excluded the use of a controlled substance "Where the manufacturing equipment has had physical contact with a controlled substance in an intermittent manner, not as a routine part of the direct manufacturing process \* \*'' (See p. 8165). The preamble gave as an example the occasional cleaning of an ink plate, where direct contact occurs only between the controlled substance and the manufacturing equipment, not between the controlled substance and the product itself (other than the first one or two products going through the equipment following equipment maintenance). However, the preamble, in addressing this point, specifically noted that this exclusion should also apply in the case of a controlled substance having intermittent contact with the product itself, such as a textile where direct contact occurs through spot cleaning of some individual textiles, but where direct contact is not a normal or usual occurrence in the manufacture of the product.

The Agency intended for the regulatory text to reflect the full discussion in the preamble to the final rule. Therefore, EPA proposed to exempt from the labeling requirements products where there are intermittent uses of controlled substances that may involve an initial contact with the product itself, as well as with the equipment. The exception was proposed to read: "[W]here the manufacturing equipment or product has had physical contact with a controlled substance in an intermittent manner, not as a routine part of the direct manufacturing process  $^{*}$  \*" EPA received no comments on this issue. EPA therefore will revise the regulatory text as proposed.

## XII. Request for Comments Regarding Plasma Etching

In the preamble of the original labeling rule, EPA states that "plasma etching" is considered a process that entails transformation, and thus products manufactured using plasma etching need not be labeled, unless they are otherwise subject to the regulations." Since publication of the final rule, EPA has heard from one plasma etcher who has discovered that the plasma etching process may not necessarily transform all but trace quantities of controlled substances used in the process. At times, it is estimated that as much as 40 percent may not be transformed.

EPA has not received any additional comments on whether plasma etching can be considered generally to constitute transformation under the final labeling rule, which defines

transformation as, "to use and entirely consume a class I or class II substance, except for trace quantities, by changing it into one or more substances not subject to this subpart in the manufacturing process of a product or chemical." Consequently, without further data illustrating that plasma etching does or does not transform all but trace quantities, EPA cannot make any general statements about plasma etching; however, if a particular plasma etching process meets the requirements for "transformation", then the manufacturer need not label the product.

### XIII. Miscellaneous

One commenter requested clarification on the requirements in the original rule (February 11, 1994), to list multiple class I or class II substances on a warning label (§ 82.110), and whether the word "may" implies that it is not mandatory to list all applicable substances. In situations where products are manufactured with or contain multiple substances, those substances must be represented on the warning label. These substances can be identified by either 1) listing them directly on the label, or 2) by using an asterisk (\*) in place of the substance name with a corresponding list of those substances in a legible and conspicuous location. The word "may" is intended to imply the option to use of either of the above labeling alternatives, not to imply that labeling is not mandatory in cases where multiple class I or class II substances are used.

## XIV. Summary of Supporting Analysis

# A. Executive Order 12866

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

(1) Have an annual effect on the economy of \$100 million or more, or adversely and materially affect 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 entitlement, 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 by OMB and EPA that this amendment to the final rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

### B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–602, requires that Federal agencies examine the impacts of their regulations on small entities. Under 5 U.S.C. 604(a), whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available for public comment an initial regulatory flexibility analysis (RFA). Such an analysis is not required if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, pursuant to 5 U.S.C. 605(b).

EPA believes that any impact that this amendment will have on the regulated community will serve only to provide relief from otherwise applicable regulations, and will therefore limit the negative economic impact associated with the regulations previously promulgated under Section 608. An examination of the impacts on small entities was discussed in the final rule (58 FR 28660). That final rule assessed the impact the rule may have on small entities. A separate regulatory impact analysis accompanied the final rule and is contained in Docket A-92-01. I certify that this amendment to the labeling rule will not have any additional negative economic impacts on any small entities.

# C. Paperwork Reduction Act

Any information collection requirements in a rule must be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. Because no additional informational collection requirements are required by this amendment, EPA has determined that the Paperwork Reduction Act does not apply to this rulemaking and no new Information Collection Request document has been prepared.

#### XV. Judicial Review

Under Section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of this action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit