

## Pharmaceutical Production MACT Summary

The Pharmaceuticals Production MACT was promulgated on September 21, 1998. To be considered an affected source, the facility must produce a pharmaceutical product and be a major source of HAPs. To obtain a copy of the regulation: [www.epa.gov/ttn/atw/pharma/fr21se98.pdf](http://www.epa.gov/ttn/atw/pharma/fr21se98.pdf).

This rule provides facilities with an alternative, pollution prevention-based standard as an option for complying with the rule's requirements. The pollution prevention-based option would require a reduction in the use of solvents (which are also toxic air pollutants) during the manufacturing process.

*The pharmaceutical manufacturing process consists mainly of chemical production operations used to produce drugs and medication. These operations include chemical synthesis (deriving a drug's active ingredient) and chemical formulation (producing a drug in its final form.). This rule sets an emissions limit or control efficiency requirements for the following emissions points at affected sources or facilities: storage tanks, process vents, equipment leaks, wastewater collection and treatment systems, and cooling towers.*

Industry has the option of complying with the regulation through an alternative, pollution prevention-based standard. The alternative standard would require reductions in the amounts of solvents (also toxic air pollutants) used during the manufacturing process. It would allow facilities to focus on improving processes by reducing solvent loss and incorporating solvent recovery and reuse techniques.

EPA's rule also contains a market-based provision, "emissions averaging," that would allow facilities flexibility to choose certain emissions points to control in order to achieve the required emissions reductions in the most cost-effective manner possible. The proposal would allow facilities to use emissions averaging among process vents and storage tanks. In some situations, facilities may find it more cost-effective to overcontrol these emissions points and undercontrol others, so that the overall result would be greater emissions reductions at lesser control costs. *The rule spells out how facilities would be able to use emissions averaging.*

Pfizer, located in Lincoln, is subject to the MACT but they have taken voluntary limits to reduce their emissions and will not be required to comply with additional requirements until 2007.

**There are tools available that will assist states and facilities in understanding and complying with the rule ([www.epa.gov/ttn/atw/pharma/pharmmpg.html](http://www.epa.gov/ttn/atw/pharma/pharmmpg.html)). The tools include the Pharmaceutical MACT Rule Assistant (which walks you through the applicable requirements, controls, and options available for each process) and inspection checklists.**