Chapter 3

POLLUTION PREVENTION AND PREMANUFACTURE NOTIFICATIONS

3.1 Introduction: Pollution Prevention

The preceding chapters describe the evolution of EPA's PMN Program and the approaches that EPA uses to characterize and understand the risks new chemical substances may pose to human health and the environment. Characterized risks are then balanced against the expected economic and societal benefits of a new chemical. TSCA empowers EPA to regulate risks associated with the manufacture, use, and disposal of a new chemical substance. Traditionally, however, the focus of the PMN Program has been on the toxicity of a new chemical substance itself and the risks associated with its use and disposal, with less emphasis on the risks from the pollution created as a result of the manufacture or use of the new substance.

Although TSCA and the other environmental statutes have had a positive impact in protecting human health and the environment, the United States still produces millions of tons of pollution annually and spends tens of billions of dollars per year controlling this pollution. EPA realizes that there may still be significant opportunities for industry to reduce or prevent pollution at the source through cost-effective changes in production, operation, use of raw materials, or chemical design. Such changes have the potential to offer industry substantial savings in reduced costs for raw material, pollution control, and liability as well as to help protect the environment and reduce risks to the environment and human health. In addition, EPA realizes that the costs of complying with regulations imposed under existing statutes are becoming prohibitive for the chemical industry and the consuming public. A more preventative way of solving the problem of pollution is needed.

In 1990, the EPA embarked on a new approach, termed "pollution prevention," to reduce the releases of toxic wastes into the environment through eliminating or minimizing creation of such wastes. At approximately the same time, the Pollution Prevention Act (PPA) was passed by Congress (PPA 1990). This act articulates the interest of Congress to have both the EPA and industry apply pollution prevention principles to their efforts to reduce toxic waste generation and subsequent discharge. The underlying philosophy of pollution prevention is fundamentally simple: the creation of pollution must be avoided whenever and wherever possible. The pollution prevention paradigm is very much like the preventative medicine paradigm. The goal of preventative medicine is to prevent illnesses from occurring rather than to find cures or treatments after illnesses have occurred, whereas the goal of pollution prevention is to prevent the creation of pollution, so as not to have to deal with the health and ecological damage it causes. The basic pollution prevention strategy, therefore, is to avoid generating waste in the first place.

Any practice that reduces the amount of any hazardous substance entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling (except in-process recycling), treatment or disposal is considered pollution prevention.

The PPA identifies several general approaches to preventing pollution and establishes a pollution prevention hierarchy as a national policy. The approaches, starting with the most important, are:

- pollution should be ***prevented at the source*** wherever feasible;

- pollution that cannot be prevented at the source should be ***reduced at the source*** wherever feasible;

- pollution that cannot be prevented or reduced at the source should be ***recycled in an environmentally safe manner*** wherever feasible;

- pollution that cannot be recycled should be ***treated in an environmentally safe manner*** whenever feasible;

- ***disposal or other release into the environment should be employed only as a last resort*** and should be conducted in an environmentally safe manner.

Pollution prevention has become the preferred method in the hierarchy of environmental practices and the foremost priority of the EPA (Browner 1993).

Although recycling, treatment, and disposal are clearly important components of pollution control, they are *not* included in the definition of pollution prevention because they do not represent preventative approaches to controlling pollution.

The PPA also provides the framework for creative thought and collaborations on the part of the chemical industry and the EPA to reduce pollution and exposure to toxic substances. Newer EPA programs (e.g., OPPT's Design for the Environment Program, Green Chemistry Program, and Pollution Prevention Division) devoted to pollution prevention have evolved in recent years, and many of EPA's existing programs, including the PMN Program (see below), have been or are being analyzed to determine how pollution prevention can be incorporated. In addition, many collaborations and initiatives between EPA, the chemical industry, and academia are identifying and implementing new ways of preventing pollution.

EPA's Design for the Environment (DfE) Program, for example, is a voluntary initiative that forges partnerships with stakeholder groups in an effort to incorporate environmental considerations into the decision-making of the chemical industry and to build incentives for continuous environmental improvement. EPA's 33/50 Program is another voluntary program under which EPA and the chemical industry collaborate to reduce the environmental releases of certain substances on the Toxics Release Inventory.[19]

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19. The Toxics Release (TRI) Inventory is a publicly-available compilation of chemical releases updated annually under the authority of Section 313 of the Emergency Planning and Community Right to Know Act (EPCRA 1986). More information on TRI is available from TRI User Support (phone: 202-260-1531).

These and other EPA initiatives aimed at pollution prevention have been very successful in pollution prevention and in establishing collaborations between the chemical industry, EPA, other federal agencies, and academic institutions.

A very recent EPA initiative is Green Chemistry. Green Chemistry strives to encourage the development of safer commercial substances and non-polluting commercial syntheses. Traditionally, during the commercial development of chemical substances, chemists concentrate on those chemicals that can be synthesized in the highest yield at the lowest direct cost to satisfy particular intended uses. Generally, chemists give little or no consideration to the inherent toxicity or hazardous nature of a desired chemical substance, or to alternative syntheses that neither use toxic reagents or solvents, nor produce toxic byproducts. This traditional approach to chemical design creates pollution and is clearly incompatible with achieving the pollution prevention needs of society and the goals of the Pollution Prevention Act.

EPA's Green Chemistry initiative represents a more rational approach to the design of chemicals and syntheses. Green Chemistry is based on the premise that the most desirable and efficient way of preventing pollution is to: 1) intentionally design chemicals such that they will have minimal or no toxicity, while maintaining their commercial efficacy with respect to intended use; and, 2) intentionally design synthetic pathways such that they neither utilize toxic reagents or solvents, nor produce toxic byproducts. Through the Green Chemistry initiative, the federal government, universities, and the chemical industry are forming collegial relationships (Anastas and Farris 1994; Anastas and Williamson 1996; DeVito and Garrett 1996), and the Agency hopes that these relationships will lead to the design and commercialization of less toxic chemical substances and less polluting syntheses. In fact, President Clinton has made Green Chemistry one of the highest priorities of the EPA (Clinton 1995).

3.2 Pollution Prevention Initiatives within EPA's PMN Program

Because the PMN Program characterizes the risks new chemical substances may pose to human health and the environment before they enter commerce and takes necessary action to prevent or control such risks, the PMN Program may be considered a pollution prevention program. In addition to traditional PMN review, however, the PMN Program offers other approaches to preventing pollution. These are not regulatory, but rather voluntary or collaborative on the part of EPA and the chemical industry. This section discusses two relatively recent pollution prevention initiatives that have been incorporated into the review of PMNs.

3.2.1 Optional Pollution Prevention Information (page 11 of the PMN form)

In 1991 the PMN form was modified to include a section containing "optional pollution prevention information" (page 11 of the PMN form). This was the first direct indication that pollution prevention had become an important component of PMN review. On this page, the submitter may provide information regarding its efforts to reduce or minimize pollution associated

with activities surrounding manufacturing, processing, use, and disposal of the PMN substance. PMN submitters should describe net benefits such as: 1) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment; 2) a reduction in the volume of the new substance manufactured compared to a competitive existing substance, if the new and existing substances are equally toxic but more of the existing substance is required for commercial use; 3) elimination or reduction in the amount of waste materials through source prevention, source reduction, recycling, or other means; 4) low toxicity of the PMN substance; and 5) a reduction in human exposure to the PMN substance and/or a reduction in environmental release.

It is up to the discretion of the submitter to provide EPA with this information. All pollution prevention information provided in this section of the PMN is considered by EPA during PMN review, and EPA strongly encourages PMN submitters to incorporate such information in their PMNs as it helps the Agency to balance the benefits of a PMN substance against any risks it poses. This information is, of course, considered confidential by EPA if so indicated by the submitter.

Most current PMN submissions contain some optional pollution prevention information. However, most of the information currently provided by submitters deals with the benefits of the PMN substance with respect to its intended use, and *little* information is provided with respect to pollution prevention in the manufacture of the substance, even when such benefits exist. PMN submitters probably know (or should at least be able to discern) whether the manufacturing process for their PMN substance offers pollution prevention advantages over an alternative process used for a similar substance. Although ICB chemists are sometimes able to identify the advantages of such syntheses during routine PMN review, PMN submitters should compare their manufacturing processes to known alternative processes for making the same substance (or similar substances) and indicate on page 11 of the PMN form any advantages that their processes may have.

3.2.2 Synthetic Method Assessment for Reduction Techniques (SMART) Review

Simultaneous with the traditional chemistry review of PMN substances (discussed in Chapter 1), ICB chemists now perform a pollution prevention review known as the Synthetic Method Assessment for Reduction Techniques (SMART) Review for PMN substances (Farris et al. 1994). The SMART review is a non-regulatory review designed to identify PMN substances (or related substances) for which individual companies may be able to prevent pollution in an economically feasible manner. In this review ICB chemists attempt to identify potential pollution prevention opportunities based on information in the PMN and reference sources. Pollution prevention opportunities may include: using an alternative reaction pathway that is less polluting; switching to a less toxic solvent; recycling of solvents or unreacted starting reagents; or, recovery of toxic byproducts, unreacted starting

reagents, or PMN substance lost to waste streams.

The SMART review process is described briefly here; a detailed description is also available (Farris et al. 1994). The SMART review is performed as follows. During the regular chemistry review of a PMN, the chemist will also screen the PMN to determine if the submission meets the criteria for a SMART review. These criteria include: the notice must be a non-exempt Premanufacture Notice; the PMN substance must be a Class 1 substance (see Appendix, section A.3.3); the third year production volume must be greater than 10,000 kg/year; and manufacture of the PMN substance must take place within the United States. These criteria are merely guidelines; a PMN submission that does not meet these criteria may still undergo a SMART review. For example, PMN submissions for which pollution prevention opportunities are readily apparent will most likely undergo a SMART review in any case.

Each PMN submission selected for SMART review is first subjected to a preliminary assessment. The objective of the preliminary assessment is to determine the source, identity, and quantity of each waste component associated with the manufacture of the PMN substance. Sufficient information needs to be provided in PMN submissions in order for a preliminary review to be completed (much of this information is required). General information that is necessary for preliminary reviews includes: chemical name; chemical structure; process description; identity of impurities; and production volume.

Chemists also assess the types of wastes (i.e., extremely toxic, hazardous, potentially hazardous, or innocuous) produced by (or during) the manufacture or processing of the PMN substance, as well as the sources and quantities of such wastes (Farris et al. 1994). The classification of waste in terms of relative toxicity is based upon several Agency lists. ICB chemists estimate the percentages of waste substances relative to the production volume of the PMN substance. These percentages are compared to trigger levels (the quantity of a given type of waste relative to the quantity of the PMN substance produced) established by ICB chemists, to ascertain whether a particular waste component from a given manufacturing process is present in an excessive quantity. Different sets of trigger levels are used for hazardous wastes and for potentially hazardous wastes.

The outcome of the preliminary SMART assessment determines whether a detailed assessment is warranted. If the quantities of the hazardous wastes produced from the manufacture of a PMN substance do not exceed their trigger levels, ICB chemists do no further assessment. In cases where the hazardous wastes exceed their trigger levels, ICB chemists perform a more detailed assessment. The main purpose of the detailed assessment is to determine the fate of hazardous wastes. In cases where hazardous wastes are treated or will enter the environment from waste streams, stack emissions, or other sources, ICB chemists try to identify opportunities for preventing or reducing these wastes. These opportunities may include: (1) using a less toxic solvent (if the hazardous waste is a solvent used in the manufacture of a PMN substance); (2) using an alternative synthesis that utilizes

fewer or no toxic reagents or solvents, or does not generate toxic byproducts or wastes; and, (3) in cases where these two opportunities are not feasible, recycling of the waste materials. If as a result of the detailed assessment ICB chemists identify possible pollution prevention opportunities, the ICB chemist performing the assessment will inform the PMN submitter of the findings (either orally or in writing).

The purpose of such communication is to solicit the submitter's voluntary consideration to study and perhaps incorporate the pollution prevention opportunities identified by ICB. To date, several PMN submitters have responded that they will attempt to incorporate Agency suggestions into their manufacturing processes, and will inform the Agency of their success or failure. In some instances, PMN submitters have replied that the pollution prevention opportunities identified by ICB chemists may not be feasible for reasons that are apparent only to the submitter. For example, an alternative synthesis identified by an ICB chemist may already have been studied by the submitter prior to PMN submission and found to be unsuccessful for commercial synthesis of the PMN substance.

Feedback from PMN submitters is very important to ICB chemists, because PMN submitters are generally in a better position to evaluate the practicality of incorporating changes into their manufacturing processes than are ICB chemists. The Agency appreciates the additional insight from such feedback that may not be available from PMNs or other sources. Such non-regulatory communication stimulates creative collaboration between PMN submitters and the Agency in identifying feasible opportunities for preventing pollution.

3.3 Considerations in Implementing Pollution Prevention Practices Prior to Submission of PMN Substances

Pollution prevention is an overarching goal of the Agency, particularly OPPT. This chapter has briefly described two EPA pollution prevention initiatives (the Optional Pollution Prevention section of the PMN form, and the SMART review) that were designed specifically for incorporating pollution prevention into PMN review. EPA is currently pursuing additional initiatives such as: funding universities to develop new, environmentally-benign synthetic strategies for the manufacture of commercial substances; funding universities to develop synthesis software that can assist in the identification of environmentally-benign syntheses; and the Green Chemistry Challenge, which encourages, identifies, and awards innovative chemistry achievements in preventing pollution. Although these additional initiatives are not formally part of PMN review, the Agency expects they will eventually influence PMN submissions. Information on these broader pollution prevention projects may be obtained from the TSCA Assistance Information Service and the Pollution Prevention Information Clearinghouse. (See Table A-1 for addresses and phone numbers.)

The EPA realizes that PMN submitters are faced with many challenges in developing substances that must not only satisfy customer needs and remain competitive with other products, but must also comply with existing regulations.

Some PMN submitters may view EPA's recent emphasis on pollution prevention as an additional burden to product development. It is not the intent of EPA to stifle or impede the creativity of chemical producers in the development of chemical products by encouraging pollution prevention practices. In fact, the pollution prevention initiatives described in the preceding paragraphs are intended to help PMN submitters design products that are useful and safe for human health and the environment, and are manufactured safely. As safer substances and environmentally friendly syntheses replace existing toxic chemical substances and polluting syntheses, respectively, fewer regulations will be needed.

In recent years the EPA has noticed that PMN submitters are beginning to incorporate pollution prevention practices into the design and synthesis of new chemical substances. Specific examples cannot be provided here due to the confidentially of the submissions. Generally, some PMN submitters are using available toxicity data on related existing chemicals as a basis for designing new chemicals that are less toxic but equally efficacious for commercial use. In such instances PMN submitters often obtain data on the structure-activity (toxicity) relationships and biochemical (mechanistic) bases of toxicity of existing related substances, and from these data infer structural modifications that reduce toxicity without affecting use efficacy (see Chapter 2 in DeVito and Garrett 1996). In addition, some PMN submitters are beginning to develop and use syntheses that require fewer toxic reagents or solvents, or do not produce toxic byproducts. More detailed discussions of approaches that can be used for the design of safer chemicals and the design of environmentally friendly syntheses are available (Devito and Garrett 1996; Anastas and Farris 1994; Anastas and Williamson 1996).

PMN submitters may find the following considerations helpful in implementing pollution practices prior to submission of PMN substances to EPA.

- ***Consider any toxicity or environmental hazard potential of the chemical product.*** Decide if the chemical product must be made, or if an analogous substance (or use substitute) that is known or likely to have less hazard potential can be used instead. Gather any available toxicity data on related substances and, if possible, use the data to design a new substance that is less toxic.

- ***Consider potential savings by thinking of environmentally safer products or reaction pathways during product development.*** Keep in mind that regulations generally have become stricter over time and may become even more strict in the future. For example, certain methods of disposal and treatment of hazardous wastes may one day be outlawed or become prohibitively costly. On-site disposal or treatment may not be practical or economically feasible. It is best to consider the long-term cost of making a PMN substance.

- ***Rethink your approach to organic chemistry and the synthetic reactions traditionally used to construct chemical substances.*** Do not consider reaction yield only; put more emphasis on alternative, environmentally-friendly reaction pathways. When selecting a reaction, consider the following:

  - what reactions can be used to make the PMN substance ?

  - why has a particular reaction been selected ?

  - is it environmentally friendly ?

  - is the reaction cost-effective in the long run ?

  - how feasible is commercial scale-up of the reaction ?

  - what will disposal of the PMN substance and associated substances cost ?

  - what are the liability costs of waste treatment on-site ?

  - what are the liability costs from potential release of the PMN substance and associated substances ?

  - what are the costs of storing hazardous wastes on site ?

These considerations help to establish a framework that can be used to incorporate pollution prevention strategies in the design and synthesis of new chemical substances, and ultimately prevent many of the environmental and human health problems that have occurred in the past as a result of the manufacture and use of chemicals.

References for Chapter 3

Anastas PT, Farris CA. 1994. Benign by Design. Alternative Synthetic Design for Pollution Prevention. ACS Symposium Series 577, American Chemical Society, Washington, DC, 1994.

Anastas PT, Williamson TC. 1996. Green Chemistry: Designing Chemical Syntheses for the Environment. ACS Symposium Series 626, American Chemical Society, Washington, DC, 1996.

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PPA. 1990. The Pollution Prevention Act, 42 U.S.C. §§ 13101-13109 (1990).

List of Selected Readings for Chapter 3

For Additional Information on Pollution Prevention and EPA Pollution Prevention Initiatives see:

Chemical and Engineering News, September 5, 1994 issue.

Breen JJ, Dellarco M. 1992. Pollution Prevention: The New Environmental Ethic. In: Pollution Prevention in Industrial Processes; the Role of Process Analytic Chemistry. Breen JJ, Dellarco MJ, eds. ACS Symposium Series 508, American Chemical Society, Washington, DC, 1992, pp 2-12.

Ford AM, Kimerle RA, Werner AF, Beaver ER, Keffer CW. 1992. Industrial Approaches to Pollution Prevention. In: Pollution Prevention in Industrial Processes; the Role of Process Analytic Chemistry. Breen JJ, Dellarco MJ, eds. ACS Symposium Series 508, American Chemical Society, Washington, DC, 1992, pp 13-20.