Questions & Answers for the New Chemicals Program (Q&A)

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Washington, DC 20460

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HIGHLIGHTS OF THE NEW CHEMICALS PROGRAM Q&A

Interested parties have asked many questions of the New Chemicals Program over the years. While responsive to the specific individuals asking the questions, EPA recognizes that it would be useful to a broader array of stakeholders to provide one, easily referenced document which compiles this guidance information. This Questions and Answers document (the Q&A) is derived from these compiled questions, rather than having been designed as an overall explanation of the program.

- A general program description is provided at the New Chemicals Website, at www.epa.gov/oppt/newchems/, and in the New Chemicals Brochure, available from the TSCA Hotline at (202) 554-1404, or e-mail at tsca-hotline@epa.gov.
- In addition, the Instruction Manual for submission of §5 notices (also available at the New Chemicals Website) discusses program policy and intent in the context of the PMN form.

This Q&A document is available both in hard copy and electronically. Although the content is the same, we believe the electronic version will be easier to use, utilizing a search function, if a computer is available to you. The electronic version can be downloaded from the New Chemicals Website. The paper version is also available from the TSCA Hotline by mail.

This Q&A document is intended only to explain the requirements of TSCA §5 and selected EPA regulations implementing §5, and to provide useful information to persons subject to these requirements. It is not a substitute for applicable legal requirements, nor is it a regulation itself. Thus, it does not impose legally-binding requirements on any party, including EPA or the regulated community.

1. GENERAL PROGRAM INFORMATION

100. General

100-1. Q. How can I obtain a copy of the printed §5 Pre-Manufacture Notice (PMN) form?

A. The §5 PMN form (EPA Form 7710-25) is available from the TSCA Hotline upon request by voice (202-554-1404), facsimile (202-554-5603) or by e-mail (tsca-hotline@epa.gov). An instruction manual is also available from the Hotline to assist you in filling out the §5 submission form. There is a printable copy (.pdf) of the form at the New Chemicals Website (www.epa.gov/oppt/newchems/).

The TSCA Hotline is a source of general program information.

100-2. Q. When does EPA expect to publish a format for electronic submissions so that I can submit my PMNs electronically?

A. As of this writing, EPA has developed an early version of an electronic form. This current version and further instruction are available at the New Chemicals website (www.epa.gov/oppt/newchems). Submitters are invited to download this form and fill it out on their computers. At this time, we are only accepting paper copies made using this form. In the near future, we intend to develop the procedures to accept CD-ROMs containing the PMN form. Input on such a form is welcomed, and you may send comments to:

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100-3. Q. A PMN has completed review, but when actual production starts, the manufacturing process must be changed. Is notification to EPA required?

A. TSCA §5 requires submission of a PMN for a chemical substance or mixture that is not on the TSCA Inventory (unless exempt). Thus, if the change in the manufacturing process results in a chemical substance or mixture whose identity is different from that specified in the PMN and is not on

the Inventory, a new PMN is required. 40 CFR 720.40(f) requires the PMN submitter to report to EPA new information that materially changes the information included in the PMN, if the information comes to light during the PMN review period. Therefore, if, during the PMN review period, the submitter decides that the manufacturing process will change from the process described in the original submission, EPA must be notified. EPA may require additional time to review the change.

PMN regulations at 40 CFR part 720 do not provide for notification to EPA of changes to information reported in the PMN that occur after the review period. Therefore, if the decision to change was made after the review period, and there is no change in chemical identity, a new PMN is not required. In this case, if the process change takes place soon after close of the PMN review period, it is recommended that the submitter keep a record of its decision process which led to the change, to clearly show that this change was not decided *before* the close of the PMN review period.

100-4. Q. If there is a change of sites after submission and review of the PMN by EPA, can that change be made without further review by EPA?

A. Yes. The change of sites can be made without notice to EPA.

100-5. Q. When a PMN is submitted, or when the review period for a PMN expires, does EPA publish a notice in the Federal Register?

A. EPA regularly publishes monthly status reports in the Federal Register under the title "Certain Chemicals; Premanufacture Notices". These reports give notice of PMNs received and their projected expiration dates. EPA does not publish a notice when the review period expires, but information on Notices of Commencement (NOCs) received is included in these status reports. PMN status for notifications received in 1999 and beyond is also posted on the New Chemicals website approximately midway through the review period and can be viewed at www.epa.gov/oppt/newchems/dropstat.htm.

100-6. Q. Will I be notified that my PMN has been approved? Denied?

A. If, by the expiration of the PMN review period, EPA does *not* notify you that your chemical will be subject to regulation, under §5, you are free to commence manufacture of the substance after the review period expires. During the PMN review period, the EPA Program Manager or other EPA personnel may contact you if EPA identifies concerns or seeks clarification of information provided in the PMN.

The EPA Program Manager will also notify you before the review period expires if the review period will be extended under TSCA §5(c) or if regulatory action is being considered on the new

substance under TSCA §5(e) or §5(f). You may also refer to the New Chemicals Program website at www.epa.gov/oppt/newchems/dropstat.htm to obtain the status of PMNs or Low Volume Exemptions (LVEs) currently under review by EPA.

100-7. Q. What if EPA believes that the scenario described in the PMN may present unreasonable risk?

A. If the EPA review finds that there is insufficient information to adequately assess the risk from a chemical, and that human exposures and/or environmental releases associated with the manufacture, processing, distribution, use, or disposal of a new chemical substance as described in the PMN may pose unreasonable risk, EPA may:

- require testing, under §5(e), before manufacture to assess the risk, if the risk cannot otherwise be adequately mitigated
- impose regulatory restrictions via a combination of §5 (e) Consent Order and Significant New Use Rule (SNUR) to control exposures or uses pending development of test data; or
- request the submitter to amend its PMN to include appropriate exposure controls and issue a "non-§5 (e) SNUR."

A §5(e) Consent Order places requirements on the manufacture, processing, distribution, use or disposal of the new chemical substance to reduce the risk. The Order may also require the manufacturer to submit testing to EPA before exceeding a specified production volume. A 5(e) SNUR normally mirrors the terms of the Consent Order and extends those terms to any person who may manufacture, process or use the subject chemical. In those cases where EPA does not determine that the use/exposure scenario for a new chemical substance as described in a PMN may present an unreasonable risk or have the potential for substantial production volume and substantial or significant human exposure or substantial environmental release, but where EPA has concerns about other uses, EPA may issue a non-5(e) SNUR. If the submitter wishes to engage in a "significant new use(s)" as specified in either type of SNUR, under §5(a)(1)(B) notice to EPA is required to provide for an EPA review.

100-8. Q. How do "expedited §5(e) Orders" work?

A. The procedures that EPA uses to develop §5(e) Consent Orders provide for expedited handling in certain circumstances. Much time can be consumed by negotiations concerning deviations from standardized or "boilerplate" §5(e) Order language, particularly because EPA officials must carefully consider and approve any deviations from previously approved language. Elimination of this negotiation can greatly accelerate preparation and review of a §5(e) Consent Order. An expedited procedure can be used when both parties are expected to accept and sign the Order (as developed by

EPA), without any modifications.

The expedited procedure has two primary differences from a negotiated procedure. First, instead of EPA sending a draft Order to the submitter for comment, EPA sends an "Action Letter" intended to provide the submitter with an understanding of the terms of the proposed §5(e) Order. The Action Letter utilizes the most appropriate model or generic §5(e) Consent Order on EPA's website (www.epa.gov/newchems/boilerpl.htm) and describes in some detail the specific terms intended for the individual case. Second, EPA signs the Order before the submitter signs it. These procedures eliminate certain internal and external review procedures and can halve the time necessary for the negotiated, non-expedited Consent Order process.

This expedited procedure for developing §5(e) Orders has been used by EPA since 1988. This option has been made available in the standard Action Letters EPA sends to PMN submitters for every PMN which EPA intends to regulate by Order under §5(e) of TSCA.

100-9. Q. Why do non-"expedited" Consent Orders require so much review?

A. Most Consent Orders are "expedited", and require little review, because they are developed using one of several standard templates based on EPA's risk or exposure findings. If the expedited process is not used, negotiation of the terms of the §5(e) Order invariably delays completion of the Order since additional consideration and approval by EPA personnel is required for terms that differ from those previously approved. The large variety of different chemicals and factual circumstances creates enough complexity to require that additional scrutiny be given to cases which deviate from the norm. In cases where EPA or the submitter find that they cannot agree to the standard language or other terms, EPA's development of §5(e) Orders to achieve the appropriate balance between legal, risk management, economic, and other interests can become lengthy.

100-10. Q. How do I request a modification of an existing §5(e) Order?

A. Pursuant to the terms of a §5(e) Order, the submitting company may petition EPA at any time to modify the terms of the Order. The petition should be based on new information about the health or environmental effects of, human exposure to, or environmental release of the PMN substance. In making a determination of whether to grant or deny a modification, under §5(e)(1) EPA must find that the activities proposed will not increase the exposures or risk to a level that is unacceptable or may be unreasonable. To petition for a modification, a submitter should send a letter with supporting information to the Chief of the New Chemicals Notice Management Branch. Although OPPT does act on petitions for modifications to existing §5(e) Orders, Order modification petitions generally rank relatively low in the Agency's priorities.

To avoid the need to request a modification based on newly developed data, submitters are encouraged to ensure that any ongoing study is completed before submission of the PMN, in which case the study would be provided along with the PMN in accordance with 40 CFR §5720.50. In cases where the submitter hopes for new market opportunities, it is suggested that testing be planned based on an optimistic sales scenario and anticipated new market opportunities to avoid losing time involved in modification of a Consent Order.

100-11. Q. Is there a production volume limit for PMNs?

A. Unless EPA takes regulatory action (such as a §5(e) Order or SNUR) in response to a PMN, there is no production volume limit for the PMN. The anticipated production volumes listed in the PMN by the submitter do not establish production volume limits for a substance. EPA may, however, place a production limit on a PMN substance through a §5(e) Order or a SNUR at the time of review where appropriate under §5. Production volume limits are often used in §5(e) Orders and SNURs to trigger testing requirements. Production volume limits are often used in §5(e) Orders and SNURs when EPA identifies potential risk from use of the substance. These limits can often be lifted if EPA recommended testing is completed and mitigates the risk identified in the review process.

100-12. Q. What is EPA's exposure-based policy and has any information on it been published?

A. EPA's exposure-based policies for new chemical substances are based on §5(e)(1)(A)(ii)(II) of TSCA and are described on the New Chemicals Website at www.epa.gov/oppt/newchems/expbased.htm.

TSCA Section 5(e) provides EPA with the authority to regulate new substances pending development of health and environmental effects data based on either the potential risk presented by the substance ("risk-based") or the potential for substantial production volume and substantial or significant human exposure or substantial environmental release ("exposure-based"). Action under Section 5(e) for a new chemical substance is taken based under either or both of these authorities. In 1988, EPA developed internal guidelines to assist in identifying new chemical substances received as PMNs which would meet the "exposure-based" finding. These guidelines were announced to the chemical industry in a letter to Geraldine V. Cox of the Chemical Manufacturers Association (now the American Chemistry Council). See www.epa.gov/opptintr/newchems/cmaxpltr.htm.

Limited test data are submitted or otherwise available on new chemical substances, and as a result EPA often relies on Structure Activity Relationship (SAR) predictions to evaluate potential effects associated with these substances. Data obtained from PMN submitters by EPA using the exposure-based finding, can better characterize the tested chemical, confirm or refute a "negative" prediction of

no risk or low risk, and supplement and validate the use of SAR in the review of PMNs. Expanded use of this finding was warranted for these reasons and because Congress intended that a greater priority for testing exists for high volume/exposure chemicals. Exposure-based testing is usually required via a negotiated 5(e) consent order.
These exposure-based guidelines capture all PMN chemicals with estimated production volumes greater than or equal to 100,000 kilograms per year, and include specific exposure/release criteria (such as $\geq$ 10,000 kg/year total release to environmental media or $\geq$ 0.003 mg/kg/day exposure via air). The objectives of this approach were to encourage fair and consistent decisions across numerous chemical categories and uses, to provide clear guidance to the public and industry about EPA's policy and expectations, and to implement the policy in the simplest, least resource-intensive way.

EPA's exposure-based policies for new chemical substances are based on §5(e)(1)(A)(ii)(II) of TSCA and are described on the New Chemicals Website at www.epa.gov/oppt/newchems/expbased.htm.

100-13. Q. What will happen if the submitter refuses to agree to conditions EPA regards as necessary if the PMN substance is to be used without unreasonable risk, or under an exposure-based Consent Order?

A. If EPA and the submitter cannot agree on EPA's specified conditions where EPA has predicted that the activities proposed for the PMN substance may present or will present an unreasonable risk, or projected production and exposure exceed EPA's exposure-based policy criteria, EPA can unilaterally issue a non-consensual Order banning or otherwise controlling the substance under §5(e) or §5(f) of TSCA. If the submitter objects, further proceedings may be necessary to enforce the order. This is not a typical scenario- usually EPA and the submitter agree to a Consent Order under §5(e). In order to be effective, a §5(e) Order must be issued before expiration of the 90-day review period.

Usually a unilateral "extension" (under TSCA §5(c)) or a consensual "suspension" (under 40 CFR §720.75(b) - requested by the submitter) of the 90-day statutory review period is necessary to allow sufficient time for development of an EPA response when EPA review suggests that activities proposed for the PMN substance may or will present an unreasonable risk or have the potential for substantial production volume and substantial or significant human exposure or substantial environmental release. An EPA Program Manager will notify the submitter if regulatory action is being considered on the new substance under TSCA §5(a), 5(e) or 5(f). The EPA Program Manager will contact the submitter before the review period expires to request a consensual suspension. If this is not granted, EPA can unilaterally extend the review period under §5(c). If an extension under §5(c) is required, it can be up to and usually is granted for 90 days. The §5(e) or §5(f) Order must be issued by day 135, which gives the submitter time to respond.

101 Guidance for Completion of §5 Submission Form

101-1. Q. Can I use commercially available software to generate the §5 submission form?

A. Yes, if the format generated by the software has been pre-approved by EPA's TSCA Document Control Officer. One such form is sold by the American Chemistry Council, of Arlington, Virginia, and another is sold by the Bureau of National Affairs, of Washington, D.C. Please note that EPA cannot endorse the purchase of a particular company's products or services, and identification of these forms as sufficient for PMN use should not be taken as an endorsement of the software products. EPA is willing to identify any other forms once such forms are approved by the Document Control Officer. Information on potential approval is available from the Chief of the Records and Dockets Management Branch at 202-564-8952.

101-2. Q. How does the New Chemicals Program assess completeness of PMNs?

A. Completeness of PMN submissions is determined by compliance with EPA regulations at 40 CFR §720.45 and EPA's PMN user fee requirements at 40 CFR §700. These regulations are available to all PMN submitters on the New Chemicals website or the Government Printing Office (GPO) web site.

Once a submission is received, it is first prescreened. In the prescreen, pages 4-8 are reviewed for completeness (is all the information provided), correctness (is the provided information right), and consistency (does the information provided contradict itself). The chemical name, structure and CAS Registry Number are reviewed as are lists of impurities and byproducts. The method of chemical nomenclature determination, the presence of a generic name when identity is claimed as confidential business information (CBI), production volume and TSCA use, and process diagram information are examined. Additional information required for polymers is reviewed on page5.

When a submitted form does not fulfill the above requirements, EPA will notify the submitter.

The checklist used to notify submitters of the specific problems in their submissions is presented below, and reflects the common errors EPA has seen in PMN submissions. The most frequent reason for an incomplete submission is a chemical name which does not conform with the Chemical Abstracts Ninth Collective Index (9CI) nomenclature rules and conventions, as required by 40 CFR §720.45(a)(1)(i). (This definitive guide to Chemical Abstracts nomenclature has been used since 1972.)

§5 SUBMITTER ERROR CHECKLIST (REV 1/7/98 VER 51)

Your chemical identity information as submitted according to Method 1 or Method 2 is not acceptable because:

_____(a) The correct Chemical Abstracts name has not been provided.
_____(b) The correct CAS Registry Number, if one already exists for the substance, has not been provided.
_____(c) The correct molecular formula has not been provided, where applicable.
_____(d) A complete, correct chemical structure diagram for a Class 1 substance has not been provided.
_____(e) A correct partial or representative chemical structure diagram has not been provided for a Class 2 substance or polymer, where such information is known or reasonably ascertainable.
_____(f) There is an inconsistency among two or more parts of the chemical identity information, which involves the:

_____ reported chemical name,
_____ CAS Registry Number,
_____ molecular formula,
_____ chemical structure diagram,
_____ identity of immediate chemical precursor or monomer
_____ manufacturing process information, or
_____ other:

_____(g) Because the reported substance is polymeric, page 5 of the §5 submission form (concerning information on polymers) must be completely filled out.
_____(h) Correct chemical names and CAS Registry Numbers (where numbers are available) have not been provided for all monomers and other reactants used to manufacture a reported polymer.
_____(I) Correct chemical names and CAS Registry Numbers (where numbers are available) have not been provided for all immediate chemical precursors used to manufacture a Class 2 substance.
_____(j) For a Class 2 substance, information about the nature of the manufacturing reaction/process or the typical (or range of) product composition (where appropriate) has not been provided.
_____(k) A letter of support has not been received from the supplier of the reported substance or a chemical precursor in order to provide the required specific chemical identity information not included in the notice.
_____(l) Supporting information from a prior notice (PMN, *bona fide* Intent Notice, etc.) you reference is not consistent with your reported chemical identity information.
_____(m) The reported generic chemical name is misleading or does not provide a sufficient level of chemical identity information.
_____(n) The manufacturing process information does not include specific chemical names and/or weights for all starting materials.
_____(o) Method 1 was used, but the information provided to the CAS Inventory Expert Service is not identical to that included in the PMN.
_____(p) Not all of the chemical names reported for substances in a consolidated PMN have been obtained from the CAS Inventory Expert Service.
_____(q) Other:

101-3. Q. If a PMN submission is judged to be incomplete well into the 90 day review period, will the 90 day clock be stopped and restarted when the additional information is received, or will a new 90-day period begin upon receipt of the new information?

A. When a notice is declared incomplete, the review period is not considered to have started, regardless of when in the review period the notice is declared incomplete. Day-1 of the review period begins when EPA receives a complete notice. See 40 CFR §720.65(c)(2)(ii).

101-4. Q. What are some common errors made in filling out the §5 submissions form or a Notice of *bona fide* Intent? How can I avoid having my §5 notice declared incomplete?

A. The administrative procedures applicable to incomplete notices are specified at 40 CFR §720.65. For more detail on EPA's review for completeness, see Q&A #101-2. One of the most frequent errors is incomplete chemical identity information. Another very common error in a submission is an inconsistency between the chemical name, the CAS Registry Number, the structure, the molecular formula, and/or the manufacturing process information. There can be other deficiencies with respect to the form that could cause EPA to consider a notice incomplete. See Q&A #101-7 The following is a list of chemical identity errors which under 40 CFR §§720.45 and 720.65 can result in incomplete notices.

A §5 submission form (EPA Form 7710-25) or a Notice of *bona fide* Intent to Manufacture/Import will be considered incomplete if any of the following problems (1-10) exist with respect to chemical identity information submitted via Method 1 or Method 2 (see Q&A #103-1 below), according to the Premanufacture Notification Regulations at 40 CFR 720.45.

1. The correct Ninth Collective Index (9CI) Chemical Abstracts (CA) name of the reported substance and the corresponding Chemical Abstracts Service (CAS) Registry Number (if a CAS Registry Number exists for the substance) are not included in the Chemical Identity Information section of the notice form (Part I, Section B).

2. The correct molecular formula of the reported substance (if a single molecular formula is known to exist for the substance or is reasonably ascertainable) is not included in the chemical identity information section of the notice form (Part I, Section B).

3. The complete, correct chemical structure diagram for a reported Class I substance is not included in the chemical identity information section of the notice form (Part I, Section B).

4. A correct representative or partial chemical structure diagram for a reported polymer or Class 2 substance (as complete as possible, based on what is known or reasonably ascertainable) is not included in the chemical identity information section of the notice form (Part I, Section B).

5. A non-CA name, a generic chemical name, a chemical synonym, a CAS Registry Number, a trade name, or the PMN, Exemption, or *bona fide* Intent notice number/User Fee number/TSCA accession number of another notice is written in the chemical name box of the notice form in place of the correct CA name.

6. When reporting a polymer, the submitter does not provide all of the information required in the

chemical identity information section for polymers (Part I, Section B.2) comprising page 5 of the §5 submission form.

Note: (1) A "polymer" includes an oligomeric substance having a molecular weight distribution as well as any substance that is or incorporates a polymer, even if the last reactions did not involve further polymerization. For example, persons who intend to manufacture salts, adducts, or other derivatives or reaction products from polymers must fill out page 5 of the §5 submission form. (2) Not all polymers contain the word "polymer", "polymers", or "poly" in their CA names; for example, siloxanes and silicones. These conventions have been in place largely without changes since the inception of the Inventory, and can be found in "TSCA Inventory Representation for Polymeric Substances" at www.epa.gov/oppt/newchems/polymers.txt.

7. The specific chemical name and corresponding CAS Registry Number (if such a number exists) for (1) each monomer or other reactant used to make a reported polymer, or (2) each immediate precursor substance used to make a reported Class 2 substance, is not included in Part I, section B of the notice. Note: The notice is considered incomplete even if the reported CA name of the PMN substance itself is correct. The specific chemical names used to identify such monomers, reactants, or chemical precursors do not have to be CA names although correct CAS Registry Numbers must be provided if they exist.

8. There is at least one discrepancy or inconsistency in the reported chemical identity information that could possibly cause some ambiguity about the correct chemical identity. This discrepancy or inconsistency may involve the chemical name, CAS Registry Number, molecular formula, chemical structure diagram, immediate chemical precursors, monomers, or manufacturing process information.

9. A letter of support has not been submitted by a chemical supplier in order to provide required chemical identity information not included in the notice.

10. The submitter indicates as part of the manufacturing process information or precursor substance/reactant/monomer information that a neutralizing reagent is used, but neither represents the reported substance as a salt nor provides a reasonable explanation for why the substance should not be considered a salt, even though the process information or list of reactants would indicate the formation of a salt. This description is inconsistent with the Ninth Collective Index (9CI) of Chemical Abstracts nomenclature rules and conventions as required by 40 CFR 720.45(a).

101-5. Q. When does the PMN review period begin? Are the review periods of 90 days for PMNs, 30 days for Low Volume and Low Release/Low Exposure Exemptions (LVEs/LoREXs), and 45 days for Test Marketing Exemptions (TMEs) based on calendar days or working days?

A. TSCA §5 submissions review periods are based on calendar days. If EPA determines that your notice is "complete," the review period begins on the date that the submission (PMN, LVE, LoREX, or TME) is received and logged in by EPA's Document Control Officer (DCO). You will receive an acknowledgment letter indicating the identification number assigned to your notice by EPA and the expiration date of the review period. If your notice is declared "incomplete" as described at 40 CFR 720.65, you will receive written notification, and your review period will not begin until EPA receives a complete notice.

In addition, following receipt of a PMN, LVE, LoREX, or TME, EPA searches the TSCA Chemical Inventory to ensure that the substance for which the notice is submitted is not already listed. If your chemical substance is on the Inventory, you will be notified that your substance is not subject to premanufacture notification requirements and you are free to begin manufacture immediately.

During the review period, status information on your PMN, LVE, LoREX, or TME submission can be obtained at www.epa.gov/oppt/newchems/dropstat.htm. The EPA Program Manager or other EPA technical personnel may contact you to clarify information you have provided in the notice, or if concerns are identified. If you are not contacted before expiration of the review period, you are free to begin manufacture of the substance identified in your notice once the review period expires.

101-6. Q. If a submitter objects to a finding that the PMN is incomplete, how many days will EPA take to decide on the appeal?

A. As required at 40 CFR 720.65(c)(5), EPA will notify the submitter in writing within 10 days of receiving the objections. Please note that objections must be received within ten days of EPA notification of the submitter for a submission that is determined to be incomplete. See 40 CFR §720.65(c)(4).

101-7. Q. May I claim information submitted on a §5 submission form to be confidential?

A. Under TSCA §14 as specified in regulations at 40 CFR Part 720 Subpart E, you may assert a claim of confidentiality for any §5 related information submitted to EPA. Note, however, that information in health and safety studies is normally not entitled to confidentiality, except as provided in 40 CFR 720.90. Under 40 CFR §720.90(c) confidentiality claims for chemical identity in a health an safety study may be denied unless 1) disclosure would reveal manufacturing or processing information, 2) would disclose the fraction of a mixture which the substance comprises, or 3) the study could be

interpreted without knowing the identity of the substance, and that disclosure would have harmful competitive effects on the submitter. Not only is information which arises as a result of a formal, disciplined study included in EPA's definition of health and safety studies, but other information relating to the effects of a chemical substances or mixture on health or the environment is also included.

Confidentiality claims must be made at the time your information is submitted. 40 CFR 720.80(b). After the 90-day review, you will be required to accompany your Notice of Commencement (NOC) with substantiation of your confidentiality claims for the chemical identity, 40 CFR 720.90(b), and may be required to substantiate other confidentiality claims in the future if, for example, EPA receives a Freedom of Information Act (FOIA) request concerning that information. Dealing with TSCA confidential business information is a substantial burden for EPA, and we discourage submitters from claiming confidentiality unless they have sound business reasons for doing so. TSCA §14 describes circumstances under which EPA shall disclose information even though it has been claimed confidential by its submitter. See also EPA confidentiality regulations at 40 CFR 2.209 and 2.306. See Q&A # 107-6 to obtain the requirements for substantiation at the time a NOC form is submitted to EPA for a PMN substance which can serve to guide your considerations about the appropriateness of making a CBI claim.

To ensure that confidential information is not disclosed to the public, you must submit an additional copy of the notice form, including attachments, which does not contain confidential information. This "sanitized" or redacted version will be placed in the public file. It must contain all non-confidential information, including health and safety studies. "Health and safety study" is defined at TSCA §3(b) and 40 CFR 720.3(k) (see also Q&A #117-1, #117-2, and #117-3). You are responsible for ensuring that all information claimed as confidential is removed from the sanitized version; EPA does not double-check this.

To assert confidentiality for specific information on the form e.g., submitter identity, chemical identity, or use information, mark the "Confidential" or Confidential Business Information (CBI) box located to the right of the information on the form. Also mark the box at the bottom of page 1 of the form if you claimed any information in the notice as confidential.

If you do not provide the "sanitized" or redacted copy with your submission, the submission will be considered incomplete and the review period will not begin. Also any subsequent amendment to your PMN or additional information/data you provide to EPA must be accompanied with a non-confidential version for the public file.

101-8. Q. What should I do to ensure that EPA will treat my submission as confidential?

A. See Q&A #101-7. You must take the following actions to meet EPA's requirements

regarding submission of confidential information:

(1) Mark the appropriate boxes on the §5 submission form, to indicate confidential information.

(2) Submit appropriate numbers of copies of each notice form and the attachments (three for PMNs and SNUNs, one for LVEs, LoREXs, TMEs). If any information is claimed confidential, an additional "sanitized" or redacted copy of the relevant documents must also be submitted. The "sanitized" or redacted copy will be placed in the public file.

(3) When submitting information in an attachment, also state any confidentiality claim in the relevant attachment.

101-9. Q. How many copies of the §5 submission form must be sent to EPA?

A. You must submit an original and two complete copies of the §5 submission form, including all test data and any other information attached to the notice form, for a PMN or a SNUN (Significant New Use Notice). 40 CFR 720.40(d)(2). For a Low Volume Exemption (LVE) or Low Release, Low Exposure Exemption (LoREX) submission, you need only file one copy of the form. 40 CFR 723.50(e).

If any information is claimed as confidential, however, you must also include a "sanitized" or redacted copy of the notice for any §5 submission (PMN, LVE, SNUN, etc). 40 CFR 720.80(b)(2). Information claimed as confidential must be deleted from the "sanitized" or redacted copy and replaced with generic information, e.g., generic chemical identity, use, production volume, etc.

101-10. Q. What is the definition of an authorized official? Must it be a company officer?

A. An authorized official is one who according to company documents, policy or interpretation, is responsible for the truth and accuracy of each statement in the PMN notice. Depending on the size and organization of the submitting company, this person may be, for example, the president or vice-president, or director or manager of a division. The submitter determines who will act as the authorized official.

101-11. Q. How can a submitter use an agent to submit a PMN? What role and responsibility does the agent assume?

A. An agent is someone whom the submitter designates to submit a PMN, who may have more knowledge or experience in completing PMN notices. Both the submitter and the agent must sign the certification on the form. The agent may speak for, and bind, the person submitting the PMN .

Responsibility, however, is generally with the submitter. The submitter is responsible for ensuring accuracy, and that all information known to or reasonably ascertainable by the submitter, and all test data in the submitter's possession or control, are submitted to EPA. See 40 CFR 720.(e).

101-12. Q. I have a new site-limited chemical intermediate that requires a PMN. My normal practice is not to prepare a Material Safety Data Sheet (MSDS) for site-limited intermediates. Do I have to prepare one to be included with this PMN?

A. Submitters are not required to develop a MSDS solely for the purpose of submitting a PMN. If it is not your practice to develop a MSDS, you need not do so to accompany a PMN. However, as indicated on page 12 of the PMN form, if a MSDS is developed for the material, EPA strongly recommends that you should attach the MSDS to the completed PMN form. An MSDS aids EPA reviewers in the assessment of the chemical. It enables EPA reviewers to understand the precautions the submitter employs for worker safety and environmental release. If you have prepared no MSDS, it can be helpful to prepare a summary statement on these subjects for EPA's consideration. OSHA's hazard communication requirements appear at 29 CFR 1910.

101-13. Q. In my early research, I will be using a batch process. Later on, during manufacture, I plan to use a continuous process. This could lead to different by-products, impurities, etc. However, the only data I have at the time of the PMN submission is batch data. Do I use this for my PMN or speculate on what I hope to do in manufacture?

A. Both can be useful to EPA's PMN reviewers. You should provide information concerning your intended commercial activities to the extent that is known or reasonably ascertainable to you (see 720.40(d)). You should estimate the identity of by-products and impurities to the best of your ability based on information available to you, such as the results of R&D activity.

101-14. Q. If one site operates a batch type process and another site operates a continuous process, which process is described in Section A?

A. You must describe <u>both</u> processes in Section A. See 40 CFR 720.45(g)(2). Use a separate sheet for each description and clearly indicate your intended operations.

101-15. Q. What is the difference between industrial use and commercial use?

A. A use is industrial if the new chemical substance or products containing it will be used at a facility where chemical substances or mixtures are manufactured, imported or processed, *e.g.*, textile dyeing or paint formulation. The use is "commercial" if the chemical substance or products containing it will be used by a commercial enterprise providing saleable goods or a consumer service, *e.g.*, use by

painting contractors or commercial dry cleaning establishments. See 40 CFR 721.3.

101-16. Q. Must information on the trade name of formulated products which contain the new chemical substance as part of a mixture be reported on page 5 of the §5 submission form?

A. No, trade names of formulated products are helpful in the PMN review, but not required. However, the trade name for the PMN substance is required. 40 CFR 720.45(c).

101-17. Q. Should I list a pilot plant operation as an industrial site on Page 7 of the §5 submission form?

A. If the pilot plant will continue to produce the chemical after R&D is complete, it should be listed on the §5 submission form; if not, no. See 40 CFR 720.36.

101-18. Q. In the process description, does the product containing the PMN material constitute an environmental release? Does it have to be numbered on the diagram and listed on Page 8 of the §5 submission form? Is a waste stream a release to the environment? Incineration? At page 10 "industrial sites controlled by others" - should pesticide application be considered a release to the environment?

A. EPA is asking here that you identify releases to the environment in the course of manufacturing and processing of the material, as required by 40 CFR 720.45 (g) and (h). This includes waste streams, process losses, incineration, etc. To enable EPA to assess these releases, you must clearly identify the steps in the process description at which the new chemical substance is susceptible to release. Clearly, the end product can have environmental impacts, depending on its use, and EPA will consider environmental impacts of dispersive uses in EPA's review (an example of a dispersive use would be as an ingredient in artificial smoke or in a fragrance formulation for outdoor use). The PMN Instruction Manual discusses dispersive use/degree of containment in the "Use information" section (pp. 8-9). See www.epa.gov/oppt/newchems/tscaman2.pdf. The use will be assessed by Agency reviewers, based on the detailed description you provide at I.C.2. on page 7 of the PMN form. It does not need to be numbered and listed on Page 8, however.

Release to the environment during use as a pesticide is not considered under TSCA PMN review. Pesticides are excluded from the definition of "chemical substance" at 40 CFR 720.3(e)(2) and in Section 3(2)(b)(ii) of the TSCA. Pesticides are reviewed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA reviewers will consider the potential harm which can be caused by dispersion of pesticides in the environment. Intermediates used in pesticide manufacture are not excluded from consideration as chemical substances, however, so TSCA PMN review is provided for intermediates used in pesticide manufacture, and this will include their dispersion into the environment. For more on TSCA jurisdiction over pesticides, see Q&A #213-2.

101-19. Q. For Environmental Release and Disposal, the manufacturers must identify the media to which the new substance will be released from the "release point." Does that release point refer to release before or after control technology?

A. The PMN form provides specific places for the submitter to provide environmental release information as required by 40 CFR 720.45 (g) and (h). For sites controlled by the submitter, the PMN form at item II.A.3. calls for identification of release directly to the environment (item 2a) and after technology (item 2b), identification of control technology at (5a) and amount released after technology at (5b). For sites controlled by others, similar information is requested at item II.B.2. This enables reviewers to assess release of the substance both before and after control technology.

101-20. Q. Our company has a problem finding our old file copy of a PMN we submitted to you as confidential in 1984. Since we filed the PMN, we have merged with another company, the person who filed the PMN has left, and our company name has changed. We want to get a copy of the confidential PMN we filed at that time. How can we do it?

A. For EPA to send confidential information it must be certain that it is sending the information to the legitimate owner of the information. This includes successors to the companies and individuals who originally filed. EPA needs evidence that the requester is legitimately entitled to the information. To initiate this request, a corporate officer should send a signed letter (signature notarized) with as clear a description as possible of the information sought (original submitter identity required, PMN numbers and accession numbers are important, if available) on company letterhead to:

TSCA Records and Dockets Management Branch
Information Management Division (7407M)
Office of Pollution Prevention and Toxics
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460.

If there is a succession situation, describe corporate changes which have happened since the original information was submitted to EPA (mergers, buy-outs, etc.) and how, if we need assurance on the situation, EPA can check the validity of the succession.

101-21. Q. What does the "binding option" mean in legal terms when filing a PMN?

A. In filing a PMN, the "binding option" enables you to indicate your willingness, if EPA review finds it to be necessary, to be bound to certain submitted information on the form. By indicating your willingness to make these commitments, you would be indicating an interest in future negotiations if

EPA deems them necessary, generally in working to a §5(e) Consent Order and/or a SNUR. The binding option is offered for questions related to the potential risks - such as use, production volume, protective equipment, engineering controls, and/or process description.

Marking the binding boxes helps EPA (if necessary) to efficiently negotiate with a PMN submitter the development of §5(e) Consent Orders and promulgate Significant New Use Rules (SNURs) for those new chemical substances that EPA determines may present an unreasonable risk, substantial exposures, or significant new uses, if certain control actions are not implemented. This option is intended to reduce delays that can slow the development of consent orders absent such agreement. Should EPA wish to discuss development of binding control measures for your PMN, you will be contacted by a Program Manager and negotiations may ensue. Therefore, indicating a willingness to be bound by the terms of your notice does not by itself prohibit the submitter from deviating from the information (except chemical identity) reported in the form.

In the case of exemption applications (i.e. Low Volume/Low Release, Low Exposure), however, certain statements are automatically binding on the submitter when EPA approves the exemption applications. See Q&A #303-5 and 40 CFR 723.50(j).

102 Inventory Searches/Bona Fides

102-1. Q. A potential manufacturer of a substance needs to find out whether the chemical substance is included on the Inventory. If the chemical is on the Inventory, a PMN would not be required. How is a submitter to determine whether the chemical it wants to manufacture is on the Inventory?

A. The potential manufacturer ("manufacture" includes import) should check the public version of the TSCA Inventory, which lists chemicals submitted non-confidentially for the Inventory. The Inventory is maintained at Federal depositary libraries throughout the country. The TSCA Inventory can be purchased from the National Technical Information Service (NTIS).

Email info@ntis.gov. Or visit their website at www.ntis.gov. Then click on "NTIS Products and Services". Click on "Simple Search". Type in TSCA Inventory. Choose from several Inventory products to buy.

A submitter can also consult a commercial service which has the NTIS computer-accessible TSCA Inventory. These services include:

i. Scientific and Technical Network International (STN), maintained by Chemical Abstract Service (CAS) telephone 1-800-848-6538 x3731

ii. Dialog Information Services (Lockheed) File 52, telephone 1-800-334-2564;

The Inventory is carried, as well, by Cornell University, at http://msds.pdc.cornell.edu/tscasrch.asp

EPA cannot be responsible for the quality of Inventory data in these outside services.

If no listing for the substance is found on the public Inventory, the submitter may request that EPA check the confidential portion of the Inventory. Before EPA will do so, the submitter must establish a "bona fide intent" to manufacture or import the chemical pursuant to 40 CFR 720.25.

102-2. Q. How may a *bona fide* intent to manufacture or import a chemical be established?

A. In order to establish a *bona fide* intent to manufacture or import a chemical, information must be submitted to EPA, as described at 40 CFR §720.25. EPA in 1995 revised certain provisions of the *bona fide* procedures to establish a genuine intent to manufacture or import a substance. (60 FR 16298, March 29, 1995) This amendment reduced and simplified the then-existing analytical information requirements, modified and clarified other existing information requirements, and requires submitters to provide some additional types of information in *bona fide* submissions.

Broadly, the amendments identify an infrared spectrum as the usual practice for characterizing the new chemical substance. Requirements for chemical identity information, and the description of research and development (R&D) activities and use were modified and/or clarified. Three new information requirements were established regarding the most probable manufacturing site and process to be used, as well as an approximate date when the submitter would be likely to submit a §5 notice for the substance if it is not found in the Inventory. The amendments enable submitters to demonstrate a *bona fide* intent and EPA to better protect the CBI of the original submitters of Inventory substances.

Submitters of a *bona fide* must provide:

(1) The CA Index Name, and a correct CASRN (if the substance already has a CASRN assigned to it) (correct CA nomenclature is not required when a reported substance involves the use of a purchased proprietary reactant. This is due to logistical obstacles involved in generating correct CA identifications for substances based on multiple submissions of parts of the overall identity from different sources. However, the submitter must coordinate with the supplier to ensure that the remaining specific chemical identity information is sent by the chemical supplier directly to EPA in a timely manner, to complete the *bona fide* request and initiate review by EPA. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the submitter's bona fide, the *bona fide* will be considered incomplete).

(2) A molecular formula and a complete or partial chemical structure diagram if these are`known or reasonably ascertainable.' (Failure to fully comply with the chemical identification elements of this requirement will result in the *bona fide* being declared incomplete by EPA and returned to the submitter.)

(3a) A brief description of the research and development activities conducted to date related to the substance, including the year in which the person first started to conduct research or development activity on the substance, and the general types of research and development activities conducted thus far (e.g., synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The submitter must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of the substance.

(3b) *(alternative to 3a, above)* If an importer is unable to provide the information described in (3a) from a foreign manufacturer or supplier, the following information shall be submitted instead:

(i) A brief statement indicating how long the substance has been in commercial use outside of the United States.

(ii) The name of a country in which it has been commercially used.

(iii) Whether the importer believes that the substance has already been used commercially, in any country, for the same purpose or application that the importer is intending.

(4) A specific description of the major intended application or use of the substance.

(5) An infrared spectrum of the substance, or alternative spectra or other data which identify the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, the person must submit a spectrum or instrumental readout for the substance.

(6) The estimated date (month/year) in which the requestor intends to submit a Premanufacture Notice (PMN) or exemption request under §5 for this substance if EPA informs the notice submitter that the substance is not on the Inventory.

(7) The address of the facility under the control of the submitter at which the manufacture or processing of the substance would most likely occur. For an imported substance, the facility under the control of the importer at which processing of the substance would likely occur, if any.

(8a) For substances intended to be manufactured in the United States, a description of the most probable manufacturing process that would be used by the submitter to produce the substance for non-exempt commercial purposes.

(8b) *(alternative to 8a, above)* For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the substance is not expected to be processed or used at any facility under the importer's control, a statement to this effect must be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.

If an importer cannot provide the chemical identity information required because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier must supply the required information directly to EPA in accordance with §720.45(a)(4) and reference the importer's notice. If the appropriate supporting document from the foreign party is not received within 30 days after EPA receives the importer's notice, the notice will be considered incomplete.

If a manufacturer cannot provide all of the required information in accordance with §720.45(a)(1), (2), and (3) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as known by the manufacturer. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of the proprietary reactant, in accordance with 40 CFR 720.45(a)(5). The letter of support must reference the manufacturer's notice. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the manufacturer's notice, the notice will be considered incomplete.

On receipt of an adequate statement of *bona fide* intention, EPA will search both the non-confidential and the confidential portions of the Inventory for the substance; and will notify the intended submitter whether the substance can be found on the Inventory.

102-3. Q. What are the benefits of filing a Statement of *bona fide* Intent To Manufacture instead of a full PMN or LVE or LoREX application?

A. For the submitter, there are benefits to each: there is no fee for filing a bona fide, and the review period is shorter (30 days). It is frequently less costly to develop the Statement of *bona fide* Intent than it is to develop a PMN or exemption application. On the other hand, EPA will search the Inventory on receipt of a PMN or exemption application, and will reject the PMN and return your fee if it is found to be already listed on the Inventory. If the material was not on the Inventory the 90-day

review period for the PMN will start on receipt of the PMN. See 40 CFR 720.65(a).

102-4. Q. How soon will EPA notify the requester of the results regarding an Inventory search?

A. The submitter will be notified within 30 days after the submission is considered by EPA to be complete and without chemical identity problems.

102-5. Q. Is EPA capable of recognizing if a chemical substance covered by a submitted PMN is identical to one already submitted by another submitter? What would be done in this case?

A. Yes. EPA has put substantial effort into developing unambiguous naming rules for chemical substances, so that Inventory listings will be unique and consistent. Using these rules, an Inventory search upon receipt of a §5 submission would identify other submissions for the identical chemical substance. If a chemical was on the initial Inventory or if a Notice of Commencement has been received for a previously identified new chemical, the PMN substance would be viewed as an existing chemical substance, the PMN substance would be declared excluded from reporting, and the PMN submitter would be notified. In such instances, any user fee submitted with the PMN would be refunded.

102-6. Q. How can a submitter find out whether: **(a)** a particular polymer is on the confidential TSCA Inventory? or, **(b)** a reactant in a particular polymer is on the confidential Inventory?

A. The Inventory status of your polymer can be determined by filing a Notice of *bona fide* Intent to Manufacture (see 40 CFR §720.25 or contact the TSCA Hotline on 202 554-1404). You may not file a *Notice of bona fide Intent to Manufacture* on the reactant unless you have a *bona fide* intent to manufacture or import it. It is the responsibility of the manufacturer or importer of the reactant to determine the Inventory status of the reactant. If you file a PMN on your polymer EPA will check its Inventory status and, if it is on the Inventory, will notify you that you are free to proceed with manufacture of the polymer.

102-7. Q. I wish to import a polymer under the Polymer Exemption containing greater than two percent of a reactant (monomer) not on the public TSCA Inventory, but which may be on the confidential Inventory. On what do I file a *bona fide*? If all I plan to import is the final polymer, how do I know whether it now qualifies for the new Polymer Exemption criteria or if I need to file a PMN for the polymer?

A. If the monomer is on the confidential Inventory, your polymer may be eligible for exemption. See 40 CFR 723.250(d)(4). If it is not, a party that intends to manufacture or import the monomer must have it go through the PMN review process and commence its manufacture or

importation to allow it to be used in an otherwise exemptible polymer. You may not file a Notice of *Bona Fide* Intent to Manufacture on the reactant (monomer) unless you have a *bona fide* intent to manufacture or import it. Your supplier, if in the U.S., could file a *bona fide* on the monomer. If your supplier is not in the US, it does not have standing to file a *bona fide* on the monomer.

There is really no way to find out whether a substance is on the confidential Inventory unless you intend to import or manufacture that substance itself. Therefore, the only substance for which you can file a Notice of *bona fide* Intent is the final polymer. If the polymer is on the Inventory, no PMN will be needed. If not, you will need to file a PMN for the polymer. See www.epa.gov/oppt/newchems/polyguid.pdf.

102-8. Q. Is there a required form to use in submitting a Notice of *bona fide* Intent?

A. No.

102-9. Q. Can a *bona fide* intent notice be sent by courier service? I had a *bona fide* notice returned by my courier service. What went wrong?

A. The room at which *bona fide* submissions are accepted is only open until 4 pm. If a courier service comes after that time it will be turned away. The address for sending a *bona fide* by courier is:

Confidential Business Information Center
OPPT Document Control Office (DCO)
EPA East Building (old ICC)
1201 Constitution Avenue, NW
Room #6428
Washington, DC 20004

You can give the courier the phone number (202) 564-8930, to call if there are delivery problems.

103 Chemical Identification

103-1. Q. As required by the 1995 amendments, how can a correct Ninth Collective Index (9CI) Chemical Abstracts (CA) name for a new chemical substance be obtained?

A. This is governed by 40 CFR 720.45(a)(3). A CA name can be obtained directly from the Chemical Abstracts Service (CAS) Inventory Expert Service (CAS-IES, IES), by using an alternative source, or by developing your own CA name. If a source other than the CAS-IES is used and any chemical identity information is determined by EPA to be incorrect, the notice will be declared

incomplete and the submitter will be responsible for correcting the chemical name prior to the start of the review period.

(NOTE: non-IES CAS personnel, including other Registry Services employees, assign CA names and numbers. They are not specifically trained in TSCA Inventory requirements and policies, and the requirements of Method 1 are not satisfied by giving a CAS name and number assigned by any non-IES source. See www.epa.gov/oppt/newchems/guideman.htm and choose the link titled "Revisions of Premanufacture Notification Regulations; Final Rules" (60 FR 16298; March 29, 1995)" for the complete mechanism for obtaining the CA nomenclature under Method 1 or Method 2.)

Persons who use the CAS Inventory Expert Service must submit a copy of the chemical identification report from CAS with their notice. The person must also identify in the §5 submission form which method was used to develop or obtain the specified chemical identity information. Mark Method 1 for the CAS Inventory Expert Service. Mark Method 2 for any other source.

You must provide the correct CA name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.

EPA only considers a submitter to have used Method 1 if a copy of the CAS-IES report is attached to the notice submitted to EPA. If a CAS-IES report is not attached to the notice, EPA considers the chemical identity information to have been obtained under Method 2, even if the Method 1 box is marked on the notice.

103-2. Q. How can I obtain information about CAS Inventory Expert Service?

A. Information on this service including available resource materials is available via telephone (614-447-3600 or 800-848-6538 ext. 2308) or by facsimile (614-447-3747).

103-3. Q. I am manufacturing a new chemical substance using my supplier's proprietary chemical as a reagent. How can I obtain a CA name for the new substance when I only possess partial information?

A. You can't, and in this case, you need not obtain a CA name. You should provide all the information you have on the chemical identity of the new substance (including the specific identities of the reactants you know, the nature of the reaction, and the types of products formed) and the proprietary reactant directly to EPA and also have your supplier submit a letter of support with the specific chemical identity of the confidential reactant to EPA, referencing your company's name and either a prenotice communication (PC) number or the TSCA user fee identification number. See 40 CFR 720.40(e)(2). The notice will not be considered complete until the supplier has provided the proprietary chemical information to EPA, appropriately referencing your notice. EPA will develop the name for its own use on the Confidential Inventory, but will not divulge the name to you.

103-4. Q. How does a submitter obtain a CAS Registry Number for a PMN substance when the PMN substance identity is confidential? Does EPA assign a CAS Registry Number to every chemical which has gone through the PMN process and for which a Notice of Commencement has been received?

A. EPA itself does not assign CAS Registry Numbers, they are developed by the Chemical Abstracts Service. PMNs for chemicals whose specific chemical identities are claimed as CBI in a §5 submission, and which have no existing CAS Registry Number, can be submitted without a CAS Registry Number. For such a confidential substance, EPA will develop an Accession Number. See 40 CFR 720.25(b)(1). An Accession Number is a five- or six- digit number used to identify CBI chemicals listed in the Inventory by their generic chemical names.

If a CAS Registry Number is obtained for a substance, CAS will in all cases publish that chemical name and the number. The existence of the substance will then be public knowledge through CAS's publicly available databases. However, a submitter can (but need not) request a CAS Registry Number for the substance in the course of getting a name from the Inventory Expert Service, and can claim that CAS Registry Number confidential in the filing. This can keep the association of that substance with the submission of the PMN a secret. It is also possible for a submitter to file a PMN on a substance which received a CAS Registry Number long before (for R&D use, for example, or for commerce in other countries), and have the association of that number with the PMN be kept confidential. If there is a CAS Registry Number for a substance, the submitter must include it in the PMN, at least in the CBI version of the PMN.

In filing a non-confidential PMN for a chemical, the submitter need not report a CAS Registry Number unless one already exists for that substance. If the PMN successfully completes review and the submitter files a Notice of Commencement, EPA will then have CAS develop a CAS Registry Number for the substance.

103-5. Q. How can I obtain a Ninth Collective Index (9CI) Chemical Abstracts (CA) name for an

imported substance whose identity is claimed as confidential by its foreign manufacturer?

A. Your foreign supplier must follow the same procedures as a U.S. submitter to obtain a CA name and provide the correct chemical identity to EPA as a letter of support, clearly referencing your notice and the PMN user fee identification number or a prenotice communication number, if one has been obtained. Information can be obtained from the CAS Inventory Expert Service by telephone (614-447-3600 or 800-848-6538 x2308) or by facsimile (614-447-3747). See 40 CFR 720.40(e)(2) and the PMN Instructions Manual for further information on joint submissions or letters of support.

103-6. Q. To what extent must Chemical Abstracts Service (CAS) nomenclature be used in an exemption application considering these substances are not on the TSCA Inventory?

A. Correct CAS nomenclature is required in exemption applications. See generally 40 CFR part 723. The efficient characterization and assessment of associated risks of a substance proposed for exemption in a short time period relies on the receipt of accurate and consistent nomenclature. EPA must make the finding that the substance proposed for exemption will not present an unreasonable risk before EPA may approve an exemption. A correct Ninth Collective Index (9CI) Chemical Abstracts (CA) name must be provided in an exemption notice. Submitters may directly use CAS Inventory Expert Service or develop a name on their own or through another source.

103-7. Q. If a chemical substance is claimed confidential, must a generic chemical name be submitted?

A. Yes. A generic name must be submitted. The name must be only as generic as necessary to protect the confidential chemical identity and must reveal chemical identity to the maximum extent possible. See 40 CFR 720.85(a)(2).

103-8. Q. What would happen if the PMN chemical identity is claimed as CBI but the generic name submitted in the PMN is too broad? Would EPA declare the PMN incomplete?

A. Typically we wouldn't declare the PMN incomplete. However, the PMN may be declared incomplete if the generic chemical name is so insufficient as to reveal little or nothing about the chemical composition. EPA will not usually review the adequacy of the generic name or generic description of uses during the review period. We may choose to review the generic name/use at the time we receive a Notice of Commencement under 40 CFR 720.102. More importantly, if EPA decides to regulate a PMN substance, we would notify the submitter that she will have to negotiate with us the generic chemical identity for Inventory purposes if that name is not considered adequate.

103-9. Q. What is EPA's procedure when EPA develops a replacement generic name for the

Inventory? Will the manufacturer or importer have an opportunity for input prior to publication?

A. If the generic name submitted on the PMN is too general, as determined by EPA, the submitter is contacted and encouraged to work with EPA to develop a generic name acceptable to both. See 40 CFR 720.85(a)(3).

103-10. Q. I am intending to submit a PMN on a material which I will make with a confidential supplied feedstock, which will be identified to EPA in a Letter of Support. However, I have a pretty good idea what is in this material, and I do not want to be tied to this supplier indefinitely to make my material. What do I need to do to be able to use alternate sources for my feedstock? In a similar situation, I am using a process stream (byproduct) material bought from another company as a raw material. What should I call it? If I call it by the name its maker sells it under, am I going to be committed to purchasing their material only, even though other materials (currently higher-priced) would serve my needs?

A. If you are unable to reach an agreement with your supplier to divulge to you a chemical identity, or if you are using a material which has a chemical name specific to that provider, you can file a consolidated PMN with EPA. See 48 FR 21734, May 13, 1983, and www.epa.gov/oppt/newchems/consix.htm. One of your filings will include the current intended feedstock, and your other filing(s) will include other feedstock(s) or reactants (either other confidential materials or fully identified material[s]) that can be used to make the PMN substance you want to manufacture. When you purchase a fully identified feedstock or reactant, you must use the same name for it as is used by its manufacturer for TSCA purposes.

In the case of a confidential material, EPA clearly cannot offer you any information about such a consolidated PMN which would enable you to determine that the PMN substance you plan to manufacture from a proprietary reactant is the same as one you would make from a reactant that is fully identified to you. Thus, EPA cannot respond to a consolidation in a way that would provide information which could help you determine the specific chemical identity of the confidential feedstock.

103-11. Q. I intend to submit a PMN on a product which as synthesized will contain an impurity which is difficult to remove, and therefore will remain in the product as sold. What should be tested, the intended sale product or the product with the impurity removed?

A. Test the product as it is intended to be sold. See 40 CFR 720.45(a)(1). It is important that, in the PMN, you ensure that the description of the product tested is unambiguous.

104 Nomenclature

104-1. Q. What method does EPA prefer a submitter use when describing a chemical substance?

A. 40 CFR §720.45(a) requires that submitters of §5 notices provide the correct Chemical Abstracts (CA) Name or CA Preferred Name for each chemical substance included in the notice ("reported substance") that is consistent with TSCA Inventory listings for similar substances.

Persons who request a search of the confidential Inventory by demonstrating a *bona fide* intent to manufacture or import a chemical substance for commercial purposes ("bona fide") are also required to provide correct CA nomenclature and chemical identity information in accordance with 40 CFR §720.25. EPA also requires that a valid Chemical Abstracts Service (CAS) Registry Number (CASRN) consistent with the CA name be reported in a Section 5 notice or Notice of *bona fid*e Intent to Manufacture for the substance if a CASRN already exists for that substance.

Before the 1995 amendments, the PMN regulations indicated that CA nomenclature was the preferred chemical nomenclature system for PMN reporting, but it was not required. Therefore, submitters were able in the past to identify the PMN substance using alternative nomenclature. Currently, however, having the correct CA identification for a substance is important to EPA because the reporting of incorrect, inconsistent, ambiguous, or obsolete chemical names, molecular formulas, or chemical structure information, or names that are not CA Index or CA Preferred Names, causes extra resources to be spent by EPA to search the Inventory and establish the best descriptions for substances under TSCA.

Although the amended regulations only require that CASRNs be reported for substances that already have them, EPA strongly recommends that submitters provide CASRNs for all reported substances, especially when the chemical identity is not being claimed as confidential business information (CBI). The fact that a CASRN exists does not prohibit a submitter from claiming this information as confidential. Having more substances reported with CASRNs will save EPA resources involved with chemical review and Inventory searching.

Submitters must provide a CA Index Name or CA Preferred Name that is consistent with the application of the Ninth Collective Index (9CI) of CA nomenclature rules and conventions. (This definitive set of rules and conventions for CA nomenclature has been used since 1972.) Whether to report a CA Index Name or Preferred Name for a substance depends on whether the chemical identity of the substance is well-defined, indefinitely described, or poorly defined.

All of the chemical identification requirements described above should be satisfied if the submitter uses the CAS Inventory Expert Service, which is a special service of CAS for identifying substances to be submitted under TSCA. Submitters may also choose to use the services of another chemical information service or consultant that the submitter considers capable of generating correct

CA names, chemical structure diagrams or molecular formulas where appropriate, and obtaining existing CASRNs. Alternatively, the submitter can search publicly available databases to retrieve this information, if available, or attempt to generate a name without assistance from another person or organization, if the submitter has sufficient knowledge about the Ninth Collective (9CI) Index of CA nomenclature rules and conventions and about how similar substances are named for the Inventory.

Information describing CA nomenclature rules and conventions can be obtained from CAS. In addition, EPA has prepared a series of Inventory nomenclature guidance documents that are intended to generate better understanding of how various classes of substances or types of complex product combinations are identified for TSCA purposes. Several of these guidance documents have been posted to the New Chemicals Program's Internet site: New Chemicals Program Website, which can be found at www.epa.gov/oppt/newchems. The Inventory guidance documents provide informal technical guidance that is intended solely to illustrate how various types of substances are represented on the TSCA Inventory based on the information provided by the submitters. The guidance documents are not intended to be used for identifying substances for reporting purposes or for determining the need to report. Generally, EPA has attempted to maintain a consistent Inventory by closely following the guidance contained in the guidance documents . However, EPA cannot guarantee that the guidance discussed in these guidance documents has been applied to all substances listed on the Inventory.

These guidance documents are also available from the TSCA Hotline at (202) 554-1404, TTD (202) 554-0551, or tsca-hotline@epa.gov

For well-defined substances appropriately named using CA Index nomenclature, the specific chemical name chosen as most accurately describing the substance should be based on all information that the submitter can reasonably ascertain about its chemical structure, including, where applicable, the degree of structural specificity of the substance (e.g., whether a specific isomer is intended to be manufactured in the reaction that produces the substance). For poorly defined substances properly named using CA Preferred nomenclature, the specific name of choice should be based on the submitter's knowledge of the identities and sources (synthetic, isolated by processing from certain naturally occurring materials, etc.) of the chemical precursors used, the nature of the reaction or method of isolation, and the types of chemical substances constituting the product combination, etc. For naming any kind of substance, the submitter's knowledge of impurities or byproducts is also a consideration.

When more than one substance results from a reaction, one should determine whether the product combination can be viewed for TSCA purposes as a mixture of separately reportable substances. For example, when the intended product combination is known to always be completely composed of a specific number of identified substances that do not react with one another, the combination can be represented as a mixture of individual components. If this is not the case, a single chemical name must be used to collectively describe the product combination as one substance. See 40

CFR §720.3(e). Where the chemical components can be represented as a mixture, they may be reported in a single PMN as long as the components are all produced in the same reaction. Otherwise, multiple PMNs or a consolidated PMN (requiring pre-approval by EPA) must be submitted.

Other chemical identity information required at 40 CFR §720.45(a) includes molecular formula and chemical structure information. However, for substances not able to be characterized by a single chemical structure, the regulations require the submitted representative or partial structural diagram to be as complete as known to or reasonably ascertainable by the submitter. Failure to fully comply with the chemical identification elements of this requirement will result in the notice being declared incomplete by EPA pursuant to 40 CFR §720.65(c)(1). Such incomplete notices will not be processed or reviewed by EPA until the chemical identification requirement is satisfied, and in some cases EPA will require that the notices be re-submitted.

Concerning the degree of chemical structure information that can be reasonably ascertained for a given substance, submitters should understand that, for TSCA Inventory purposes, all substances are categorized by EPA into two groups according to the degree of certainty about the chemical structure of a substance: Class 1 and Class 2. Class 1 substances are those of precisely known chemical composition for which a single, complete structural diagram can be drawn. Class 2 substances are those having chemical compositions not completely definite or known; therefore, a Class 2 substance cannot be characterized by one definite, complete chemical structure diagram. The amended regulations require complete structural diagrams to be provided for Class 1 substances; for Class 2 substances, representative or partial structure diagrams are required that are as complete as can be reasonably ascertained from the Class 2 chemical identity.

104-2. Q. When a prepolymer is one of the precursors of a polymer, what should be considered to be the constituents of the final polymer: the ultimate reactants from which the prepolymer was manufactured, the prepolymer itself, or what?

A. The choice should follow Chemical Abstracts (CA) nomenclature rules and conventions for its Ninth Collective Index (9CI). See 40 CFR 720.45(a)(1)(i). With relatively few exceptions, polymers are named on the basis of their starting monomers/reactants. Thus the name of a prepolymer derived from dimethyl terephthalate and 1,4-butanediol would be based on those particular reactants. As an example of an exception to this generalization, although polyethylene glycol may be thought of as a homopolymer of ethylene oxide, it is not named as a homopolymer under CA naming practices, but rather according to the structural repeating unit (SRU) and end groups present: "*alpha*-Hydro-*omega*-hydroxy-poly(oxy-1,2-ethanediyl)." Similarly, polydimethylsiloxane is named on the basis of its structural unit: di-Me Siloxanes and Silicones (and is considered to be end-capped with trimethylsilyl groups). If a prepolymer is named so as to represent a certain structural feature or

definite repeating unit, its name cannot be decomposed into ultimate monomers for the purpose of naming the final polymer. EPA's conventions for representation of polymeric substances are discussed in greater detail in a 1995 nomenclature guidance document, "Toxic Substances Control Act Inventory Representation for Polymeric Substances" which can be retrieved at www.epa.gov/opptintr/newchms/polymers.txt and is also available from the TSCA Hotline: voice (202) 554-1404; facsimile (202) 554-5603.

104-3. Q. Does the "Two Percent Rule" apply to the actual reactants used, or to the ultimate or putative reactants?

A. With relatively few exceptions (such as when polymers or prepolymers having SRU names are used), the ultimate reactants should be the basis of the applicability of the 2% rule to the chemical identity of the polymer, if their weight percent values are all known. Thus, if a new polymer is made from the polymer of dimethyl terephthalate and 1,4-butanediol in the answer above, plus additional dimethyl terephthalate and ethylene glycol, the final polymer name would be based on three constituents (assuming each is used at over 2%), and the total amount of dimethyl terephthalate would be the sum of the separate contributions. If the weight percentage is known for each of the starting monomers, those contributing no more than two percent by weight to the final polymer may be omitted from the identity. If a homopolymer is used as a prepolymer constituent, the identity of the derived polymer should be based on the ultimate monomer, except where CA practice differs due to the applicability of SRU or other structure-based nomenclature (see the document referenced in the answer to the previous question). Although calculation of the percentage composition of a polymer may be based either on your determination involving the amount incorporated or from the amount charged to the reactor, the identity should be based on the ultimate monomers or other reactants if their weight percentages are all known.

When a charged polymer (or prepolymer) is named using SRU or other structure-based (e.g., siloxanes and silicones) nomenclature, the 2% rule is applied to the charged polymer as a whole, because one doesn't know exactly which ultimate monomers were used to make that polymer. On the other hand, if the charged polymer or prepolymer has a monomer-based name and one knows the percentage which each of the ultimate monomers constitutes in the charged polymer, then the 2% rule applies to the ultimate monomers. Where one does not know the percent composition of each of the ultimate monomers, the 2% rule should be applied to the charged polymer as a whole entity.

104-4. Q. Is a substance which is chemically identical to one on the Inventory, except that one of the elements present has been isotopically enriched, covered by the Inventory listing of the material made with the corresponding non-enriched (natural isotopic ratio) element?

A. No, it is not covered. For such substances the depletion/enrichment process is generally

accomplished chemically, not by nuclear reactions. Consequently, it is differences in chemical properties which allow the depletion/separation. Nuclear-source materials, as defined at §720.3(a)(3), are excluded from the definition of a chemical substance at 40 CFR 720.3(e), and if there were a specific case of enrichment accomplished by nuclear reactions we would consider whether this policy applied. Consequently, EPA considers a substance of which the isotopic composition has been modified to be a different chemical substance, and if it does not have a separate Inventory listing it will be "new," regardless of how similar its chemistry is to that of the ordinary-ratio (non-depleted, non-enriched) substance.

The Inventory contains a number of listings for substances enriched for specific isotopes (e.g., Zinc oxide (ZnO), Zn-64 depleted [CASRN 175449-32-8].) There are also a number of isotopes which have different chemical properties, which are separately listed on the Inventory (e.g., hydrogen, deuterium, tritium), as well as chemical compounds which differ only in the isotopes used to make them (deuterosulfuric acid, D_2O_4S, deuterotrifluoroacetic acid, $C_2DF_3O_2$).

104-5. Q. We will be making an isotopically engineered product. We may change our views on which level of enrichment is optimal. Can we cover the range from the lowest to highest contemplated level of enrichment in one submission?

A. Yes, unless the enrichment level is so high that the substance should be considered and named as containing just one isotope (that is, the other isotopes would be appropriately considered to be impurities.)

105 Inventory Issues

105-1. Q. When the notice period expires without specific action by EPA, is the chemical automatically listed on the Inventory?

A. No. A new chemical substance is added to the TSCA Inventory only after a Notice of Commencement (NOC) of manufacture or import is submitted to EPA under 40 CFR 720.102. The PMN submitter must submit the NOC to EPA no later than 30 days after the first day of non-exempt commercial manufacture or import. The NOC may NOT be submitted before manufacture or import commences.

105-2. Q. If the non-hydrated form of a chemical substance is on the Inventory, must I file a PMN on the hydrated form?

A. A hydrate of a chemical substance or a hydrate ion, formed by association of a substance with water, is considered a mixture and not reportable as such under TSCA. Only the non-hydrated

form is included in the TSCA Inventory, and this non-hydrated form will represent all hydrated forms of that substance. However, this provision does not apply to the products of discrete chemical reactions in which water is a reactant; for example. a metal hydroxide formed by the reaction of a metal oxide and water [See 40 CFR 720.3(u)(2).]

106 Review Process

106-1. Q. What is the review process for a PMN or exemption notice?

A. Briefly, a PMN, LVE, LoREX, or TME submission is received by EPA and initially checked for completeness. The Inventory is checked to see if the subject material has already been listed. If the material is found on the TSCA Inventory, EPA will inform the submitter that they are free to commence non-exempt commercial manufacture of the new chemical substance.

If the substance is not on the Inventory, it will be presented at the Chemical Review Meeting, which will consider the substance. "Early review drops" can take place at this stage, if the substance is similar to already-reviewed substances for which EPA has little concern. EPA uses the term "drop" to mean that the chemical will not be regulated with a §5(e) Consent Order or SNUR.

Most substances move forward through a Structure-Activity meeting (and development of profiles of exposure and releases) to a Focus meeting at approximately Day 23-27, which, for a PMN, can result in the following regulatory decisions:

1. request for up-front testing,
2. a risk or exposure-based §5(e) Consent Order,
3. a non §5(e) SNUR,
4. a decision that the PMN should move forward for a "Standard Review" for further analysis by a team of experts in various disciplines,
5. a request for a small amount of additional information to enable one of the decisions above (called a "short question"), or
6. drop, or a drop with a "drop letter" expressing EPA's concern and recommending certain precautions.

(Focus meeting decisions are available on the PMN Status Report, posted within 2 weeks of decision at www.epa.gov/oppt/newchems/pmnstat.htm).

It should be noted that in recent years, less than 5% of cases continue on from Focus through the "Standard Review" process. For such substances, there is a meeting of multi-disciplinary staff, followed by intensive hazard-exposure-risk assessment for the substance. At Day 79-82, an

interdisciplinary Decision Meeting is held and one of the following regulatory actions is chosen:

1. request for up-front testing,
2. a risk or exposure-based §5(e) Consent Order,
3. a non §5(e) SNUR, or
4. drop or drop with a "drop letter" expressing EPA's concern and recommending certain precautions.

PMN exemptions, such as the 45-day review test market exemptions, the 30-day review low volume exemptions, and the 30-day review low release/low exposure exemptions, are either granted, granted with conditions, or denied at the Focus Meeting. Regardless of the point during the review at which a regulatory decision is made, pursuant to TSCA §5 the submitter is not free to begin manufacture or import until the review period expires.

107 Notice of Commencement

107-1. Q. What information is required for a Notice of Commencement (NOC)?

A. A submitter is required to use the NOC form (EPA Form 7710-56) to provide all the information required for a Notice of Commencement. The form must be signed and dated by an authorized official. If the chemical identity of the PMN substance was claimed confidential and the submitter wishes to maintain that claim of identity as CBI, the submitter is required to substantiate the CBI claim when submitting the NOC. Please refer to 40 CFR §720.102 for NOC requirements and 40 CFR §720.85(b) for CBI substantiation.

107-2. Q. To whom is a Notice of Commencement (NOC) submitted?

A. The completed NOC form should be submitted to the TSCA Document Control Office. The mail address is:

United States Environmental Protection Agency
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
Attention: Notice of Commencement

If delivering in person or sending by a courier service:

United States Environmental Protection Agency
Office of Pollution Prevention and Toxics
Confidential Business Information Center (CBIC)
EPA East Building, Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004-3302

If using a courier service, please instruct the courier that the Confidential Business Information Center closes its doors at 4 pm, and delivery will not succeed if attempted after 4:00 PM.

107-3. Q. Where can a copy of the Notice of Commencement (NOC) form be obtained?

A. The NOC form (EPA Form 7710-56) is available from the TSCA Hotline at (202) 554-1404, by facsimile (202-554 5603), or on EPA New Chemicals Website at www.epa.gov/oppt/newchems/pmnforms.htm.

107-4. Q. For Notice of Commencement (NOC), when does Day 1 start for manufacturing? Is it the day the reactor is first charged or the date of completion of the first lot? When does Day 1 start for importation?

A. For a new chemical substance manufactured for nonexempt commercial purposes for the first time after expiration of the PMN review period, the first day of manufacture for NOC purposes ("Day 1")is described at 40 CFR 720.102(c)(iv) as the date of completion of the first lot, and for importation as the date the new chemical substance clears US Customs. (For more detail regarding import, see US Customs Service regulations at 19 CFR Part 101 and §141.68.)

107-5. Q. Is a Notice of Commencement (NOC) required for the first batch of a new chemical substance, after the PMN review period is over, if it is manufactured for R&D?

A. If the first batch of a new chemical substance manufactured after expiration of the PMN review period is "solely for R&D purposes" and the research is conducted in compliance with the R&D regulations, the submitter need not file a NOC. See 40 CFR 720.102(a).

A NOC must be submitted within 30 days of manufacture for a nonexempt commercial purpose; "nonexempt commercial purpose" includes commercial R&D not in compliance with the R&D regulations at 40 CFR 720.36. Thus, under 720.102(a) if the manufacturer does not comply with the R&D regulations and record keeping requirements, a NOC must be filed.

107-6. Q. If you substantiate your confidentiality claims up front when you submit your PMN must

you repeat that substantiation at the time of the Notice of Commencement (NOC)?

A. Yes. You must substantiate your claim of confidentiality for chemical identity at the time you submit a NOC, if you want EPA to maintain your confidentiality claim after you begin manufacture. According to 40 CFR 720.85(b), other types of CBI claims need not be substantiated at time of NOC.(Notice of Commencement requirements are described in 40 CFR §720.102.) To substantiate that claim, you must provide EPA with detailed answers to the questions listed at 40 CFR 720.85(b)(3)(iv). This substantiation must accompany your NOC. You may be required to substantiate other confidentiality claims if EPA receives a Freedom of Information Act request on that information.

107-7. Q. A submitter is required to submit a Notice of Commencement (NOC) on or no later than 30 days after the first day of manufacture or import. What is the official reporting date of the NOC, the date the letter is postmarked or the date EPA acknowledges receipt?

A. The date that EPA's Document Control Officer receives the letter is the reporting date of the NOC. (This is consistent with the rule for receipt of PMNs at 40 CFR 720.75(a)).

107-8. Q. Does the Notice of Commencement (NOC) only apply to PMN chemicals or does it also apply to the first time a submitter manufactures or imports an existing chemical?

A. The NOC is used by EPA to determine that a chemical substance which has been through PMN review has actually gone into nonexempt commercial manufacture. Once a NOC is received, the substance is put onto the Inventory. Thus, the requirement for a NOC only applies to new chemicals manufactured or imported for the first time for a nonexempt commercial purpose by the PMN submitter after expiration of the PMN review period.

107-9. Q. Can excess material produced for R&D purposes be used for commercial purposes after the PMN review period expires? How does this impact Notice of Commencement (NOC) requirements? Must such use be precleared with EPA?

A. Excess R&D substance can be used for commercial purposes after the PMN review period expires without any additional authorization from EPA. However, no NOC may be filed until the new chemical substance is first manufactured for a nonexempt commercial purpose after expiration of the PMN review period. In other words, a NOC may not be filed solely on the basis of quantities previously manufactured under the R&D exemption.

40 CFR §720.30(e) and (f) allow certain commercial uses of excess R&D materials, without the submission of a PMN prior to such use. Additional information on the R&D exemption is provided in EPA's Chemical Information Bulletin "Exemptions for R&D and Test Marketing" (1986-1,

November 1986, Office of Toxic Substances), which is available from the TSCA Hotline and on EPA's New Chemicals Website at www.epa.gov/oppt/newchems.

107-10. Q. Is it true that no Notice of Commencement (NOC) is required for chemicals whose use has been approved under an exemption (LVE, TME, LoREX)

A. Yes. No NOC is required to initiate use of chemicals approved under an exemption. This is because the NOC is used to trigger entry of PMN substances onto the Inventory, and exempted substances are not entered onto the Inventory.

108 User Fee

108-1. Q. What are the fees for submitting Premanufacture Notices and consolidated Premanufacture Notices?

A. Persons other than small businesses are charged a fee of $2,500 for each PMN or consolidated PMN submitted. The same fee is required for a Significant New Use Notice (SNUN). See 40 CFR 700.45.

108-2. Q. What is the fee for small businesses submitting a Premanufacture Notice or consolidated Premanufacture Notice?

A. Small business concerns pay a fee of $100 for each PMN, consolidated PMN, or SNUN submitted (small is defined at 40 CFR §700.43 as a company having less than $40 million in annual sales, where the amount includes sales of any parent or subsidiary company as well as those of the submitting company. This includes a parent company's overseas sales as well as those of the United States subsidiary company. See 40 CFR 700.45).

108-3. Q. What are the fees for exemption applications and exemption notices?

A. There is no fee for a Test Market Exemption, a Low Volume Exemption, or a Low Release-Low Exposure (LoREX) exemption.

108-4. Q. What is the fee for Premanufacture Notices (PMN) involving intermediates in a synthetic sequence?

A. The fee for each intermediate PMN is $1,000, except that small business concerns are charged a fee of $100 for each intermediate as well as each final PMN. The PMN for the final product (except for a small business) is $2,500. Intermediates MUST be in a direct sequence with the final

product - the reduced fee for each chemical intermediate in a synthetic pathway when accompanied by PMN for the final substance on that pathway only applies for a sequence. That is, if a submitter chooses to file for "a", "b", "c", and "e" of a synthetic sequence "a"6"b"6"c"6"d"6"e", the submitter can file as an intermediate for "a" and "b", must file as a final for "c", and as a final again for "e", because "d" is missing from the sequence. Each final product is subject to a full user fee. See 40 CFR 700.43 and 700.45.

108-5. Q. Does a pesticide intermediate qualify for the intermediate user fee?

A. Most do not. A single pesticide intermediate can never qualify for the intermediate user fee of $1,000 because the final pesticide product does not come under the jurisdiction of TSCA, but rather FIFRA. See 40 CFR 700.43. Therefore a substance which will be transformed directly into a pesticide is a final product in relation to TSCA, and does not meet the definition of an intermediate Premanufacture Notice, at 40 CFR §700.43 because the final product and intermediate(s) cannot be submitted simultaneously to the New Chemicals Program. Thus a submitter of a PMN for a substance which will be made into a pesticide in a single synthetic step pays the full PMN review fee. If, however, a submitter is filing for "a", "b", "c", and "d" of a synthetic sequence "a"6"b"6"c"6"d"6"e", where "e" is a pesticide, the submitter can file intermediate PMNs for "a" and "b" and "c", and must file a final product PMN for "d", because "d" is the final product subject to TSCA jurisdiction.

108-6. Q. What is the fee for a significant new use notice (SNUN)?

A. The fee for each SNUN is $2,500, except for small businesses the fee is $100. See 40 CFR 700.45.

108-7. Q. What is the fee for a joint PMN submission?

A. Joint submitters of a §5 notice are required to remit one appropriate fee for the type of notice being submitted, e.g., a PMN, a consolidated PMN, an intermediate PMN, or a SNUN, regardless of the number of joint submitters for that notice. To qualify for the reduced fee for small businesses, each joint submitter of a §5 notice must qualify as a small business concern under 40 CFR §700.43 -- if any submitter is not "small", the non-reduced fee must be paid. The small business definition includes a parent company's overseas sales as well as those of the United States subsidiary company. See 40 CFR 700.45.

108-8. Q. When does EPA refund a fee?

A. EPA will refund any fee paid for a §5 notice whenever EPA determines that the notice or fee was not required. See, e.g., 40 CFR 720.62. This can happen, for example, when the intended use

described in the PMN is not actually subject to TSCA jurisdiction or when the substance is already on the Inventory. In addition, EPA will refund when it determines that a notice is incomplete.

108-9. Q. Are separate alpha-numeric identification numbers used to identify and link a notice with the remittance fee otherwise known as "TS-numbers" needed when submitting an intermediate notice and a final product PMN?

A. Yes. A separate TS User Identification number is needed when submitting for each intermediate and the final product PMN, since they are separate notices. However, both/all numbers may be used to identify a single check.

108-10. Q. We are developing a 3 step process to make a new chemical. An Inventory substance in step #1 will yield new substance "A" that will only be used (Step #2) as our intermediate to make new chemical substance "B", then "B" will be used to make new chemical substance "C" (Step #3). "B" will predominantly be used as an intermediate for chemical "C" but a small portion will be sold to other companies. "C" is entirely a final product that will be sold externally. All PMNs will be filed at the same time. If the PMN filing fee for intermediates is $1,000 if filed concurrently with the final product, and the fee is $2,500 for a final product, what filing fee must we pay for chemical "B"?

A. If any portion of a PMN chemical is intended for sale or use as a final product, you must pay the $2,500 fee. You can file for "A" as an intermediate at $1000, but "B" and "C" cost the full fee for each. See 40 CFR 720.45.

108-11. Q. How do I submit the user fee for PMNs and other §5 submissions?

A. A user fee must be remitted for PMN and SNUN §5 notices in accordance with 40 CFR §700.45. You must create a unique alpha-numeric identification number ("TS-number") to identify and link your notice with the remittance fee. This six digit number must be placed on the first page of the form in the boxes that have been provided. This number must also be placed on your fee remittance which is sent to:

EPA, Washington Financial Management Center (Mail Stop 3303)
P.O. 360399M
Pittsburgh, PA 15251-6399
Attn. TSCA User Fee

EPA uses a private bank in Pittsburgh to receive these fees. The bank will accept certified checks, money orders and bank drafts only; after the bank has processed the payment, the TS-Number is sent to EPA Headquarters with certification that payment has been made. EPA Headquarters then

verifies that the appropriate remittance with a TS identification number corresponds to a user fee identification number on a PMN and further processing of the notice commences. However, if a problem arises in the payment procedure, (i.e., insufficient funds, improper usage of the TS-number), the notice will be given incomplete notice status in accordance with 40 CFR §720.65(c). EPA will inform the submitter in writing if this action is taken.

The notice and the fee are sent separately. Send your completed notice with original signatures and two copies to the OPPT Document Control Officer (DCO), whose address appears on page 1 of the form. If you claim any confidential business information (CBI), a fourth, "sanitized" or redacted copy is also required.

108-12. Q. How do I choose a user fee number ("TS-number")? What is it used for?

A. The submitter chooses this number. It is used by the bank which receives money for EPA when it notifies EPA that the fee has been received, and also to enable us to assemble the parts of a submission when additional communications (letters of support, joint submissions, corrections) are sent before a PMN/LVE number has been assigned. There are six spaces in the TS-number block on the PMN form. In the past, we have actually had duplication of TS-numbers, and these instructions should make duplication less likely in the future: your TS-number should be a 6-character alphanumeric string. It should include 2, 3, or 4 letters. One or more numerals must be interposed between two letters (that is, LLNNLL, LNNNLL, NNLLNL, NLNLNL are okay, LLLNNN, NNNNLL are not). We recommend against company names, recognizable words and numerical series (ROY01X, X01DOW are not good ideas). The TS-number should be unique to this submission from your company. Do not give this number to a subsequent submission. If we get a TS-number with a submission and it does not comport with this guidance, we will call the submitter and ask for a new number which does.

109 Consolidated Notices

109-1. Q. Is there an abbreviated procedure for submitting PMNs on structurally related new chemical substances?

A. EPA allows consolidation of PMN notices for up to six chemical substances with similar use, structure, and probable toxicology at the same time and for the same fee as a single substance. See 48 FR 21734, May 13, 1983. Consolidated PMNs benefit submitters by reducing the administrative burden of developing multiple §5 submission forms for manufacture of two or more structurally related new chemical substances which have similar use, exposure, environmental release, and test data. EPA's review process is also facilitated by reviewing similar substances simultaneously.

EPA limits the number of substances that may be included in a consolidated PMN to six. See

www.epa.gov/oppt/newchems/consix.htm.

Persons who intend to submit a consolidated notice shall first contact the Prenotice Coordinator in the New Chemicals Prenotice Branch (refer to New Chemicals Program Contacts List) for approval before submission of the notice. The Prenotice Coordinator will determine if the criteria for consolidation are met.

In the consolidated notice, the submitter shall identify new chemical substances individually by submitting a separate chemical identity page for each new chemical substance, and each identification must be supported by a separate report from the CAS Inventory Expert Service since Method 1 must be used to name each substance. When other pages of the §5 submission form differ between the substances in the consolidated submission, they should be submitted separately as well (generally identified as, e.g., page 6a, 6b, 6c,, etc). See www.epa.gov/oppt/newchems/confaq.htm for more details. This is not an abbreviated procedure: the 90-day statutory notice review period applies for consolidated PMNs as it does for singular ones.

109-2. Q. Where is the consolidated PMN described in the Federal Register or in other publications? What is the justification for the six-member limit on consolidations?

A. EPA announced a policy that it would accept submission of consolidated notices, subject to the approval of each submission by a Prenotice Coordinator, in the preamble of the May 13, 1983 Federal Register (Part III (C)(1)(b), 48 FR 21722, 21734-35) and discusses procedures for acceptance of consolidated notices in Section II (E) of the Instruction Manual for Premanufacture Notification of New Chemical Substances.

When EPA initially accepted consolidations there was no limit on the number of substances which could be submitted in one consolidation. A consolidation, though less demanding of EPA's resources than the same number of separate submissions of related chemicals, still requires a substantially increased amount of effort over the assessment of a single submission. EPA has decided that it is appropriate to limit the number of substances in a consolidation to six.

109-3. Q. Why must a submitter get a name from the Chemical Abstracts Service Inventory Expert Service (CAS-IES) for each substance in a consolidation? Often, if one name has been bought from the Inventory Expert Service, the others can be easily determined. The additional reports from the IES seem to be an unnecessary additional expense to the submitter.

A. Consolidations are a two-step process: the intending submitter requests (from the Prenotice Coordinators) approval to consolidate the PMN submissions for two to six substances. The Coordinators approve or do not approve that request in consultation with New Chemicals Program

chemists. For that initial request, the names used for requesting consolidation need not be from the IES. They should be specific enough that our chemists and other review personnel can decide whether the materials are similar enough (chemically and toxicologically) that their reviews can be conducted concurrently with resulting savings of review costs.

For the PMN itself, however, the submission can lead to inclusion in the Inventory. Sources other than the IES have a higher, overall, error rate in generating names, and this includes submitters who try to develop additional names by analogy to that of one member of an approved consolidation. Though it has not been required, EPA encourages that any PMN submission covering a single substance be named by Method 1 (i.e., CAS-IES; see 40 CFR 720.45(a)(3)). If a submission is incorrectly named, the process of declaring it incomplete and returning it to the submitter diverts EPA resources from other important work of the New Chemicals Program. The New Chemicals Program will not review any consolidated PMN submission which does not include a complete and correct CAS-IES (that is, Method 1) name for each substance, to prevent EPA from having to deal with one or more nomenclature errors. See www.epa.gov/oppt/newchems/confaq.htm. The Method 1 requirement for consolidations is not satisfied by simply giving a CAS name and registry number to substances which have been previously examined by non-IES CAS personnel.

Information on the CAS-IES service including available resource materials is available through 614-447-3600 or 800-848-6538 (ask for the Inventory Expert Service).

109-4. Q. How should a new chemical which, in aqueous solution, exists in equilibrium with a "similar species" (also a new chemical) be reported on the §5 submission form?

A. If you have structurally-related substances in the situation described above, you will likely be given permission to submit a consolidated PMN notice (contact a Prenotice Communications Coordinator for a PC number.) If there is no intent to sell any of the components separately, and if they are synthesized together, such a material can also be reported as a Class II chemical substance per 40 CFR 720.45(a)(2).

109-5. Q. If production of a series of metal salts of a modified organic acid is intended does each salt require a PMN or can the entire series be declared in one PMN?

A. Each salt that is intended to be manufactured must be reported in a PMN, and a Notice of Commencement is required for each salt that is manufactured. It may also be possible, however, to submit a consolidated PMN for up to six such salts. Please note that consolidations will not be granted for substances which are of different toxicological concern even if they are chemically similar. Consult a Prenotice Communications Coordinator for further assistance.

110 Joint Submissions

110-1. Q. May persons submit PMN notices jointly?

A. Yes. For example, a manufacturer may submit jointly with a toll manufacturer, or an importer with a customer. The person responsible for the PMN requirements under §5(a) is required to complete all mandatory sections of the form, to the extent that he or she knows or can reasonably ascertain the required information, even if another person also submits a certain section. If a joint notice is submitted, the notice review period will not begin until EPA has received all required parts of the notice. Therefore, the person subject to the notice requirements should indicate to EPA who else will be submitting parts of the notice and identify those parts. EPA will acknowledge receipt of the notice when it has received parts from all of the joint submitters. Each person submitting the notice must also assert all confidentiality claims according to the procedures specified in the rule. See 40 CFR 720.40(e)(2).

110-2. Q. How would a submitter file a PMN for an imported substance whose identity is claimed as confidential by its foreign manufacturer? How would the submitter obtain a Chemical Abstract (CA) name?

A. The PMN would be submitted with a letter of support from the foreign supplier. The foreign supplier must follow the same procedures as a U.S. submitter to obtain a CA name and provide the correct chemical identity. Both submissions must clearly reference the PMN notice and PMN user fee identification number or a prenotice communication number.

A letter of support should be provided on the supplier's company letterhead. Since a letter of support may be received separately by EPA, an identification number such as a TS-user fee number or a Prenotice Communications number should be used to link a PMN with information from a supplier or foreign manufacturer. The identical identification number should appear on both pieces of correspondence submitted to EPA; otherwise, there may be a delay in processing the PMN. They may be submitted no more than 30 days apart. See 40 CFR 720.40(e)(2) and the Instructions Manual for further information on joint submissions or letters of support.

Information on the CAS Inventory Expert Service (CAS-IES) including available resource materials is available through 614-447-3600 or by facsimile (614-447-3747). For general Chemical Abstracts Services call 800-848-6538.

110-3. Q. What should I do to ensure that EPA correctly identifies the parts of my joint PMN submission? Can a TS-number (the alpha-numeric identification number used to identify and link a notice with the remittance fee) be used instead of a prenotice communication number to identify parts of

a joint PMN submission?

A. Identify the joint submitter in your notice and identify the section(s) which the person will submit. We need an identifier which can be used to associate the different parts and it can be a TS number (check ID number) or a prenotice communication number. The TS number is required for use in associating a PMN or SNUN with its fee, and can also be used to associate the parts of a joint submission. A TS number will not ordinarily be generated in the case of a no-fee exemption application (LVE, LoREX, etc.), however in cases where no fee is required the submitter can still generate a TS number and use it to associate the parts of a joint submission, or can call a Prenotice Coordinator to have a prenotice communication (PC) number assigned specifically to identify parts of a joint submission.

111 Toll Manufacture

111-1. Q. What is the definition of a "toll manufacturer?"

A. According to 40 CFR 720.22(a)(2), "If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice." The "customer" who contracts for the specific material and who has basic control over the process, amount made, etc., is for purposes of TSCA §5 the manufacturer, and files the PMN, etc., and takes responsibility for the activity. The toll manufacturer who actually produces the chemical for the "customer", does not file the PMN, though the toll manufacturer can in some cases have proprietary process information, etc., which will come to EPA with the PMN in the form of a letter of support or joint submission.

112 Foreign Supplier

112-1. Q. How is the chemical identity determined when the substance is received from a foreign supplier?

A. If a principal importer does not know the specific identity of the new substance, the submitter must contact the foreign manufacturer or supplier and have the specific chemical identity information required in the PMN provided directly to EPA by the foreign party. See 40 CFR 720.25(a)(3)(i). In this way, foreign manufacturers can protect confidential business information. The same holds true for U.S. manufacturers reporting chemical substances made from reactants identified only by a generic or trade name. The submitter of the new chemical substance must have the supplier

provide specific chemical identity information directly to EPA before the notice can be considered complete. This information may be provided in a letter of support from the supplier or as a joint submission (discussed in 40 CFR 720.40(e)(2), the PMN Instruction Manual, and in Q&A section 110, Joint Submissions, above).

112-2. Q. Does a letter of support allow the supplier or foreign manufacturer to keep information confidential?

A. Yes, a letter of support allows the supplier or foreign manufacturer to keep information confidential. The PMN submitter can substitute information not in their possession or control with a trade name or brand name. However, the specifics of the unknown information must be provided by the supplier or foreign manufacturer in order for the PMN review period to begin.

112-3. Q. How can I obtain a CA name for an imported substance whose identity is claimed confidential by its foreign manufacturer?

A. Your foreign supplier must follow the same procedures as a U.S. submitter to obtain a CA name and provide the correct chemical identity to EPA as a joint submission or letter of support, clearly referencing your notice and PMN user fee identification number. Information on the IES service including available resource materials is available through 614-447-3600 or by facsimile (614-447-3747). Chemical Abstracts Services in general can be reached on 800-631-1884. See 40 CFR 720.40(e)(2) and the PMN Instructions Manual for further information on joint submission or letter of support. In cases where the entire identity is known to neither party, each must tell EPA what it does know, and provide EPA with a CA name for the component(s) it provides.

113 Trade Mark Reactant (TMR) Supplier

113-1. Q. Who is considered a trade mark reactant supplier?

A. Trade mark reactant suppliers manufacture chemicals and supply them to other companies, generally under a trade name. Trade mark reactant suppliers can be either foreign or domestic manufacturers. They may or may not be toll manufacturers, depending on the extent of control exerted by the customer companies. EPA requires the exact chemical identity of a trade mark reactant for purposes of new chemical review. See 40 CFR 720.25(a)(3)(ii).

113-2. Q. How is the identity of a chemical supplied by a trade mark reactant supplier determined?

A. The chemical identity of the substance supplied by trade mark reactant suppliers is often kept confidential. If the company being supplied is submitting a PMN and needs the chemical identity

of the chemical substance supplied by the trade mark reactant suppliers to complete its PMN, the trade mark reactant supplier can provide this information to EPA by a letter of support or a joint submission. The trade mark reactant supplier and the company are co-partners in providing chemical identity.

It is our experience that joint submissions are unusual in such cases: generally the trade mark reactant companies do not want to get involved in PMN submissions and prefer to submit letters of support. EPA does not have a preference between letters of support and joint submissions.

Manufacturers do, in such cases, need to take reasonable steps to protect themselves against a change of materials in a trade mark reactant material with confidential specific chemical identity, if the trade mark reactant material is used as a constituent in, e.g., a polymer. EPA does not use brand names in maintaining its Inventory, in part because formulations in branded materials can change and in part because the TSCA regulatory apparatus is focused on substances rather than on formulations. Reliance on EPA's, or a supplier's, confirmation of TSCA Inventory status at the time of PMN filing should be supplemented with an agreement that the supplier will notify the PMN submitter of any changes in the chemical identity of the material. A letter of support can be used.

114 Analytical Method Recommendations for Polymers

114-1. Q. There is no guidance on measurement of oligomer content. Is accumulated weight fraction on a gel permeation chromatography (GPC) trace an adequate determination? In the absence of GPC, how can this be done?

A. Cumulative weight fraction is a commonly accepted method. EPA has not prescribed any analytical methodology, so others may be acceptable, depending on circumstances.

114-2. Q. What are the analytical requirements with respect to insoluble polymers? Can inference from melt flow data and comparison to other polymers be adequate? Can I use Monte Carlo simulation methods (such as Oligo 5) to estimate the MW of an insoluble polymer theoretically?

A. EPA does not require any specific analytical methodology. Inference from physical behavior, from comparison to close analogues, and from theoretical calculation is acceptable where appropriate or where other methods are inapplicable. Monte Carlo methods, while widely used, have not been subjected to much experimental verification. If your polymer is expected to have values of MW or oligomer content near the allowable thresholds, you should probably not rely too strongly on such methods.

115 Test Data Requirements

115-1. Q. What is EPA's definition of health or environmental test data?

A. According to 40 CFR 720.3(ff), "Test data" means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analysis, recorded observations, monitoring data, measurements, and conclusions from a test or experiment. "Health and safety study" is defined at TSCA §3(b) and 40 CFR 720.3(k). The scope of the definition is quite broad and all-encompassing. The statutory definition is, "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study." The scope of the definition elaborates that the study can be formal or informal, and can include assessment of exposure effects and risk to human health or the environment. See Q&A section 117 below for more on health and safety studies.

115-2. Q. What type(s) of test data must a submitter include with a §5 Notice to EPA?

A. Under §5(d)(1) of TSCA and 40 CFR 720.50, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form. The following types of test data must be submitted with a full report or standard literature citation: health effects data, ecological effects data, physical and chemical properties data, environmental fate characteristics, monitoring data, and other test data related to human exposure to or environmental release of the chemical substance.

There is no required minimum data set. If, however, you are expecting to make a high volume of the chemical substance ("high" is 100,000 kilograms per year or greater) you are likely to be asked to conduct the New Chemicals Exposure-Based Core Data Set or High Production Volume Data Set. A related discussion can be found on the Internet at: www.epa.gov/chemrtk/volchall.htm. See Q&A #100-12 for more on EPA's exposure-based policy. If EPA reviewers find that they need data not included with the submission to be able to appropriately assess the substance, the submitter will be required either to suspend review and develop the needed data for submission to EPA before any manufacture, or to agree to develop the data as part of a §5 Consent Order with EPA. (There is an exception to this requirement, if the data is available in the open scientific literature. See 40 CFR 720.65(c)(1)(iii) and Q&A #115-5.) In addition, all data must be submitted in English.

In addition, the submitter must describe other data known to, or reasonably ascertainable by,

the submitter. See 40 CFR 720.50(b) for additional details.

115-3. Q. Does your office want test data on similar substances when a company submits a PMN?

A. Test data on similar substances can be extremely helpful, particularly if no data exist on the new chemical substance itself. EPA encourages the submission of data on similar substances with the premanufacture notice. If the submitter plans to submit a series of notices on members of a chemical class, EPA encourages submitters to contact EPA and negotiate a testing program for that class prior to submission of the PMNs.

115-4. Q. Can alternatives to the exposure-based base set of tests requested by EPA be submitted if there are valid scientific reasons?

A. Yes, if you reach agreement with EPA to do so, the standard §5(e) Consent Order can be modified. EPA realizes that there are often a number of different but acceptable means to provide testing information. Companies can always submit any data to EPA but EPA reviewers may not accept the data as satisfactorily addressing the risk assessment issues EPA believes need to be addressed for a given chemical. EPA believes that the core tests on the PMN substance are the preferred testing and in any request to substitute a different test protocol, the protocol must be submitted to EPA in writing with the rationale for that change. EPA must then approve the different test(s). EPA's acceptance of a proposed test protocol not specified by EPA depends on multiple factors including the specifics of the test substance, purpose of the testing, familiarity with specific procedures and equipment, validation of the method, etc. Typical TSCA §5(e) Consent Orders require the use of OPPTS Harmonized Test Guidelines. The OPPTS Harmonized Test Guidelines are available through the Internet at www.epa.gov/opptstrs/home/guidelin.htm -- these guidelines have been developed by OPPTS for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to EPA for review under Federal regulations.

OPPTS has developed these guidelines through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in title 40, chapter I, subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS), and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose for harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements both of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136

et seq.) and of other regulatory bodies in OECD countries.

115-5. Q. How should test data be submitted if the data is available in open scientific literature?

A. Per 40 CFR 720.50(a)(3)(ii), if data appears in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers. EPA encourages the submitter to assist EPA by providing a photocopy of the article, if desired. This is the only exception to the requirement that all information must be submitted in English; open-literature reports can be submitted in their original languages. If an English translation is available, EPA encourages its submission.

115-6. Q. How should test data be submitted if the data is not available in the open scientific literature?

A. Per 40 CFR 720.50(a)(3)(i), if the data does not appear in the open scientific literature, the submitter must provide a full report, and it must be in English. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and addresses of the laboratory that developed the data.

115-7. Q. What should a submitter do if a study, report, or test is not complete when the notice is submitted?

A. This question is answered by 40 CFR 720.50(a)(4). EPA encourages the notice submitter to schedule any testing so that it will be complete before the submission of a §5 notice. However, if a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date. If a significant preliminary result of a test or experiment is completed before the notice review period ends, the person must submit the study, report, or test to the address listed on the notice form within ten days of receiving it, but no later than five days before the end of the review period. If information becomes available during the last 5 days of the review period, the submitter must immediately inform EPA by telephone. (See also the provision at 40 CFR 720.40(f) on "new information" obtained during the notice review period.)

115-8. Q. Does a submitter need to resubmit data previously sent to EPA?

A. Not if the data was previously submitted as non-confidential. Per 40 CFR 720.50(d)(1), a submitter need not submit any data previously submitted to EPA with no claims of confidentiality if the PMN includes the office or person to whom the data were submitted, the date of submission, and, if

appropriate, a standard literature citation. On the other hand, if data were submitted with claims of confidentiality, the submitter must resubmit the data with the §5 notice and any claim of confidentiality under 40 CFR §720.80.

115-9. Q. Does a submitter need to collect data outside the United States for EPA?

A. Per 40 CFR 720.50(d)(3), a PMN submitter need not provide any data which relates only to exposure of humans or the environment outside the United States. However, under 40 CFR 720.50(b), any non-exposure data known to or reasonably ascertainable by the submitter such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics must be provided.

115-10. Q. What scientific disciplines are represented on the Structure-Activity Team (SAT)?

A. The following scientific disciplines are represented on the SAT: chemistry, environmental fate, ecotoxicity, absorption/ metabolism, mutagenicity, oncogenicity, developmental/ reproductive toxicity, neurotoxicity, acute toxicity, and subchronic/ chronic toxicity.

115-11. Q. Does EPA recommend pre-meetings to discuss new chemical testing needs?

A. Consultation with EPA's personnel prior to submission of a PMN (referred to as pre-notice communication) can help submitters strengthen future §5 submissions. This consultation can be accomplished through a letter to EPA outlining the proposed submission which may or may not need to be supplemented by a meeting with EPA's personnel. If a submitter plans to perform toxicity or other testing on a new chemical substance, EPA will provide guidance on the types of tests that would be useful to EPA in assessing the health and environmental effects of the new chemical substance. This can enable a potential submitter to begin needed work in advance of PMN review. Prenotice personnel will coordinate EPA's response to a proposed submission, including scheduling of a meeting if necessary. Prenotice personnel can usually do at least as well, and often better, in meeting a submitter's information needs through written communication supplemented by phone calls as through a meeting.

Pre-notice meetings, as opposed to phone and letter consultations, are most often useful when a potential submitter wants an overall understanding of the review process and of the criteria which will be used to assess applications.

115-12. Q. We have studies provided to us by our parent company in a foreign country. They are not written in English. We understand that we have to provide material to EPA in English. How formal does our translation have to be?

A. The translation has to be good enough that our scientists can confidently use the translated studies in assessing the risk potential of the chemical substance. A relatively informal translation can be adequate, if it is clear to our assessors what has been done and how. If the translation is unsatisfactory, the New Chemicals Program may ask you to suspend the review period on your PMN until an adequate translation is submitted.

115-13. Q. How will the toxicity information I provide be used by EPA to assess my PMN chemical?

A. EPA uses toxicity data for the PMN substance when available and fills in data gaps with toxicity data on other chemicals with molecular structures similar to the PMN substance ("structural analogs") to conduct risk assessments. If it is determined that a potential risk exists during any part of the life cycle of the chemical, EPA will look for ways to minimize potential risks. Risk management may be accomplished through use of appropriate controls, including prohibition of releases to water, use of workplace personal protective equipment or, for inhalation exposures only, the development of a new chemical exposure limit (NCEL). A NCEL is an air-borne exposure concentration in the workplace at which an adult would be unlikely to suffer adverse effects if exposed for a working lifetime. Exposures above the NCEL require the use of respirators.

To conduct a risk assessment for non-cancer endpoints, EPA compares the estimated exposures with no adverse effect levels (NOAELs) or lowest adverse effect levels (LOAELs) from the toxicity studies. The ratio between the estimated exposure level and the NOAEL or LOAEL is called the margin of exposure (MOE). The new chemicals program is usually looking for a MOE of 100 or greater for a NOAEL from a developmental toxicity study or a subchronic study. The MOE should be one order of magnitude larger when using a LOAEL (a MOE of 1000).

To conduct a risk assessment for carcinogens, the estimated exposure is multiplied by the q1* (or slope factor) derived from a cancer study (usually for a structural analog) to give a cancer risk estimate. EPA generally uses an acceptable risk of 10^{-5} (1 in 100,000) for workers and 10^{-6} (1 in 1,000,000) for the general population. A NCEL for a cancer concern is developed based on a cancer risk of 10^{-4} (1 in 10,000) but assumes a worker is exposed over an entire lifetime - a maximum of 250 days per year for 40 years out of a 70 year lifespan.

116 Environmental Fate Data

116-1. Q. What information on physical and chemical properties is routinely needed for an assessment of the environmental fate of a PMN substance?

A. PMN reviewers assessing environmental fate generally need:

- for solids, the melting point;
- for inorganic substances, water solubility at 25 degrees C, pH 7;
- for organics which hydrolyze, hydrolysis half-life at 25 degrees C, pH 7; and
- results of a ready aerobic biodegradation test

See Chemical Assistance Manual for Premanufacture Notification Submitters at www.epa.gov/oppt/newchems/chem-pmn/chap2.pdf. EPA guidelines for testing methods, both for Physical/Chemical properties and specific environmental fate values, are at www.epa.gov/opptstrs/home/guidelin.htm.

117 Health and Safety Data

117-1. Q. What types of data are covered by EPA's definition of health and safety studies?

A. "Health and safety study" is defined at TSCA §3(6) and 40 CFR 720.3(k). A health and safety study means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. In sum, any data bearing on the effects of a chemical substance on health or the environment would be included.

117-2. Q. What types of health studies is EPA interested in?

A. Examples of health studies EPA is concerned with include: tests on mutagenicity, carcinogenicity, developmental toxicity, aquatic toxicity, etc.; data on behavioral disorders; dermal toxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects, subchronic, and chronic effects; worker inhalation and dermal exposure monitoring; and structure/activity analysis.

117-3. Q. What are some of the core health studies that EPA may require? What are some additional data which can be useful?

A. For those PMN substances meeting significant or substantial human exposure criteria (see www.epa.gov/opptintr/newchms/expbased.htm) and warranting testing as determined by EPA, a submitter may be asked to perform some or all of the following health core tests on the PMN substance: an Ames assay; an in vivo micronucleus (mice, gavage); an acute oral toxicity (rats, gavage);

and a 28-day repeated dose oral study. This list is not exhaustive; if another study is believed to be more appropriate for a specific substance, it may be substituted for one or more of these studies. Examples of other types of information which may be sought include: for salts of pigments, dissociation or stability at pH 1.0; for powdered solids, particle size distribution; for aerosols, aerosol size distribution.

EPA's guidelines for testing methods, both for physical/chemical properties and specific environmental fate values, appear at www.epa.gov/opptstrs/home/guidelin.htm. See Q&A section 115 for more on testing.

117-4. Q. What are some of the endpoints of maternal toxicity?

A. Maternal toxicity refers to mortality, infertility, changes in body weight, lessened weight gain, or organ weight, gestation length, clinical signs of toxicity, food and water consumption, and necropsy and histopathology findings.

117-5. Q. What is the study design for a short-term *in vivo* developmental toxicity study?

A. An example of a satisfactory short-term *in vivo* study design is one that includes:
- timed mating;
- implantation success;
- exposure of the mother during major organogenesis midway to end of term (exposure groups: vehicle control, high dose-minimal maternal toxicity, second dose-recommended); and
- condition of offspring at term (maternal evaluation, litter size/gross malformations, viability/weight).

(See the OPPTS Harmonized Test Guidelines #870.3700 at www.epa.gov/opptsfrs/home/guidelin.htm. A comparable test guideline appears at 40 CFR 799.9370.)

117-6. Q. What are some of the endpoints of developmental toxicity?

A. Some of the endpoints of developmental toxicity are pre-implantation loss, post-implantation loss, structural abnormalities, fetal weights, sex ratio, stillbirths, postnatal offspring weights, clinical signs, functional deficits, necropsy and histopathology findings.

117-7. Q. What are the objectives of the guidelines for developmental toxicity testing?

A. The objectives of the guidelines on developmental toxicity testing are to: provide guidance for evaluating risk to humans from exposure to chemicals during development; define developmental toxicity and provide the rationale for approaches to evaluating data; detail types of adverse effects seen

in developing organisms and the relationship to adult toxicity; provide guidance for evaluating animal study data; and lastly, establish consistency in evaluating data and assessing risk for developmental toxicity.

117-8. Q. Who reviews toxicology data on a PMN?

A. OPPT toxicologists who are specialists in either human health or environmental/wildlife effects review PMN toxicology data. The PMN review process is diagramed and discussed in the New Chemicals Program brochure (available from the Hotline) and at www.epa.gov/oppt/newchems/.

117-9. Q. A PMN for a chemical I wish to import in liquid phase has just passed the 90 day review. The first batch we want to import is going to be in powder phase, not liquid, though it is the same exact chemical identity. Does this require submission of a new PMN?

A. The PMN/§5 form asks for information about the physical form of the substance [e.g., solid (crystals, granules, powder, dust), liquid (solution, paste, slurry, emulsion, mist, spray), gas (vapor, fume), wet press cake] to which individuals or the environment will be exposed, percent new chemical substance (if in a mixture), and protective equipment and engineering controls employed to safeguard the worker from potential exposure associated with the new chemical substance, i.e., gloves, goggles, respirators, etc. This is for the purpose of enabling reviewers to assess worker exposure and environmental release. Clearly, if the physical form identified in the §5 submission form is not the one which is to be used, the ability of EPA reviewers to do their job in protecting workers' health and the environment effectively is compromised.

PMN submitters are required to describe their intended process to the best of their knowledge and intent as of the time the PMN is filed (and, as required at 40 CFR 720.40(f), to notify EPA of any new information becoming available during the PMN review period.) A NOC may be filed years after the PMN was submitted. NOC submitters are required only to file the information required at 40 CFR §720.102, most recently amended at 60 FR 16298-16351 (March 29, 1995). Changes in the submission, including physical form, is not addressed in the NOC. In the interim, the information provided in the original PMN may have changed due to advances in synthetic technique, change of location, change in ownership, change of toll manufacturer, etc.

It is very important to try to identify all conditions which may be important in assessing exposure in the originally submitted §5 submission form, and to describe the submitter's intent as accurately as possible. Although EPA recognizes that a company may make changes after the PMN review period has expired such as switching from import to domestic manufacture (or vice versa), from liquid to powder form, changing synthetic process, etc., it would be unusual for such a change to happen immediately after the PMN review period has expired without prior intent/knowledge on the

part of the submitter. In such a case, EPA may find cause to investigate such changes. In a case such as this, it would be prudent for a submitter to prepare a narrative for its files to describe how it came to make such a shift so quickly after the PMN was filed, to enable any future EPA inspector to understand how it came to be. See, *e.g.*, *In re* DuPont, TSCA-III-731.See www.epa.gov/aljhomep/orders/denemour.htm.

117-10. Q. If a high-volume PMN substance is recognized as having low toxicity, what size of exposed population does EPA consider to be significant? Is there a formula?

A. §5(e)(1)(A)(ii)(II) of TSCA authorizes EPA to regulate a new chemical for which there is insufficient information about the chemical's effects on human health and the environment and for which substantial production volume and substantial or significant human exposure or substantial environmental release is anticipated.

EPA's rationale for selecting cases for exposure-based actions was first discussed publicly in a September 22, 1988 letter. This letter is available through EPA's TSCA Hotline. A current discussion of EPA's exposure-based policy, as well as the scanned text of this letter with updated attachments, is available at www.epa.gov/oppt/newchems/expbased.htm.

118 Ecotoxicity Data

118-1. Q. What types of ecological or other environmental effects studies is EPA interested in?

A. EPA is concerned with studies on ecological or other environmental effects on fish, invertebrates, or other animals, and plants. These studies include: acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies. EPA's New Chemicals Program pays particular attention to potential aquatic toxicity.

118-2. Q. What is the base set for ecotoxic concerns?

A. The base set for ecotoxicity includes acute toxicity to fish, acute toxicity to daphnia, and algal growth inhibition. See www.epa.gov/oppt/newchems/expbasedtesting.htm and www.epa.gov/oppt/newchems/co-xbeco.txt. Beyond the base set, additional testing will be requested depending in part on how an organism responds to base set tests, comparison to similar substances (SAR), expected amount of the substance to be released to the environment, testing on biodegradability and abiotic degradation, and on what the producers recommend as appropriate.

118-3. Q. What are some of the ecotoxicity tests that EPA may require?

A. For those PMN substances meeting the substantial environmental release criterion and warranting testing as determined by EPA, submitters may be asked to perform some or all of the following core environmental tests on the PMN substance (this is called the aquatic acute toxicity "base set"): 96-hour LC50 in fish (flow through method and measured concentrations), 48-hour LC50 test in daphnia (flow through method and measured concentrations), and a 96-hour bioassay in algae (static method and measured concentrations).

118-4. Q. How does EPA utilize the information from structure activity relationships (SARs)?

A. Structure activity relationships (SARs) can provide estimates of the inherent toxicity of chemicals based upon the relationship among the physico-chemical properties of chemicals and toxicity to organisms. Relationships vary from statistical regression techniques to identification of the nearest analogs. The product of statistical regression is generally an equation whose predictive capability is measured by the degree of correlation between the independent and dependent variables.

118-5. Q. What estimation methods are used by EPA when characterizing a chemical's ecotoxicity?

A. Fewer than 5% of all PMN submissions contain ecotoxicity data. Therefore, when data are not available to characterize a chemical's toxicity, estimation methods are used to predict the chemical's ecotoxicity based on its chemical structure and physical/chemical properties.

The most important estimation method is the substance's similarity to others with known properties. This assessment is called structure activity relationship (SAR) analysis. Current SAR techniques for ecotoxicity allow prediction of inherent toxicity to fish, invertebrates, and algae. Analysis of large ecotoxicity data sets has revealed predictive relationships which are useful in determining a chemical's toxicity. As examples:

- when the 24/96-hour ratio of acute fish LC50s or 24/48-hour ratio of acute daphnid LC50s are equal to or greater than 2, the chemical has a higher probability for chronic toxicity;

- when the acute LC or EC50 is less than 1 ppm the chemical has a higher probability for chronic toxicity; and

- for anionic surfactants, the chronic value can be predicted by dividing the fish and daphnia acute values by 6.5.

119 Polymer Issues

119-1. Q. Where can I find more information about the Polymer Exemption Rule?

A. See Q&A section 304.

119-2. Q. Is a PMN required for Inventory listing of a polymer if the monomers comprising the polymer are on the Inventory?

A. If the polymer is not included on the Inventory then a PMN is required for Inventory listing unless the polymer qualifies for manufacture under one of the Exemptions. A PMN may be filed, even on a polymer which is eligible for the Polymer Exemption, if the submitter desires Inventory listing. See 40 CFR 723.250(d)(4).

119-3. Q. If a polymer is on the Inventory but contains a non-Inventory monomer, can you import it?

A. Yes. If the polymer is on the Inventory it is an existing chemical, and no PMN or other notice or exemption is required to import it. Even if a polymer is on the Inventory, however, it may not be manufactured domestically unless all the reactants are on the Inventory, because, in the US, a chemical may not be manufactured, processed, or used unless it is on the TSCA inventory. See TSCA §5(a).

Please note that the Polymer Exemption cannot be used for a material which contains a non-Inventory monomer or reactant. See 40 CFR 723.250(d)(4). Unless you have a real intent to import or manufacture a monomer, you cannot file a PMN or an exemption for that monomer. Thus a PMN (or an LVE or LoREX exemption) is the only mechanism to import a polymer which contains a non-Inventory monomer.

119-4. Q. An imported polymer is described as a sodium salt and the submitter determines analytically that sodium is present at two percent or less. Can the submitter assume that sodium hydroxide was the neutralizing agent used to produce that material, and should the submitter therefore use the sodium hydroxide molecular weight in determining the percent incorporated (and hence the chemical identity)?

A. Yes. In the absence of information about the source of the sodium ion, sodium hydroxide should be used as the default source and the calculations should be based on the molecular weight of sodium hydroxide. The hydroxides of magnesium, aluminum, potassium and calcium should also be used as the default sources of the respective ions. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

119-5. Q. Is a regular PMN for a polymer ever necessary, if a Polymer Exemption PMN was submitted prior to the effective date (May 30, 1995) of the 1995 amendments and approved? If a

Polymer Exemption PMN is already commercialized, when would the commercialization of such a regular PMN for the polymer begin, if the manufacturing process was not changed?

A. A pre-1995 Polymer Exemption would have been listed in the Inventory (with a "Y1" flag if meeting the general category for exemptible polymers, and a "Y2" flag if meeting the Exemption category for certain polyester polymers). The filing on which the listing was based would ordinarily have included limits on composition (maximum percentage of residual amounts of unreacted monomers and low molecular weight species below 500 and 100 molecular weight, *e.g.*). If a person plans to manufacture the polymer outside the composition limits of the already-granted Polymer Exemption, or if the intending manufacturer does not want to meet the procedural requirements of the 1995 amended Polymer Exemption, or if the polymer itself is not compliant with the requirements of the 1995 amended Polymer Exemption, then a PMN will be required.

As noted above, the composition limits are not published with the Inventory, so someone who was not the original submitter of the notice filed under the original (pre-1995) Polymer Exemption could manufacture the material under the exemption (if within the composition limits) only after first contacting EPA to determine whether they would satisfy the composition limits.

If a PMN is filed for the purpose of removing the composition limits, manufacture after the end of the PMN review period can be either within or outside of the composition values or ranges specified in the exemption notice submitted under the original (pre-1995) Polymer Exemption. The submitter MUST submit a NOC when the polymer is manufactured outside of the compositional values or ranges specified in the pre-1995 Polymer Exemption notice for the first time after expiration of the PMN review period. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

119-6. Q. Is it acceptable to submit a PMN for a polymer already being manufactured under the terms of the Polymer Exemption?

A. Yes. Certain manufacturers choose to do so, in order to have the polymer listed on the TSCA Inventory.

119-7. Q. Would chain transfer agents used in polymer manufacturing be in the same category as free radical initiators or must they be included in the polymer identity?

A. Chain transfer agents that are used in the manufacturing of a polymer at a level of greater than 2% (by weight) must be included in the polymer description. If a monomer or other reactant, such as a chain transfer agent, is used at a level of 2% or less, the submitter has the option to either include or exclude it from the polymer description to be used in the Inventory listing.

If a monomer or other reactant is not included or reflected in the Inventory polymer name, that monomer or other reactant cannot later be used at greater than 2 percent in the polymer. See 40 CFR 720.45(a)(2)(iii). Conversely, if monomers or other reactants are included in the Inventory name, they may be used at any level as long as they are not eliminated completely without the resulting polymer name (not including those monomers/reactants) also being on the Inventory or unless the manufacturer's PMN for that resulting polymer has completed review. In such situations, it may be appropriate for a manufacturer to request permission from the Prenotice Coordinator to submit a consolidated notice encompassing a series of similar polymers.

Note that a free-radical initiator must also be included in a polymer name when used at more that 2% unless the corresponding polymer name without the initiator was "grandfathered" onto the Inventory by July 28, 1989. Refer below to Q&A #119-8. Also, see the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

119-8. Q. Polymer A-B-C is already on the Inventory. A new proposed process now uses a free-radical initiator. Must a PMN be filed?

A. If the polymer A-B-C was on the Inventory before July 28, 1989 (the effective date of the FR notice clarifying the policy on manufacturing polymers using free-radical initiators), then polymers of that`composition using initiators are also considered to be A-B-C, and consequently on the Inventory, regardless of the level of initiator. If Polymer A-B-C was not on the Inventory prior to July 28, 1989, and the initiator D is used at 2% or more, the resulting polymer must be identified as A-B-C-D. If that polymer is not on the Inventory, a PMN [or exemption] is necessary. Thus, free-radical initiators must be reported and included in polymer names when used at more than 2% by weight in the manufacture of any post July 28, 1989, new polymer. (See 54 FR 27174).

119-9. Q. A submitter wants to manufacture a polymer of 4 monomers plus use an initiator at >2% (The initiator will be incorporated into the final polymer). The polymer of the 4 monomers plus the initiator is not on the TSCA Inventory. What options are available to the submitter to begin commercialization as soon as possible?

A. If the polymer name of the specified 4 monomers without the free-radical initiator was not on the Inventory as of July 28, 1989, then a PMN {or Exemption other than the Polymer Exemption} will need to be filed unless the polymer qualifies for the 1995 amended Polymer Exemption. If the polymer name without the initiator was added to the Inventory after July 28, 1989, an alternative in this situation could be to switch to two or more different TSCA listed initiators, either charging each at # 2% or determining via the "incorporation method" that each would be considered present in the polymer at #2%. (Refer to the 1995 PMN Rule Amendments and Q&A #119-10 below.) In addition, one should set up procedures to ensure that the 2% level will not be exceeded at some later

date. One might also consider using the Polymer Exemption, if the polymer is eligible for it.

119-10. Q. In light of the modified "Two Percent Rule," which now allows reporting of polymers as incorporated as well as charged, can all polymer listings on the Inventory now be read either as incorporated or as charged?

A. Yes. All polymers on the Inventory can be interpreted either as incorporated or as charged. Remember that "incorporated" means the minimum amount of free-radical initiator in theory required to be charged in order to account for the amount of initiator molecules or fragments found in the polymer itself.

119-11. Q. How do you apply the molecular weight (MW) distribution requirement of the polymer definition (i.e., <50 percent of any one MW) to highly cross-linked polymers of essentially infinite MW?

A. For polymers of "essentially infinite" MW, unless the entire mass of polymer produced were in one continuous phase, the actual molecular weight would be limited by the size of the individual droplets, beads, pellets, flakes, etc. No two of these would be likely to have the exact same mass, and the distribution criterion would be met. For that matter, the molecular weight (MW) determination itself would produce a range of values because of the finite precision of the instrument. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

119-12. Q. Would the following example (where the longest continuous chain of reactant units is 1 + 1 + 2 = 3 + 1) count as a "polymer molecule?"

H(oxypropylene)-O-sorbitol-O-(propyleneoxy)$_2$-H

A. No. Sorbitol cannot be a repeating monomer unit under the conditions of the relevant polymerization reaction (propoxylation), so it is considered an "other reactant". Therefore the longest sequence of monomer units (considered as derived from propylene oxide) is two. A continuous string of at least three monomer units is required, plus one additional monomer unit or other reactant. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

120 Principal Importer

120-1. Q. Who is considered the principal importer?

A. 40 CFR §720.3(z) states that: "The principal importer is the first importer, who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the

identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed or doing business in the United States may be principal importers." The principal importer may specify the chemical identity and amount either to the foreign producer or to a US entity (customs broker, *e.g.*) which transmits the order abroad.

120-2. Q. We are the sole customer for a compound being imported by another company. Can we be considered the principal importer and submit a PMN?

A. The sole customer in the U.S. may meet the definition of "principal importer" by specifying the chemical substance and the amount to be imported. The Prenotice Communications Coordinator can provide guidance on particular situations.

121 Import Issues

121-1. Q. For the purpose of TSCA, is importation considered to be manufacture? If so, if a PMN has been filed for an imported product, will a domestic manufacturer have to file a PMN prior to manufacture in this country?

A. TSCA defines "manufacture"to include "import". See TSCA §(3)(7) and 40 CFR 720.3(q). Once EPA receives a NOC and the chemical is listed on the Inventory, it may be manufactured or imported by anyone, unless there is a restriction as described below. If as a result of the original PMN submission, a Significant New Use Rule (SNUR) was issued restricting the chemical to import only, a Significant New Use Notice (SNUN) would have to be filed and successfully reviewed before the chemical could be manufactured domestically.

In any case, even after filing and successful review of the submission, if no NOC has been received by EPA from the submitter, no one but the submitter can initiate manufacture.

121-2. Q. For imported chemicals, what is considered the first day of commercialization - the day it leaves the shipping country, the day it arrives in customs, or the day it clears customs?

A. "Day 1" is the date the new chemical substance clears US customs.

121-3. Q. How can a Ninth Collective Index (9CI) Chemical Abstracts (CA) name be obtained for an imported substance whose identity is claimed as confidential by its foreign supplier?

A. Your foreign supplier must follow the same procedures as a U.S. submitter to obtain a CA name and provide the correct chemical identity to EPA as a joint submission or letter of support, clearly

referencing your notice and PMN user fee identification number.

Information on the CAS Inventory Expert Service (CAS-IES) including available resource materials is available through 614-447-3600 or by facsimile (614-447-3747). For general Chemical Abstracts Services call 800-848-6538.

122 Biotechnology

122-1. Q. Are microbes/microorganisms subject to TSCA?

A. Yes, certain microorganisms are subject to TSCA. However, the required notification form called a Microbial Commercial Activity Notice (MCAN), is necessary only for intergeneric microorganisms formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera. Non-intergeneric microorganisms are considered implicitly on the Inventory. See 40 CFR Part 725; G2 FR 17910, April 11, 1997; and 59 FR 45526, Sept. 1, 1994.

Microorganisms that are used as foods, food additives, drugs, cosmetics, medical devices, and pesticides are regulated by the Food and Drug Administration (FDA), USDA, or EPA's Office of Pesticide Programs. Requirements for foods, food additives, drugs, cosmetics, and medical devices are described in the FDA and USDA notices in the Federal Register and Code of Federal Regulations.

122-2. Q. Are plants and animals subject to TSCA?

A. As EPA has previously stated, although plants and animals do fall within the scope of the definition of a "chemical substance" under TSCA §3, plants and animals are not currently subject to the new chemical provisions of TSCA, either as whole organisms or as *in vitro* cultures. EPA has stated that it is reserving authority under TSCA to screen transgenic plants and animals in the future as needed. See 59 FR 45526, 45527 (September 1, 1994). However, if plant or animal gene segments are intentionally incorporated into microorganisms, the microorganisms that contain those plant or animal genes would be subject to the TSCA §5 requirements established at 40 CFR part 725, providing that the microorganism does not fall within one of the specific exclusions found in TSCA section 3 (*e.g.*, the microbe is not itself a food, food additive, or tobacco). In addition, a chemical extracted from a plant or animal would generally be subject to TSCA, presuming that it does not fall within the exclusions listed at TSCA section 3. See 40 CFR §720.3(e).

123 Significant New Use Rule (SNUR)

123-1. Q. What are consent orders and significant new use rules?

A. EPA review of a PMN can result in a finding of potential unreasonable risk or substantial production and exposure. In these cases, EPA can negotiate a TSCA §5(e) Consent Order, which generally allows the PMN submitter to manufacture or import the new substance for the PMN-identified use(s) only under specified conditions (e.g., use of worker protective equipment or environmental release controls). However, a §5(e) Consent Order is not binding on any companies that may subsequently manufacture or import the substance other than the submitter who signed the §5(e) Consent Order. Consequently, after signing a §5(e) Consent Order with the PMN submitter, EPA generally promulgates a Significant New Use Rule (SNUR), which applies similar restrictions as in the §5 (e) Consent Order to other potential manufacturers and processors. Such a SNUR is often referred to as a "§5(e) SNUR." SNURs require that manufacturers, importers and processors of certain substances notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use." The new use designations in a §5(e) SNUR correspond with activities prohibited by the §5(e) Consent Order and are generally promulgated on an expedited ("direct final", see 54 FR 31299) basis. The advance notification required by SNURs (called a Significant New Use Notice or SNUN) allows EPA to prevent or limit potentially adverse exposure to, or effects from, the new use of the substance.

When the EPA review determines that the exposure scenario proposed in a PMN is not expected to pose an unreasonable risk, EPA generally does not issue a §5(e) Consent Order. The reviewers may, however, identify potential new uses different from those identified in the PMN which could result in increased exposures to or releases of the substance, and in turn a potential unreasonable risk to health or the environment. In such cases, EPA can issue a SNUR that requires the submission of a SNUN 90 days prior to commercial manufacture not conforming to the conditions reviewed under the PMN. Such a SNUR is called a "non-§5(e) SNUR," and may also be issued on an expedited basis. (The 1995 TSCA PMN rule amendments expanded the types of significant new use designations that EPA may promulgate in expedited "non-§5(e)" SNURs. This change is intended to improve the efficiency of the SNUR procedure for both EPA and the chemical industry. See Q&A #123-2 and 60 FR 16298ff.)

123-2. Q. Why did EPA create the non-5(e) Significant New Use Rule (SNUR) amendment to 40 CFR 721.170 (c)(1)? What did the amendment change?

A. EPA created the non-5(e) SNUR amendment to enable the regulation of potentially risky new chemicals using fewer EPA resources, and to allow PMN submitters to commence commercial manufacture sooner. The amendment to 40 CFR §721.170(c)(1) eliminated the provision that prevented EPA from promulgating expedited non-5(e) SNURs containing worker protection or hazard communication requirements. Before the amendment, expedited non-5(e) SNURs were limited to requirements controlling disposal (§721.85), releases to water (§721.90), and certain industrial, commercial and consumer activities (§721.80). After the amendment, expedited non-5(e) SNURs may

include any of the requirements in Subpart B, including worker protection (§721.63), hazard communication (§721.72), and all of the industrial, commercial and consumer activities (§721.80).

123-3. Q. What chemicals are affected by the non-5(e) Significant New Use Rule (SNUR) amendment to 40 CFR 721.170(c)(1)?

A. This amendment of the "Generic SNUR" did not automatically apply to any specific chemical substance. It is merely a procedural tool that EPA can use to impose "significant new use" reporting requirements in individual, chemical-specific SNURs for PMN substances where EPA reviewers identify other potential uses that may present unreasonable risk or have the potential for substantial production volume and substantial or significant human exposure or substantial environmental release.

123-4. Q. What is the difference between a §5(e) Order and a Significant New Use Rule (SNUR)?

A. An order under §5(e) applies only to the manufacturer who submitted the PMN. SNURs apply to everyone who manufactures or processes the chemical substance. A SNUR establishes a requirement to notify EPA 90 days before commencing any activity that the SNUR defines as a "significant new use." In response to a Significant New Use Notice (SNUN), EPA will review the proposed use, and may issue a §5(e) Order to control potential unreasonable risks or substantial and/or significant exposures that may be presented by the significant new use.

123-5. Q. What is the difference between a §5(e) SNUR and a Non-5(e) SNUR?

A. A §5(e) SNUR is a SNUR which is promulgated only after a §5(e) Order is issued for the same chemical substance, and which extends to all subsequent manufacturers/users the provisions of the §5(e) Consent Order. "Non-5(e) SNURs" are those SNURs which are promulgated without issuance of a §5(e) Order, because EPA did not find that the exposure scenario described in the PMN "may present unreasonable risk," but other exposure scenarios might. See Q&A #100-12 for more on EPA's exposure-based policy.

123-6. Q. What is the difference between a "Notice and Comment SNUR" versus an "Expedited SNUR"?

A. Notice and Comment rulemaking involves publishing a proposed rule, receiving public comment, and publishing a final rule. This is the "standard" rulemaking process. Expedited rulemaking involves publishing a "Direct Final" rule that automatically becomes final unless someone requests a comment period. Expedited rulemaking also allows batching of individual SNURs and abbreviated review within EPA. If a comment period is requested, this process takes more of EPA's resources and

takes longer than Notice and Comment rulemaking. EPA uses expedited rulemaking in cases where it does not think comment is likely (*e.g.*, SNURs which put into place restrictions already agreed upon between EPA and a PMN filer). Expedited rulemaking enables those who wish to manufacture under the terms of a SNUR to initiate their activity quickly, and saves EPA resources. Both types of rulemaking provide opportunity for comment by interested persons, as required by the Administrative Procedures Act. See 40 CFR 721.160(c) and 721.170(d)(4).

123-7. Q. What type of case is appropriate for a non-5(e) SNUR?

A. A non-5(e) SNUR is typically appropriate when a PMN is filed for a chemical substance which is expected to be toxic but the PMN describes intended use(s) and an exposure scenario that is not expected to pose unreasonable risk of injury to human health or the environment. Intended uses and activities can be limited, or the submitter can state that it will implement control measures, or otherwise adequately mitigate human exposures and environmental releases. Although activities described in such PMNs may be judged not to present an unreasonable risk of injury to human health or the environment, if there are significant deviations from the described activities the substance may present an unreasonable risk warranting the imposition of regulatory controls pending the development of information. In those cases, a non-5(e) SNUR may be the most appropriate regulatory alternative for EPA to pursue, as it will allow the PMN submitter to proceed with planned activities while requiring notification to, and review by, EPA for activities which have not been reviewed and may involve significantly increased exposures. Such review will be undertaken upon receipt of a SNUN.

123-8. Q. How can I determine whether my substance is subject to a SNUR?

A. To facilitate determining whether a substance is subject to a SNUR, substances on the Inventory that are subject to SNUR requirements are indicated by an "S" flag in the Inventory listing (In electronic versions of the Inventory, the flags may be on another line, rather than following the substance name.) If your chemical substance is subject to a SNUR and you intend to engage in an activity defined as a "significant new use" in the SNUR, you would be required to submit a SNUN to EPA at least 90 days before commencing that activity.

Several options are available to ascertain the TSCA Inventory/ SNUR status of a chemical substance. See Q&A section102. Information on non-confidential chemical substances can be found in the TSCA Chemical Substance Inventory. If an intended manufacturer submits a PMN or a Notice of *bona fid*e Intent to Manufacture (pursuant to 40 CFR §720.25) on a substance/mixture which has a listing on the Confidential Inventory, EPA will notify the submitter of the existence of the SNUR when it informs the submitter a PMN is not necessary. Any manufacturer of a substance subject to a SNUR must notify anyone they distribute the substance to about the SNUR.

124 Pollution Prevention

124-1. Q. What type of pollution prevention information does EPA want?

A. EPA would like to collect information on pollution prevention activities, such as source reduction and recycling. In addition, EPA would like waste management information (i.e., treatment, and disposal data). This information will be used in the evaluation of the new chemical substance and in comparison of the relative risks and benefits of the substance as a substitute for substances currently on the market. The PMN form (EPA Form 7710-25) encourages submitters to report on page 11 any and all relevant information not reported elsewhere which is believed to be important for a thorough regulatory evaluation. There is a substantial discussion of how to provide this information in the PMN Manual, posted at www.epa.gov/oppt/newchems/tscaman2.pdf.

125 Recycling

125-1. Q. An intending recycler will take articles from municipal waste, and grind and melt them to cast them into new articles. The recycler will make a good faith effort to select articles (for example, soda pop bottles) of uniform probable composition, but the chemistry of each article is known to the recycler only in general terms. In addition to the intending recycler's lack of specific knowledge and control on the materials in the articles, it is expected that, if any new chemical substances had been formed during final manufacture of the articles, they would have been exempt from PMN requirements per 40 CFR § 720.30(h)(6) (which excludes substances that form during the manufacture of an article destined for the marketplace without further chemical change ("end-use")). Because of the availability of the (h)(6) exclusion, the intending recycler believes that the articles were probably manufactured without premanufacture notification (PMN) to EPA for any new substances formed during manufacture.

The recycler intends to prepare for recycling by grinding, chipping, or other physical manipulation. No actual chemical reactions are believed to be involved in this process, just the physical manipulation of the material. It is the recycler's plan to melt the material and cast or form it into new articles for sale.

Is a PMN required for this activity?

A. Where no chemical reactions are believed to be taking place, EPA considers melting and manual grinding to constitute "processing" under TSCA, and a PMN would thus not be required. However, if the component substances in the articles were to be chemically changed (e.g. partially de-synthesized, depolymerized, etc., e.g.), the intending recycler would need to submit a PMN and describe the material using a reaction product or process type name that indicates the nature of the chemical conversion. See 40 CFR 720.(3)(s) and (aa).

While TSCA holds a person strictly liable for the illegal manufacture or import of a new chemical substance, a person processing an illegally manufactured new chemical substance would not be in violation of TSCA unless the person knew or had reason to know that the substance had been illegally manufactured. See §15(2) of TSCA.

126 New Chemical Exposure Limits

126-1. Q. What are New Chemical Exposure Limits?

A. New Chemical Exposure Limits (NCELs) are workplace respiratory exposure limits established in TSCA 5(e) Consent Orders and incorporated by reference in corresponding TSCA 5(a)(2) SNURs. They are modeled after OSHA Permissible Exposure Limits ("PELs") and are comprehensive standards. NCELs set what are considered to be safe airborne concentrations for new chemicals that may cause toxicity via inhalation exposure. Periodic monitoring is required and, if concentrations above the NCEL are measured, respirators must be worn.

126-2. Q. Where can I find the actual NCELs values listed for various new chemicals?

A. The internet address is www.epa.gov/oppt/newchems/nceltbl.htm. The NCELs values originate in TSCA §5(e) Consent Orders that are signed by the individual PMN submitters who propose to manufacture the PMN substance. The NCELs provisions are incorporated by reference in corresponding TSCA §5(a)(2) SNURs, which essentially extend the requirements of the §5(e) Order to other manufacturers and processors of the same chemical substance. SNURs are published in 40 CFR Part 721.

126-3. Q. Where does EPA's exposure limit jurisdiction end and OSHA's begin?

A. There will generally be no overlapping regulation of new chemicals, because EPA's NCELs apply to new chemicals with little or no data, so risk assessment is generally based on analog data from similar substances. EPA added an explicit sunset provision to its §5(e) Orders which states that the NCEL and respirator requirements are automatically nullified if OSHA promulgates a permissible exposure limit (PEL) for the same substance. (This would automatically nullify the NCELs in SNURs as well, since the NCELs provisions in SNURs simply incorporate by reference the §5(e) Consent Order provision.) EPA may raise NCELs cases to the attention of OSHA and NIOSH, in the unlikely event that a referral is warranted by the toxicity data and production volume associated with the new chemical substance.

EPA has sought to make its program consistent with OSHA's wherever possible. EPA has ongoing communication with OSHA and NIOSH on worker protection issues and has solicited input on the NCELs program. EPA's NCELs provisions are modeled after OSHA PELs and comprehensive

standards.

126-4. Q. When setting NCELs concentrations for specific chemicals, does EPA consider feasibility issues and relevant concentration limits set by other organizations?

A. On a case-by-case basis, EPA will consider setting NCELs concentrations based on relevant OSHA PELs and American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and will consider economic and technological feasibility, especially in cases where there is sufficient evidence that the new chemical may present less risk than existing substances which the new chemical may replace.

2. EXCLUSIONS

201 Impurities

201-1. Q. What is an impurity?

A. "Impurity" is defined at 40 CFR §720.3 to mean a chemical substance which is unintentionally present with another chemical substance. The term "manufacture or import for commercial purposes" also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes. See 40 CFR 720.3(r).

Information on all impurities anticipated to be present with a chemical substance must be included in a PMN, and is considered in the assessment of risk posed by that substance. Maximum weight percent, as well as the CASRN, if available, should be provided on page 6 of the §5 submission form. If the impurities are unidentified, their presence should be noted and their total weight percent estimated.

201-2. Q. Are impurities included in the chemical identification for the Inventory?

A. No, impurities are not included in the chemical identification for the Inventory listing of a chemical substance. EPA has determined that chemical substances which are identical except with respect to their impurities will not receive separate Inventory listings. Impurities that are discovered in a chemical substance after a Notice of Commencement (NOC) has been submitted do not change the Inventory status of the chemical substance. If there are unreasonable risks posed by impurities present in existing chemical substances, TSCA §4, §6, §7, and §8 can be used to identify, prevent, and reduce those risks.

This differs from the identification of a new component determined to be included in a listed chemical substance, when that component has commercial value. If a previously unknown commercially valuable component is found in a listed chemical substance and if the listed chemical substance including the new component is determined not to be accurately listed on the Inventory, then the manufacturer of the component chemical substance is considered to be the manufacturer of a new chemical substance. The submitter should contact EPA in order to determine whether a PMN or a Form C (Inventory correction) should be submitted.

201-3. Q. At what level do impurities become insignificant, i.e., not subject to reporting?

A. As defined in 40 CFR §720.3, an "impurity" means a chemical substance which is unintentionally present with another chemical substance. The definition is not based on the amount of the substance. Impurities at any level are significant and must be reported as impurities in §5 notices, to the extent they are known or reasonably ascertainable by the submitter. An impurity need not, itself, be the subject of a §5 notice. See 40 CFR §720.30(h)(1).

201-4. Q. Is there a restriction on the level or amount of an impurity detected in a chemical substance?

A. No. There is no restriction on the level or amount of an impurity detected in a chemical substance. Specifically, there is no relationship between the impurity reporting requirements and the 2% rule which applies in relation to polymers.

202 Mixtures

202-1. Q. What is the definition of a mixture?

A. "Mixture" is defined at §3(8) of TSCA and 40 CFR §720.3 as any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction. Mixture also includes the combination which occurs, in whole or in part, as a result of a chemical reaction where none of the chemical substances comprising the combination is a new chemical substance and where the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

202-2. Q. Is a PMN required for a new mixture?

A. TSCA §5 requires a PMN for new chemical substances, not for new mixtures. A PMN is not required for a mixture as a whole entity. However, if any chemical substance which is included in the mixture is a new chemical substance, a PMN is required to be submitted for that new chemical at least 90 days before a submitter intends to manufacture or import the mixture. See 40 CFR 720.30(b) and especially its footnote.

202-3. Q. Are multi-nutrient mixed fertilizers considered mixtures if they are prepared by physically blending dry products?

A. A multi-nutrient mixed fertilizer is considered a mixture of the ingredients being blended. Such multi-nutrient mixed fertilizers can be prepared by physically blending dry products such as urea,

superphosphate, and potash or by a method that involves a chemical reaction, such as by combining liquid ammonium phosphate and granulating with potash. Per the definition of 'mixture' at 40 CFR 720.3(u), these substances are considered mixtures regardless of whether they are produced by physically mixing or by chemical reaction.

202-4. Q. Are alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement, considered mixtures under TSCA?

A. Yes, alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement, are considered statutory mixtures under TSCA. See www.epa.gov/oppt/newchems/mixtures.txt. In general, a PMN is not required for these products. However, as stated in a note at 40 CFR §710.4(c)(2) and 40 CFR §720.30(b), the exclusion of these products applies only to the mixture and not to the chemical substances of which the mixture is comprised. Thus, any additive which is contained in a mixture, other than an impurity, should be included on the Inventory. The burden of reporting is incident on the manufacturers of any new chemical additive.

202-5. Q. Does the definition of mixture under TSCA include hydrates?

A. Yes. EPA views a hydrate as a mixture of water and the non-hydrated form of the substance. Hydrated forms of chemical substances are excluded from reporting if the corresponding anhydrous chemical substances are included on the Inventory. However, this provision does not apply to the products of discrete chemical reactions in which either water or a solvent is a reactant, e.g., water reacting with an ester to form an acid and an alcohol. See 40 CFR 720.3(u)(2).

202-6. Q. A submitter is manufacturing an alloy and the individual metals are on the Inventory, is a PMN required?

A. No, alloys are considered to be mixtures. As long as all the components comprising the mixture are on the Inventory, a PMN is not required. Intermetallic compounds of well-defined stoichiometry such as NbAl3 are not considered alloys and should be reported. Inventory nomenclature guidance is available on this question at www.epa.gov/oppt/newchems/mixtures.txt in the paper entitled Toxic Substances Control Act Inventory Representation For Products Containing Two or More Substances: Formulated and Statutory Mixtures.

203 Non-isolated Intermediates

203-1. Q. What is a nonisolated intermediate?

A. Nonisolated intermediates are exempt from PMN per 40 CFR 720.30(h)(8). As defined at 40 CFR 720.3(w), a "nonisolated intermediate" is any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Questions on specific manufacturing processes should be directed to the Prenotice Communication Coordinator. A fact sheet on nonisolated intermediates is available from the TSCA Hotline.

203-2. Q. What is an isolated intermediate?

A. An isolated intermediate is defined in part as any chemical substance intentionally removed from the equipment in which it is manufactured. See 40 CFR 720.3(w). This phrase includes the reaction vessel in which the substance was manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.

Some manufacturers have questioned whether storage for a period of two or three hours is still considered to be part of a continuous flow process. Without a complete description of the manufacturing operation, it is difficult to give a precise answer. In general, any chemical substances which are held temporarily in an otherwise continuous flow process for purposes that are clearly related to the necessity of the manufacturing process - such as heating, cooling, filtration or reaction - are not considered reportable, while those that are held principally for purposes of storage would be considered reportable. If manufacturers have further questions, they should consult EPA individually.

The following examples offer clarification:

(1) Reaction in the Same Vessel: Reactants A and B are charged to a reaction vessel to form a chemical substance X. Then C is added to react with X to form another substance Y, which is then drummed for shipment. In this example, X is considered to be nonisolated, since it is not intentionally removed from the process equipment of manufacture. Y will be considered to be isolated, since it is intentionally removed by drumming for transport.

(2) Reaction in one vessel with Purification in Another and Transfer to a Second Vessel: The reaction is carried out in one enclosed reactor and the reaction mixture is then pumped through an enclosed drum filter to another vessel for the next reaction step. The reaction intermediate is considered to be nonisolated since there is no intentional removal and all transfer is mechanical and through closed equipment. However, if the filtration is not closed or if the transfer is manual (for example, involving the removal of the intermediate as a filter cake), then the intermediate would be

considered to be isolated since the transfer would not be through closed equipment. A similar interpretation applies to other processing steps between manufacture and subsequent reaction (e.g., distillation, drying size reduction, etc.).

In the case of batch processes, which for purposes of discussion also includes semi-continuous processes, intentional storage is considered isolation, regardless of whether the equipment is closed or not. As discussed in the March 6, 1978 Federal Register (43 FR 9256), any chemical substances which are held temporarily in an otherwise continuous flow process principally for purposes of storage are considered reportable. The fact that a material remains in the reaction vessel for a period of time does not determine whether the material is isolated and must be reported. It is a matter of intent: if the residence time is for storage purposes, the material is reportable. If the material is held for a non-storage purpose (e.g., if holding an intermediate in a vessel is to provide for maintenance or repair), it is not considered to be isolated. The period of time is not crucial, as long as the intent is not for storage.

As an example, the annual removal and replacement of an enzyme catalyst used in the production process or the exchange of filters during routine maintenance would not affect the nonisolated status of an intermediate in an otherwise closed system. However, if a filter is opened to manually transfer a filter cake containing an intermediate substance, this intermediate is considered to be isolated. In addition, the removal of samples of an intermediate substance strictly for quality control testing would not affect the nonisolated status of an intermediate substance.

203-3. Q. What is the difference between a batch and continuous flow process?

A. In a batch process, a reaction occurs when the reagents are charged as a fixed quantity (usually expressed as mass per batch) and the reaction is allowed to go to completion. In a continuous reaction, the reagents are added continuously (generally given in terms of mass per unit time) and the reaction mixture is constantly flowing; its residence time in any piece of equipment can only be given by a probability function.

EPA defines "nonisolated intermediate" at 40 CFR 720.3(w) as "any intermediate that is not intentionally removed from the equipment in which it is manufactured .... but not including tanks or other vessels in which the substance is stored after its manufacture." "In general, any chemical substances which are held temporarily in an otherwise continuous flow process for purposes that are clearly related to the necessity of the manufacturing process – such as heating, cooling, filtration or reaction – are not considered reportable, while those that are held principally for purposes of storage would be considered reportable." 43 FR 9256, March 6, 1978.

203-4. Q. Does removal of substance from a reaction vessel for sampling constitute isolation?

A. Quality control sampling of a nonisolated intermediate is not isolation and does not disqualify the intermediate from the premanufacture notification exclusion for nonisolated intermediates at 40 CFR 720.30 (h)(8).

204 Byproducts

204-1. Q. What is the definition of a byproduct?

A. As defined at 40 CFR 720.3(d), a "byproduct" is a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes. See 40 CFR 720.3(r). A byproduct is subject to notification requirements unless its only commercial purpose is use by public or private organizations that burn it as a fuel, dispose of it as a waste, or extract component chemical substances from it for commercial purposes. See 40 CFR 720.30(g). (This exclusion only applies to the byproduct; it does not apply to any component substances extracted from the byproduct.) In addition, any byproduct which is not used for commercial purposes is not subject to notification requirements. See TSCA §5(i) and 40 CFR 720.22.

204-2. Q. A product is already on the TSCA Inventory but its by-product is not listed in the Inventory. At a later date, if there is a demand for the by-product, is the manufacturer required to submit a PMN before he begins to manufacture the by-product for commercial purposes?

A. Yes, you must submit a PMN if a by-product begins to be produced with a separate commercial intent, unless its only commercial purpose is for use by public or private organizations that burn it as fuel, dispose of if as waste, or extract component chemical substances from it for commercial purposes, per 40 CFR 720.30(g).

204-3. Q. Can a by-product which is not on the Inventory be used as an intermediate in the manufacture of another chemical substance which is on the Inventory?

A. Not without first submitting a PMN. As with any new chemical, use as a raw material or intermediate in the manufacture of another chemical is commercial use requiring submission of a PMN, unless the by-product is on the Inventory or has gone through PMN review. A by-product cannot (unless it is never isolated) be used in manufacture.

204-4. Q. We have filed a PMN and the 90-day review period has expired. This is a material which, until now, had been manufactured as a waste byproduct that was typically disposed of by incineration

(and thus was exempted from PMN at 40 CFR §720.30(g)(2)). Can we now distribute material which had been generated prior to the expiration date of the PMN review period?

A. Until the PMN review period is over, a new chemical cannot be manufactured for commercial use or sale. During the review period, the only permitted manufacture is for R&D purposes or for disposal as a waste. Obviously, once the substance is manufactured with the intention of being used for TSCA-nonexempt purposes, it is subject to PMN requirements if it is not already included on the TSCA Chemical Substance Inventory (Inventory). See 40 CFR 720.30(g).

Once the PMN review period has expired, if the substance was previously manufactured as a byproduct, and was stored with the intent that it would be disposed of in case the PMN was not approved, it may be used for commercial purposes. However, a Notice of Commencement (NOC) cannot be filed until the first manufacture with intent for commercial use after the end of the 90-day PMN review period.

The material manufactured prior to the termination of the 90-day PMN review has to be dealt with as a substance manufactured for R&D purposes, thus subject to the R&D procedural and record keeping requirements at 40 CFR 720.36 and 720.78.

Once a NOC has been filed on later (post-PMN review) manufacture of the same material, the material produced prior to the termination of the 90-day PMN review period can also be used for commercial purposes.

205 End Use Reactions

205-1. Q. When is a chemical substance that is formed upon end use of another chemical substance (which is on the Inventory) not subject to notification requirements?

A. 40 CFR §720.30(h)(5) excludes from PMN requirements "any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate."

206 Modifier of Physicochemical Characteristics

206-1. Q. When is a substance that modifies a physicochemical characteristic not subject to notification requirements?

A. A substance is subject to notification requirements even if its sole intention is to act as a modifier of a physicochemical characteristic. This is to be distinguished from a chemical substance that is exempt from PMN notification requirements under 40 CFR 720.30(h)(7)(ii) if it results from a chemical reaction that occurs when a chemical substance intended solely to modify a specific physicochemical characteristic, functions as intended.

207 Articles

207-1. Q. What is the definition of an article?

A. "Article" is defined at 40 CFR §720.3 as a manufactured item which: (1) is formed to a specific shape or design during manufacture; (2) has end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) either has no change of chemical composition during its end-use or only those changes in composition which have no commercial purpose separate from the article of which it is a part and that may occur as described in 40 CFR §710.4(d)(5) and 40 CFR §720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design. Substances imported as part of an article are exempt from PMN per 40 CFR 720.22(b)(1), and certain chemicals formed during manufacture of an article are exempt from PMN per 40 CFR 720.30(h)(6).

207-2. Q. Is brake fluid in a domestically manufactured car reportable? Is brake fluid in an imported car reportable? Is the same brake fluid imported in a drum reportable?

A. A substance such as brake fluid would be subject to premanufacture notification when made for installing in a vehicle that is manufactured domestically. With respect to imports, 40 CFR section 720.22(b)(1) states, that "Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under section 720.30 or unless the substance is imported as part of an article." Chemical substances or mixtures will be considered to be imported as part of an article if the substance or mixture is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part. Chemical substances or mixtures which are imported within articles such as drums, barrels, or other containers used for purposes of transportation or containment are considered to be chemical substances imported in bulk and are subject to PMN reporting requirements, because they are intended to be removed from the container eventually and have an end use or commercial purpose separate from the container.

Therefore, brake fluid is exempt from Inventory/PMN reporting when imported as a component of an article (for example in the brake system of an imported car), provided the article which it accompanies in commerce is not solely a container for it, and it is not intended to be released

during use, and does not serve a function during use that is related to its release. However, brake fluid imported in a drum would be reportable.

207-3. Q. Is a pen an article? Is the ink in the pen a part of an article?

A. A pen meets the definition of an article at 40 CFR 720.3(c). However, the ink is intended for release during use, and thus is not exempt from PMN requirements. (Refer to the above question).

207-4. Q. Is a candle an article? Is the substance released by a candle as it burns considered part of an article?

A. A candle meets the definition of an article at 40 CFR 720.3(c). With respect to the combustion products of a candle, 40 CFR 720.30(h)(5) excludes from PMN requirements any chemical substance which results from a chemical reaction that occurs upon end use of an article and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate. Therefore, combustion products of a candle are exempt.

207-5. Q. Is a candle or pen that contains a new chemical substance excluded from premanufacture notification?

A. A substance that forms during the manufacture of an article destined for the marketplace without further chemical change is excluded from premanufacture notification per 40 CFR 720.30(h)(6). Thus, any new substances which comprise the candle or pen would be excluded from PMN reporting as part of an article, but new substances isolated before the domestic manufacture of a candle or pen would be reportable. On the other hand, ink, which is intended to be released from the pen is not exempt. See Q&A #207-3.

207-6. Q. Are fibrous materials considered articles?

A. They can be. Fibrous materials are considered articles (see 40 CFR §710.2(f) & §720.3(c)) if their end-use functions depend in whole or in part upon their shape or design and they are functional in their end-use without a change of chemical composition except for changes that have no commercial purpose separate from the articles of which they are a part. If a person shapes a chemical substance into a filament or fiber, he would be a processor of that substance and would not have to report the fiber based on the fact that the final product of the processing meets the definition of an article. The chemical substance would be reportable by the manufacturer. However, if that fibrous material was intended to be used as an intermediate in the manufacture of another chemical substance, it would not be considered an article, but rather a chemical substance or mixture. Particles are not articles whether they are round or asymmetric. If a whisker or other fibrous material may be used as a

particle in its subsequent processing, it would not be considered an article.

207-7. Q. Are dyes and/or fire retardants excluded from reporting with regard to the finishing process of an article?

A. The intent of the exclusions at 40 CFR §§710.5(d)(6) and 720.30(h)(6) with regard to the finishing process of an article (i.e., dyes and fire retardants) is to exclude chemical substances that are not manufactured for distribution in commerce as a chemical substance *per se* and have no commercial purpose separate from the mixture or article of which they may be a part. This excludes chemical substances formed when the dye or fire retardant reacts with fibers of a garment or other article upon end-use of those substances by a processor. The dyes and fire retardants themselves are not excluded from reporting requirements if applied domestically, but could be exempt when imported as part of an article. End-use reaction products should not be reported.

207-8. Q. Please clarify what is covered by the article exemption: what about chemical components of articles?

A. "Article" is defined at 40 CFR §720.3(c). In general, an item would meet the definition of an article if it is manufactured in a specified shape or design for a particular end use application, and this design is maintained as an essential feature in the finished product. An example would be an automobile bumper, which had to fit the auto model for which it is made. If an item is manufactured in a particular shape for the purpose of shipping convenience and the shape of the item has no function in the end use, it would not be viewed as an article. An example would be a metal ingot, or a pellet intended to be melted and extruded in the manufacture of an article.

Chemical substances that are imported "as part of an article" are excluded from the PMN requirements by 40 CFR §720.22 (b)(1). It is EPA's policy that a chemical substance is not "part of an article" where (1) the article is a container of the substance used to transport, contain, and/or dispense it, and/or (2) the substance is intended to be removed (or released) from the article and has an end use or commercial purpose separate from the article. A substance which is intended to be removed or released from its article/container, and serves a function during use related to the removal/release of the substance, is considered to have an end use or commercial purpose separate from the article. Components contained by articles that are released upon end use and have a function separate from the article are subject to PMN reporting requirements. Depending on circumstances, the same component can meet, or not meet, the criteria. For example, brake fluid contained in the brake cylinder of an imported automobile would be part of the automobile, which is an article. The same brake fluid contained in a can (which is an article), and intended to be installed in the automobile after import, is considered to have an end use or commercial purpose separate from the article.

207-9. Q. Would a chemical substance formed upon end use of an article, such as adhesive or photographic film, be subject to notification requirements?

A. No. 40 CFR §720.30(h)(5) provides that any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate, is excluded from notification requirements.

207-10. Q. Would a chemical substance that results from a chemical reaction that occurs upon use of any other chemical substance, and formed during the manufacture of an article, such as curable plastic, be subject to notification requirements?

A. No. 40 CFR §720.30(h)(6) exempts any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in §720.30(h) is excluded from notification requirements.

208 The Two Percent Rule for Polymers

208-1. Q. Please explain the changes in the "two percent rule" for polymers.

A. The "two percent rule," which has been in effect since 1977, allows manufacturers and importers of polymers to add monomers or other reactants to an Inventory-listed polymer at levels of 2 percent or less (based on the dry weight of the manufactured polymer) without being considered to have made a polymer with a different chemical identity than the Inventory-listed polymer. The two percent rule also serves as a basis for determining the identity of a polymer that must be reported. This method is calculated based on the weight percentage of the monomer or other reactant "charged" to the reaction vessel. The 1995 amendments to the New Chemicals Program regulations (60 Federal Register 16298, 16310, 40 CFR 720.45(a)(2)(iii)) allow persons greater flexibility in determining the two percent level. In addition to being able to use the "charged" method, the 1995 amendments allow persons to use an alternative method, e.g., to determine the amount of monomer or other reactant that is “chemically incorporated (chemically combined)” in a polymer, and to report the minimum weight percent of that monomer or reactant that is needed in theory to account for the amount incorporated. A manufacturer is free to use either method to determine a two percent level, however the "incorporated" method, while providing more flexibility, also requires supporting analytical data or

theoretical calculations per 720.45(a)(2)(iv).

This change in the "two percent rule" applies to all polymers under TSCA, including Inventory listings, PMN submissions, and Polymer Exemptions.

208-2. Q. In light of the modified "two percent rule," which now allows reporting of polymers as incorporated as well as charged, can all polymer listings on the Inventory now be read either as incorporated or as charged?

A. Yes. All polymers on the Inventory can be interpreted either as incorporated or as charged. Remember that "incorporated" means the minimum amount that theory requires to be charged in order to account for the amount of monomer/reactant molecules or fragments found in the polymer itself.

208-3. Q. Does a manufacturer need to test every batch of polymer to prove that less than two percent is incorporated, or would one documented test on a typical batch be sufficient?

A. A company is not required to test every batch, but is required to maintain in its records analytical data or theoretical calculations to demonstrate compliance with the "two percent rule" when using the "incorporated" method. See 40 CFR 720.28. If the amount normally incorporated is expected to be close enough to two percent that occasional batches might exceed that level, either more frequent testing, or always considering the reactant to be part of the chemical identity, or manufacturing a separate exempt polymer with the reactant present at greater than two percent and included in the polymer identity, might be appropriate.

208-4. Q. If a non-Inventory-listed monomer is charged or incorporated at less than or equal to two percent can the resultant polymer still be eligible for the Polymer Exemption?

A. Yes. However, under §5(a), if a monomer or other reactant is not on the Inventory or otherwise excluded from reporting or exempted from §5 requirements, it cannot be used for domestic manufacture, regardless of its concentration in the product polymer.

A polymer containing a non-Inventory-listed monomer at less than or equal to two percent may be eligible for the polymer exemption provided that the monomer does not "introduce into the polymer elements, properties, or functional groups that would render the polymer ineligible for the exemption". 40 CFR 723.250(g)(1).

It is important to note that a non-Inventory-listed monomer that is not on the list of permitted reactants for the §723.250(e)(3) exemption (polyesters) will render it ineligible for that exemption. There are in fact reactants on that list that are not on the Inventory. These are not subject to the two

percent limitation, since they have already been reviewed for inclusion in this list by EPA and are considered not to be of concern.

208-5. Q. Can polymers that utilize less than or equal to two percent of non-Inventory listed monomers be eligible for the Polymer exemption?

A. Such polymers would be eligible for exemption as long as they meet all the other exemption criteria. However, a monomer used at any concentration must be on the Inventory or exempt before it can be used in the domestic manufacture of the polymer.

208-6. Q. A prepolymer that is on the Inventory, is used to make a polymer. The prepolymer contains a non-Inventory monomer, and the final polymer contains greater than two percent of that monomer. Will my polymer be ineligible for the Polymer exemption?

A. Not on the basis of the non-Inventory monomer; §723.250(d)(4) bars the use of "monomers and/or other reactants... that are not already included on the TSCA Chemical Substance Inventory...". However, in this case the Inventory-listed prepolymer is the reactant that is actually charged to the polymerization reaction vessel. Thus, the polymer is eligible for exemption as long as it meets all the other exemption criteria. The name of the final polymer will include the non-Inventory-listed monomer if the prepolymer is identified for TSCA Inventory purposes with a random monomer-based polymer name.

208-7. Q. If an initiator is incorporated at no more than two percent, does it have to be on the TSCA Inventory for the polymer to be eligible for the Polymer Exemption?

A. An initiator or other reactant present at no more than two percent does not have to be on the Inventory for a polymer to be eligible for the Polymer exemption. However, if the reactant is not on the Inventory, it cannot be used for commercial manufacture in the United States. Consequently, this discussion will for all practical purposes be applicable only to imported polymers. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

208-8. Q. Can I use less than or equal to two percent of any monomer that is on the Inventory and still be eligible for the Polymer Exemption?

A. Yes, as long as that monomer does not introduce elements, groups or properties that would render the polymer ineligible at the concentration of monomer used. Note, though, that for the §723.250(e)(3) "polyester" exemption, all components of the polymer must be on the list of allowable reactants. In this case the use of non-listed monomers, even at two percent or less, would render the polymer ineligible for the (e)(3) exemption.

208-9. Q. If the "chemically combined" method is used and a company claims that two percent or less of a reactant is incorporated into the polymer even though the company charges a higher level to the reaction vessel, what records need to be maintained?

A. The company's records must contain analytical data or appropriate theoretical calculations to demonstrate that the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer of other reactant molecules or fragments chemically incorporated is 2 percent or less. In addition, your records should take into account potential batch-to-batch variation. See 40 CFR 723.250(j).

208-10. Q. If a TSCA-listed brominated flame retardant is mixed at greater than two percent in a polymer base, is the polymer subject to PMN requirements or is it exempt?

A. The material is considered to be a mixture of polymer and the flame retardant. Mixtures are not subject to reporting under TSCA, provided that there is no intended reaction between the components of the mixture. The components of the mixture are separately subject to reporting if they are not on the Inventory. See Q&A section 202 above and 40 CFR 720.3(u). If they are both on the Inventory, no reporting is required. If the polymer is eligible for the exemption, the presence of the other component will not render it ineligible. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

208-11. Q. A company has been importing a polymer containing a cross-linking agent used at a concentration of less than 1% by weight. If the cross-linking agent is used at a level greater than 2%, will a PMN be required?

A. Monomers and other reactants (including cross-linking agents), added at greater than 2% by weight, must be included in the polymer description in the Inventory. See 40 CFR 723.250(e). A PMN would be required if no polymer is listed in the Inventory with the same composition including the cross-linking agent.

208-12. Q. It appears from the Polymer Exemption rule that a person does not have the option of including a reactant/monomer at less than or equal to two percent in the polymer identity. Is this true?

A. Yes, it is true. See 40 CFR 723.250(e). Polymers covered by a Polymer Exemption, however, do not have a formal name. The "identity" is established by the percentages monomers/reactants charged or incorporated in the polymer, and is maintained in the exemption-holder's records. If a polymer has less than or equal to two percent of a monomer/reactant, the identity does not contain that monomer/reactant. If an otherwise identical polymer is made, and the same monomer/reactant is used at greater than two percent, the identity of the second polymer is

different from the first. Two exemptions would have to be claimed to cover both polymers, and a second end-of-year notification would have to be made to EPA. See the Polymer Exemption Guidance Manual at www.epa.gov/opptintr/newchems/polyguid.pdf for more details.

For polymers for which a PMN is submitted, the submitter does have the option of including a reactant/monomer used at two percent or less in the polymer identity. See 40 CFR 723.250(e).

209 Chemicals Manufactured Solely for Export

209-1. Q. What does "manufacturing solely for export" mean?

A. As defined at 40 CFR 720.3(s), "manufacture solely for export" means to manufacture or import a chemical substance solely for export from the US, except for: (1) distribution solely for export or processing solely for export, or (2) R&D per 40 CFR 720.36 and 720.78. According to TSCA §12(a) and 40 CFR 720.30(e), chemicals manufactured solely for export and labeled as such are exempt from much of TSCA, including §5 and the PMN requirement. The chemical substance may not be used in the United States. TSCA §12(a)(1)(A).

209-2. Q. Do chemicals manufactured solely for export require premanufacture notification?

A. No. See Q&A #209-1.

209-3. Q. Who is considered an exporter?

A. An exporter is defined at 40 CFR 707.63(b) (covering reporting regulations under §12(b) of TSCA) as the person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the chemical substance or mixture to a destination out of the customs territory of the United States.

209-4. Q. Under what circumstances is an exporter required to notify EPA of export to a particular country?

A. Section 12(b) of TSCA requires any person who exports or intends to export a chemical substance or mixture to notify EPA of the export of that chemical to a particular country if any of the following actions has been taken with respect to the chemical substance or mixture:

(1) Data are required under §4 or §5(b);
(2) An order has been issued under §5;
(3) A rule has been proposed or promulgated under §5 or §6; or

(4) An action is pending or relief has been granted under §5 or §7.

EPA's regulations implementing TSCA section 12(b) are at 40 CFR 707 Subpart D.

209-5. Q. To whom at EPA must export notices be sent, and what information must they include?

A. Mark the notice and the envelope containing the notice "Section 12(b) Notice". Mail to:

US EPA
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
1200 Pennsylvania Ave., NW
Washington, DC 20460

If the notice is sent by courier, the delivery address is:

US EPA
Office of Pollution Prevention and Toxics
Confidential Business Information Center (CBIC)
EPA East Building, Room 6428
1201 Constitution Ave.
Washington, DC 20004-3302

Please note that , for courier deliveries, the CBIC is open from 8 AM to 4 PM. If you send the notice by courier service and the courier comes after that time he or she will be turned away. You can give the courier the phone number (202) 564-8930 and (202) 564-8940, to call if there is a problem with delivery. If using US mail, the room number is not necessary. Non-uniformed (bicycle, etc) couriers will be met at the 1201 Constitution Ave. entrance by CBIC personnel. Uniformed couriers are admitted to deliver directly to the CBIC.

Per 40 CFR 707.67, a Notice of Intent to Export should contain the following information:

(1) the name of the regulated chemical as it appears in the §4, 5, 6, or 7 action (If a category is regulated, the name of the individual regulated chemical within that category, as well as the name of the category, must be given. Use the name which appears in Volume I of the EPA Chemical Substance Inventory or its supplements, if the chemical appears there.);
(2) the name and address of the exporter;
(3) the country(ies) of import;
(4) the date(s) of export or intended export; and
(5) the section of TSCA under which EPA has taken action.

According to 40 CFR 707.65, a Notice of Intent to Export must be submitted for the first export or intended export to a particular country in the calendar year if the substance is the subject of any of the following actions:

(1) data are required under §5(b),
(2) an order has been issued under §5,
(3) a rule has been proposed or promulgated under §5 or 6, or
(4) an action is pending or relief has been granted under §5 or 7.

In addition, a Notice of Intent to Export must be submitted for the first export or intended export to a particular country when data are required under §4.

A Notice of Intent to Export must be in writing (after EPA develops procedures for receipt of electronic notices, these will be acceptable, too). A Notice of Intent to Export must be based on a definite contractual obligation or an equivalent intra-company agreement, to export the chemical. Your Notice of Intent to Export must be postmarked within seven days of forming the intent to export or on the date of export, whichever is earlier.

Less than 2% of Notices of Intent to Export contain any assertion of confidential business information (CBI). For submitters who do feel they have a need to have information about their submissions kept confidential, the requirements for making a CBI claim are discussed at 40 CFR §707.75.

209-6. Q. Are isolated intermediates used in the manufacture of a final chemical substance which is solely for export subject to the PMN requirement?

A. Yes. Only the specific chemical substance which is manufactured solely for export is excluded from PMN requirements. See 40 CFR 720.30(e).

210 Uses Covered by FIFRA

210-1. Q. Are pesticides included in the definition of a chemical substance?

A. No. The definition of the jurisdictional term"chemical substance" under §3(2) (and at 40 CFR 720.3(e)) of TSCA excludes any chemical when manufactured, processed, or distributed in commerce for use as a pesticide, food, drug, cosmetic, tobacco, tobacco product, or special nuclear material. The term pesticide has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. and the regulations issued under it.

210-2. Q. Do pesticides fall under the jurisdiction of FIFRA or TSCA?

A. Pesticides are regulated under FIFRA. A substance that is regulated under FIFRA would not be regulated under TSCA, unless the substance has multiple uses. In the case of multiple uses, some of which come under FIFRA and others which come under TSCA, the substance would fall under the jurisdiction of both TSCA and FIFRA. If a substance is manufactured, processed, or distributed for undifferentiated uses, then the substance will be presumed to be subject to TSCA. See 42 FR 64585 (comment 37), Dec. 23, 1977.

210-3. Q. How is it determined whether a substance is regulated under FIFRA or TSCA?

A. If a manufacturer, processor, or distributor of a substance has intent, either by making express or implied pesticide claims for the product, or by the product's having no other significant commercially valuable use except as a pesticide, or if the seller or distributor has knowledge that the product will be used or is intended to be used as a pesticide, it would be considered a pesticide within the meaning of FIFRA. If the manufacturer is making a pesticidal claim for the material, this is evidence that a substance is a pesticide within the meaning of FIFRA. Also, if the substance bears no pesticidal claims, but has no commercially valuable use except as a pesticide, it could still be a pesticide under FIFRA.

211 Pesticide Inerts

211-1. Q. Are inert ingredients used in the manufacturing of a pesticide subject to the reporting requirements of TSCA or FIFRA?

A. Inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA. In order to be considered a pesticide, a substance must be intended for use as a pesticide. An inert ingredient which is not itself a pesticide would, accordingly, be a chemical substance within the jurisdiction of TSCA; it comes within the jurisdiction of FIFRA when it becomes a component of a pesticide product. 42 FR 64586 (comment 39), Dec. 23, 1977.

211-2. Q. Are there situations where the manufacturer, processor, or distributor of pesticides are covered by TSCA versus FIFRA?

A. Any single chemical substance is subject to TSCA and FIFRA only if it has both pesticidal and non-pesticidal uses. TSCA authority covers the substances involved in manufacturing a pesticide. It also covers inert ingredients until they become a part of the pesticide product, i.e., the formulation of the pesticide product. Once formulated, the pesticide product, including its inert ingredients, is solely regulated by FIFRA for distribution and sale.

If a substance is also used in non-pesticide products, the ingredient may be regulated in those products under TSCA at the same time that it is regulated under FIFRA as a component of the pesticide product.

211-3. Q. Are ingredients used in either pesticide or non-pesticide products that fall under the jurisdiction of TSCA eligible for the TSCA R&D exemption?

A. In some circumstances, yes. There is no specific R&D exemption in FIFRA. However, the pesticide products containing the inert ingredients may require an experimental use permit (EUP) under FIFRA, or if used in small quantities, may not require an EUP (40 CFR 172.3). EUP requirements apply only to the pesticide products, not the ingredients separately.

A new chemical substance used in small quantities as a pesticide inert ingredient falls within the jurisdiction of TSCA and is eligible for the R&D exemption if the research and development is conducted on the inert substance itself. A new chemical will be covered by TSCA's R&D exemption until it becomes part of a pesticide product. Once it becomes part of a pesticide product, it becomes subject solely to FIFRA requirements. Note that 40 CFR 720.36(g) waives compliance with the R&D requirements for activities intended solely to determine whether a substance can be used as a pesticide.

212 Pesticide Ingredients

212-1. Q. Are the raw materials or intermediates used in the manufacturing of a pesticide subject to the reporting requirements of TSCA or FIFRA?

A. Raw materials and intermediates used in the manufacture of a pesticide can be regulated under TSCA. In order to be considered a "pesticide" under FIFRA, a substance must be intended for use as a pesticide. A raw material or intermediate which is not itself a pesticide would, accordingly, be a chemical substance within the jurisdiction of TSCA; it would come within the jurisdiction of FIFRA only when it becomes a component of a pesticide product. 42 FR 64586 (comment 39), Dec. 23, 1977.

213 Pesticide Intermediates

213-1. Q. Are intermediates produced or used in the manufacturing of a pesticide subject to the reporting requirements of TSCA or FIFRA?

A. In order to be considered a "pesticide" under FIFRA, a substance must be intended for use as a pesticide. An intermediate which is not itself a pesticide would, accordingly, be a chemical substance within the jurisdiction of TSCA; it would come within the jurisdiction of FIFRA when it

becomes a component of a pesticide product. 42 FR 64586 (comment 39), Dec. 23, 1977.

213-2. Q. When is reporting required under TSCA versus FIFRA regarding the manufacturing, processing, or distribution of pesticides?

A. Discussion of EPA's position on this topic can be found at 42 FR 64585-86, comments 37-39, Dec. 23, 1977, and 51 FR 15098, April 22, 1986. To summarize, as a general rule, a pesticide may be subject to TSCA prior to registration under FIFRA or application for an Experimental Use Permit. However, "a person who manufactures or imports a chemical substance in small quantities solely for research and development is not required to comply with the requirements of [the TSCA R&D exemption from the PMN requirement] if the person's exclusive intention is to perform research and development activities solely for the purpose of determining whether the substance can be used as a pesticide." 40 CFR 720.36(g). A chemical substance may be subject to TSCA and FIFRA if it is manufactured for both pesticidal and non-pesticidal uses. TSCA authority also covers substances involved in manufacturing a pesticide. It also covers inert ingredients until they become a part of the pesticide product, i.e., the formulation of the pesticide product. Once formulated, the pesticide product, including its inert ingredients, is solely regulated by FIFRA for distribution and sale. If a substance is also used in non-pesticide products, the ingredient may be regulated in those products under TSCA at the same time that it is regulated under FIFRA as a component of the pesticide product.

213-3. Q. Are pesticide intermediates that fall under the jurisdiction of TSCA eligible for the R&D exemption?

A. The intermediate of a FIFRA-registered pesticide is eligible for the R&D exemption only if the research and development is conducted on the intermediate itself. Under FIFRA, an Experimental Use Permit (EUP) may be used to allow a pesticide maker to undertake scientific experimentation, research or analysis or to determine customer acceptance or economic viability. An intermediate for a pesticide allowed under an EUP is eligible for the TSCA R&D exemption if the intermediate is only being used in small quantities for scientific experimentation, research or analysis.

214 Uses Covered by FDA

214-1. Q. Are food, food additives, drugs, or cosmetics included in the definition of a chemical substance?

A. Under TSCA §3(2) (and 40 CFR 720.3(e)), the definition of "chemical substance" does not include any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. The terms

cosmetic, device, drug, food, and food additive have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., and the regulations issued under it. However, if these same chemicals are also intended for a TSCA use, then they are subject to TSCA. See 42 FR 64585 (comment 37), Dec. 23, 1977.

214-2. Q. What is FDA's definition of a drug?

A. The definition of "drug" in the Federal Food, Drug, and Cosmetic Act (FFDCA) includes articles intended for use as a component of substance included in the definition of drug. (Note that the FFDCA uses the term "article" in a generic sense to mean item, thing, substance, material, and not the term of art that "article" connotes under TSCA.) See http://www.fda.gov/opacom/laws/fdcact/fdcact1.htm for a more complete definition of drug under the FFDCA. As used in that Act, the term "component" does not mean only an item which may be identified as an ingredient of a drug in its final dosage form, but also includes any item used in the production of the drug. Thus, precursors, intermediates, and catalysts intended for use in the production of drugs in their final dosage form are drugs within the meaning of FFDCA.

Moreover, FFDCA clearly covers drugs during the investigation or research stage. Consequently, the definition of drug in that Act includes chemical substances used for drug research and development. The same is true of the definitions of food, food additives, and cosmetics.

214-3. Q. Are detergent substances, other than soap, included in FDA's definition of cosmetics?

A. In its definition of the term "cosmetic", FFDCA §201(i), 21 USC 321(i), specifically excludes soap. The term "soap" is not defined in the Act. At 21 CFR 701.20(a), the Food and Drug Administration interprets the term "soap" to apply only to articles that meet the following conditions: the bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and the product is labeled, sold, and represented only as soap.

Products intended for cleansing the human body and which are not soap as described above are cosmetics, thus they are subject to the requirements of the FFDCA and its regulations. Detergents NOT intended for cleansing the human body are TSCA-regulated.

214-4. Q. Are intermediates and catalysts of a drug or cosmetic regulated under FFDCA or TSCA?

A. The definitions of FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components.

Therefore, they are subject to regulation under FFDCA. Any such substance is excluded from regulation under TSCA if it is actually manufactured, processed, or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic or device.

214-5. Q. How would a substance with multiple uses which falls under the jurisdiction of FFDCA and TSCA be regulated in order to avoid duplicative requirements?

A. If a substance has multiple uses only some of which are regulated under FFDCA, then the manufacturing, processing, distribution, and use of the substance for the remaining uses would be within the jurisdiction of TSCA. Under these regulations, that substance should be reported for the Inventory. EPA does not intend to impose duplicative requirements on manufacturers and processors subject to regulation under another Federal authority. Accordingly, EPA will consult with FDA or any other Federal agency, as appropriate, prior to taking regulatory action on substances which are also regulated under other authorities.

214-6. Q. Are new substances that are isolated intermediates used only in the manufacture of a drug subject to PMN?

A. No, if the intermediates are regulated by FDA, they are not subject to TSCA requirements.

215 Naturally Occurring Substances

215-1. Q. What is the definition of a naturally occurring chemical substance and what are some examples?

A. According to 40 CFR 710.4(b), any chemical substance which is naturally occurring and which is either unprocessed or processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or which is extracted from air by any means, shall automatically be included in the Inventory under the category Naturally Occurring Chemical Substances. Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

216 Precipitation Inhibitors

216-1. Q. If a new chemical is formed when a precipitation inhibitor is added to a product and acts as intended, is the new chemical subject to PMN reporting requirements?

A. No PMN needs to be filed for any chemical substance which results from a chemical reaction that occurs when a precipitation inhibitor, stabilizer, colorant, odorant, antioxidant, filler,

solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended. See 40 CFR §720.30(h)(7)(i).

217 pH Adjustment

217-1. Q. If a new chemical is formed when a specific reagent is used to adjust the pH and acts as intended, is the new chemical subject to PMN reporting requirements?

A. No. If a new chemical substance is formed when a pH adjuster is included in a product and functions as intended, and the pH adjuster is not the substance itself, the substance formed is excluded from PMN. See 40 CFR §720.30(h)(7)(i).

217-2. Q. What is the difference between pH adjustment and pH neutralization?

A. The terms pH adjustment and pH neutralization are not synonymous terms. pH adjustment deals with the fine tuning of the pH of a solution. For example, an acid with a pH of 3 is made more acidic by adjusting the pH to 2. In this example, material used to adjust the pH is of course potentially subject to PMN reporting, but the chemicals resulting from the adjustment reaction are excluded from PMN reporting. However, if the change in pH is undertaken for the purpose of making a new substance, the substance with the new pH will qualify for PMN reporting.

pH neutralization, on the other hand, means that the pH of a solution brought to neutrality or near neutrality. This is generally a larger change in conditions. For example, a change in pH from 14 to 7 would be considered a pH neutralization. This change in pH will usually result in a substantial change in the chemical species present and contribute to the function of the chemical. The new chemicals resulting from the pH neutralizing reaction are subject to PMN reporting requirements. If you have a situation for which you think this guidance is ambiguous, it is appropriate to contact an EPA prenotice coordinator for resolution.

218 The "(h)(7)" Exemption - 40 CFR §720.30(h)(7)

218-1. Q. What are the criteria that must be met, for a substance to be excluded from the Inventory or PMN reporting under 40 CFR 720.30(h)(7)?

A. It must fully satisfy all of the following criteria:

1. The substance is formed from a chemical reaction that involves the use of a chemical substance of the type described under 40 CFR 710.4(d)(7) or 720.30(h)(7);

2. The substances does not function to provide one or more primary properties that would determine the use of the product or product mixture distributed in commerce, even though it may impart certain physicochemical characteristics to the product or product mixture of which it is a part; and

3. The substance is not itself the one intended for distribution in commerce as a chemical substance per se. Although it may be a component of the product, product mixture, or formulation actually distributed in commerce, it has no commercial purpose separate from the product, product mixture, or formulation of which it is a component.

(See EPA's published clarification on this issue available through the TSCA Hotline (202) 554-1404: the package from Joseph Carra, Deputy Director, Office of Pollution Prevention and Toxics, to the regulated community, dated June 29, 1994.)

218-2. Q. If a polymer is partly ionized during use by a pH change which increases its water absorption to greater than 100 percent by weight, is the polymer no longer eligible for the exemption? Does the so-called "(h)(7)" pH neutralizer exclusion apply to polymers >10,000 MW that absorb more than 100 percent of their weight of water upon neutralization? Does the "(h)(7)" exclusion take precedence over the Polymer Exemption, or vice versa?

A. If the polymer becomes water-absorbing upon use in neutral water, it is a water-absorbing polymer, whether or not ionization is involved. Treatment of high-molecular-weight polymers in the New Chemicals Program is described at "www.epa.gov/oppt/newchems/hmwtpoly.htm." Water absorbing high molecular weight polymers are ineligible for the Polymer Exemption per 40 CFR 723.250(d)(5). See 60 Fed. Reg. 16,319-16,320 (March 29, 1995).

If the substance is deliberately converted to a water-absorbing polymer by neutralization, that conversion constitutes manufacture for commercial purposes as a chemical substance, rather than processing. The resulting substance would be a different polymer that would be considered water-absorbing and consequently not eligible for the Polymer Exemption (even if the neutralizing agent used is less than or equal to two percent, a polymer must still meet the eligibility requirements in order to be exempt). The resulting neutralized substances would also not be excluded from reporting under 720.30(h)(7). The unneutralized starting polymer could still be eligible for the Polymer Exemption, if it met the other exemption criteria.

On the other hand, if the neutralization results in a substance excluded from reporting under 40 CFR §720.30(h)(7) (which basically covers processing rather than manufacture), that substance remains excluded from reporting even if it would have been ineligible under the Polymer Exemption. If an exempt polymer is converted into a water-absorbing substance as a result of a chemical process or reaction that produces a substance excluded from reporting under (h) (7), the starting polymer remains exempt. Both the Polymer Exemption and 40 CFR §720.30(h)(7) apply, independently, to the

respective substances.

218-3. Q. If a chemical manufacturer supplies a customer with a TSCA listed acid and the customer, without making notification under §5, makes a salt not on the Inventory, is the customer in violation of TSCA or subject to an exclusion?

A. The salt would be a reportable chemical substance, and therefore would be subject to the PMN requirements if it is not on the Inventory. If, however, the customer makes the salt under circumstances which are covered by an exclusion (common exclusions are those at 40 CFR §§720.30(h)(5), (h)(6), and (h)(7)), notification is not required.

219 New Chemical Formed Incidental to Storage

219-1. Q. If a chemical substance is formed incidental to storage or disposal, is the new chemical subject to PMN reporting requirements?

A. No, 40 CFR §720.30(h)(4) excludes any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article from PMN reporting requirements.

3. EXEMPTIONS

301 Research and Development

301-1. Q. What does the term "research and development" (R&D) encompass?

A. Under §5 of TSCA, “research and development” (R&D) has a specific meaning.. First, §5(i) of TSCA and 40 CFR 720.30(i) exempt non-commercial research and development from the PMN requirement. Second, §5(h)(3) of TSCA and 40 CFR 720.36 exempt substances that are manufactured in small quantities solely for commercial research and development (R&D) from the §5(a) notice requirements. No application is required for the R&D exemption under §5(h)(3). To qualify for the R&D Exemption, the substance must be manufactured in small quantities for research and development and the manufacturer and users must comply with the regulations at 40 CFR §720.36 and §720.78.

EPA has published additional guidance on the R&D exemption in: the preamble to the Inventory Reporting Requirements at 42 Fed. Reg. 64572 (December 23, 1977); the notice entitled "TSCA Chemical Substances Inventory; Removal of Inappropriately Reported Synfuel Substances" at 48 FR 7683 (February 23, 1983); and the preambles to the proposed and final revisions of the PMN regulations published at 49 FR 50201 (December 27, 1984) and 51 FR 15096 (April 22, 1986), respectively. There is a good summary of R&D requirements in the New Chemical Information Bulletin "Exemptions for Research and Development and Test Marketing" (1986-1, November 1986, Office of Toxic Substances), available from the TSCA Hotline at (202) 554 1404 or at www.epa.gov/oppt/newchems/tmeranddbulletin.pdf.

In the course of R&D activities, professional researchers using the substances must be engaged in collecting information about and monitoring tests of the chemical substances being studied or developed. General distribution of chemical substances to consumers does not constitute R&D.

Chemical substances used exclusively for R&D are eligible for the R&D exemption if their manufacturers meet all the requirements associated with the exemption. (See discussion of requirements below). The substance must either be the focus of R&D itself, or be used in an R&D activity focusing on another chemical substance. The latter category encompasses reagents, chemicals to be used as standards for chemical analysis in laboratories, and intermediates used solely to produce R&D substances, including intermediates used in the production of pesticides used exclusively for R&D.

The purpose of R&D is distinct from test marketing pursuant to TSCA §5(h)(4) and 40 CFR 720.38. The PMN regulations define R&D and test marketing at 40 CFR 720.3(cc) and 720.3(gg), respectively. R&D focuses on the analysis of the chemical or physical characteristics, the performance,

or the production characteristics of a chemical substance, a mixture containing the substance, or an article. Test marketing focuses on customers' acceptance of a chemical substance, and the probable demand for a product in a market where it will be competing with other goods.

R&D encompasses a wide range of activities which may occur in a laboratory, pilot plant, commercial plant outside the research facility, or at other sites appropriate for R&D. The following activities which test the physical, chemical, production, and performance characteristics of a substance may be considered R&D:

- chemical synthesis and physical/chemical properties testing in the laboratory,
- health and environmental effects testing,
- tests or demonstrations of equipment or production processes, which typically take place in pilot facilities, but may also involve production in full-scale commercial runs (e.g., testing a new chemical to ascertain whether it can be produced in commercial scale equipment, or testing a new or modified process to determine process capabilities such as yield, uniformity, or process scale-ups),
- efficacy and performance tests (e.g., testing of color fastness of a dye, or the efficiency or lifetime of a new catalyst in a chemical manufacturing process), and
- consumer panel testing of the performance characteristics of a new chemical substance. (EPA encourages manufacturers and importers to check with the Office of Pollution Prevention and Toxics to determine whether their consumer panel testing activities comply with the requirements of the rule.)

Because consumer panel testing could involve broad exposures to new chemical substances, manufacturers and importers using a consumer panel should be sure that, to meet the requirements of the R&D exemption, they:
(1) consider the activities of the consumer panel in any assessment of risk,
(2) notify panel members of the potential for risks in a manner that adequately informs them, and
(3) provide the services of a technically qualified individual who will supervise the tests directly in a manner which offers panelists no less protection than would be provided to workers engaged in R&D in a laboratory.

301-2. Q. Is R&D conducted entirely in laboratories under prudent practices exempt from the risk evaluation requirement?

A. Yes, under 40 CFR 720.36(b)(2), R&D conducted entirely in laboratories under prudent practices is exempted from the requirement for risk evaluation. EPA has determined that a laboratory's compliance with OSHA's laboratory standard at 29 CFR §1910.1450, requiring the formulation and implementation of a Chemical Hygiene Plan, is sufficient to exempt a laboratory from the evaluation of risks. However, persons who engage in R&D for, or obtain an R&D chemical from, a manufacturer

must be notified of any risk to health which may be associated with the chemical.

301-3. Q. What records must be retained when performing R&D?

A. Per 40 CFR 720.78(b), the following records must be retained: information reviewed and evaluated to determine the need to make any notification of risk, documentation of the nature and method of risk notification, documentation of prudent lab practices used instead of risk notification and evaluation and, if an R&D substance is manufactured at greater than 100 kgs/year, records regarding the chemical identity of the substance to the extent known, the production volume, and the disposition of the R&D chemical must also be retained.

301-4. Q. The PMN regulations state that any R&D substance must be supervised by a technically qualified individual (TQI). What is the definition of a TQI?

A. A TQI is defined at 40 CFR 720.3(ee) as a person or persons who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision. A TQI is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

301-5. Q. Is there a production volume limit for R&D exemptions? How do the PMN regulations define the term "small quantities"?

A. "Small quantities" is defined at 40 CFR 720.3(cc) as quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes. EPA has not attempted to define "small quantities" quantitatively. EPA recognizes that the quantity of a chemical substance needed for legitimate R&D activities varies considerably with the category of substance, the use of the substance, and the nature and stage of R&D. For example, 80,000 barrels of crude shale oil produced in a pilot plant operation, 500 pounds of a resin produced for performance testing, and 1 pound of a dye additive developed at the laboratory stage may all qualify as "small quantities" relative to the respective commercial activity.

301-6. Q. Our company manufactured substantial excess material under the R&D exemption, because, to make the material at all, we had to make a full batch in our pilot plant. Based on our research, we have filed a PMN, and the PMN review period has expired without regulatory action. Can this excess material now be used for commercial purposes? How does this impact Notice of

Commencement (NOC) requirements? Must such use be precleared with EPA?

A. Excess R&D substance can be used for commercial purposes after the PMN review period expires. The NOC may not be filed until the new chemical substance is first manufactured for a nonexempt commercial purpose after expiration of the PMN review period. After the PMN is submitted and the review period expires, no additional review by EPA is required prior to use of the excess R&D material for a nonexempt commercial purpose. In this situation, it is prudent to make a memorandum to the file describing the situation and your reliance on this advice, particularly if a NOC will not be filed until long after expiration of the PMN review period.

In addition, 40 CFR §720.30(e) and (f) allow certain commercial uses of excess R&D materials, prior to clearance of a PMN. Additional information on the R&D exemption is provided in EPA's New Chemical Information Bulletin: Exemptions for R&D and Test Marketing, which is available from the TSCA Hotline at (202)554-1404 or at www.epa.gov/oppt/newchems/tmeranddbulletin.pdf.

301-7. Q. We are developing a new polymer that is not on the TSCA Inventory but which meets EPA's Polymer Exemption criteria. Do I need to follow the R&D exemption criteria, and if so, for how long?

A. Basically, you can choose. If you meet the R&D exemption criteria at 40 CFR 720.36 (broadly: you have a clear plan of what you are trying to find out, you notify the appropriate people that the material is not on the TSCA Inventory, the substance can only be used for R&D purposes under the supervision of a Technically Qualified Individual (TQI), you keep the required records, and you supply a hazard information document) then you need not meet the Polymer Exemption criteria. If you meet the criteria for using the Polymer Exemption at 40 CFR 723.250 (broadly: you conduct an internal review to verify that the polymer based on the monomers/reactants in the name satisfies the criteria, you have an intent for commercial use, you fulfill record keeping requirements and year-end notification of EPA) you need not meet the R&D exemption requirements.

301-8. Q. Please clarify the requirements for a Notice of Commencement (NOC) with regards to the R&D exemption?

A. A NOC must be submitted within 30 days of manufacture for a nonexempt commercial purpose. "Nonexempt commercial purpose" includes commercial R&D not in full compliance with the R&D regulations at 40 CFR 720.36 and 720.78(b). If the first batch of new chemical substance manufactured after expiration of the PMN review period is "solely for R&D purposes" and will be used in compliance with the R&D regulations, the submitter may not file a NOC. If, however, the manufacturer does not wish to comply with the R&D regulations and record keeping requirements, a

NOC must be filed.

301-9. Q. Direct shipments of chemicals not on the Inventory from foreign suppliers to U.S. sites pose a problem on how to provide notification as an R&D exemption. How do you suggest this best be handled?

A. Under TSCA, the importer of the material has the responsibilities of a manufacturer. Importers of R&D substances that are not listed on the Inventory must provide positive certification under section 13 of TSCA and comply with the R&D regulations and record keeping requirements at 40 CFR §720.36 and 720.78(b). Persons who receive direct shipments of imported R&D substances must also comply with the R&D regulations and section 13 certification requirements.

302 Test Marketing Exemption

302-1. Q. What does a test-marketing exemption (TME) involve?

A. As provided in TSCA §5(h)(1) and 40 CFR 720.38, any person may apply for an exemption (from the requirement for PMN) to manufacture or import new chemical substance for test marketing. The manufacturer is required to submit a test-marketing exemption (TME) notice to EPA at least 45 days prior to manufacturing the substance. Under 40 CFR 720.3(gg), test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

EPA may grant the TME if it determines that activities involving the substance will not present an unreasonable risk of injury to health or the environment. In addition, EPA may grant an exemption subject to limitations such as the use of measures/controls to protect human health and the environment. (TSCA §5(h)(1)(B) and 40 CFR 720.38(e)).

302-2. Q. What information should be submitted when applying for test-marketing exemptions (TME)?

A. The §5 PMN form is used to submit the information required of an TME. For an adequate review, test-marketing exemption applicants should, at a minimum, include the following information in their applications:

(1) all existing data regarding health and environmental effects of the substance including

physical/chemical properties or, in the absence of such data, a discussion on toxicity based on structure-activity relationships and relevant data on chemical analogues,
(2) the maximum amount to be manufactured or imported for test marketing,
(3) the maximum number of persons who may be provided the substance during test marketing,
(4) the maximum number of persons who may be exposed to the substance as a result of test marketing,
(5) information on estimated duration and routes of exposure, and
(6) a description of the test-marketing activity, including the length of time that will be required and how the activity may be distinguished from full-scale commercial production and from research and development. These items are set out in 40 CFR §720.38(b).

302-3. Q. What is EPA's procedure after receiving a test-marketing exemption (TME) application?

A. In accordance with §5(h)(6) of the Act, after EPA receives an application for a TME, EPA will publish in the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential. No later than 45 days after EPA receives an application, EPA will either approve or deny the application. Thereafter, EPA will publish a notice in the Federal Register explaining the reasons for approval or denial. In approving a TME, EPA may impose any restrictions necessary to ensure that the substance will not present an unreasonable risk of injury to health and the environment as a result of test-marketing.

302-4. Q. What information must be maintained by the person or persons who maintain a test-marketing exemption (TME)?

A. According to 40 CFR 720.78(c), any person who obtains a test-marketing exemption must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA the TME is granted. This information must be retained for five years from the final date of manufacture or import under the TME.

302-5. Q. What is the difference between test marketing and R&D?

A. Test-marketing and R&D differ in the following ways:

Test marketing must be approved by EPA before it is conducted and the submitter of the application must distinguish the test marketing activity both from R&D and from full-scale commercial production. In any test marketing activity, the amount of material produced and distributed, the number of potential customers to whom it is distributed, and the time period of the test must be specified to EPA in advance of distribution. Test marketing involves distribution of a chemical substance in commerce to a defined market to evaluate demand for, or customers' acceptance of, the substance

being tested. See New Chemical Information Bulletin: Exemptions for Research and Development and Test Marketing at www.epa.gov/oppt/newchems/tmeranddbulletin.pdf.

R&D does not involve pre-approval by EPA. Persons must meet the requirements of the R&D exemption at 40 CFR §720.36 (procedures) and 720.78 (record keeping.) R&D involves monitored tests of physical, chemical, production or performance characteristics of a substance, and requirements for R&D include generally applicable safeguards for workplace safety (presence of a technically qualified individual in non-laboratory settings, procedures for warning workers of potential hazards, etc.)

303 Low Volume Exemption

303-1. Q. Are amendments to a low volume exemption effective on receipt or is a review by EPA still necessary?

A. Approval of LVE amendments is by no means automatic. Under 40 CFR 720.50(j), some amendments which will result in a change in site, production volume or physical form, and all amendments which will result in a change in use or exposure controls require a submission of a new exemption request. Such submissions are subject to the 30 day review and may not take effect until the review period expires.

A manufacturer may, without submitting a new notice, begin to manufacture the new chemical substance at a site not listed in its exemption application without prior review by EPA, and notify EPA within 30 days after initiating manufacture, only under the following conditions described at 40 CFR §723.50(j)(6)(ii)(A): exposure of workers to the new chemical substance at the new site is equal to, or less than, that at the site for which EPA performed its original risk-assessment; and at the new site either the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or 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 an alternative level previously approved by EPA in writing). If the manufacture initiates manufacture at a new site under this provision, it must notify EPA of the new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the LVE at the new manufacturing site.

The notification to EPA 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. 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. The notification must contain an original signature of an authorized official of the manufacturer.

303-2. Q. What is the maximum cumulative production volume a company must adhere to if they want to submit a LVE?

A. LVEs cannot exceed 10,000 kg/yr cumulative production for the holders. See 40 CFR 723.50(a)(i). Above that volume, a regular PMN is needed. However, under 40 CFR 723.50(e)(2)(vi), a manufacturer can bind themself to a lower production volume and EPA will conduct its risk assessment at that level.

303-3. Q. The LVE production volume limit is stated in kilograms per year (kg/yr). Is that on a calendar year or fiscal year basis?

A. Neither. It is on an "anniversary" basis. At 40 CFR 723.50(a)(2)(i) the application is required 30 days before manufacture begins, and at 40 CFR 723.50(a)(1)(i) manufacture is enjoined at greater than 10,000 kg (or smaller approved quantity) per year. In other words, EPA intends that the 12-month production volume period begins the date following expiration of the 30-day notice review period.

303-4. Q. How do I designate a lower than 10,000 kg/yr production volume?

A. Place the production volume in the designated box in Part I, Section (C)(1) of the form and mark (x) the corresponding binding box. In filing an LVE you are offering enforceable conditions for your use of a substance, including amount. If, after the LVE is granted, you manufacture the substance outside of those conditions, you are in violation of TSCA. EPA bases its review of an LVE on the amount agreed by the submitter, and does not have to consider plausible scenarios for greater use of the material. However, if the binding box is not checked, EPA will assess the LVE application at the maximum use level of 10,000 kilograms/year.

303-5. Q. What does the "binding option" mean in legal terms when filing a LVE?

A. In filing a LVE or a Low Release or Exposure Exemption (LoREX) you are proposing enforceable conditions for your use of a substance. If, after the LVE/LoREX is granted, you manufacture the substance outside of those conditions, without first obtaining EPA's approval of those changes, you are in violation of TSCA. EPA bases its review of an LVE/LoREX on the conditions you have proposed, and does not have to consider other plausible use scenarios for the material. See in

particular 40 CFR 723.50(j).

303-6. Q. I currently hold a LVE under the 1,000 kg ceiling (of the pre-1995 LVE rule). Do I have to submit a new LVE to continue making 1,000 kg/year?

A. No. You are free to continue manufacturing your LVE substance under the terms of that exemption. However, if you want to make any change (e.g., increase the volume to 10,000 kg/year or change manufacture site, use, human exposure or environmental release controls) you will have to apply for a new LVE pursuant to the amended regulations (see 40 CFR §723.50 (m) - Exemptions granted under superseded regulations).

303-7. Q. May an LVE application be submitted simultaneously with a PMN? If not, is there a time-period after a LVE has been submitted in which a PMN may not be submitted?

A. EPA generally does not allow the simultaneous submission of a LVE and PMN for the same substance from the same submitter. Any LVE submitter has certified that he/she intends to manufacture under the terms of the exemption which includes a production volume at, or less, than 10,000 kg/yr. The simultaneous submission of a PMN for a greater production volume is considered a contrary statement of intent, that is the submitter does not intend to manufacture under the terms of the exemption. It is EPA's general policy however that, following submission of a LVE application, the same company may submit a PMN for the same chemical 90-days before the end of the 1 year period commencing with EPA's approval of the LVE. This policy has been adopted on the understanding that no more than 10,000 kilograms per year would be produced under the LVE. Although there is no prohibition in the LVE regulations against the submission of a PMN immediately after the expiration of the LVE review period, an applicant's good faith certification may be questioned.

EPA discourages such practices and may request the submitter to support the apparent change in intent. It is important to note here that the burden of proving eligibility for an exemption rests with the person claiming the exemption. EPA advises manufacturers and importers of exempt substances to be prepared to meet this responsibility should a question arise concerning their compliance.

303-8. Q. Will an LVE application be considered incomplete if the §5 submission form, which is now required, is not filled out completely?

A. No. EPA requires the use of the §5 submission form to standardize the presentation of information by submitters. EPA's internal work flow is improved: EPA Form 7710-25 enables our reviewers to go to the information they need easily, and facilitates our review. You need only provide the information required for the LVE. Both for PMN and LVE submissions, you must provide all the information you have which can be relevant to the risk case. If there is information needed for a PMN

submission which you think is not needed for an LVE submission, you can leave the space blank or contact a prenotice coordinator to ask for advice.

Before the §5 submission form was required, reviews of many LVE applications were delayed because EPA had unresolved concerns on exposures and releases, or controls for either. Although submitters are encouraged to provide human exposure and environmental release information, submission of this information is considered optional. The notice will not be declared incomplete without this information; however, if not provided EPA will generate its own estimates and there may be delays in the review. It is worth noting that more information can be necessary to support a "will not present an unreasonable risk finding" for the higher production volume chemicals being reviewed under the 10,000-kg expanded LVE exemption than may have been necessary for a 1,000-kg LVE.

303-9. Q. What happens if I do not commence manufacture of the LVE substance within one year of EPA approval of my LVE submission ?

A. In your LVE submission you certify that, at the time you are submitting the exemption application, to the best of your knowledge it is your intent to commence manufacture within one year. If you fail to manufacture within that year, a new notice would not be required, however, you may have additional reporting if there is a second exemption request by another manufacturer for the same substance. If EPA finds it is in the position to consider denying the second request based on cumulative exposures or environmental releases of the substance, EPA will notify the first exemption holder that it must provide certification to EPA that he/she has commenced manufacture/ import, will commence manufacture/ import, or EPA may withdraw the exemption. If the first exemption holder does not respond to EPA within the required 21 days, EPA may revoke the exemption. See 40 CFR 723.50(f).

303-10. Q. Must the §5 submission form be used to make changes to a LVE?

A. Any changes in use, exposure, release, controls, production volume (if bound at a lower level), importation only, and certain changes in site of manufacture, require the submission of a new exemption application using the §5 submission form (EPA form 7710.25). However, duplicative information need not be re-submitted. You need only submit those pages of the §5 submission form in which new information is provided in support of the modification request. The new notice must include chemical identity, manufacturer's name, a name and telephone number of a technical contact, new signed certifications, and the change. A modification must also include the identity of the previous exemption number. A box on the cover page of the form is provided to identify that the type of notice is an exemption modification. See 40 CFR 723.50(j)(5).

303-11. Q. What is the advantage to me of submitting a LVE instead of a PMN if I'm required to use EPA Form 7710-25 (the §5 submission form) and provide the same information in an LVE application

as in a full PMN.

A. Each type of submission has advantages, depending on the submitter's needs. The most substantial submitter advantages to a LVE application instead of a PMN are: 1) a new substance may be marketed earlier (30-day review instead of 90) and, 2) it allows the manufacturer to self-impose exposure and release controls without requiring development of a §5(e) Consent Order or SNUR. For EPA, since an LVE application is an agreement to make (a) particular use(s) at (a) particular site(s), an LVE allows EPA's reviewers to focus only on the use scenario contemplated by the submitter. This self-limitation by the submitter simplifies the review and under some circumstances allows EPA to authorize materials for which other plausible uses pose greater potential danger than the use(s) identified by the submitter.

Although the information requirements for a PMN and an exemption are very similar they are, in fact, not identical. For LVEs, the submission of human exposure and environmental release data for sites not controlled by the submitter is optional. In addition, the exemptions have only a 30-day review period. As well, the exemptions do not require the submission of a fee or additional notice copies.

303-12. Q. Must an LVE substance manufacturer immediately cease distribution of an exempt substance upon learning that a customer is not following all the exemption requirements?

A. If a manufacturer of an LVE substance learns that a direct or indirect customer is processing or using the exempt substance outside the terms of the exemption, that manufacturer must cease distribution to the customer unless the manufacturer: 1) notifies the customer in writing within 5 working days that the customer has failed to comply with the terms of the exemption, and 2) within 15 working days of such notification, the manufacturer receives written assurance from the customer that the customer is aware of terms and will comply. The manufacturer need not report a first offense to EPA if customer assurance is received. See 40 CFR 723.50(k).

303-13. Q. Are there any other sources of information on the terms of the LVE to share with my customers?

A. A fact sheet on the March, 1995 revisions to the LVE regulations (60 FR 16336-16351) has been developed and is available from the TSCA Information Service at 202-554-1404.

303-14. Q. How do I make the import certification under 40 CFR 707.20 if I have obtained an LVE for a substance? Is it a positive or a negative certification?

A. The certification is the same as the certification for a substance which has been the subject of PMN. It would be a positive certification assuming the import is in compliance with the LVE and

other relevant TSCA regulations.

303-15. Q. Do I need to submit a NOC for a Low Volume Exemption substance?

A. No. A NOC is not required for an LVE because the purpose of a NOC is to enable EPA to update the Inventory, and LVE substances are not put on the Inventory.

304 Polymer Exemption

304-1 Q. I thought the new Polymer Exemption was going to excuse me from notifying EPA about a qualifying polymer chemical substance. What is the point of requiring the January letter? It doesn't even have to include a substance identification - why bother requiring a letter, if it doesn't give EPA any real information? How do you know you aren't getting notified several times about the same polymer?

A. The purpose of the January letter (required by 40 CFR 723.250(f)) is to enable EPA inspectors to know where they might want to go to monitor compliance with the Polymer Exemption Rule, particularly since EPA will no longer receive notification prior to manufacture. The January letters also keep EPA informed as to the frequency of use of the Polymer Exemption.

The requirements of the new Polymer Exemption for the manufacturer are not trivial. The manufacturer needs to determine that the substance is a qualifying polymer, and needs to record that determination, along with the substance identity, amount made, etc., for ready retrieval if requested by an EPA inspector. The January letter notifies EPA that your company has made a new substance for the first time under the terms of the exemption, and you need to tie it, internally, to the records you are maintaining. Thus, if an EPA inspector comes to your plant with a copy of your notification letter, you will be able to provide that inspector with the required information about the material.

It's quite possible that EPA receives multiple notifications. Each manufacturer is required to tell EPA once about its first manufacture of a non-Inventory material.

304-2 Q. I have a polymer which I think conforms with the Polymer Exemption. When I called EPA's Prenotice Coordinators to get that confirmed, they refused to tell me whether it did or not. Why won't they answer my question?

A. This is partly a resource problem. One of the reasons the Polymer Exemption Rule was changed in 1995 to a notification-only system from a review system was to limit the resource demands on EPA in reviewing low-risk polymer substances. If EPA did such reviews, even people who had a high level of certainty that their substances were compliant would request them, and EPA would be back to putting large amounts of staff time into review of low-risk materials.

304-3. Q. Some determination/analysis has been made to demonstrate that a polymer my firm intended to make is eligible for the exemption. This evaluation is valid. However, after making it in the plant for 1 year my lab finds through plant quality assurance that the material we have been in fact making is outside the requirements of the exemption. Does a violation exist?

A. Yes, you have a violation, and you should self-report to the Office of Enforcement and Compliance Assistance (OECA). If the polymer as normally synthesized is expected to be close enough to the limits of the exemption that occasional batches might be outside the limits, either plan to conduct more frequent testing or have another strategy to ensure that you stay within the limits of the exemption.

304-4. Q. My company made a material, which is eligible for the Polymer Exemption, for R&D last year. I did not notify EPA, because I did not have intent to sell it outside the scope of R&D. Then this year we decided we could sell the material. We have some material left from the synthesis for R&D use, and we do not need to make any more of the material to meet this year's needs. The question is when to notify EPA? We didn't have non-R&D commercial intent last year, and we're not going to make it this year.

A. You may not notify us that you have made a polymer-exempt material until you first make it with *intent* for non-R&D commercial use. See 40 CFR 720.36. EPA understands that this may well be next year. You can sell the material now. This is a somewhat unusual case, and it would be prudent to make a note to the files so that you can show any inspectors who visit your plant that you thought about the issue and researched EPA position on the matter, if the question is raised.

305 LoREX Exemption

305-1. Q. Must the §5 submission form be used to make changes to a LoREX?

A. Yes. Any changes in use, exposure, release, controls, production volume (if bound at a lower level), importation only, and certain changes in site of manufacture, require the submission of a new exemption application using the §5 submission form, EPA form 7710.25. However, duplicative information need not be re-submitted. You need only submit those pages of the §5 submission form in which new information is provided in support of the modification request. The new notice must include chemical identity, manufacturer's name, a name and telephone number of a technical contact, new signed certifications, and the change. A modification must also include the identity of the previous exemption number. A box on the cover page of the form is provided to identify that the type of notice is an exemption modification. See 40 CFR 723.50(j)(5).

305-2. Q. What is the difference between a LoREX application and a PMN, if I must use the §5

submission form and provide the same information in a LoREX application as in a full PMN? Why would I want to submit a LoREX?

A. The main advantages to the submitter of a Low Release and Exposure Exemption (LoREX) application are (1) with a 30-day review period, a new substance may be marketed earlier, and (2) it allows manufacturer to self-impose exposure and release controls without developing a §5(e) Consent Order or SNUR. The LoREX eligibility requirements are listed at 40 CFR §720.50(c)(2). They are similar to requirements often imposed through a §5(e) Consent Order. Thus, a submitter, particularly one which regards its candidate chemical as likely to require a §5(e) Consent Order, can agree to restrictions and avoid a drawn-out process to receive approval. EPA gets a clearer scenario for substance use, the ability to re-review the substance if new uses (which may pose different risks) are to be initiated, and also avoids the effort of developing a §5(e) Order.

The LoREX exemption request does not require the submission of a fee or additional notice copies.

305-3. Q. Is there a volume or other use restriction for LoREX substances?

A. There are no manufacturing volume or import volume restrictions for LoREX substances. LoREX exemption holders may manufacture/import any amount of the exempted substance provided they maintain releases and exposures within the stated LoREX criteria. Regarding uses, LoREX substances may be used only for uses described in the approved exemption application. New uses will be approved by EPA if the new uses do not present an unreasonable risk to human health or the environment, but they must go through a review process. The fact that new uses will be reviewed allows EPA to limit the review necessary for the original application, and is part of EPA's ability to expedite and limit review for LoREX substances.

305-4. Q. Please elaborate on how you will determine potential for workers to really use the designated protective equipment from an exemption application. It seems EPA is more likely to grant a LoREX to larger companies with a larger industrial hygiene staff. Is this true?

A. When an applicant for any PMN exemption states in the application that designated protective equipment will be employed, EPA has accepted, and will continue to accept, that statement as true without regard to the size of the applicant company. If a given applicant has an established history of misrepresenting actual workplace conditions, or if EPA has a known basis for believing that specified exposure controls will not be used under actual workplace conditions, EPA may choose to require additional documentation to ensure that the designated equipment is used.

305-5. Q. Will the worker inhalation caveat for "adequate inhalation protection" be tied to a §5(e)

Consent Order?

A. The basis for a LoREX grant is essentially an agreement between the submitter and EPA that its conditions will be adhered to. This agreement can be enforced by EPA. To a large extent, this has the effect of a Consent Order, but no specific Order will be developed.

To provide "adequate inhalation exposure controls" submitters of LoREX exemption notices should (1) 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 EPA 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. If there is a potential for inhalation exposure, EPA generally requires respirator testing to demonstrate the adequacy of respiratory equipment so that there is "no inhalation exposure", and compliance with the general requirements regarding respiratory protection used in TSCA §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 "no inhalation exposure", as in a nonvolatile dye manufactured, processed, and used only in solution, such that inhalation of particulates will not occur.

305-6. Q. In regard to the LoREX general population inhalation provisions, what happens when one renegade molecule escapes from my plant and is breathed by a plant neighbor? The general public has been exposed! How do I demonstrate "no exposure?"

A. The general population inhalation exposure criterion was not intended to preclude manufacturers of substances with minute fugitive air emissions from utilizing the LoREX exemption. As explained in the preamble to the rule, EPA has found, based on its PMN review experience, that 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. However, no absolute criterion for fugitive emissions has been set and EPA will review each LoREX application to determine exemption eligibility in regard to emissions. Some persistent, bioaccumulative, and toxic materials may be ineligible even below a 23 kg/year level.

305-7. Q. Must a LoREX substance manufacturer immediately cease distribution of an exempt

substance upon learning that a customer is not following all the exemption requirements?

A. If a manufacturer of an LoREX substance learns that a direct or indirect customer is processing or using the exempt substance outside the terms of the exemption, the manufacturer must cease distribution to customers unless the manufacturer: 1) notifies the customer in writing within 5 working days that the customer has failed to comply with the terms of the exemption, and 2) within 15 working days of such notification, the manufacturer receives written assurance from the customer that the customer is aware of terms and will comply. The manufacturer need not report a first offence to EPA if customer assurance is received. See 40 CFR 723.50(k).

305-8. Q. Incineration does not appear to be an acceptable means of disposal unless complete decomposition is determined. Is this correct?

A. No. Incineration is permissible under the LoREX criteria if the estimated annual average concentration of the exempted substance after incineration, using the formula provided in paragraph (c)(2)(iv) of the rule, is at or below 1 microgram per cubic meter. Consult the rule preamble (60 FR 16338) for further information on the incineration criteria.

4. COMPLIANCE AND ENFORCEMENT

401 Compliance Issues

401-1. Q. I submitted a PMN for a chemical, and we have been manufacturing for several years. I have manufactured a batch in which there is an impurity as a result of a manufacturing error. My company had ordered a material from my supplier, and the supplier had, in error, supplied us with a small amount of another raw material along with the desired raw material. My synthesis then resulted in, along with approximately 97-99% of the desired (Inventory) material, an unintentionally present impurity (non-Inventory), by our analysis present at approximately 1-3% of the desired product. The impurity has no commercial value. Can we use this chemical for another purpose besides R&D or designation for disposal?

A. Such an impurity is exempt from Premanufacture Notice requirements based on 40 CFR §720.30(h)(1) since it was not produced with a separate commercial intent during the manufacture, processing, use or disposal of another chemical substance or mixture. You can sell the material containing it as your Inventory material, with an impurity present.

402 Enforcement Issues

402-1. Q. Since Polymer Exemptions are based on expected low risk, is there any discussion with the Office of Enforcement & Compliance Assistance to decrease the penalty under the gravity based penalty policy?

A. EPA has made a finding, in developing the Polymer Exemption, that polymers which qualify for the exemption have low risk. With respect to penalties associated with failure to submit Polymer Exemption notifications or PMNs, EPA's TSCA §5 Enforcement Response Policy does take into account the low risk associated with these types of chemicals. Violations of the premanufacture notice requirement by failure to submit a Polymer Exemption notice can range in penalties from $1,100 to $11,000 per day. This can be compared to other PMN violations which can range in penalties from $1,100 to $27,500. See www.epa.gov/Compliance/resources/policies/civil/tsca/tsca5erp.pdf.

OPPT has already exempted many polymers from PMN review via the PMN rule amendments which allow manufacturers of new polymers to notify EPA during January about any new exempt polymers they first made during the preceding year. Other polymers that do not qualify for this exemption are required to submit PMNs because we have not made a finding that they are not of concern to EPA, and would not be subject to the lowered penalty range discussed above. Other polymers that do not qualify for this exemption should be submitted as PMNs because EPA has not made a finding that these polymers will not present unreasonable risk. These polymers would not be

subject to the lowered penalty range discussed above.

As for other types of penalty reductions or mitigations to the gravity-based penalty of failure to submit Polymer Exemption notifications, companies can self-disclose via EPA's audit policy. If a company meets all of the audit policy's requirements (and there is no economic gain from noncompliance), the gravity-based penalty can be (depending on review of the individual case) reduced to zero.

402-2. Q. I have found that I committed a TSCA violation. EPA hasn't caught the violation and I have fixed the problem. I don't think I hurt anybody. You are telling me that I should "self-report" to your Enforcement group. Why should I? If I don't, you may never catch me, and your penalties are very high.

A. EPA encourages self-disclosures through special incentive programs. It is possible EPA will find violations through our inspection activities or through a tip. TSCA penalties are substantially higher if you don't self-report. TSCA penalties may be as high as $27,500 per violation per day. See TSCA §16 and 40 CFR Part 19. Under EPA's TSCA §5 Enforcement Response Policy, self-confession may earn a 25% discount in penalty, and timely self-confession within 30 days of discovery may reduce the penalty another 25%, for a total penalty discount of 50%. (See www.epa.gov/Compliance/resources/policies/civil/tsca/tsca5erp.pdf.)

Furthermore, violators that self-disclose and satisfy all nine conditions of EPA's "Audit Policy" – including "systematic discovery" of the violation through an environmental audit or a compliance management system – can be excused from gravity-based penalties. Gravity-based penalties are that portion of the penalty over and above the economic benefit. EPA retains its discretion to collect any economic benefit that may have been realized as a result of noncompliance. Entities that fail to meet the first condition -- systematic discovery -- can still be eligible for 75% penalty mitigation and for no recommendation for criminal violations. See "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations" (65 FR 19,618, April 11, 2000). See, also, www.epa.gov/compliance/incentives/auditing/auditpolicy.html.

403 European Community

403-1. Q. Please compare and contrast polymer regulatory exemptions in the European Union with EPA's Polymer Exemptions.

A. The EU and US notification systems for polymers differ in several important ways: in the US, there are two major ways to legally enter into commerce with a polymer that is subject to TSCA regulation- through the Polymer Exemption (described at 40 CFR §723.50) or through premanufacture

notification, resulting in an Inventory listing (if applicable, the Low Volume or Low Release, Low Exposure exemptions can be used). A polymer which fits the requirements of the Polymer Exemption (these requirements were set by EPA based on common characteristics of polymers which had been reviewed by the New Chemicals Program and found not to engender an unreasonable risk) can be entered into commerce without having been reviewed by EPA, and only a notice that a new polymer has initiated manufacture during the preceding year need be submitted. Persons who want an Inventory listing for their new polymers for commercial reasons, and those whose polymers do not fit the profile EPA has identified as not posing an unreasonable risk, need to submit premanufacture notification.

In the EU, polymers are treated essentially as though they were mixtures. Notification is not required if the polymer does not contain greater than 2% of any "new" monomer (that is, a monomer which is not on the European Inventory of Existing Commercial Substances (EINECS) of approximately 100,000 substances which were in commerce in the EU in 1981), but if the polymer contains a "new" monomer at greater than 2%, the full premarket notification requirements apply for that monomer. The effects of this policy are similar to the effects of the Polymer Exemption in the US, except that it is substantially more difficult to enter a polymer with a non-EINECS monomer onto the market in the EU. The EU notification system is described briefly below, as it relates to polymers:

Polymer-related Aspects of New Chemicals Notification System in the EU

The EU notification system was established 9/18/79 via Directive 79/831/EEC, a.k.a., the 6th Amendment to the basic Directive 67/548/EEC, and went into effect in 1981.

The EU requires submission of a notification dossier before placing a new substance on the market in quantities greater than 1 metric ton per year per manufacturer. In the case of polymers, the new substance is the non-EINECS monomer (The EU scheme is pre-market versus the U.S. scheme which is pre-manufacture.) The EU does not allow test marketing.

A “new substance” is defined as one not listed on the European Inventory of Existing Chemical Substances (EINECS). EINECS does not include any polymers, because they are treated as though they were mixtures of their component monomers.

New chemicals are not placed on EINECS; subsequent marketers of the same substance are also required to notify.

The notification dossier relates to the substance as marketed, rather than the pure substance.

The notification dossier must contain a “base set” of tests approximately equal to the OECD Minimum Pre-Marketing Data (MPD) Set. At 10 tons/year, the authorities may require further

testing, and at 100 and 1,000 tons/year additional testing packages are required (known as the "step system").

The notifier can market the substance anywhere in the EU 45 days after submitting the notification dossier to the Member State where the substance is manufactured or imported. That lead Member State circulates a summary dossier to the other Member States, who may request the lead authority to make changes or ask the notifier for further information.

The EU classification system generally only accepts testing on the substance itself rather than reliance on Structure Activity Relationship (SAR) analysis. The EU classification system is based on specific objective criteria (e.g., "toxic" = rat oral LD50 between X and Y mg/kg body weight) which determines how a substance will be classified and labeled.

Notable Differences Between EU System and New Chemicals Notification System in the U.S.

The U.S. notification system requires pre-manufacture notification, which is at an earlier point in the development of a chemical than the EU pre-market notification system.

The PMN form itself requires all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure. EPA also requires that the following information be submitted with the PMN: all existing health and environmental data in the possession of the submitter, parent company, or affiliates, and a description of any existing data known to or reasonably ascertainable by the submitter. However, no minimum set of test data is required: §5 of TSCA does not require chemical companies to test their new chemical substances for potential toxic effects. Therefore, EPA's review (and §5(e) regulatory actions) are often conducted in the absence of such data and relies on SAR.

A new chemical is eligible for addition to the TSCA Inventory after the PMN review has been completed. To add a substance to the TSCA Inventory, the company that submitted the PMN must provide a Notice of Commencement of Manufacture or Import ("NOC") to EPA within 30 days of the date the substance is manufactured or imported for nonexempt commercial purposes. Once a substance is listed on the TSCA Inventory, it is considered an existing chemical. Currently, about 45% of PMN substances commence manufacture.

404 Canada

404-1. Q. Have the polymer eligibility criteria been discussed with Environment Canada (EC)? If yes, does EC agree so that someday we can get North American harmonization?

A. A general description of the Canada program on new chemical substances can be found at www.ec.gc.ca/substances/nsb/eng/index_e.htm. There are several major features of the Canada program which are developing towards harmony with that of USEPA; most notably Canada's process for a substance moving from the Non-Domestic Substances List ("NDSL"), based on Inventory status in USA, to Domestic Substances List ("DSL") status, based in part on experience gained elsewhere.