

should be denied an exemption based on the potential risks presented by those substances. For a further discussion of how EPA will determine when to deny an exemption, see Unit III. of this notice.

b. *New information and EPA revocation.* In addition to these safeguards, the rule contains several other provisions that further limit the possibility that exempted substances may present unreasonable risks. Most important, the rule establishes procedures for revocation of the exemption if EPA later determines that the substance may cause serious acute or chronic human effects or environmental effects. In addition, EPA has the authority to require documents relevant to an exemption from the manufacturer (in addition to the information provided in the exemption notice), and the manufacturer would be required to submit promptly to EPA any new data indicating that a substance is ineligible. These provisions will ensure that eligibility for and continuation of the exemption will be determined on the basis of the best available information, regardless of when the information becomes available.

3. *Benefits.* EPA believes that these exemptions will allow many manufacturers to introduce new chemical substances in commerce much more rapidly than via the PMN process. The time and resource savings will also benefit EPA which will, by utilizing its limited assets more efficiently, be able to apply more staff time to reviewing higher risk chemical substances and uses.

4. *Pollution prevention considerations.* The LoREX exemption is expected to further the Agency's pollution prevention efforts by encouraging development of manufacturing processes and technologies which reduce chemical releases and exposures at their source. Such reductions not only limit potential risks to people and the environment, but may also produce significant long-term cost savings to industry through the recapture and reuse of substances which would otherwise have been released into workplaces or the environment.

5. *Risk/benefit balance.* As discussed above, EPA has determined that the risk presented by exempting these two categories of new chemical substances is low. At the same time, there are significant benefits to be achieved by the exemptions, which encourage innovation and permit manufacturers to introduce new chemical substances into commerce more rapidly. Thus, EPA has determined that, under the terms of this rule, the risks associated with low

volume substances and low release/low exposure substances are outweighed by the benefits to society of exempting these substances from full PMN review.

VII. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS-50596B). The record includes basic information considered by the Agency in developing this rule. A public version of the record is available in the TSCA Nonconfidential Information Center from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The TSCA Nonconfidential Information Center is located in Rm. NE-B607 (Northeast Mall), 401 M St., SW., Washington, DC.

VIII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51835, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the Order defines a "significant regulatory action" as an action that is likely to (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 (also referred to as "economically significant") (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts 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 this Executive Order.

Pursuant to Executive Order 12866, it has been determined that this rule is not "a significant regulatory action" under section 3(f) of the Order. This action is therefore not subject to OMB review.

B. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency has determined that this regulatory action will not impose any adverse economic impacts on small entities. EPA believes that, even if all of the notice submitters were small firms, the number of small businesses affected by this action will not be substantial. In

addition, since this action will generally reduce the existing burden and cost imposed on notice submitters, the impact of this action on small entities should be an overall positive one.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et. seq. and have been assigned OMB control number 2070-0012. The public reporting burden for this collection of information is estimated to vary from 96 to 116 hours per response, with an average of 106 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

List of Subjects in 40 CFR Part 723

Chemicals, Environmental protection, Premanufacture notification, Hazardous materials, Reporting and recordkeeping requirements.

Dated: March 21, 1995.

Carol M. Browner,
Administrator.

Therefore, 40 CFR chapter I, part 723 is amended as follows:

PART 723 — [AMENDED]

1. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

2. By revising §723.50 to read as follows:

§723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

(i) Chemical substances manufactured in quantities of 10,000 kilograms or less per year.

(ii) Chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.