heptane will require more development work to determine viability. Additionally, the team is exploring offsite recycle opportunities for these streams.

Objective 2c: Evaluate two solvent waste streams in a specific manufacturing process for on-site or off-site recycle. DMF and acetonitrile, which are used in a manufacturing process, will be evaluated for recycling feasibility during the scale-up of this process.

Achievement: Engineering evaluations have been completed, as well as initial evaluation of off-site recycling. Acetonitrile recovery will be demonstrated in the plant in 2020. DMF will require more development work to determine viability.

Objective 2d: Evaluate one process wastewater stream for treatment in the CordenPharma Colorado onsite wastewater treatment plant instead of being shipped offsite for incineration.

Achievement: Initial studies were completed in 2019, and unfortunately onsite wastewater treatment does not appear to be feasible for this stream. Instead, 2020 efforts now include evaluation of this stream for offsite recovery opportunities.

Objective 2e: Evaluate one process manufacturing step for a reduction in acetonitrile usage. If viable, the target will be a 50 percent reduction in acetonitrile usage in this step of the process.

Other Pollution Prevention Goals

In addition to the energy efficiency and process waste minimization efforts listed above, CordenPharma Colorado also set the following additional pollution prevention goal:

Objective 3a: Reduce paper usage by electronically managing some business records that the company currently prints on paper.

Achievement: CordenPharma Colorado has previously converted several document types to electronic files. CordenPharma Colorado is currently working on a multi-year implementation of an electronic data management system to convert additional records and forms to electronic storage.

Other Pollution Prevention Activities

In addition to the projects and plans mentioned above, all CordenPharma Colorado process teams continue to identify and evaluate pollution prevention opportunities in their areas of expertise. The Pollution Prevention Team supports and tracks all pollution prevention efforts at CordenPharma Colorado, with a focus on reducing energy consumption and solvent usage and increasing solvent recovery in production processes.

2019 Summary Tables

2019 Production at CordenPharma Colorado

In 2019, as measured by mass, CordenPharma Colorado increased the production of bulk pharmaceuticals and pharmaceutical intermediates by 6 percent from 2018. At the same time, the company's raw materials usage also increased by 11 percent. The environmental figures below reflect the result of both CordenPharma Colorado's production changes as well as the company's implementation of pollution prevention measures.

Recycling of Raw Materials – Onsite Recycling

The list below compares process requirements and recycling volumes for chemicals that were recycled onsite. The "process requirement" represents the amount of each material needed during the year. The "amount recycled" reflects the reuse of a compound in a process, rather than disposing of it. The "percentage recycled" is the percentage of the process requirement that was met using recycled material instead of virgin material. The low numbers are due to a significant increase in recent years in the production of short-campaign clinical development processes that do not allow for recycling of solvents.

Chemical ¹	Usage (lbs)	Amount Recycled (lbs)	Percentage Recycled
Ethyl Acetate	119,059	19,030	16%
Methanol	1,186,879	21,980	1.9%
TOTAL		41,010	

¹ Offsite recycling is not included in this list. See table below, "Bulk Liquid Sent Offsite- Waste and Recycling"

Water Usage

The following table details water use at CordenPharma Colorado.

Type of Usage	2015 (gallons)	2016 (gallons)	2017 (gallons)	2018 (gallons)	2019 (gallons)
Process	18,899,536	19,019,464	20,893,779	17,414,096	20,613,118
Commercial	1,747,121	1,655,609	1,838,633	1,930,145	2,433,331
Cooling	8,557,277	7,853,316	8,230,401	10,221,153	11,042,487
Irrigation	1,494,764	1,459,250	1,587,350	1,513,788	1,751,800
Total	30,698,698	29,987,639	32,550,163	31,079,183	35,840,736

Wastewater Pretreatment Plant Discharge

CordenPharma Colorado sends aqueous wastes from production activities through its onsite pretreatment facility. Wastewater leaving the system is discharged to the City of Boulder treatment facility. The following table lists the major components of the wastewater that CordenPharma Colorado discharges to the City of Boulder treatment facility:

	Discharge (in Pounds unless otherwise indicated)					
	1995 (Baseline)	2015	2016	2017	2018	2019
Volume, gal	21,035,000	8,890,417	7,378,314	8,752,348	9,720,383	11,107,944
Total Organic Content (TOC)	115,000	6,906	3,673	3,878	6,504	5,990
Chromium	31	1.6	1.3	1.0	1.1	1.0
Copper	4.3	12.2	16.6	10.4	11.2	11.5
Lead	2.8	3.7	3.1	3.6	0.0	0.0
Nickel	4.1	2.3	1.8	2.6	2.9	2.8
Zinc	73	43.2	55.6	40.0	51.7	42.1

Bulk Liquid Sent Offsite - Waste Disposal and Recycling

The following values represent the amount of material CordenPharma Colorado sent offsite in bulk quantities for recycling, energy recovery, or incineration. Due to an increase in production, a change in production mix, and the different solvents required for each product, from 2018 to 2019, the total bulk liquid sent offsite increased by 40 percent, and bulk liquid sent offsite per unit of product produced increased by 32 percent. However, the percentage sent offsite for the beneficial purposes of recycling or energy recovery improved from 72 percent to 92 percent.

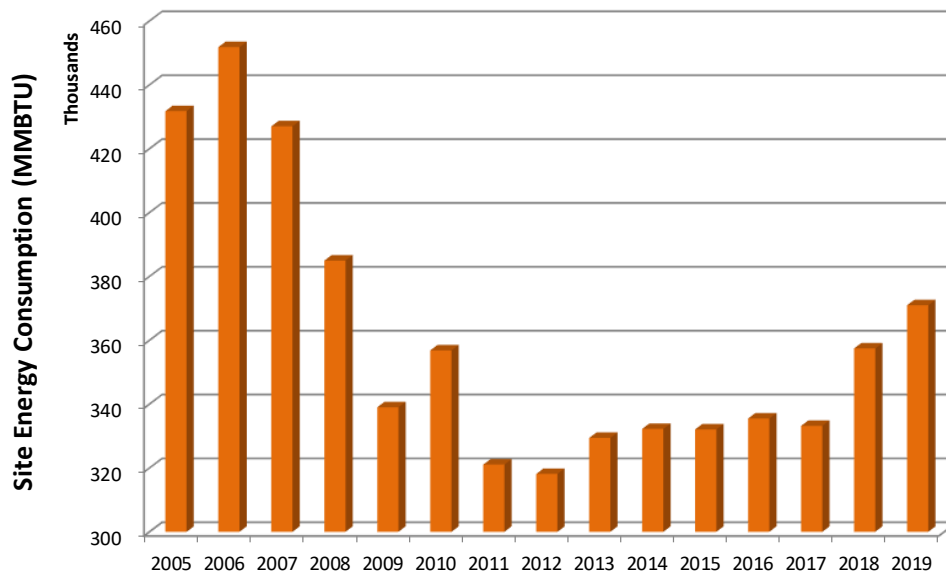
Description	2015	2016	2017	2018	2019
Total bulk liquid sent offsite (kg)	2,349,820	1,704,338	2,587,731	3,401,666	4,768,507
% Change from previous year	-55%	-27%	+52%	+31%	+40%
% Sent offsite for recycling	1%	0%	1%	0%	0.4%
% Sent offsite for energy recovery	98%	71%	53%	72%	92%

Energy Consumption

The following table presents the standard energy metrics of natural gas and electricity consumption at CordenPharma Colorado. Additionally, off-site nitrogen consumption converted to energy equivalents is also presented since it has been a focus area for the company, and since it has a positive impact on global energy consumption. From 2018 to 2019, natural gas usage increased and electricity decreased slightly.

Energy Type	2015	2016	2017	2018	2019
Natural Gas (therms)	1,128,570	1,135,760	1,083,400	1,180,350	1,350,160
Electricity (KWH)	21,922,788	22,469,916	22,484,035	23,735,366	23,596,124
Off-site Nitrogen (KWH equivalent)	4,009,166	2,377,549	3,146,304	3,675,456	3,199,255

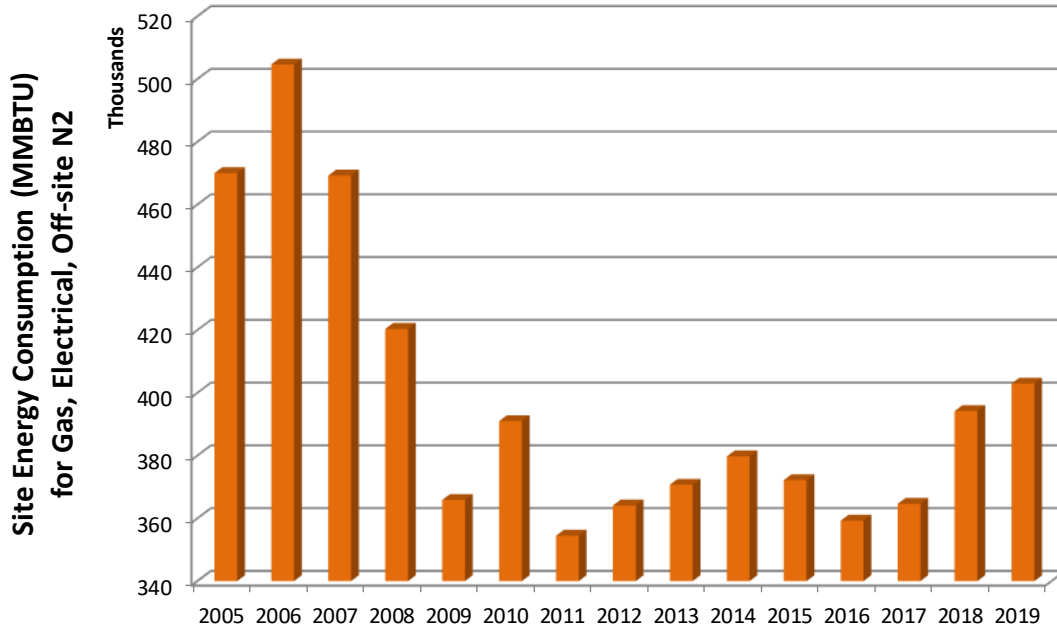
Combined Onsite Energy Use (Electricity & Natural Gas)



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Additionally, when the graph is updated to include the energy used offsite to produce nitrogen for the site, CordenPharma Colorado's nitrogen use reduction efforts, especially in 2015 and 2016, are shown to have a positive impact on global energy use:

Combined Onsite and Offsite Energy Use
(Electricity, Natural Gas, & Offsite Nitrogen Energy Equivalents)



NOTE: Electricity unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Air Emissions

The following table displays CordenPharma Colorado's air emissions, divided into Toxic Release Inventory (TRI) compounds, Hazardous Air Pollutants (HAPs), and Volatile Organic Compounds (VOCs). From 2018 to 2019, overall VOC emissions increased by 25 percent and HAP emissions increased by 50 percent. An overall increase in production and differences in products manufactured resulted in the increase.

	1989 (Baseline)	2015	2016	2017	2018	2019
Acetone ³	242,500	1,400	3,200	3,700	5,200	4,130
Acetonitrile ^{1,2}	--	2,600	2,100	2,700	5,100	8,800
Dimethylformamide ^{1,2}	--	130	150	190	280	1,120
1,4-Dioxane ^{1,2}	--	60	260	250	620	570
Hexane ^{1,2}	36,600	2,600	1,400	950	100	1,450
Hydrochloric acid ¹	4,000	160	190	160	160	390
Methanol ^{1,2}	109,600	9,100	4,900	4,790	6,000	6,420
Methyl chloride ^{1,2}	6,700	--	--	--	--	--
n-Methyl-2-pyrrolidinone ²	--	10	7	3	40	5
Methyl Tert-Butyl Ether ^{1,2}	--	4,230	680	1060	1,750	3,420
Methylene chloride ¹	103,300	1,840	1,230	850	1,270	1,240
Pyridine ²	--	2	3	0	1	--
Toluene ^{1,2}	284,400	550	240	220	730	640
Triethylamine ^{1,2}	--	3	19	20	30	30
Total TRI air emissions (tons)	375	11	5	6	8	12
% change from previous year	--	0%	-55%	+20%	+33%	+50%
% change from 1989	--	-97%	-99%	-98%	-98%	-97%

Total HAP emissions (tons)	293	11	6	6	8	12
% change from previous year	--	0%	-45%	0%	+33%	+50%
% change from 1989	--	-96%	-98%	-98%	-97%	-96%

Total VOC emissions (tons)	490	13	8	10	16	20
% change from previous year	--	+8%	-38%	+25%	+60%	+25%
% change from 1989	--	-97%	-98%	-98%	-97%	-96%

¹ These chemicals are also classified as HAPs and are included in the HAP total above.

² These chemicals are also classified as VOCs and are included in the VOC total above.

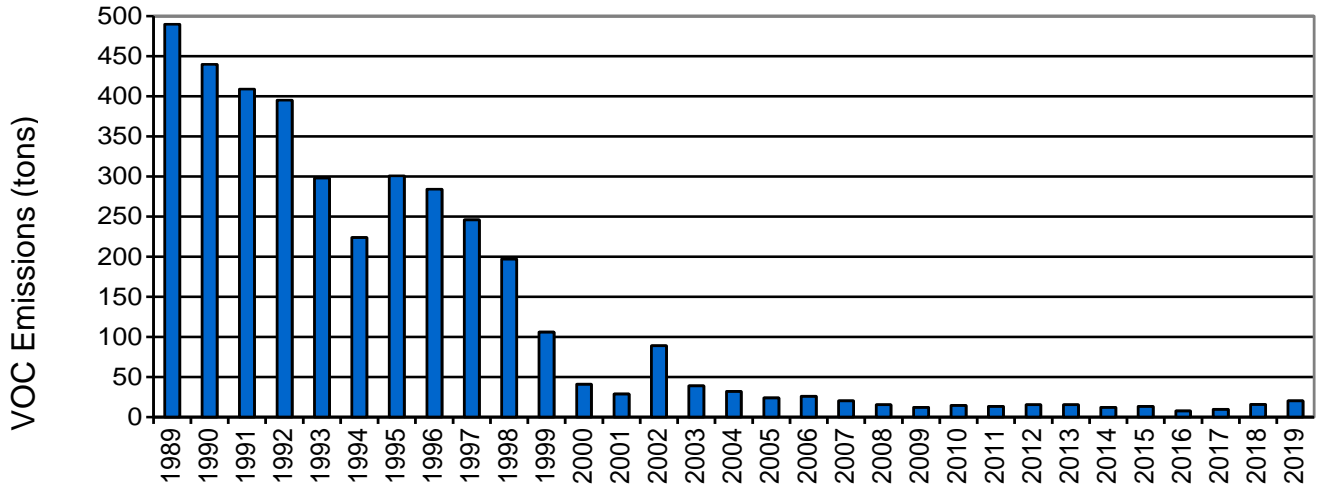
³ Acetone is no longer included in TRI. It is also no longer classified as a VOC. After 1996, it is not included in the VOC total.

⁴ Shaded blocks indicate that TRI reporting for that chemical was not required during that year. They are not included in the TRI emissions total.

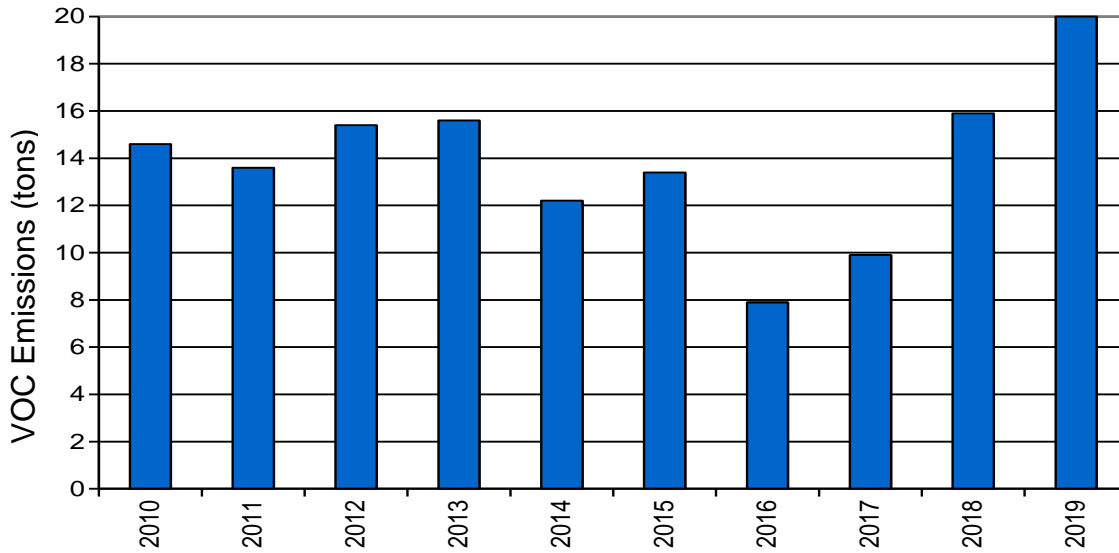
HAP = Hazardous Air Pollutant

VOC = Volatile Organic Compound

Volatile Organic Compounds (VOC) Air Emissions Trend, since 1989



Volatile Organic Compounds (VOC) Air Emissions Trend, Last 10 Years



General Waste Recycling

In 2019, CordenPharma Colorado recycled a considerable amount of general waste. The recycled metals volume presented here includes recycling of removed manufacturing equipment. In 2019, CordenPharma Colorado recycled about 61,000 pounds of office paper, shredded documentation, newspaper, cardboard, magazines, and phone books. These efforts helped CordenPharma Colorado save an estimated 530 trees from destruction.

Type of Material	Pounds Recycled
Paper and Cardboard	61,000
Metals	154,000
Plastic	2,200
Compost	~10,000