permit such person at all reasonable times to have access to and to copy these records.

(k) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(l) *Compliance.* (1) A person who manufactures or imports a new chemical substance and fails to comply with any provision of this section is in violation of section 15 of the Act (15 U.S.C. 2614).

(2) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by this section and section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Violators may be subject to the civil and criminal penalties insection 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this section may be subject to penalties calculated as if they never filed their notices.

(6) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation of this section or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(m) *Inspections.* EPA will conduct inspections under section 11 ofthe Act to assure compliance with section 5 and this section, to verify that information submitted to EPA under this section is true and correct, and to audit data submitted to EPA under this section.

(n) *Confidentiality.* If a manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in 40 CFR part 2. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

[FR Doc. 95–7712 Filed 3–24–95; 3:32 pm]

BILLING CODE 6560–50–F

40 CFR Part 723

[OPTS–50596B; FRL–4923–1]

RIN 2070–AC14

Premanufacture Notification Exemption; Revision of Exemption for Chemical Substances Manufactured in Small Quantities; Low Release and Exposure Exemption; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires that persons notify EPA before they manufacture or import a new chemical substance for commercial purposes. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule to exempt the manufacturer or importer of any new chemical substance from some or all of the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk of injury to health or the environment. EPA is amending the current TSCA section 5(h)(4) limited exemption defined at 40 CFR 723.50 for persons who manufacture certain chemical substances in quantities of 1,000 kilograms or less per year. This amendment will increase the volume limit to 10,000 kilograms or less a year. Also, this amendment adds a new section 5(h)(4) exemption category for certain chemical substances with low environmental releases and human exposures. This amendment will significantly reduce administrative burdens on EPA and industry and will expedite the Agency review process so that lower risk chemical substances may be marketed more quickly. To ensure that these chemical substances will not present an unreasonable risk, EPA has included procedural safeguards, including a 30–day review, and other conditions in the exemption.

DATES: This rule is effective May 30, 1995. This rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time, on April 12, 1995.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554–1404, TDD: (202) 554–0551.

SUPPLEMENTARY INFORMATION: The original exemption for chemical substances manufactured in quantities of 1,000 kilograms or less per year became effective on August 26, 1985. The supporting rationale and background for that exemption were published at 50 FR 16477 on April 26, 1985 and 47 FR 33896, August 4, 1982. This rule was proposed in the **Federal Register** on February 8, 1993 (58 FR 7646). Public hearings on this and related PMN exemptions were held in Washington, DC. on April 26–28, 1993. While general background information is presented here, readers should also consult the preambles for those notices for further information on the objectives and rationale for the rule and the basis for finding under TSCA section 5(h)(4) that activities involving the exempt chemical substances will not present an unreasonable risk of injury to human health or the environment.

I. Background

Section 5(a)(1) of TSCA (15 U.S.C. 2604 (a)(1)) requires any person who intends to manufacture or import a new chemical substance to notify EPA 90 days before manufacture or importation begins. Section 5(h)(4) of TSCA (15 U.S.C. 2604(h)(4)) allows the EPA, by rule, to grant an exemption from any or all of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of a substance will not present an unreasonable risk of injury to health or the environment.

II. Final Exemption

A. Summary of the Rule

1. *Chemical substances manufactured at 10,000 kg or less per year.* Manufacturers of all new chemical substances manufactured in quantities of 10,000 kilograms or less per year are eligible to apply for a new category of exemption. (Note that throughout 40 CFR parts 720, 721, and 723, the term ''manufacturer'' is defined in TSCA section 3(8), 15 U.S.C. 2602(8), to include persons who import the specified chemical substance; the term ''manufacture'' is defined to include importation.) Upon approval, manufacturers will be permitted to manufacture up to 10,000 kilograms of the new chemical substance during

every 12 month period following the date of review period expiration without submitting a full premanufacture notice (''PMN'') under section 5(a)(1) of TSCA.

As with the prior exemption for new chemical substances produced at 1,000 kg or less, new chemical substances will not be approved under the new exemption if the Agency believes that they or their reasonably anticipated metabolites, environmental transformation products, byproducts, or impurities raise a concern for serious acute or chronic human health effects or significant environmental effects under reasonably anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal. Any exemption application will be denied if the Agency is unable to affirmatively find that manufacture, processing, distribution in commerce, use, and disposal of the exempted substance pursuant to the exemption will not present an unreasonable risk of injury to human health or the environment.

Manufacturers requesting this exemption must submit notices 30 days prior to commencement of manufacture or import. As with the prior exemption, where manufacturers provide information on human exposure controls or environmental release controls to support the exemption notice, the manufacturers must maintain those controls throughout the duration of the exemption. If EPA identifies a potential risk from a new chemical substance, but believes that the risk may be sufficiently mitigated through pollution prevention techniques and/or exposure and release controls, the Agency may conditionally approve the exemption pending the manufacturer's submission of an amended exemption notice which includes those or equivalent techniques or controls. If there is insufficient time remaining in the review period to provide the amended information, manufacturers may request a temporary suspension of the review period under 40 CFR 720.75(b). All amended pages of the exception notice must be received by the Agency prior to the expiration of the exemption review period.

Manufacturers are similarly bound to the uses described in their exemption notices and may not change the manufacturing sites identified in their notices unless they either meet the conditions specified in paragraph (j)(6) of the exemption or submit a new exemption notice.

In accordance with practice under the superseded 1,000 kilogram exemption, the Agency will generally perform the risk assessment under the new exemption as if the total amount permissible under the exemption (10,000 kilograms) were being produced. However, submitters wishing their exemptions to be reviewed based upon annual production volumes lower than 10,000 kilograms may so indicate in their exemption notice by marking the binding box adjacent to the production volume space on the form. Submitters who so elect, however, are bound by their election. Submitters who subsequently wish to increase their maximum production volume under the exemption must submit a new exemption notice cross-referencing the original exemption number on the cover of the notice. If the new exemption is granted, it will supersede the previous exemption.

As of the effective date of this rule, the existing 1,000 kilogram exemption category will no longer be available for new exemptions. All exemptions previously granted under the 1,000 kilogram exemption will remain binding and effective under the superseded provisions of 40 CFR 723.50 even though such provisions will no longer be contained in the Code of Federal Regulations. Any modification of the terms of a previously granted exemption must be requested via a new exemption notice. For example, a manufacturer or importer who was granted an exemption under the prior 1,000 kilogram per year or less exemption may submit a new exemption notice to increase the production volume up to 10,000 kilograms per year for the same chemical substance. If such manufacturer does apply for the 10,000 kilogram exemption, its notice will be reviewed for unreasonable risk at the increased production volume. A new risk assessment will be performed based on the information submitted in the new notice. A submitter of a subsequent 10,000 kilogram exemption may continue to manufacture under the terms of the 1,000 kilogram exemption until a regulatory decision is made on the new exemption notice. If the new notice is granted, it will supersede the 1,000 kilogram exemption.

2. *Low release and exposure chemicals.* In connection with the Agency's overall pollution prevention strategy, EPA is adding a new exemption category for chemical substances with low environmental releases and low human exposures during their manufacture, distribution in commerce, processing, use, and disposal. All manufacturers and importers of new chemical substances subject to PMN requirements meeting the stated release and exposure criteria are eligible to apply for this low release and exposure (LoREX) exemption, regardless of production volume. The LoREX exemption is intended to encourage companies to develop manufacturing, processing, use, and disposal techniques which minimize exposures to workers, consumers, the general public, and the environment.

As with the low volume exemption, the uses of the new chemical substance are restricted to those approved in the exemption notice, and submitters must maintain any exposure or release controls throughout the period of the exemption. Manufacturing sites identified in the exemption notice are binding unless specified conditions are satisfied. (See Comment 3, unit II.B. of this preamble). EPA believes that these binding provisions of the LoREX exemption will, in many instances, prove to be an effective substitute to regulation under section 5(e) of TSCA. Thus, EPA expects this new exemption category to significantly reduce the administrative costs presently devoted to section 5(e) consent order development and review, and to permit manufacturers to commence commercial production of their new products more quickly, while ensuring against unreasonable risk of injury to human health or the environment.

Prospective submitters should be mindful that the principal focus of the LoREX exemption is on release and exposure, not toxicity. Except where specifically noted in paragraph (c) of the regulation, EPA will generally be unable to conduct a thorough review of any submitted test data within the allotted review period and may request a temporary suspension of the review period if data are submitted. Although the Agency encourages data development for new chemical substances, manufacturers with submissions which involve extensive data reviews may, in some cases, be better served under a PMN review. Such manufacturers are envouraged to contact the Pre Notice Communications Staff for guidance prior to notice submission. To the extent that the Agency must undertake extensive detailed examination of the inherent toxicity of a given chemical substance, submission of a PMN may be more appropriate. (Of course, any toxicity data on the new chemical substance in the possession or control of the manufacturer must accompany the submission whether necessary for exemption approval or not).

To satisfy the required section 5(h)(4) findings of no unreasonable risk, the exemption notice submitter must first meet the eligibility criteria listed in paragraph (c) of the rule indicating that exposure to the new substance, and

hence the risk presented by the substance, is low. Except as provided under the surface water and ambient air criteria, the human exposure side of the eligibility criteria requires the submitter to show that there are no exposures to consumers or the general public inherent in the proposed manufacturing, processing, or uses of the substance, and that any worker exposure which is likely to occur will be adequately controlled through use of engineering controls, work practices, and/or personal protective equipment.

In terms of environmental releases, LoREX eligibility criteria for releases to three environmental media are listed. In assessing the potential for environmental release, the submitter is required to consider all routine releases from manufacture, processing, and use, including releases associated with cleaning of equipment and from disposal or cleaning of containers and packaging. For ambient surface water, submitters must either (1) prevent all direct and indirect releases of the exempted substance to surface waters; or (2) demonstrate that any releases to water that may occur will result in surface water concentrations of the substance that are no greater than 1 part per billion (ppb) using the surface water concentration calculation method described in 40 CFR 721.90 and 721.91.

As stated in paragraph (c)(2)(iii) of the rule, the Agency may approve of a surface water concentration level above 1 ppb for a new chemical substance if the manufacturer supports a request for a higher concentration with relevant and scientifically valid data on the new chemical substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration. When such data is submitted, the Agency may request the manufacturer to temporarily suspend the review period to permit adequate time to review the data.

Based on the Agency's conservative assumptions for drinking water exposure estimates, surface water concentrations of 1 ppb will result in human drinking water exposures at or below the 1 mg/year LoREX drinking water criteria in nearly every case; therefore, compliance with the drinking water exposure criteria will be presumed from compliance with the 1 ppb surface water level. The Agency reserves the right, however, to require lower surface water concentrations on a case-by-case basis when concerns for carcinogenicity, neurotoxicity, or other serious chronic effects are raised, or under conditions where actual drinking water exposures are likely to significantly exceed the 1 mg/yr dosage if the Agency makes the findings in §723.50(d).

The LoREX eligibility criterion for maximum annual average ambient air release concentration from incineration is 1 $\mu g/m^3$. This level was derived from air exposure modeling estimates of maximum ground level concentrations from incinerator stacks, using worst case meteorological data sets. To determine whether a particular substance meets the criterion, submitters must calculate exposure levels using the method described in §723.50(c)(2). As with drinking water exposures, the Agency may require lower air release levels in individual cases as the Agency makes the finding in §723.50(d).

For land/groundwater disposal, LoREX substances must not be disposed of by landfill or other land disposal methods unless the submitter demonstrates that the groundwater migration potential of the new substance is negligible. To make such a demonstration, a submitter must provide (1) data on the biodegradation and leaching potential of the new substance or a close analogue of the substance, (2) data on the inherent physical or chemical properties of the new substance (e.g., solubility in water), or (3) other data which clearly establishes that significant releases to groundwater will not occur. To fulfill this requirement, EPA suggests the following core set of tests to establish groundwater migration potential: (a) An inherent biodegradability in soil test (40 CFR 796.3400); (b) an anaerobic biodegradability of organic chemicals test (40 CFR 796.3140); and (c) depending on the substance's chemical properties, either a sediment and soil adsorption isotherm test (40 CFR 796.2750) or a soil thin layer chromatography test (40 CFR 796.2700). Although the Agency prefers test data on the specific new chemical substance, it will consider submitted data on close structural analogues to the new chemical substance. EPA strongly suggests that submitters contact the TSCA Prenotice Coordinator for guidance prior to commencement of the above testing.

Although it is difficult to state in advance precisely what combinations of results from the above testing would clearly establish that the groundwater migration potential of a chemical substance is ''negligible'', some broad parameters may be given. For example, manufacturers who perform soil adsorption testing that result in values for the logarithm of the soil adsorption coefficient (''log KOC'') of their new chemical substances of 4.5 or greater will generally be found to have satisfied the ''negligible groundwater migration potential'' standard, unless there is reason to believe that the substance is extremely persistent in the environment. Similarly, biodegradation test data demonstrating half-lives of chemical substances of under 1 week, or complete degradation in under 2 weeks, would satisfy the LoREX criterion in most instances. Hydrolysis data showing that a new chemical substance hydrolyses at a rapid rate would also generally be accepted by the Agency. Chemical substances which do not show either a 4.5 or greater Log KOC value alone or a half-life of under 1 week alone may nonetheless qualify for the LoREX exemption if the two values in combination, or together with other relevant data, support a conclusion that significant amounts of the substances will not reach aquifers.

The Agency encourages potential submitters to consult with the Agency prior to the initiation of any testing. Such consultation frequently results in more relevant data and can often lower the submitters' test costs.

Upon approval of a LoREX exemption, the submitter is bound to the uses and the exposure and release controls described in the approved exemption. The submitter is also bound to the listed manufacturing sites unless the conditions described in paragraph (j)(6) are met. The Agency will deny an exemption application despite satisfaction of the LoREX exemption criteria if EPA makes the findings in §723.50(d) or if there are issues concerning exposure or toxicity that require further review beyond 30 days under §723.50(h)(1).

B. Discussion of the Public Comments and the Final Rule

This unit of the preamble summarizes the major public comments received, clarifies several areas of confusion identified by the public comments, and discusses the differences between the final rule and the proposal. Readers are also encouraged to consult the preamble of the proposed rule (58 FR 7646) for further explanation of these provisions.

Comment 1—Information reporting burden. Several commenters suggested that the information reporting requirements for both proposed exemption categories are overly burdensome and would discourage use of those exemptions; they believed that, because of this burden, many potential applicants would choose to submit full PMNs rather than use either of these two exemptions.

Response. The Agency reviewed the proposed information reporting requirements and has, to lesson that burden, revised those requirements in several areas, as described below. However, after close examination, EPA concluded that, in the context of these two exemption categories, some additional reporting burden is inevitable if the exemptions are to be practicable. This conclusion was based upon several factors. First, EPA believes that more information is necessary to support the TSCA section 5(h)(4) ''will not present an unreasonable risk'' finding for the higher production volume chemical substances likely to be reviewed under both the expanded low volume exemption, and for the new LoREX exemption category which does not contain any production volume limitations for eligibility. Second, in the Agency's experience under the prior low volume exemption (LVE), resolution of many exemption applications has been significantly delayed because additional information was needed to make regulatory decisions. Between June 1992 and January 1993, for example, over 12 percent of the LVE submissions were suspended during the review period pending receipt of additional human exposure, environmental release, worker protection, and/or environmental release control information necessary for the Agency's risk assessment. The percentage of submissions delayed for additional information would likely be significantly higher for the new higher-volume exemptions without some augmentation of the reporting requirements. Such delays would be very costly to both industry, through lost sales, and to EPA, through higher administrative expenditures.

One reporting area which several commenters identified as being particularly burdensome on manufacturers was human exposure/environmental release estimates, especially estimates for processing and use sites controlled by others. This burden was asserted to be especially acute on manufacturers of small volume specialty chemical products.

Upon review of these comments, EPA believes that, if provided with basic process descriptions for the proposed manufacturing, processing, and use operations of a new chemical substance, EPA can generate adequate exposure and release estimates for most types of new chemical substances which may be manufactured under the new low volume exemption. This belief is based on the experience gained from reviewing TSCA section 5 submissions for over 25,000 new chemical substances over the past 16 years. Therefore, the final rule has been amended to make information on human exposures and environmental releases for low volume exemption applicants optional if that information is not known by or readily available to the manufacturer. Manufacturers should be aware, however, that EPA-generated exposure and release estimates will generally be very conservative due to the uncertainties over the actual operating conditions which will be present at the manufacturing, processing, and use sites. Therefore, it will generally be in the applicants' interest to supply exposure and release data wherever possible. To assist in reporting such data under both the low volume and LoREX exemptions, the Agency has prepared a draft guidance document: Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50. This document may be obtained through the TSCA Assistance Information Service at (202) 554–1404; TDD (202) 554–0551; online service modem (202) 554–5603.

Comment 2— Customer noncompliance reporting provisions. Several companies expressed concern over the provisions in the proposal which would require exemption holders to immediately cease distribution of the exempted substance to any downstream recipient the holder learns is processing or using the exempt substance in violation of use, environmental release, worker exposure, or other restrictions of the exemption, and to report such violations to the Agency. It was suggested that the Agency adopt the alternative procedures for dealing with customer noncompliance now used by the Agency in its TSCA section 5(e) consent orders.

Response. The provisions in the proposal for customer notification of exemption restrictions and for reporting customer noncompliance and ceasing distribution pending EPA's investigation into deviations from exemption conditions are not new; they were retained from the prior low volume exemption regulation. (See existing 40 CFR 723.50(j)). The Agency has serious concerns over the environmental and human health risks which may result from any failures by downstream recipients to comply with the requirements of an approved exemption. Nevertheless, the Agency appreciates the difficulties which may flow from a requirement to immediately cease distribution to noncomplying customers, regardless of the gravity of the violation, and believes that the procedures developed in the section 5 consent order context would be appropriate in this exemption also. Therefore, the final rule has been modified as follows: If a manufacturer holding an exemption learns that a direct or indirect customer is processing or using the exempt substance in violation of any provisions of the exemption, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following: (1) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in §723.50 and the exemption notice; and (2) that, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of §723.50 and the exemption notice and will comply with those terms. If, after receiving a statement of assurance from a customer, the manufacturer obtains knowledge that the customer has failed to comply with any of the conditions specified in the §723.50 and the exemption notice, the manufacturer must immediately cease supplying the exempted substance to that customer and must report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the new chemical substance to the customer may resume.

Comment 3— Changes in manufacturing site. Several commenters requested that the Agency consider providing greater flexibility regarding changes in manufacturing sites for both categories of exemptions. They stated that such unanticipated changes as a sudden increase in demand or equipment failure at the original site can quickly create a need to employ an alternative manufacturing site on short notice. In such cases, the proposed process of obtaining approval for a new site may preclude the start up of another manufacturing operation in a timely fashion.

Response. In response to these comments, the Agency has added a new provision to the final rule which permits applicants to change manufacturing sites under the following conditions: First, where the magnitude, frequency, and duration of exposure of workers to the chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of worker exposures to the

chemical substance at the manufacturing sites for which the Agency performed its risk-assessment pursuant to the original exemption notice; and second, where either (1) at the new manufacturing site, the manufacturer does not release to surface waters any of the chemical substance, or any waste streams containing the chemical substance; or (2) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 ppb, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described at 40 CFR 723.50(c)(2)(iii) of the rule. The surface water concentrations shall be calculated using the method described at 40 CFR 721.91 and 721.92.

To meet the first condition described above regarding worker exposure, a manufacturer need only maintain records showing that the new manufacturing site is employing the same basic manufacturing technology as that described in its initial exemption notice, such that there is not an appreciable difference in worker exposures during operations at the new site compared to the original sites. Alternatively, a manufacturer could show that the technology at the new site, though different, actually decreases worker exposure levels because of improved containment equipment, mechanization of manufacturing processes, or similar improvements.

The water release conditions may be satisfied simply by calculating the surface water concentrations using the method described at 40 CFR 721.90 and 721.91 and maintaining records of the calculations. For chemical substances regulated under either LoREX or the low volume exemption, the surface water concentrations must be at or below 1 ppb. If the Agency has approved a higher concentration level for a particular LoREX chemical substance under the procedures described at 40 CFR 723.50(c)(2)(iii), the water concentration must be at or below that higher level. The Agency will, upon request, provide LVE holders with the water concentration of concern (''COC'') used by the Agency in its risk assessment for the new chemical substance. LVE holders changing manufacturing sites must maintain surface water concentration levels at or below 1 ppb or the Agency-prescribed COC, whichever is greater.

All manufacturers who change or add manufacturing sites pursuant to these procedures must inform the Agency of the address of the new sites no later than 30 days after the commencement of manufacture at each new site. All other terms and conditions of the original exemption will continue in effect.

Comment 4—LoREX eligibility criteria. Several commenters suggested that the proposed LoREX eligibility criteria were too stringent, that very few chemical substances could meet the eligibility requirements, and that the Agency would achieve its streamlining objectives more directly by establishing an exemption for site-limited intermediates.

Response. The Agency largely disagrees with these comments. As explained in unit II. A. 2. of this preamble, EPA believes that the performance-based eligibility criteria for the LoREX exemption will be achievable for a significant number of new chemical substances, and that, once manufacturers become more familiar with the criteria, they will find it to be much more versatile than a site-limited intermediate exemption.

As discussed above in this preamble, the Agency has prepared a draft guidance document to assist manufacturers in reporting exposure and release information under this exemption. The draft document, entitled Guidelines for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, explains in detail the type of information EPA will need to assess the potential risks of new chemical substances manufactured under the LoREX and low volume exemptions, and the type of documentation the Agency believes is adequate to support an exemption. The document may be obtained through the TSCA Assistance Information Service at (202) 554–1404; TDD (202) 554–0551; online service modem (202) 554–5603.

As stated throughout the proposal, the Agency was very interested in considering any alternative LoREX criteria which commenters might suggest. Despite those invitations, very little comment was offered on the specific proposed criteria itself. Nevertheless, the Agency reexamined the proposed criteria and has decided that the ambient surface water criteria could be amended to permit higher water concentrations in certain cases. Specifically, EPA determined that it could permit surface water concentrations above the standard 1 ppb if the higher level is supported by relevant and scientifically valid data on the new chemical substance or on a close structural analogue to the new chemical substance which adequately demonstrates that the new chemical substance will not present an unreasonable risk of injury to aquatic species or human health at the higher surface water concentration. Because scientific review of submitted test data will often require more than the normal 30–day review period, the Agency may, on a case-by-case basis, request manufacturers to temporarily suspend the review period pending data review.

Comment 5—Revocation provisions. Several commenters objected to the proposed provisions regarding revocation of exemptions after expiration of the review period. Under the proposal, the Agency could, based on new information, notify an exemption holder that EPA had determined that the new chemical substance did not meet the terms of the exemption and, after providing an opportunity for the holder to submit objections, could issue a final determination revoking the exemption if it disagreed with the exemption holder's objections. Numerous commenters were very concerned over the potential for business interruptions and loss of credibility with customers, and predicted that many prospective exemption applicants would choose submission of a full premanufacture notification rather than risk revocation of an exemption under the proposed provisions. Many suggested that the Agency reinstate the original notice of ineligibility provisions contained in the prior low volume exemption regulations.

Response. The Agency believes that manufacturers' concerns over unwarranted revocations overstate the potential for commercial harm coming to them as a result of these provisions. In fact, as the Agency stated during public hearings on the exemption, in the 9 years that the low volume exemption has been in effect, EPA has yet to invoke the post-review period revocation provisions in a single instance. Moreover, the Agency believes that the type of information which would convince it to invoke the revocation provisions would also convince most exemption holders to voluntarily withdraw their exemptions or undertake appropriate measures to mitigate the potential risk posed by the new chemical substance. Nevertheless, the Agency understands that a perceived risk of sudden business interruptions by prospective applicants and their customers may greatly discourage utilization of the exemption. In the final rule, therefore, EPA has reinstated the post-review period notice of ineligibility provisions as they were promulgated in the original low volume exemption. Those provisions differ from the

proposed provisions in 2 principal respects: first, the decision to invoke the provisions must be made by the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances; and second, if the Assistant Administrator determines, after a final determination that the substance does not meet the terms of the exemption, that the exemption holder acted with due diligence and in good faith to meet the terms of the exemption, the exemption holder may, if it submits a PMN for the new chemical substance, continue to manufacture, process, use, and distribute the new chemical substance unless EPA subsequently takes action under section 5(e) or 5(f) of TSCA.

Comment 6—User fees. Most commenters stated that, because exemption applications are less burdensome upon the Agency than a full PMN submissions, the proposed $2,500 user fee for the exemptions should be lowered to reflect this savings.

Response. Although the applications submitted under these two exemptions will be less costly, on average, for the Agency to review than PMN submissions, the average cost to the Agency of reviewing an exemption will still exceed $2,500; however, as a further incentive for manufacturers to utilize these exemptions wherever possible, the Agency has at this time decided not to impose a user fee requirement for these exemptions.

III. Rationale for Expanding the Low Volume Exemption Category

A. Chemical Substances Manufactured at 10,000 Kilograms or Less Per Year

The basic rationale for expanding the low volume exemption category from 1,000 kilograms per year to 10,000 kilograms per year is the same as that for proposing the exemption initially: chemical substances produced in lower quantities generally involve correspondingly lower human exposures and environmental releases, and thus generally present less risk than high volume substances. In the Agency's experience reviewing PMN substances in the 1,000 to 10,000 annual production range, very few of these substances present risks of injury to human health or the environment significantly greater than the substances produced under the existing low volume exemption. Additionally, the Agency believes that the low volume exemption has been a very successful regulatory mechanism as measured by the level of EPA administrative resources needed to implement it and the relative burden it places on manufacturers. Because of this success, EPA believes that both its interests and the interests of industry will be served by enlarging the portion of new chemical substances which may be manufactured under the exemption.

B. Low Release and Exposure (LoREX) Chemical Substances

In addition to the production volume-based category described above, EPA is promulgating a new TSCA section 5(h)(4) exemption category based on low levels of environmental release of and human exposure to the new chemical substance. Eligibility is independent of production volume level.

The Agency believes that the concept of basing an exemption on low release and exposure offers several potential advantages over a more broad volume-based exemption. First, an exposure-driven exemption generally provides a more direct gauge of the magnitude of risk presented by a given new chemical substance. Production volume alone is only an indirect indicator of exposures and releases. Secondly, EPA believes that the existence of a LoREX exemption will encourage pollution prevention techniques by rewarding manufacturers able to meet the low release and exposure criteria with more timely regulatory decisions, and in many cases, with less burdensome regulatory controls. Such a result would entail substantial time and resource savings for both EPA and industry.

1. *LoREX criteria.* EPA has decided to set general performance standards for the LoREX exemption. Persons applying for exemptions are responsible for complying with these performance standards. Section 723.50(c) sets out the performance standards as ''criteria.'' Some are absolute, e.g., no releases to surface waters resulting in water concentrations above 1 ppb. Others set a goal but allow compliance to be achieved without an absolute guarantee (e.g., no dermal or inhalation worker exposure) but this result is assumed to occur if ''adequate'' controls are used. In others, a general standard is set, but EPA can approve a different level for a specific new chemical substance (e.g., no surface water releases resulting in surface water concentrations above 1 ppb unless a higher concentration is approved based on data provided by the applicant in the notice). In all cases, EPA does not specify how the exemption applicant is to achieve the performance standard. In its exemption notice, the applicant will describe how it limits exposure with respect to all the criteria in the exemption. EPA will evaluate whether these meet the criteria in §723.50(c)(2). If they do, EPA will grant the exemption. If the exemption is granted by EPA, the exemption holder is responsible for complying with the standards throughout the period of the exemption and with any controls or limitations specified in its exemption notice.

a. *Human exposure.* In determining the appropriate criteria for defining the types and/or levels of exposure which should constitute ''low exposure'' to humans, EPA considered three distinct populations: workers, consumers, and the general population. EPA believes that, for purposes of this exposure-based exemption, any direct exposures to consumers and the general population would be, in the context of an abbreviated review period, inconsistent with the Agency's statutory obligation under section 5(h)(4) to affirmatively find that the exempted substances will not present an unreasonable risk of injury to human health. Therefore, the Agency believes that any consumer and/or general population exposures (other than the negligible drinking water and ambient air exposures discussed later in this preamble) should automatically disqualify new chemical substances from LoREX exemption eligibility.

Exposures to workers may be more readily monitored and controlled through engineering controls, workplace practices, and/or protective equipment requirements. Therefore, the Agency believes that it may, consistent with its section 5(h)(4) obligation, approve a high percentage of LoREX exemption notices where appropriate control measures are instituted in the workplace.

Workplace exposures may occur through inhalation or dermal contact. For dermal exposures, the Agency believes that the general dermal exposure requirements used in section 5(e) consent orders and significant new use rules (SNURs) generally provide ''adequate dermal exposure controls.'' These include that all workers reasonably likely to be exposed to LoREX substances be provided with, and required to wear, chemical protective equipment which provides a barrier to prevent all dermal exposure to the substance. Chemical protective clothing used to provide this barrier is demonstrated to be impervious to the substance under the expected conditions of use and duration of exposure. Such demonstration could be accomplished under the procedures described at 40 CFR 721.63(a)(3)(i) - (ii) of the SNUR provisions by actually testing the material used to make the chemical protective clothing and/or by evaluating the specifications from the

manufacturer or supplier of the chemical protective clothing to establish that it will be impervious to the exempted substance alone and in likely combination with other chemical substances in the work area.

To provide ''adequate inhalation exposure controls,'' submitters of LoREX exemption notices will (i) identify the workplace operations where inhalation exposure is likely to occur; (2) assess the magnitude, frequency, and duration of potential exposure; (3) assess the effectiveness of the various exposure controls; and (4) select the method or combination of methods that will provide workers with the appropriate protection for the given workplace. While the Agency strongly encourages submitters to reduce workplace exposures at their source, where feasible, submitters could also ''provide adequate inhalation exposure controls'' based on the use of appropriate respiratory protection equipment. To achieve adequate controls, the Agency believes it most appropriate for a submitter to comply with the general requirements regarding respiratory protection used in TSCA section 5(e) consent orders and SNURS. These requirements stipulate the use of respiratory protection in accordance with the National Institute of Occupational Safety and Health (NIOSH) regulations at 30 CFR part 11, and the Occupational Safety and Health Administration (OSHA) regulations at 29 CFR 1910.134. (See generally 40 CFR 721.63). Similarly, the inherent physical or chemical properties of the substance submitted for an exemption may form the basis for a conclusion of adequate exposure controls, as in a nonvolatile dye manufactured, processed, and used only in solution, such that inhalation of particulates will not occur.

b. *Environmental release*— i. *Water releases.* The LoREX water release eligibility criterion of <1 ppb surface water concentration was established on the basis of EPA's experience in conducting environmental risk assessments on PMN substances. The concentration level must be calculated by the submitter using the method described in 40 CFR 721.90 and 721.91. Based on EPA's PMN experience, aquatic toxicity concern levels have only very rarely been established at levels below 1 ppb. Thus, EPA is confident that the vast majority of LoREX exemption notices satisfying this criterion will not present an unreasonable risk of acute or chronic aquatic toxicity, and that the Agency's risk assessment capabilities will identify those few exemptions which may require more strict concentration levels to protect against potential aquatic risks during the 30–day notice period.

ii. *Air releases from incineration.* The LoREX incineration air release eligibility criterion of $< 1\ \mu g/m^3$, like the ambient surface water criterion, was selected on the basis of experience gained in conducting risk assessments on over 25,000 new chemical substances since 1979. At this maximum annual average concentration, EPA believes that, using worst case estimates, the maximum human exposures downwind from incinerators will be toxicologically insignificant for most of the chemical substances it is likely to review under the LoREX exemption. As noted above, however, the Agency may require individual submitters to adhere to lower incineration release levels for substances for which chronic toxicity concerns are raised during the risk assessment.

The methodology for calculating maximum annual average concentration (see subparagraph (c)(2)(iv) of the rule) was based on computer modeling similar to that used by the Agency in the PMN review process. Those interested in more detail on this methodology should consult the docket established for this rulemaking.

Submitters should also be aware that, although the final rule has not established generic eligibility criteria for fugitive air emissions unrelated to incineration, the Agency will review the potential for such emissions on a case-by-case basis, and will deny exemptions if the air emissions reach such levels as to undermine the Agency's ability to conclude that the substances in question will not present an unreasonable risk. Based on EPA's PMN experience, chemical substances with fugitive air emissions under 23 kilograms per site per year are seldom found to present an unreasonable risk of injury to the general population. Therefore, manufacturers submitting a LoREX exemption notice for substances with fugitive air emissions below that level are unlikely to be denied an exemption on that basis.

iii. *Land/groundwater releases.* The final rule excludes from eligibility all chemical substances which will be disposed of via landfill unless the submitter demonstrates to EPA in the notice that the exempted substance has negligible ground-water migration potential. This standard was deemed most appropriate for this purpose because the Agency was unable to develop a broadly applicable method for estimating groundwater concentrations of chemical substances based on landfill disposal volume that would allow development of a generic criterion. Given the many variables involved in making such estimates (e.g., migration rates, biodegradation rates, sediment/soil adsorption rates), EPA does not believe it will be possible to develop a generic model for estimating groundwater concentrations for a significant number of substances with sufficient reliability to support the requisite ''will not present an unreasonable risk'' finding. Consequently, the Agency believes that, in the context of an abbreviated review period in which in-depth case-by-case assessments of groundwater leaching potential are infeasible, prudence dictates that negligible release be the primary standard.

However, potential LoREX exemption submitters with no viable alternatives to landfill disposal have the option of demonstrating to the Agency's satisfaction that their substance will not migrate to groundwater. A list of suggested tests to establish groundwater migration potential is contained in Units II.A.2. of this preamble. If such a demonstration is made, a submitter would be permitted to landfill excess quantities of the exempted substance up to the amounts approved in its exemption notice. In all cases, however, the Agency strongly encourages submitters to strive for total elimination of releases through employment of the best available pollution prevention techniques. (See Unit II.A.2. of this preamble for further guidance on this criterion).

IV. Regulatory Analysis

A. Summary of Risk Assessment

1. *10,000 kilogram/year chemical substances.* To assess the risk associated with raising the ceiling for new chemical substances eligible for the low volume exemption from 1,000 kilograms/year to 10,000 kilograms/year, the Agency relied primarily upon the risk assessment developed to support the 1985 final low volume rule, along with the earlier version used to support the 1982 proposed low volume and site-limited intermediate rules.

a. *Exposure assessment.* The exposure assessment illustrates that, while low production volume in itself limits potential for exposure and environmental release, manufacture, processing, and use of new chemical substances can in some circumstances result in significant exposures at both the 1,000 and 10,000 kilogram annual production levels.

i. *Occupational exposure.* Based on PMN data, the number of workers exposed during manufacturing ranged from an average of about four for new

chemical substances manufactured in quantities of 1,000 kilograms or less per year to an average of about eight for new chemical substances manufactured in quantities of 10,000 kilograms or less per year. Duration of exposure associated with manufacture averaged about 5 hours per day at both production levels, and the average number of days of production per year was 62.

Only a limited number of PMNs included estimates of workplace concentration. The average concentrations associated with manufacture were most often in the ranges of 0 to 1 and 1 to 10 mg/m^3 for airborne solids and in the 1 to 10 ppm range for vapors. EPA's evaluation of OSHA data (USEPA, OTS ''Site-Limited Intermediate Exemption: Occupational Exposure and Environmental Release Assessment.'' March 19, 1982) indicated a time weighted average (TWA) of 6 ppm, with a maximum value of 72 ppm for vapors. EPA believes that data obtained from OSHA monitoring activities provides more reliable estimates of workplace concentrations.

EPA's analysis of processing and use of low volume chemicals indicated that the wide variety of possible processing and use operations can result in a wider range and higher level of exposures than is typically associated with manufacturing operations. The average number of workers exposed during processing and use operations exceeded the average numbers typically exposed during manufacturing. The number ranged from an average of 12 workers for a chemical processed in quantities of 1,000 kilograms or less per year to an average of 141 workers for chemicals processed or used in quantities of 10,000 kilograms or less per year.

ii. *Consumer exposure.* Consumer exposures were assessed for five use scenarios: photographic chemicals used in home darkrooms; spray adhesives; paints; dyes; and fragrances used in detergents. The use scenarios, which reflected actual uses reported in PMNs, were selected to represent divergent and potentially significant exposure situations. In these scenarios, the individual lifetime average daily exposures were estimated to range from 0.0016 mg/kg/day for a fragrance in soap to negligible levels for dyed fabrics.

According to EPA's analysis, many of the consumer use scenarios could result in relatively large numbers of consumers exposed. The numbers of consumers potentially exposed at the 10,000 kilogram production level ranged from 76,000,000 for a fragrance in shampoo to 98,000 for a spray adhesive. Because the concentration of a new chemical substance in a final product remains constant, the production volume is likely to affect only the number of consumers exposed, not the exposure level to each individual. Therefore, the number of consumers exposed at the 10,000 kilogram production limit is about 10 times the number that would be exposed at the 1,000 kilogram limit.

b. *Environmental release.* The Agency used data derived from PMN submissions for estimating the likely magnitude, duration, and frequency of environmental releases from manufacturing chemical substances under the new low volume exemption. The exposure analysis indicated that the average quantity released to water is 0.08 percent of the production volume, with an upper bound of 0.4 percent. Amounts released to air average 0.03 percent of production volume, with a 0.2 percent upper bound. However, some processing and industrial uses result in more substantial release rates, with a range from 0.3 to 25 percent of the production volume released to water. Discharges of a new low volume chemical substance from a single site processing 10,000 kilograms of the substance were estimated to produce environmental concentrations ranging from less than 0.0005 to 5.2 ppm in a receiving stream whose stream dilution factor was equal to the national median for streams receiving effluent from industrial facilities.

In some cases, such as detergent additives, environmental releases from consumer uses equaled the total production volume; however, the actual magnitude of environmental exposure was determined to be insignificant due to the low production volume, the wide distribution of release, and the small amount of new chemical substance typically contained in each consumer product.

c. *Risk under exemption conditions.* There are several elements of the exemption amendment that will significantly reduce risks to human health and the environment.

Chemical substances with carcinogenic, teratogenic, neurotoxic, and other chronic effects appear to present the greatest risks even at relatively low exposures. The Agency will deny exemptions for new substances which may cause such effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal. These denials will significantly reduce the likelihood that chemicals that present such risks would be manufactured under the amended exemption. If the exemptions for such substances are denied, or if their submitters are required to resubmit their exemption notices to provide for more stringent release and exposure controls prior to approval, the range of potential risks would be substantially below the high end of EPA's estimates.

In addition, under the amended regulation, EPA would continue to review all exemption notices during the 30–day review period. This review will help ensure that manufacturers choose appropriate safeguards to control risks, as well as provide a screen to identify substances that do not qualify for the exemption.

2. *Low exposure/release chemical substances.* The risk associated with a given substance is a function of both the inherent toxicity (hazard) of the substance and the exposure of the relevant organism to the substance. Therefore, to the extent that releases and exposures are maintained below certain critical levels, potential risks presented by the substance are minimal. To assess the potential risk associated with the LoREX exemption, the Agency evaluated the exposure and release criteria in the context of its experience conducting risk assessments on over 25,000 new chemical substances in the PMN program over the last 16 years. Based on this experience, EPA tailored its LoREX exemption criteria in a manner to exclude from eligibility virtually all of the new chemical substances which the Agency believes could present potentially significant human or environmental exposures under conditions of manufacturing, processing, and use. For those substances which meet the eligibility criteria but may nevertheless present significant risks due to unusually high known or predicted toxicity levels, the Agency will either deny the exemptions or condition approval upon satisfaction of stricter exposure and release requirements.

a. *Human exposure.* Due to the wide range of possible consumer and general population exposures from the universe of new chemical substances, the Agency concluded that it could not develop any meaningful consumer or general population exposure criteria which would consistently screen out those substances which would present unreasonable risks from direct dermal or inhalation exposures. Consequently, EPA has excluded from LoREX exemption eligibility all new chemical substances which entail any direct consumer or general population exposure (except for negligible drinking water and ambient air exposures discussed in Unit IV.A.2.b. of this preamble). New chemical substances

intended for use in consumer paints, detergents, dyes, and other consumer products, therefore, would have to be reviewed by the Agency in a full PMN or under one of the other applicable PMN exemptions, unless the chemical substance is completely reacted, encapsulated in a polymer matrix, or otherwise not bioavailable in the final product.

EPA has substantial experience with controlling worker exposure to new chemical substances from reviewing notices for over 25,000 new substances under section 5 of TSCA and issuing several hundred section 5(e) consent orders and SNURs with worker protection requirements. EPA believes that worker exposure to new chemical substances can be controlled adequately through the use of appropriate engineering/process controls and, if such controls cannot be used, through use of appropriate personal protective equipment. EPA has prescribed such controls and personal protective equipment in several hundred section 5(e) consent orders and believes that their proper use reduces worker dermal and inhalation exposure to new chemical substances to minimal levels. Thus, EPA concluded that for workers, who can be protected adequately from exposure to new chemical substances, it would set a goal of no dermal or inhalation exposure and allow persons applying for LoREX exemptions to meet those goals by using ''adequate'' controls and personal protective equipment modelled on the sorts of controls EPA has employed in the section 5(e) context.

b. *Environmental releases.* In terms of environmental releases, there are LoREX eligibility criteria for releases to three environmental media. For ambient surface water, the Agency is requiring that submitters either (i) prevent all direct and indirect releases of the exempted substance to surface waters; or (ii) demonstrate that any releases to surface water that may occur will result in surface water concentrations of the substance that are no greater than 1 part per billion (ppb) using the surface water concentration calculation method described in 40 CFR 721.90 and 721.91. Based on Agency worst case assumptions for drinking water exposure estimates, surface water concentrations of 1 ppb will result in human drinking water exposures at or below the 1 mg/year LoREX drinking water criterion in nearly every case; therefore, compliance with the drinking water exposure criterion will be presumed from compliance with the 1 ppb surface water level. The Agency retains the authority, however, to require lower surface water concentrations on a case-by-case basis when concerns for carcinogenicity, neurotoxicity, or other serious effects are raised, or under conditions where projected drinking water exposures are likely to significantly exceed the 1 mg/yr dosage.

The LoREX eligibility criterion for maximum annual average ambient air release concentrations from incineration of the new chemical substance is 1 μg/m^3. This level was derived from air exposure modeling estimates of maximum ground level concentrations from incinerator stacks, using worst case meteorological data sets. To determine whether a particular substance meets the criteria, submitters would calculate exposure levels using the method described in §723.50(c)(2)(iv). As with drinking water exposures, the Agency may require lower air release levels in individual cases if concerns for significant health effects are raised for the new substance.

For land/groundwater disposal, EPA is requiring that a LoREX substance not be disposed of by landfill or other land disposal methods unless the submitter demonstrates that the substance will not migrate to groundwater. (Consult unit II.A.2. of this preamble for further information on this criterion.)

Upon approval of a LoREX exemption, the submitter is bound to the continuous use of the exposure and release controls described in the approved exemption notice, as well as the listed uses and, unless specified conditions are met, manufacturing sites. The Agency will deny an exemption notice notwithstanding satisfaction of the exposure-based exemption criteria if EPA determines that the new substance may cause serious acute or chronic effects or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, and disposal.

V. Economic Impact

The regulatory impact analysis estimates the costs and benefits attributable to the regulation. In this case, the analysis also contains estimates for the three additional amendments to EPA's TSCA section 5 regulations, namely the Polymer Amendment, the Procedural Amendment, and the Non-5(e) Significant New Use Rule Amendment, also published today. Because these regulations are amendments to current regulations, the costs and benefits are incremental, estimating the effect of the amendment with respect to the current regulation.

The costs and benefits associated with this amendment are partially quantified; many of the benefits are unquantified but are expected to be of significant importance. Considering only the quantified costs and benefits, there is a cost savings in most instances. Assuming either 1,000, 2,000, or 3,000 annual section 5 submissions, the savings as compared to the current regulation are estimated to be:

Annual Number of Submissions	Annual Cost Savings ($ Million)	
	Industry	Government
1000	0.2 – 0.4	1.3 – 1.5
2000	0.4 – 0.7	2.5 – 3.1
3000	0.5 – 1.1	3.8 – 4.6

This amendment expands the low volume exemption and establishes the LoREX exemption. Industry costs associated with the amendment to the low volume exemption are reporting costs and delay costs. Per submission reporting costs are increased due to the more comprehensive submission requirements. Delay costs for those substances which qualify for the current exemption are slightly higher, while delay costs are significantly reduced for those substances which currently must submit a full PMN submission but would qualify for the new exemption. Delay costs are the costs associated with the delayed introduction of the substance into the market due to section 5 regulations.

Industry costs associated with the LoREX exemption are also reporting costs and delay costs. Because this would be a new exemption, all of the submitters would have originally been required to submit a full PMN submission and would be required to pay a user fee. Also, the reporting requirements are only slightly more than current requirements.

Unquantified benefits associated with this amendment include (1) increased use of pollution prevention practices by submitters; (2) a greater emphasis on the use of low risk chemicals; and (3) bringing LoREX substance and new substances manufactured between 1,000 and 10,000 kg per year to market more quickly. Regarding the third benefit, most chemical substances eligible for the exemption will clear review at least 60 days more quickly than if they had been submitted under a PMN; those substances that would have been regulated under section 5(e) will clear review, on average, 90 to 150 days sooner.

The Agency's complete economic analysis is available in the public record for this rule (OPPTS–50596B).

VI. Finding of No Unreasonable Risk

1. *Statutory background.* Under section 5(h)(4) of TSCA, EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to human health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical substance may be taken for a category of such substances. Under this regulation, EPA is exempting two categories of chemical substances: those with production volumes less than or equal to 10,000 kilograms/year, and those with low human exposure and low release to the environment. EPA has determined that these are appropriate categories under TSCA sections 6(c) and 5(h)(4). For each of these categories, as discussed below, EPA has made a finding that new chemical substances eligible for the exemptions will not present an unreasonable risk of injury to human health or the environment when manufactured, processed, used, distributed in commerce, or disposed of under the terms of the exemptions, including EPA's 30–day review.

The term ''unreasonable risk'' is not defined in TSCA. The legislative history, however, indicates that unreasonable risk involves the balancing of the probability that harm will occur and the magnitude and severity of that harm against the effect of the proposed regulatory action on the availability to society of the benefits of the chemical substance.

2. *Risks.* In making the ''will not present an unreasonable risk'' finding under TSCA section 5(h)(4), EPA first considered the risk posed by granting each of the exemptions. Risk is the combination of the hazard presented by a chemical substance or category of chemical substances and the exposure of humans or the environment to the substances or category. EPA's determination of the reasonableness of risk involves a consideration of factors such as environmental effects, distribution, and fate of the chemical substance in the environment, disposal methods, waste water treatment, use of protective equipment and engineering controls, use patterns, and market potential of the chemical substance. These variables are difficult to quantify and standardize, thus EPA must supplement the available data with its professional judgment.

EPA's determination that manufacture, processing, use, distribution in commerce, and disposal of these two categories of substances under the terms of these exemptions will not present an unreasonable risk of injury to human health or the environment is based on consideration of (i) the limitations on risk that would result from the safeguards built into the rule, including Agency review; (ii) the limitations on risk resulting from the restriction of the exemptions to the chemical substances manufactured at volumes of 10,000 kg/yr or less and to low release/low exposure chemical substances; (iii) the benefits to industry and the public provided by new chemical substances manufactured under the exemption; and (iv) the benefits to the public and the Agency from the Agency's enhanced ability to utilize its limited resources on reviewing new chemical substances and uses of higher risk and concern. EPA recognizes that, even with the safeguards imposed by this rule, it is not ensuring that there will be no risk from new chemical substances manufactured under the exemption. The statute does not require zero risk. Rather, it defines unreasonable risk as a balancing of risk and benefit. Because of the safeguards in the amended regulation, the requirement that the provisions of the approved exemption are binding on the submitter, and the restricted nature of the exemption categories, EPA believes that risks are not likely to be any greater than if the full PMN process were completed. Furthermore, the new chemical substances provide benefits to industry and to the public. These benefits are an important element in the finding that these substances will not present an unreasonable risk.

The conditions of these exemptions are designed to mitigate risk, largely by the use of: (i) the reviews conducted by the Agency to assess whether the new chemical substances may cause chronic or acute human health or environmental effects; and (ii) the binding nature of the provisions of exemption notices, including the controls placed on exposure through worker protection requirements. For the low volume exemption, EPA determined that risks would generally be low because low production volume substances typically are not expected to result in high exposure to humans or the environment. Similarly, the eligibility criteria for the LoREX exemption directly limit permissible releases of and exposures to the exempted substances. In addition to the general finding of low release/low exposure, and therefore low risk for these categories, the restrictions and safeguards built into the exemptions will ensure that the risks presented by the exempt substances are low. For example, worker protection requirements and release restrictions imposed by the terms of the exemptions will minimize exposure, and therefore, risk.

a. *EPA review.* Within the 30–day review period, EPA is confident that it can identify the few new chemical substances under these exemptions that will pose potential risks which require more detailed and comprehensive review. EPA's abbreviated review plays an important role in the two exemptions and in the unreasonable risk finding. EPA has lengthened the review period from 21 to 30 days to ensure that staff resources will be sufficient to review the exemption notices under the amended rule. Information to be reviewed include production volume, hazard information, descriptions of the manufacturing, processing, and uses, exposure controls, releases to the environment, and certain physical/chemical data which EPA will assess in making a determination of risk. During this period, the Agency will have sufficient time to identify any issues or problems that will require more careful analysis, such as that available in a full PMN review. If EPA determines that a new chemical substance is not eligible for an exemption, manufacture will not begin. The manufacturer would then be required to comply with TSCA section 5(a)(1) before the substance could be manufactured for commercial purposes by submitting a full PMN to the Agency.

Despite the low risk generally associated with low volume and low release/low exposure substances, EPA recognizes that some substances that meet the general requirements for these exemptions, may present risks that are not appropriate for an exemption, thus EPA performs a 30–day review of each exemption notice and can deny individual exemptions. For example, a highly toxic chemical substance may present an unreasonable risk even if exposure to the substance is low. Likewise, a low production volume chemical substance may present an unreasonable risk if it is hazardous and is manufactured or processed in a manner that would result in high human exposure or high release to the environment. Thus, although EPA is making a general finding that these categories of new chemical substances will not present an unreasonable risk under the terms of the exemptions, EPA will continue to evaluate exemption notices on a case-by-case basis to determine if individual substances

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.

(ii) Comply with all other provisions of this section.

(b) *Definitions.* The following definitions apply to this subpart.

(1) *Act* means the Toxic Substances Control Act (15 U.S.C. 2601 et seq).

(2) *Consumer* means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

(3) *Environment* has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) *Environmental transformation product* means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) *Metabolite* means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) *Serious acute effects* means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) *Serious chronic effects* means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) *Significant environmental effects* means:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) *Site* means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

(10) The terms *byproduct, EPA, importer, impurity, known to or reasonably ascertainable, manufacture, manufacturer, new chemical substance, person, possession or control, and test data* have the same meanings as in §720.3 of this chapter.

(c) *Exemption categories.* Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) *Consumers and the general population.* For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section.

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) *Workers.* For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) *Ambient surface water.* For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§721.90 and 721.91, unless EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) *Incineration.* For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

(kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) *Land or groundwater.* For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) *Chemical substances that cannot be manufactured under this exemption.* A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraphs (c)(1) or (c)(2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

(1) Serious acute (lethal or sublethal) effects.

(2) Serious chronic (including carcinogenic and teratogenic) effects.

(3) Significant environmental effects.

(e) *Exemption notice.* (1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to the EPA at least 30 days before manufacture of the new chemical substance begins. The notice must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The date of submission will be the date on which the notice is received by the TSCA Document Control Officer. EPA will acknowledge the receipt of the notice by letter. The letter will identify

the date on which the review period begins. The notice shall be submitted using EPA Form No. 7710–25 (''the PMN form''), which may be obtained from EPA by writing the Environmental Assistance Division, (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC. 20460, or by calling the TSCA Assistance Information Service at (202) 554–1404; TDD (202) 554–0551; online service modem (202) 554–5603.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of §720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§720.45(a)).

(iii) Impurities (§720.45(b)).

(iv) Known synonyms or trade names (§720.45(c)).

(v) Byproducts (§720.45(d)).

(vi) Production volume (§720.45(e)). (A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000–kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12–month period during the first 3 years of production.

(vii) Description of intended categories of use. (§720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply ''bounding estimates'' (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a ''TSCA section 5(h)(4) exemption notice,'' and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710–25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30–day review period.

(xii) Sanitized copy of notice. (A) The manufacturer must make all claims of confidentiality in accordance with paragraph (l) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (l)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(3) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under this paragraph (e) of this section, the submission will be determined to be incomplete by EPA. When a submission for a new chemical substance has been determined to be incomplete, a manufacturer reapplying for an exemption for the new chemical substance must submit a new exemption notice containing all the information required under this paragraph (e) of this section including a certification page containing an original dated signature; partial submissions sent to EPA to supplement notices declared incomplete will not be accepted. Photocopied pages from previously submitted exemption forms will be accepted provided that the certifications page contains an original dated signature.

(f) *Multiple exemption holders.* (1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant's activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA's notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA's notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to the first exemption holder under the provisions of paragraph (h)(2) of this section.

(g) *Review period.* (1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will end 30 days after receipt of the notice by the TSCA Document Control Officer. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of §720.75(b) of this chapter.

(2) Upon expiration of the 30–day review period, if EPA has taken no action, the manufacturer may consider its exemption approved and begin to manufacture the new chemical substance under the terms described in its notice and in this section.

(h) *Notice of ineligibility*—(1) *During the review period.* If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30–day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) *After the review period.* (i)(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances (''the Assistant Administrator'') makes a preliminary determination that manufacture of the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, and use of the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must send that information to the address listed on the notice form within 10 days of receiving the new information, but no later than 5 days before the end of the notice review period. The new submission must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(j) *Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.* (1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used,

the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a non-volatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either (*1*) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or (*2*) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification may be submitted on EPA form 7710–56 ''Notice of Commencement of Manufacture;'' however, the manufacturer must add the statement required under paragraph (j)(6)(ii)(A) of this section that the notification is an amendment to the original exemption.

(C) The notification must contain an original signature of an authorized official of the manufacturer.

(k) *Customer notification.* (1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

(l) *Confidentiality*. (1) If the manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with ''CONFIDENTIAL'' or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in part 2 of this chapter. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph (l) must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the manufacturer will be subject to EPA review and approval in accordance with the procedures specified in §720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice with all information claimed as confidential deleted. EPA will place the second copy in the public file.

(m) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) *Recordkeeping.* (1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after date of their preparation.

(2) The records must include the following to demonstrate compliance with this section:

(i) Records of annual production volume and import volume;

(ii) Records documenting complaince with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon written request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) *Compliance* . (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

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