

Cellosolve and other pollutants which EPA's pass-through analysis concluded would pass through POTW treatment rather than be removed by POTW treatment. EPA based its determination on a chemical and engineering evaluation of which pollutants would not be susceptible to treatment in POTW biological treatment systems. EPA's pass-through analysis depended on a number of calculations, relying in part on a comparison of a parameter's Henry's Law Constant ( $H_L$ ) with a threshold  $H_L$  value.

In a letter to EPA dated November 28, 2000, the Pharmaceutical Research and Manufacturers of America (PhRMA) indicated that EPA had used an incorrect  $H_L$  value for methyl Cellosolve in the pass-through analysis by assuming an  $H_L$  value of  $2.9 \times 10^{-3}$  atm/gmole/m<sup>3</sup>. This was the same  $H_L$  value that had been used for methyl Cellosolve by EPA's Office of Air Quality Planning and Standards (OAQPS) in establishing the Maximum Air Control Technology (MACT) standards for pharmaceutical manufacturers that were promulgated in 1998, and that had been developed concomitantly with revised pretreatment standards for 40 CFR part 439. The OAQPS, however, subsequently revised its  $H_L$  value for methyl Cellosolve from  $2.9 \times 10^{-3}$  to  $3.3 \times 10^{-7}$  atm/gmole/m<sup>3</sup>, based on a value reported by Johanson G. and Dynesius B. in "Liquid/air partition coefficients of six commonly used glycol ethers," *British Journal of Industrial Medicine*, 1988, 45:561-564.

The determination of an incorrect  $H_L$  constant was reinforced when EPA also considered the analytical technique required to measure low concentrations of methyl Cellosolve in wastewater. Analytical methods to measure volatile organic analytes (VOAs) utilize an inert gas purging technique to recover VOAs from a wastewater sample. But methyl Cellosolve does not purge efficiently and so must be analyzed using a direct injection technique. This fact offered additional evidence that EPA had used an inappropriate  $H_L$  value for methyl Cellosolve in the earlier pass-through analysis of the pretreatment standards.

The revised  $H_L$  for methyl Cellosolve ( $3.3 \times 10^{-7}$  atm/gmole/m<sup>3</sup>) is well below the threshold  $H_L$  value ( $1 \times 10^{-5}$  atm/gmole/m<sup>3</sup>) that EPA used to classify a compound as a volatile organic compound (VOC) for purposes of the Agency's pass-through analysis. Thus, EPA relied on an inappropriate  $H_L$  value for methyl Cellosolve in the pass-through analysis for the 1998 rule. This caused this compound to be identified as a VOC, which the Agency's pass-

through analysis determined would pass through a POTW's treatment. When EPA used the corrected lower  $H_L$  value and found that methyl Cellosolve was not a VOC, the Agency's pass-through analysis determined that this compound would not pass through a POTW's treatment.

#### VII. Additional Edits to 40 CFR Part 439

Today's rule also includes non-substantive edits and format changes to the rule promulgated in 1998 in order to shorten and clarify 40 CFR part 439. The "Authority" citation was shortened to conform with current guidance from the Federal Register Office. The text from § 439.4 was merged into § 439.2 and the heading of § 439.2 was revised to read: "General monitoring requirements." Section 439.4 was re-designated under a new heading "General limitation or standard for pH" and the term "Subcategory" was removed from the heading of all subparts. EPA has also added definitions of "Maximum daily" and "Maximum monthly average" to § 439.1. These definitions are similar to those used in other effluent limitations guidelines and pretreatment standards regulations and reflect the definitions used to promulgate the limits in the existing 40 CFR part 439. Finally, the initial phrase, "The term \* \* \*" was removed from all definitions, column headings and titles of all tables. Corresponding text referencing these headings and titles was also revised.

#### VIII. Rationale for Direct Final Rule

EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comment. The changes here will facilitate the implementation of part 439 and will not affect environmental impacts or compliance costs. They merely clarify applicable dates, correct an inadvertent error and omission, and make other non-substantive edits. However, in the "Proposed Rules" section of today's **Federal Register**, we are publishing a separate document that will serve as the proposal to amend part 439, as described herein, if adverse comments are filed. This rule will be effective on June 11, 2003 without further notice, unless we receive adverse comment by May 12, 2003. If EPA receives adverse comment on one or more distinct amendments, paragraphs, or sections of this rulemaking, we will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn due to adverse comment. Any distinct

amendment, paragraph, or section of today's rulemaking for which we do not receive adverse comment will become effective on the date set out above, notwithstanding any adverse comment on any other distinct amendment, paragraph, or section of today's rule. We will address all adverse public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

#### IX. Statutory and Executive Order Reviews

##### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, (October 4, 1993)), the Agency must determine whether a regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

##### B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology