

US EPA ARCHIVE DOCUMENT

**KODAK POLLUTION PREVENTION FRAMEWORK  
FINAL PROJECT AGREEMENT**

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**Draft Document. For discussion purposes only.**

**July 30, 2000**

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## **I. Introduction**

### **A. What is Project XL**

Project XL, which stands for “eXcellence and Leadership,” is a national pilot program that allows state and local governments, business and federal facilities to develop with EPA innovative strategies to test better or more cost-effective ways of achieving environmental and public health protection. Project XL provides a vehicle for EPA to consider, after careful evaluation of the project, replacing or modifying regulatory requirements, policies or procedures if it is determined that the XL project will produce superior environmental benefits and promote accountability to the public. (See: 60 FR 27282)

### **B. Project Description and Purpose**

The Eastman Kodak Company (Kodak) in partnership with the United States Environmental Protection Agency (EPA) is entering into this Project XL Final Project Agreement (FPA) to pilot the application of and the dissemination of information about the Pollution Prevention Framework (P2 Framework) developed by the EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS).

In the context of this XL Project, Kodak will apply the P2 Framework early in its product development cycle to help identify and develop products and processes that can be sustained both environmentally and economically. Kodak’s application of the P2 Framework to its operations will help develop environmentally preferable products, while saving considerable time and money. Kodak believes many other companies can also develop environmentally preferable products by applying OPPT’s P2 Framework, especially at the Research and Development stage of product development. As a part of their participation in this XL project, Kodak will receive administrative flexibility in the form of a shortened pre-manufacture review period (from 90 days to 45) for those new chemicals developed under the P2 Framework and submitted to the Agency for approval. (For additional information see Section IV. B.)

### **C. Description of Facility and Geographic Area**

Kodak is the world’s leader in imaging, and a manufacturer of imaging systems (cameras, scanners) and media (film, photographic paper, photographic chemicals). Kodak employs 46,300 people in the United States and has manufacturing facilities in Rochester, NY, Windsor, CO, Peabody, MA, and White City, OR. These facilities are situated in both urban and suburban environments. As a leader in new technology development in the imaging industry, Kodak registers many new chemical substances with the EPA each year. Once approved, these substances may be used in one or several of the company’s facilities, and it is these substances that allow the company to develop and improve the products it sells.

The Health and Environment Laboratories (HAEL) is a central/corporate facility which evaluates materials and equipment that are involved in manufacturing processes or are being considered for use in new products. Approximately 128 people are employed in HAEI, which is located at 1100 Ridgeway Avenue, Rochester, NY. The facility is located on the edge of a large industrial park (Kodak Park). Functions carried out by HAEI include toxicology, environmental, and safety testing; risk assessment; risk communication; and risk management. HAEI has been in continuous operation since 1936 making it one of the first facilities of its kind in the USA. The surrounding buildings are commercial enterprises and there are no sensitive natural resource areas in the general area of the HAEI facility. The staff participates in local outreach activities including environmental awareness and cooperative education programs with local high schools and is represented on the advisory board of the outreach program sponsored by the NIEHS-funded environmental sciences program at the University of Rochester. In addition, an active neighborhood information center is in place at the Kodak Park site.

Kodak's environmental management system has been registered as ISO 14001 compliant, and the system places significant emphasis on the benefits of pollution prevention in new product design. This environmental management system has generated considerable environmental benefits to the company and its stakeholders, and these benefits have resulted in several awards for environmental performance, including the World Environment Center 1999 Gold Medal. Kodak's worldwide manufacturing sites are either registered to ISO 14001, or are in the process of being registered.

The development of environmentally preferable products is consistent with Kodak's vision of producing innovative new products for imaging while protecting the quality of the environment, and it flows from considerable previous interaction with the EPA in a partnership to evaluate and publicize the Pollution Prevention (P2) Assessment Framework.

#### **D. Purpose of the Agreement**

This Final Project Agreement ("FPA" or "the Agreement") is a joint statement of the plans, intentions and commitments of EPA and Kodak to carry out this pilot project approved for implementation at the Rochester, NY, Kodak Health and Environment Laboratories (HAEL). This project will be part of EPA's Project XL program to develop innovative approaches to environmental protection. Although the New York State Department of Environmental Conservation (NYSDEC) will participate as a project stakeholder, the project does not require changes in any state regulations, policies and procedures; thus NYSDEC will not be a signatory to this agreement.

This Agreement does not create legal rights or obligations and is not an enforceable contract or a regulatory action such as a permit or a rule. This applies to both the substantive and the procedural provisions of this Agreement. While the parties to the Agreement fully intend to follow these procedures, they are not legally obligated to do so. Neither this Agreement nor any discussions among the parties about this Agreement gives any of the parties a right to sue for any alleged failure to implement its terms, either to compel implementation or to recover damages.

All parties to this Agreement will strive for a high level of cooperation, communication and coordination to assure successful implementation of the Agreement and the Project. This FPA and associated project materials are available to the public on the Project XL Web Site at <http://www.epa.gov/ProjectXL>.

## **E. List of the Parties that Will Sign the Agreement**

This Final Project Agreement is entered into by the Assistant Administrator of the U.S. Environmental Protection Agency Office of Prevention, Pesticides and Toxic Substances and the Director, Health Safety and Environment and Vice President of Eastman Kodak Company. It will guide the working relationship of both parties in fulfilling the promise of the Kodak Pollution Prevention Framework Project XL.

## **F. List of Project Contacts**

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## **II. DETAILED DESCRIPTION OF THE PROJECT**

### **A. Summary of the Project**

The EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed a set of computerized risk screening tools, which have the potential to significantly advance EPA's pollution prevention objectives by allowing companies to calculate or estimate important risk-related properties based on an analysis of chemical structure. OPPTS uses these tools in the P2 framework to evaluate new chemicals when test data are lacking. OPPTS is also making the tools in the P2 framework available to industry, and demonstrating how they can help design safer chemicals, reduce waste generation, and identify other P2 opportunities. Kodak will pilot the application of and the dissemination of information about the P2 Framework under this Project XL Agreement, as described below.

### **B. Description of Specific Elements**

#### **What is the P2 Framework?**



The Agency encourages chemical manufacturers to incorporate health and environmental issues into product decision making during the development of new chemical substances. EPA has several ongoing initiatives intended to help stakeholders better assess risk issues during the early stages of chemical development efforts. Examples include the Design for Environment Program, the Green Chemistry Program, and the Pollution Prevention Framework (P2 Framework), among other programs. Of specific relevance to the Kodak XL Final Project Agreement is the P2 Framework as utilized in the development of safer new chemicals submitted as Premanufacture Notices (PMNs) under section 5 of the Toxic Substances Control Act (TSCA).

The P2 Framework (see Appendix A) is a set of computer models that predict risk-related properties of chemicals using structure activity relationships (SARs) and standard (default) scenarios. These models have been developed over a 20-year period by EPA's Office of Pollution Prevention and Toxics to screen new chemicals in the absence of data. Annually, EPA evaluates over 2,000 new chemicals submitted under section 5 of TSCA. TSCA requires that EPA evaluate the chemicals within 90 days, however the law does not require that the submitter conduct laboratory tests to evaluate potential hazard and risk of the chemicals. Operating under this time limitation, and often a lack of data, EPA developed methods to quickly screen chemicals in the absence of data.

The P2 Framework Models listed in Appendix A, capture the expertise of multiple EPA scientists, grantees, support contractors, as well as others in the scientific community, working for over 20 years screening chemicals in the absence of data. The P2 Framework Project presents these 18 models to industry with the hope that the models will be useful in identifying potential problem chemicals and processes early in the research and development process. The table also provides information regarding the availability of the models.

The P2 Framework, as currently constructed, does not address all biological endpoints. It is a screening-level methodology that is of most value when chemical-specific data are lacking.

### **Kodak's Use of the P2 Framework**

By using the P2 Framework early-on in product development, Kodak expects to submit pre-manufacture notices (PMNs) to EPA on new chemicals that will foster the development of new, greener products and emphasize P2 through source reduction. Kodak would then receive Project XL flexibility to manufacture PMN chemicals in 45 days as opposed to the current 90 day review period. The 45-day period would only be available for chemicals for which EPA has no further concerns. These "low-risk drops" conclude Agency involvement at the initial risk management meeting, usually coinciding with day 20-25 of the 90 day review period. (See section IV. B.3 for a more complete discussion of EPA's PMN review process, including EPA's process leading to identification of "low-risk drops.")

In return for a shortened PMN review period of 45 days for "low-risk" chemicals, Kodak will not only institute full usage of the P2 Framework at its facilities, but will also conduct a series of innovative actions to help demonstrate to other stakeholders how the P2 Framework can help to develop products that are sustainable both environmentally and economically. Kodak will complete three separate and independent initiatives beyond its own use of the P2 Framework as described



below. Each of these three initiatives is designed to make other industrial stakeholders aware of the source reduction, pollution prevention and economic benefits that flow from use of the P2 framework.

1. *Addressing the Scientific Community:* The first initiative will consist of outreach to the scientific community within the chemical industry, demonstrating how use of the P2 framework can generate risk related information previously unavailable to stakeholders - information that helps compare risk profiles of product alternatives leading to P2 outcomes. Kodak intends to act as a champion for the P2 Framework and advocate use of the P2 Framework among its industry colleagues.
2. *Addressing the Business Community:* The second initiative will address the business community within the chemical industry. Kodak will collaborate with EPA on a rigorous environmental cost accounting study to quantify the business and economic benefits gained from using the P2 Framework. The study would help those in the photochemical and other chemical industry sectors understand how they could benefit through reduced product development costs, reduced liability and reduced time to market as a result of the P2 Framework.
3. *Addressing the Management Community:* The third initiative will communicate the benefits of applying the P2 Framework to chemical development to the highest levels of management within selected large companies. Kodak will commission a management study of P2 programs in selected large companies. The study will result in a report entitled "Pollution Prevention and Risk Reduction: Case Studies of Best Practice Companies." The study will highlight state-of-the-art P2 initiatives within leading firms, including the business and risk reduction benefits of the P2 Framework.

EPA and Kodak believe that implementation of the P2 Framework across the industrial sector will change business practices, resulting in a greater focus on pollution prevention. The P2 Framework allows companies to improve the environmental performance (i.e., lower health hazard, lower environmental hazard, lower exposure potential) of products, reduce costs, decrease potential liability, and improve market share, resulting in a significant competitive advantage. Companies can improve the environmental performance of their products by using the P2 Framework to pre-screen their product development options.

### III. HOW THE PROJECT WILL MEET THE PROJECT XL ACCEPTANCE CRITERIA

The championing of the P2 Framework by Kodak through this Project XL Agreement will foster the development of new, greener product development processes at Kodak as well as in other chemical using and producing companies. As a result, manufacturing processes and waste handling processes will operate at higher levels of environmental performance in the Pollution Prevention hierarchy (source reduction vs. reuse, recycling, treatment or disposal).

Each year approximately 2000 notifications (PMN's and exemption notices) for new chemicals are received by EPA in the United States under the Toxics Substances Control Act (TSCA.) These chemicals are, in general, developed to optimize product performance and often very little health or environmental data exist because they are new substances. Many of these substances must be evaluated by EPA in 90 days (PMN submissions), as required by TSCA. Chemicals selected for commercialization based only on performance features will have varying degrees of environmental risk.

The P2 Framework provides a mechanism to promote data analysis beyond what is currently available by incorporating the following parameters (among others) into chemical development: structure activity relationships, a cancer expert system, property estimation techniques, and exposure assessment methodologies. The P2 Framework then generates important risk related parameters of chemicals based on an analysis of chemical structure. The Framework is quick and easy to use, is relatively inexpensive, and can be applied before a chemical is even synthesized. The use of an inexpensive system of assessing risk early in the product development process, where environmental data are very limited, allows health and environmental performance to be factored into the product design.

This XL Project seeks to demonstrate the source reduction and P2 benefits of moving the chemical evaluation process upstream in the product development process to a point where there are frequently multiple materials which could eventually become final products. In moving upstream, the information supplied by using the P2 Framework can be used to differentiate among otherwise equivalent chemical alternatives based on risk-related considerations. Comparing alternatives based on risk allows companies to select less hazardous chemicals for use in final products and can be used to identify and avoid the generation of hazardous waste. In addition, the P2 Framework can be used at other times when companies must make chemical decisions, but lack health and safety data on product alternatives. By sharing expertise and success stories of using the P2 Assessment Framework, Kodak would promote "green chemical" selection in both its commercialization efforts and those of other companies. In using the P2 Framework as recommended by the XL Project, the P2 Framework becomes a tool for risk reduction programs, source reduction programs, and other pollution prevention initiatives.

#### **A. Anticipated Superior Environmental Performance**

Kodak's XL proposal includes 4 components relating to superior environmental performance:

- 1) Application of the P2 Framework to screen new chemicals to be submitted for PMN review.
- 2) Communicating with, reaching out to, and working with scientific and technical staff from a variety of chemical companies and stakeholders, to support their implementation of the P2 Framework
- 3) Reaching out to the business audience to promote the use of the P2 Framework as a best business practice, and
- 4) Reaching out to the senior managers of industry counterparts to assist them in understanding what management structures can facilitate the implementation of the P2 Framework in their companies.

Each of these activities represents a voluntary commitment to go above and beyond the environmental performance criteria specified by the current regulatory system; by pursuing all four areas, Kodak's activities are anticipated to provide a high level of SEP.

1) Application of the P2 Framework in Kodak's PMN development efforts

Kodak's XL Proposal deals with new and innovative ways of improving new chemical development practices. Each year EPA receives 2,000 or more new chemical notifications, the Agency has received over 35,000 PMN notifications since Congress passed the Toxic Substances Control Act (TSCA) in 1976.

The Agency's history and experience in evaluating New Chemical notifications can serve as a baseline for determining whether Kodak's XL proposal represents Superior Environmental Performance. TSCA requires companies interested in manufacturing or importing new chemical substances to give EPA 90 days notice prior to commencing manufacture or importation of new chemical substances. While companies are required to submit health and safety data that may be available on the new chemical, TSCA does not require testing or development of data or other risk-related information as a prerequisite to premanufacture notification. As a result, the majority of Premanufacture Notifications (PMNs) lack data necessary to understand the potential risk posed by new chemicals. For example, even though the use and disposal of some new chemicals may result in exposure of the PMN chemical to fish or other components of the aquatic environment, only a small fraction (less than 5%) of PMN notices include data or information relating to hazard and/or risk of chemicals to the aquatic environment. The majority of PMN submissions lack data or information on risk-related issues, such as environmental persistence, the potential to bioconcentrate in the environment, human hazard issues and exposure information. If a company has several chemicals from which to choose, but lacks risk-related data on the available alternatives, it may choose a particular chemical to commercialize, without understanding its potential risk impacts.

In this XL Final Project Agreement Kodak is committing to using the P2 Framework in its new chemical development efforts and to submit to the Agency, as appropriate, the results of P2 Framework analysis on chemicals that are the subject of Kodak's PMNs. Kodak has had experience with the use and interpretation of P2 Framework methodologies, including practical experience in using the P2 Framework to differentiate among chemicals based on risk and to identify and selectively commercialize environmentally preferable products and processes. Kodak has submitted reports/information attesting to its experience with the P2 Framework, portions of which are excerpted below:

"The methodologies (P2 Framework) supplied by the Agency allowed those chemicals with the greatest potential hazard to be eliminated from further consideration at a point in time when the economic impact of the decision was minimal"

"...these methods, if applied early enough in a chemical or product development cycle, can have an immediate and positive impact on programs to reduce the potential hazards from chemical manufacturing operations"

The P2 Framework “enabled us to reformulate five photochemicals under development, and, in doing so, to improve their environmental performance significantly”.

Kodak’s commitment to use and apply the P2 Framework will result in development of environmentally preferable products. This effort clearly demonstrates Superior Environmental Performance when viewed against a baseline current industry practice, where little or no information regarding risk is considered in new product development.

2) Communicating with, reaching out to, and working with scientific and technical staff from a variety of chemical companies and stakeholders, to support their implementation of the P2 Framework,

Kodak’s use of the P2 Framework has resulted in pollution prevention (P2) outcomes and the development and commercialization of environmentally preferable products and processes.

Kodak’s second commitment under XL will make others in the industry aware of the P2 and risk reduction benefits of the P2 Framework. The purpose of this outreach is to demonstrate to chemical companies how the P2 Framework can help scientists gain access to chemical-specific risk related data and other previously unavailable information. Kodak will demonstrate how this new data, generated by applying the P2 Framework, helps companies differentiate among otherwise equivalent chemical choices, based on human health and environmental hazard/risk. To accomplish this goal, Kodak will conduct scientist-to-scientist dialogues, highlighting how the P2 Framework can identify environmentally sustainable products, especially at the R&D stage, when cost of substitution is minimal.

Kodak will make presentations regarding the P2 and risk reduction benefits of the P2 Framework at scientific meetings, publish papers in the scientific literature and take advantage of other scientific and technical venues. Kodak’s efforts are intended to increase awareness among various industry sectors regarding pollution prevention and risk reduction benefits associated with application of the P2 Framework in product and process development, and existing product reformulation efforts. Kodak efforts will make stakeholders aware of the P2 Framework and will encourage companies to apply the P2 Framework in the identification of environmentally preferable products and processes.

Kodak’s efforts to reach out to others in the scientific community regarding the P2 and risk reduction benefits of the P2 Framework are groundbreaking and innovative concepts. Kodak’s efforts go well beyond any requirement imposed by law or policy, clearly constituting Superior Environmental Performance.

3) Reaching out to the business audience to promote use of the P2 Framework as a best business practice.

The Agency believes that prevention pollution and development of products that are sustainable both economically and environmentally are ultimately in the economic interest of the chemical industry. Kodak’s efforts under this third component of the Final Project Agreement will serve to quantitatively demonstrate business and economic benefits that accrue from application of the P2 Framework in product and process development.

In this phase of Kodak's XL efforts, the company will demonstrate to the larger business community how the P2 Framework translates to significant business benefits and improves the bottom line, while helping develop environmentally preferable products. Approaching the business community will increase awareness of the environmental benefits of applying the P2 Framework and will stimulate greater interest in and use of the P2 Framework toward sustainable P2 outcomes.

Kodak will accomplish this objective by working with EPA in the development of a rigorous Environmental Cost Accounting Study to quantify the business and economic benefits accrued through use of the P2 Framework. The study will clearly describe a variety of benefits including reduced product development costs, reduced liability, reduced time to market, etc. The study will help businesses in industry sectors other than photochemicals, understand how they can benefit economically by application of the P2 Framework.

Demonstrating how the P2 Framework helps the bottom line, e.g., reduces cost and increases competitiveness, is an outstanding mechanism to champion the P2 Framework among industry colleagues.

4) Reaching out to the senior managers of industry counterparts to assist them in understanding what management structures can facilitate the implementation of the P2 Framework in their companies.

Under this Final Project Agreement, Kodak will work with EPA to develop and implement outreach activities designed to inform senior managers of the environmental benefits afforded by the P2 Framework. This effort will target industry leaders and focus on management and organizational issues that help drive development of environmentally preferable products and processes.

Kodak will take a leadership role and participate in a management study that seeks to understand the challenges of integrating pollution prevention into business practices. The case study approach will be used to highlight:

- What approaches are currently being used by industry leaders to weigh relative risk in establishing P2 objectives
- What organizational factors promote or impede integrating P2 considerations into business practices.
- What organizational practices, structures, linkages and incentives promote attention to risk in "leader" organizations, and
- What external influences promote or impede integrating P2 into decision making

The Bolstein School of Planning and Public Policy at Rutgers University will prepare the report with the assistance of Kodak.

Kodak's efforts to target "leader" organizations and to communicate the benefits of the P2 Framework go well beyond standard practice. Kodak's innovative efforts in this arena will help



advance understanding of the importance of the development of environmentally preferable products and processes.

Each of the four individual elements of the Kodak XL effort clearly go beyond currently required practices. Taken together, these four elements paint a picture of a progressive company and make a compelling argument that Kodak's activities under this FPA constitute a high level of Superior Environmental Performance.

## B. Anticipated Benefits

### *Bringing Products to Market More Quickly:*

The P2 Framework affords a reliable, inexpensive and rapid way of evaluating product alternatives before product development begins. By screening out potentially hazardous materials early, Kodak will greatly increase the probability that product development efforts will proceed efficiently, yielding an environmentally preferable product at significantly reduced cost. Anticipating EPA concerns will allow Kodak to engineer environmentally preferable products and generate needed data in a timely manner. Anticipating and addressing EPA concerns optimizes the regulatory review process and greatly decreases the probability of adverse regulatory action. This in turn allows Kodak to get to market as soon as possible, resulting in increased market share.

Through the implementation of this Agreement, Kodak will gain the ability to manufacture or import new chemicals soon after the regulatory decision is made, and eliminate a portion of the waiting period during which EPA performs no further evaluation.

### *Improving the Flow of the Innovative Process:*

While one of the benefits of the project to Kodak is allowing the company to bring products to market more quickly, an even more critical benefit to the company lies in its ability to innovate. Kodak typically identifies a number of new chemical alternatives that hold the promise of improving the utility or effectiveness of its products. The challenge is to bring these improvements to the marketplace quickly to test and evaluate the new product.

Submitting a PMN to EPA is a fundamental part of the innovation process. The 90 day PMN clock has the effect of temporarily halting the continuous process of improvement. Kodak cannot determine if its innovations have practical application until it has the opportunity to test and evaluate these innovations in the market place. A decrease in the PMN review period from 90 to 45 days has the effect of reducing the constant "start/stop" impact on innovation that the delay causes. Reducing the review time will facilitate innovation and reduce downtime.

## C. Stakeholder Involvement

The commercialization of new chemicals is not a site-limited action, therefore, there is no discrete stakeholder community affected by this Agreement. However, part of the project involves interaction with several business and technical stakeholders, thus directly involving other industry groups. In addition, the Kodak facility in Rochester will keep its neighbors

informed of pollution prevention activities through its active Kodak Park Community Advisory Council. Kodak will use the Kodak Park Community Advisory Council and its leadership group to involve stakeholder groups such as citizens and others interested in the implementation of this XL Agreement. Kodak also has a bi-monthly publication entitled "Update: A Newsletter to Our Neighbors Near Kodak Park." The "Update" will be used to keep the community notified about the Kodak XL project and to solicit continued participation during project implementation. Furthermore, Kodak has established a Health, Safety and Environment web site at: <http://www.kodak.com/go/hse> . Kodak will include up-to-date information about the XL project on this web site.

Kodak's Stakeholder Plan involves outreach to local, regional, and national stakeholders. The first stakeholder meeting for the Kodak XL project was held on July 11<sup>th</sup>, 2000 in Rochester, N.Y. Notifications for the meeting were sent to the 13,500 recipients of the Update newsletter published by Kodak Park, and a public notice for the meeting was also published in the Democrat and Chronicle newspaper on June 26, 2000. Individual letters were sent to Rochester and Monroe County officials and to National Stakeholders who had previously expressed an interest in the Project XL Program. Eight stakeholder representatives attended the meeting, from the local Health Department, environmental groups, and neighborhood groups. The attendees gave positive feedback and asked to be kept apprised of the Project's progress.

A copy of the Kodak XL proposal will be made available in the reading area of the Kodak Park Neighborhood Information Center. Additional meetings will be scheduled as the XL project matures. Outreach to business and scientific stakeholders will be made through presentations at regional and national meetings.

#### **D. Innovative Approach and Multi-Media Pollution Prevention**

Pollution Prevention is the central aspect of this Agreement. The P2 Framework devised by EPA's Office of Pollution Prevention and Toxics is an innovative approach to assessing chemicals where data are limited. The application of the Framework early in a product development cycle is a best practice among companies that are attempting to design products with minimal environmental impact. The sharing of this technology by the EPA and the communication of its benefits by Kodak represents a cooperative approach to pollution prevention.

In addition, reducing the length of time before manufacture to 45 days will allow Kodak to manufacture and market innovative products more quickly and reduce the length of time between innovations.

#### **E. Transferability**

The early assessment of chemicals to prevent pollution is easily transferred to other industries. The purpose of the public outreach elements of this proposal is to enable transfer of the P2 Framework and a pollution prevention philosophy.



The premise of the P2 Framework is pollution prevention through technology transfer. The entire focus is to demonstrate that EPA's methodologies included in the P2 Framework are indeed totally transferable to the industry and that these methods can drive P2 outcomes. All of the efforts described in the proposal, including a) application of the P2 Framework to Kodak PMN development, b) outreach to the scientific and technical community, c) outreach to the business audience, and d) outreach to the senior management audience are specifically structured to clearly and convincingly demonstrate the transferability of the technology reflected in the P2 Framework.

EPA is considering the transferability of the P2 framework in establishing a pilot program to encourage the application of pollution prevention principles during the development of new chemical submitted as PMNs under TSCA. Certain relief may be provided as an incentive to PMN submitters. The goal of the pilot program is two fold. Firstly, the program is intended to stimulate adoption of pollution prevention principles among chemical companies and other stakeholders. Secondly, the program would help the Agency gain additional data and experience regarding the pollution prevention, risk reduction, and source reduction benefits of use of risk screening methodologies such as EPA's Pollution Prevention Framework, among other assessment methodologies, in new product development efforts.

#### **F. Feasibility**

Kodak has the resources to support this project. In addition, the P2 Framework is an available tool, developed by EPA, to identify environmentally-friendly chemicals. The feasibility of completing the scientific, business, and managerial parts of this XL proposal is high due to the high level of interest that current outreach activities have generated.

#### **G. Evaluation, Monitoring and Accountability**

Kodak's XL proposal includes 4 components:

- 1) Application of the P2 Framework to screen new chemicals to be submitted for PMN review.
- 2) Communicating with, reaching out to, and working with scientific and technical staff from a variety of chemical companies and stakeholders, to support their implementation of the P2 Framework
- 3) Reaching out to the business audience to promote the use of the P2 Framework as a best business practice, and
- 4) Reaching out to the senior managers of industry counterparts to assist them in understanding what management structures can facilitate the implementation of the P2 Framework in their companies

*1) Application of the P2 Framework to screen new chemicals to be submitted for PMN review.*

Each PMN submitted by Kodak under this Project XL Final Project Agreement will be evaluated by EPA during the normal PMN review process. Only PMNs deemed to present low risk during the EPA review will qualify for the flexibility discussed in Section IV (B)(6). Kodak scientists will use their professional judgement in selecting the P2 models to be used for evaluating individual chemicals. Kodak will provide copies of results of P2 Framework model evaluations, e.g., computer printouts where appropriate, with PMNs submitted under this XL FPA. EPA will use model results submitted by Kodak to evaluate Kodak's use and application of the P2 Framework.

*2) Communicating with, reaching out to, and working with scientific and technical staff from a variety of chemical companies and stakeholders, to support their implementation of the P2 Framework*

EPA will monitor and evaluate Kodak's efforts relating to this component on an annual basis. Kodak will report annually regarding the dates and forums/venues used by Kodak to reach out to scientific and technical staff. Examples might include participating in EPA-sponsored P2 Framework workshops or training sessions. Other examples might include presenting papers or discussions regarding the P2 Framework at industry or academic seminars, participating in conferences or scientific meetings, publishing papers in scientific or technical journals or other publications, etc.

*3) Reaching out to the business audience to promote the use of the P2 Framework as a best business practice*

As part of this FPA, Kodak will work with EPA in the development and dissemination of an environmental cost accounting study. This study will describe the business and economic benefits that are derived from chemical risk screening using the P2 Framework or other approaches to chemical risk screening. Kodak has agreed to complete and begin dissemination of the environmental cost accounting study within one year of completion of the FPA. The Agency will monitor and evaluate progress on this issue by participating in the review and evaluation of draft reports, strategies for disseminating information on the study, etc.

*4) Reaching out to the senior managers of industry counterparts to assist them in understanding what management structures can facilitate the implementation of the P2 Framework in their companies*

As discussed in section III. A. Kodak will take a leadership role and participate in a management study that seeks to understand the challenges of integrating pollution prevention into business practices. The Bolstein School of Planning and Public Policy at Rutgers University will prepare the report with the assistance of Kodak. Kodak agrees to complete the study, and initiate efforts to disseminate the study, within one year of completion of this

FPA. EPA will seek comments and evaluations from other companies and other stakeholders relative to the observations, insights and findings of the management study.

#### **H. Shifting of Risk Burden**

This Agreement is consistent with Executive Order 12898 on Environmental Justice. No group of citizens or neighborhood will be subject to disproportionate environmental impacts. This Agreement does not involve shifting a risk burden from one population to another. The process of bringing safer chemicals to market faster benefits all populations involved.

### **IV. DESCRIPTION OF THE REQUESTED FLEXIBILITY AND THE IMPLEMENTING MECHANISMS**

#### **A. Requested Flexibility**

The Toxic Substances Control Act requires a 90 day waiting period before a new chemical that is subject to a PMN can be manufactured. Thus, EPA has 90 days to evaluate chemicals to determine whether there is an unreasonable risk to human health or the environment. In many cases, the review does not require 90 days, with a lack of agency action determined at a meeting 20-25 days into the assessment process. The remaining 65-70 days involve no further agency analysis, yet a company submitting a PMN is unable to manufacture or import the chemical during this time, which causes delays in its ability to commercialize products, with resulting loss in income those new products would generate. By using the P2 Assessment Framework, Kodak intends to commercialize chemicals of lower potential risk and these chemicals will generally have been assessed within 20-25 days. Kodak seeks to manufacture these PMN chemicals in 45 days. Importantly, Kodak is not seeking regulatory flexibility from those instances when a chemical is not completely assessed in 20-25 days and enters the standard review process. (This is discussed more fully in Section IV(B)(3) of this FPA.)

#### **B. Legal Implementing Mechanism**

##### **1.) Overview of New Chemical Regulation and New Chemical Submissions**

The Toxic Substances Control Act (TSCA) provides statutory authority to control the manufacturing, use, distribution in commerce and disposal of industrial chemicals. Section 5 of TSCA provides specific authorities for controlling new chemical substances. New chemical substances are defined in section 3(9) of TSCA as any chemical substance (as defined in section 3(2) that is not included on the Inventory compiled under section 8(b) of TSCA.

Section 5 requires notification to EPA at least 90 days before manufacture or processing of a new chemical substance (i.e., a Pre-manufacture Notification - or PMN). EPA receives 1500 to 2,000 submissions annually; over 35,000 notifications have been received

by the Agency since passage of TSCA. EPA's extensive experience in the review of PMNs has allowed the Agency to develop efficient mechanisms to identify new chemicals which are of greatest concern. EPA's approach to PMN review is designed for, among other considerations, rapid identification of low risk chemicals. EPA strives to identify low risk chemicals early so these materials can be eliminated from review early in the PMN process, allowing the Agency to focus assessment resources on chemicals of concern. Part of EPA's review of PMNs includes a series of highly focused meetings and assessment activities designed to characterize chemical assessment issues in the earliest stages of the 90 day PMN review period. These activities allow the Agency to identify low risk chemicals that can be dropped from further Agency review, early in the review process. Low risk drops are usually identified in the first 30 days of the 90 day review process. Most PMN notices are dropped early in the review process because the Agency has concluded these chemicals pose low risk to humans or the environment.

The PMN review period can be extended under TSCA section 5(c) for good cause; it may also be suspended voluntarily by the mutual consent of EPA and the PMN submitter. As noted above, during the review period, EPA may take action under TSCA section 5(e) or (f) to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. If EPA has not taken action under TSCA section 5(e) or (f), the PMN or exemption notice submitter may manufacture or import the new chemical substance when the review period expires.

No later than 30 days after the PMN submitter initiates manufacturing or importing the PMN substance, it must provide EPA with a notice of commencement of manufacture or import (NOC). Section 8(b) of TSCA provides that, upon receipt of such a notice, EPA must add the substance to the TSCA Inventory. Thereafter, other manufacturers and importers may engage in activities involving the new substance without submitting a PMN, unless the Agency has used its Significant New Use Rule (SNUR) authority under TSCA section 5(a)(2) to designate a use of a chemical substance as a "significant new use." Section 5(a)(1)(B) of TSCA would then require persons to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for the use designated as significant. The required SNUN provides EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs.

## 2) Exemptions

The following exemptions under TSCA and its implementing regulations under section 5(h) reduce or eliminate reporting requirements and waiting periods prior to manufacture for the products that meet their criteria:

- Low Volume Exemption (LVE) -- 10,000 kilograms or less of the substance will be manufactured or imported each year under the requirements at (40 CFR §723.50). Notification required, using EPA Form 7710-25 (the PMN Form). Manufacture may begin 30 days after notification for qualifying products.

- Research and Development (R&D) -- the substance is manufactured in small quantities for research and development, and special procedural and record keeping requirements are met (40 CFR §§720.36 and .78). Notification not required.
- Low Releases and Low Exposures (LoREX) – the substance is expected to have low release and exposure under the requirements at 40 CFR §723.50. Notification required, using the PMN Form. Manufacture may begin 30 days after notification for qualifying products.
- Test Marketing Exemption (TME) – the substance is being manufactured or imported for TME, under the requirements at 40 CFR §720.38. Notification required, using the PMN Form. Manufacture may begin 45 days after notification for qualifying products.
- Polymer Exemption -- the substance is a polymer that meets certain specified criteria where the substance is not considered chemically active or bioavailable under the requirements at 40 CFR §723.250. Annual report to the Agency is required for those exempt polymers commenced for the first time in the preceding calendar year.

### 3) The New Chemical Review Process

The PMN program has evolved into an efficient mechanism to identify new chemicals which are of greatest concern during the early stages of the 90-day review process and focus detailed analysis on these cases with the ultimate goal of identifying and controlling unreasonable risks. EPA utilizes an integrated approach that draws on knowledge and experience across EPA's scientific and organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release and economic impacts. PMNs and exemption notices share the early stages of the 90-day PMN review process; LVE and LoREX applications conclude review by day 30 and TME applications by day 45.

The following series of meetings and activities briefly describes the elements of EPA's chemical assessment and screening activities in the first 30 days of the 90 day PMN review period, including: 1) The Chemical Review and Search Strategy Meeting, 2) The Structure Activity Team Meeting, 3) development of The PMN Exposure and Release Profile, and 4) the Focus Meeting.

1) The *Chemical Review and Search Strategy (CRSS)* meeting (Day 8-12) examines chemical identity; structure/chemical nomenclature; structural analogs/TSCA Inventory Status; synthesis (including byproducts and impurities); use/TSCA jurisdiction as provided by the PMN submitter, open literature, or as identified by EPA for similar chemical substances; physical/chemical properties (physical state, molecular weight, melting and boiling point, vapor pressure, solubility, octanol water partition co-efficient, pH); and pollution prevention aspects, using information provided by the PMN submitter.



EPA also may make suggestions for alternate synthetic pathways. Decisions at this meeting include notice completeness, validity, reportability, eligibility for exemption or exclusion, candidacy for exposure-based review, and whether the notice meets certain CRSS drop criteria.

2) The *Structure Activity Team* meeting (Day 9-13) is an interdisciplinary meeting of scientists, including chemists, biologists, toxicologists, and information specialists which evaluates potential environmental fate, health effects and environmental hazard through the use of structure activity relationships (SAR), test data on the new chemical substance, data on structural analogs, and expert judgment.

3) The *Exposure and Release Profile* is developed by Day 10-19 and examines occupational exposure, environmental releases, environmental and consumer exposure.

4) The *Focus Meeting* (Day 15-20) is the earliest risk management meeting in the section 5 notice review period; representatives from all Agency PMN technical disciplines are involved in this assessment. Initial decisions for chemical categories, exposure-based reviews, and all exemptions are developed at this meeting. For Exemptions notices, the initial decisions are to grant or deny the notice, with ~~out~~ without certain conditions of use specified in the notice, to which the submitter is legally bound. Focus meeting decisions for PMNs can range from identifying the need to consider a ban or TSCA 5(e) regulation of the new chemical to a "drop" from further Agency review. A PMN can also continue on to a more detailed review which occupies much of the remainder of the 90-day period. Regardless of whether the Agency drops a PMN submission during the early stages of review at the Focus meeting or near the end of the statutorily mandated 90-day PMN review period, the PMN submitter is nonetheless not allowed to commence manufacture before day 90 of the review period.

#### 4) History

Historically, it has been EPA's policy to not allow simultaneous submission of LVE or TME section 5 exemption notices and PMNs for the same substance. The R&D and Polymer exemptions, involving no advance notification, require no further discussion in this context. Although simultaneous submission of a LoREX exemption and PMN on the same chemical is theoretically allowable, the narrow exposure and release requirements of the LoREX exemption make it unlikely that allowing simultaneous submission of both notices would provide any meaningful regulatory relief to the submitter.

For LVEs, EPA's policy is against submission of a PMN until nine months after the date on which a LVE is approved by EPA (i.e., 90 days before termination of the one year low volume period), and the Agency will deny a LVE when a pending PMN estimates a production volume greater than 10,000 kilograms per year. This policy, in interpreting the intent of the rule, places emphasis on the rule's use of the words 10,000 kilograms "per year," rather than per any lesser time period. Accordingly, EPA has denied a LVE because a PMN simultaneously submitted by the same company on the same chemical estimated the production volume to be over 10,000 kilograms per year.

Test Market Exemption (TME) applications have been allowed in combination with Premanufacture Notices (PMNs) only if the submitter's description clearly distinguishes the test marketing activity from full-scale commercial production or research and development. EPA's New Chemical Information Bulletin Exemptions for Research and Development and Test Marketing (1986) describes how the Agency, in order to discourage the use of simultaneous submissions to simply obtain PMN review of a chemical substance in 45 days, closely examines such submissions to determine if genuine test marketing activity is involved; if it is not, the application has been denied. The suggested mechanism for such a combination submission has been that, following the submission of a TME application, the same company may not submit a PMN for the same chemical until 90 days before the end of the test marketing period specified by the company in its TME application pursuant to 40 CFR 720.38(b)(5).

#### 5) EPA's Approach to Providing Flexibility Requested by Kodak

For purposes of this XL Project, EPA will allow Kodak simultaneous submissions of TME applications and PMNs on chemical substances for which Kodak makes application and use of the P2 Framework. This would enable Kodak, following approval of the TME by the Agency, to begin manufacture of the chemical substance in accordance with the TME after 45 days. Kodak must continue to meet the exemption requirements for an additional 45 days, at which time the 90-day PMN review may be satisfactorily completed and Kodak may then submit an NOC and begin manufacture for PMN purposes.

Under this XL Final Project Agreement Kodak may begin manufacture of qualifying simultaneous PMN/TMEs at 45 days in accordance with the TME. The Agency will contact Kodak within 45 days of receipt of the TMEA to inform the company if its TMEA has been accepted. As described above, most decisions on PMNs or TMEs are made before day 30 of their review periods, which in the case of Kodak TME/PMN submissions, would run concurrently. Kodak's approval to manufacture at day 45 under the TME will be restricted to those Kodak PMN/TME chemical substances that the Agency, in the case of the PMN, drops from review and, in the case of the TME, grants by the Focus meeting which occurs by day 30 of the 45- or 90-day review period. To qualify for a TME, the Kodak submission must be judged by EPA to meet the requirement that it "will not present an unreasonable risk of injury to human health and the environment," after which Kodak can commence TME activities at the conclusion of the 45 day TME review period. EPA will also consider the simultaneously submitted PMN, provided the TME is granted and the PMN is dropped during the first 30 days of the 90-day review period. Kodak may then commence full commercialization after day 90 of PMN review and file the NOC. All TME requirements must, however, be met until such time as commencement of manufacture occurs and the NOC is filed, at which point the substance becomes an existing chemical and is placed on the TSCA Inventory.

Simultaneous submissions will be accepted only when the Kodak TME is granted and the Kodak PMN is dropped from further review during the first 30 days of the review period. If EPA denies the TME, it will continue its review of the PMN and take action as needed. If EPA grants the TME, but does not drop the PMN during the first 30 days of review,



Kodak will be notified that the company must choose, by letter within 15 days of being notified of the Agency's decision, to continue only one of the two notification procedures (i.e., drop the TME and continue with the PMN, or continue the TME and drop the PMN).

Under the terms of this XL project, Kodak remains liable for complying with all requirements and provisions of both the Test Marketing Exemption and the relevant Pre Manufacture Notice, including the maintenance of proper records and filing all appropriate and necessary production notices. Kodak shall maintain clear records indicative of its dates and levels of production demonstrating that it is operating in compliance with the respective terms of the TME or PMN which authorizes the production of the new chemical at issue. Nothing in this Final Project Agreement relieves Kodak of its duty to comply with currently applicable regulatory requirements governing pre-manufacture authorization for the production of new chemicals.

**6) How could EPA decide to approve a Kodak TME but identify concerns with a Kodak PMN on the same chemical?**

As mentioned above, Kodak's TME submission must clearly distinguish the test marketing activity from full-scale commercial production or research and development. When EPA approves the Kodak TME, it has determined that test marketing the new chemical substance, under terms and conditions set out in the TME application and any additional controls stipulated in an accompanying Federal Register notice announcing Agency approval of the TME, will not present an unreasonable risk of injury to health or the environment. Such specific conditions of approval include the test market time period, production volume, number of customers, and use. Upon review of the same chemical when submitted as a PMN, the Agency could determine that a less restrictive production volume or distribution and use of the chemical than the limitations imposed under the TME may present an unreasonable risk to human health or the environment, and therefore decide to take regulatory action under TSCA section 5(e). The Agency also reserves the right to rescind approval or modify the conditions and restrictions of a TME should any new information that comes to its attention cast significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to human health or the environment.

**8) EPA Policy on Isolated Intermediates**

In some cases, chemical companies manufacture isolated intermediates that require the submission of a PMN and NOC before the chemical substance is added to the TSCA Inventory and enters commerce. An isolated intermediate might be sold in open commerce, or consumed or otherwise used by the same company producing the chemical substance. Under this XL Final Project Agreement, the Agency will evaluate such an isolated intermediate and, provided it meets the other XL criteria described in this FPA, EPA will offer administrative relief for PMN/TMEs that describe open market and/or internal to the company distribution of that chemical.

**C. Why Is this Flexibility Appropriate?**

EPA, Kodak, and NYDEC believe the flexibility described above is appropriate for this Project. All Parties' intentions are to grant flexibility to this Project as a result of the combination of unique elements listed below.

1. This project will promote the use of risk screening tools to develop more environmentally-benign chemicals, resulting in:
  - / development of environmentally preferable new chemical products by allowing more effective screening for human and environmental risks early in product development, when change is most cost effective;
  - / expansion of use of the Agency's P2 Framework screening models in the chemical manufacturing and formulating industries;
  - / transferability of the P2 Framework screening models to other companies; and
  - / increasing innovation in research and development.
2. Other benefits include the following:
  - / the establishment of a structured industry program employing human health and environmental risk evaluation of product alternatives before commercialization/manufacture (pollution prevention through technology transfer);
  - / an industry advocate promoting the use of the P2 Framework;
  - / when opportunities arise, Kodak will share its expertise in the use of the P2 Framework with the scientific and business communities from various chemical companies; and
  - / Kodak will complete and publish a Environmental Cost Accounting Study and a Management Study of P2 Programs in Selected Large Companies.

**V. DISCUSSION OF INTENTIONS AND COMMITMENTS FOR IMPLEMENTING THE PROJECT****A. Kodak's Intentions and Commitments**

As discussed more fully within this FPA, Kodak agrees to:

- 1) Apply the P2 Framework in Kodak's new chemical development programs,
- 2) Communicate with, reach out to, and work with scientific and technical staff from a variety of chemical companies to support their implementation of the P2 Framework,
- 3) Reach out to the business audience to promote the use of the P2 Framework as a best business practice, and
- 4) Reach out to the senior management audiences to help them understand management structures which will aid the implementation of P2 Practices.

- 5) Kodak will comply with all existing and future regulatory requirements during implementation of this project.
- 6) Kodak will continue to work with those stakeholders who have expressed an interest in the project.

#### **B. EPA's Intentions and Commitments**

- 1) EPA will provide requested flexibility by allowing Kodak to submit simultaneous TME applications and PMNs on chemical substances for which Kodak makes application and use of the P2 Framework. Requested flexibility will be limited to PMN and TMEs dropped from consideration (i.e., low risk drops) early in the 90 day PMN review process. See section IV. B. (6) for additional details.
- 2) EPA will work with Stakeholders and the appropriate, local, regional, and state agencies to facilitate implementation of this FPA.
- 3) EPA will support Kodak in the development of the Environmental Cost Accounting Study discussed in section II.A and section III. A. 3).
- 4) EPA will review the Project to determine whether it results in superior environmental performance on a yearly basis.
- 5) EPA intends to incorporate the P2 Framework concepts into a regulation applicable to all PMN submissions if, after review of PMN submission under the FPA, EPA believes it is justifiable.
- 6) EPA intends to continue to provide resources, including technical support, subject to the availability of appropriated funds.

#### **C. Project XL Performance Targets**

EPA will evaluate the results of this FPA to determine performance relating to the following measures:

- 1) Through this FPA and other related activities, EPA seeks to learn if pollution prevention and risk screening methodologies, such as those contained in the P2 Framework, can yield chemical-specific information that assists companies in the identification of environmentally preferable new chemicals and helps in the identification of pollution prevention opportunities.
- 2) Development of an Environmental Cost Accounting Study that describes the business and economic benefits that accrue from application of the P2 Framework in new product development operations.

- 3) Development of a management study that seeks to understand the challenges of integrating pollution prevention into business practices..

#### **D. Proposed Schedule and Milestones**

Under this FPA, Kodak agrees to the following milestones and associated schedule:

Milestone #1: Kodak will apply the P2 Framework in new product development operations. Kodak will provide copies of results of P2 Framework model evaluations, e.g., computer printouts, where appropriate, with PMNs submitted under this FPA.

Schedule for Milestone #1: Kodak will begin submission of P2 Framework evaluations included under this agreement with the first PMN submitted by Kodak after FPA signature. (The Agency notes that Kodak has already begun submission of P2 Framework evaluations with PMNs submitted by Kodak.).

Milestone #2: Communicating with, reaching out to, and working with scientific and technical staff from a variety of companies, to support awareness and implementation of the P2 Framework and/or other risk screening methodologies.

Schedule for Milestone 2: Kodak will engage in two or more outreach efforts within one year of FPA signature. To encourage early communications about the P2 Framework, outreach efforts conducted in anticipation of ratification of this FPA may be included in this milestone.

Milestone #3: Completion of an Environmental Cost Accounting Study.

Schedule for Milestone #3: Kodak, with the support of EPA, will complete and disseminate the Environmental Cost Accounting Study within one year of FPA signature.

Milestone #4: Development of a management study articulating the challenges of integrating pollution prevention into business practices.

Schedule for Milestone #4: Kodak will complete the management study within one year of FPA signature.

#### **F. Project Tracking, Reporting and Evaluation**

##### **Reporting**

For the duration of this Agreement, Kodak will provide an annual summary report to EPA, and upon request, to Stakeholders. Kodak will make project data and project reports, with the exception of PMN submissions, available to Stakeholders on request. The first annual report will be due one year following the signing of this Agreement. Succeeding annual reports will be due the same time each year during the life of this Agreement.

In each annual report Kodak will provide a summary of environmental performance data and will describe its progress toward completing the Project as described in this Agreement. The report should describe progress on all of the voluntary commitments contained in this Agreement. Other reports produced as part of the Project which address these subjects may be used as appropriate. An annual public meeting will be held, beginning after the first annual report is issued. Reasonable advance meeting notice will be provided to the Agencies and Stakeholders. Kodak or its representative will present the report to the Stakeholders at the public meeting.

### **1. Report Frequency and Content**

EPA, Kodak and NYSDEC will work together to draft a report outline within ninety (90) days of the signature of this Agreement. To the extent possible and consistent with applicable regulations, the outline will be structured so that streamlining of reporting on voluntary activities could continue beyond the duration of this Agreement. The report will include, but not be limited to: Stakeholder activities; achieved milestones; important announcements; and, a schedule for activities through the next reporting period. Inclusion of all relevant information in one report will streamline reporting for the Project and make information about progress available on a reliable schedule in a consistent format.

### **G. Periodic Review by the Parties to the Agreement**

The Parties to this Agreement will hold periodic performance review conferences to assess their progress in implementing the Kodak Pollution Prevention Project XL. Unless they agree otherwise, the date for those conferences will be concurrent with annual Stakeholder meetings. No later than thirty (30) days following a periodic performance review conference, Kodak will provide a summary of the minutes of that conference to all direct Stakeholders. Copies of any additional comments of participating stakeholders will be reported to EPA.

### **H. Duration of the Project**

This XL Project will continue for three years. After year three, both Kodak and EPA will conduct an independent program evaluation. If both Kodak and EPA desire to continue the FPA, the FPA will be extended for a period of time mutually agreed upon by EPA, Kodak, and all other appropriate stakeholders.

## **VI. LEGAL BASIS FOR THE PROJECT**

### **A. Authority to Enter into the Agreement**

By signing this Agreement EPA and Kodak acknowledge and agree that they have the respective authorities, discretion, and resources to enter into this Agreement and to implement all applicable provisions of this Project, as described in this Agreement.

**B. Legal Effect of the Agreement**

This Agreement states the intentions of the Parties with respect to the Kodak Pollution Prevention Project XL. The Parties have stated their intentions seriously and in good faith, and expect to carry out their stated intentions.

This Agreement does not create or modify legal rights or obligations, is not a contract or a regulatory action, such as a permit or a rule, and is not legally binding or enforceable against any Party. Rather, it expresses the plans and intentions of the Parties without making those plans and intentions binding requirements. This applies to the provisions of this Agreement that concern procedural as well as substantive matters. While both parties fully intend to adhere to these, they are not legally obligated to do so.

This Agreement is not a "final agency action" by EPA, because it does not create or modify legal rights or obligations and is not legally enforceable. This Agreement itself is not subject to judicial review or enforcement. Nothing any Party does or does not do that deviates from a provision of this Agreement, or that is alleged to deviate from a provision of this Agreement, can serve as a basis for any claim for damages, compensation or other relief against any Party.

**C. Applicability of Other Laws or Regulations**

The Parties do not intend that this Final Project Agreement will modify existing or future laws or regulations.

**D. Retention of Rights to Other Legal Remedies**

Nothing in this Agreement affects or limits Kodak's, EPA's, or any other signatory's legal rights. These rights may include legal, equitable, civil, criminal or administrative claims or other relief regarding the enforcement of present or future applicable federal and state laws, rules, regulations or permits with respect to the facility.

Although Kodak does not intend to challenge agency actions implementing the Pollution Prevention Project (including any rule amendments or adoptions, permit actions, or other action) that are consistent with this Agreement, Kodak reserves any right it may have to appeal or otherwise challenge any EPA, New York State or local action to implement the Project. With regard to the legal implementing mechanisms, nothing in this Agreement is intended to limit Kodak's rights to administrative or judicial appeal or review of those legal mechanisms, in accordance with the applicable procedures for such review.

**VII. UNAVOIDABLE DELAY DURING PROJECT IMPLEMENTATION**

"Unavoidable delay" (for purposes of this Agreement) means any event beyond the control of any Party that causes delays or prevents the implementation of the Project described in this Agreement, despite the Parties' best efforts to put their intentions into effect. An unavoidable delay can be caused by, for example, a fire or acts of war.

When any event occurs that may delay or prevent the implementation of this Project, whether or not it is avoidable, the Party to this Agreement who knows about it will



immediately provide notice to the remaining Parties. Within ten (10) days after that initial notice, the Party should confirm the event in writing. The confirming notice should include: 1) the reason for the delay; 2) the anticipated duration; 3) all actions taken to prevent or minimize the delay; and 4) why the delay was considered unavoidable, accompanied by appropriate documentation.

If the Parties agree that the delay is unavoidable, relevant parts of the Project schedule (see Section V.D.) will be extended to cover the time period lost due to the delay. If they agree, they will also document their agreement in a written amendment to this Agreement. If the Parties don't agree, then they will follow the provisions for Dispute Resolution outlined below.

This section applies only to provisions of this Agreement that are not implemented by legal implementing mechanisms. Legal mechanisms, such as permit provisions or rules, will be subject to modification or enforcement as provided under applicable law.

#### **VIII. AMENDMENTS OR MODIFICATIONS TO THE AGREEMENT**

This Project is an experiment designed to test new approaches to environmental protection and there is a degree of uncertainty regarding the environmental benefits and costs associated with activities to be undertaken in this Project. Therefore, it may be appropriate to amend this Agreement at some point during its duration.

This Final Project Agreement may be amended by mutual agreement of all parties at any time during the duration of the Project. The parties recognize that amendments to this Agreement may also necessitate modification of legal implementation mechanisms or may require development of new implementation mechanisms. If the Agreement is amended, EPA and Kodak expect to work together with other regulatory bodies and stakeholders to identify and pursue any necessary modifications or additions to the implementation mechanisms in accordance with applicable procedures. If the parties agree to make a substantial amendment to this Agreement, the general public will receive notice of the amendment and be given an opportunity to participate in the process, as appropriate.

In determining whether to amend the Agreement, the parties will evaluate whether the proposed amendment meets Project XL acceptance criteria and any other relevant considerations agreed on by the parties. All parties to the Agreement will meet within ninety (90) days following submission of any amendment proposal (or within a shorter or longer period if all parties agree) to discuss evaluation of the proposed amendment. If all parties support the proposed amendment, the parties will (after appropriate stakeholder involvement) amend the Agreement.

#### **IX. TRANSFER OF PROJECT BENEFITS AND RESPONSIBILITIES TO A NEW OWNER**

The parties expect that the implementing mechanisms will allow for a transfer of Kodak's benefits and responsibilities under the Project to any future owner or operator upon request of Kodak and the new owner or operator, provided that the following conditions are met:



- A. Kodak will provide written notice of any such proposed transfer to the EPA and NYSDEC at least ninety (90) days before the effective date of the transfer. The notice is expected to include identification of the proposed new owner or operator, a description of its financial and technical capability to assume the obligations associated with the Project, and a statement of the new owner or operator's intention to take over the responsibilities in the XL Project of the existing owner or operator.
- B. Within forty-five (45) days of receipt of the written notice, the parties expect that EPA and NYSDEC will determine whether: 1) the new owner or operator has demonstrated adequate capability to meet EPA's requirements for carrying out the XL Project; 2) is willing to take over the responsibilities in the XL Project of the existing owner or operator; and 3) is otherwise an appropriate Project XL partner. Other relevant factors, including the new owner or operator's record of compliance with Federal, State and local environmental requirements, may be considered as well.

It will be necessary to modify the Agreement to reflect the new owner and it may also be necessary for EPA and NYSDEC to amend appropriate rules, permits, or other implementing mechanisms (subject to applicable public notice and comment) to transfer the legal rights and obligations of Kodak under this Project to the proposed new owner or operator.

**X. PROCESS FOR RESOLVING DISPUTES**

Any dispute which arises under or with respect to this Agreement will be subject to informal negotiations between the parties to the Agreement. The period of informal negotiations will not exceed twenty (20) calendar days from the time the dispute is first documented, unless that period is extended by a written agreement of the parties to the dispute. The dispute will be considered documented when one party sends a written Notice of Dispute to the other parties.

If the parties cannot resolve a dispute through informal negotiations, the parties may invoke non-binding mediation by describing the dispute with a proposal for resolution in a letter to the EPA Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances. The Assistant Administrator will serve as the non-binding mediator and may request an informal mediation meeting to attempt to resolve the dispute. She will then issue a written opinion that will be non-binding and does not constitute a final EPA action. If this effort is not successful, the parties still have the option to terminate or withdraw from the Agreement, as set forth in Section XI. below.

**XI. WITHDRAWAL FROM OR TERMINATION OF THE AGREEMENT**

**A. Expectations**

Although this Agreement is not legally binding and any party may withdraw from the Agreement at any time, it is the desire of the parties that it should remain in effect for

three years, and as discussed in section V.(H.) may be extended beyond three years, and be implemented as fully as possible unless one of the conditions below occurs:

1. Failure by any party to (a) comply with all applicable requirements or, (b) act in accordance with the provisions of this Agreement. The assessment of the failure will take its nature and duration into account.
2. Failure of any party to disclose material facts during development of the Agreement.
3. Failure of the Project to provide superior environmental performance consistent with the provisions of this Agreement.
4. Enactment or promulgation of any environmental, health or safety law or regulation after execution of the Agreement, which renders the Project legally, technically or economically impracticable.
5. Decision by an agency to reject the transfer of the Project to a new owner or operator of the facility.

In addition, EPA does not intend to withdraw from the Agreement if Kodak does not act in accordance with this Agreement or its implementation mechanisms, unless the actions constitute a substantial failure to act consistently with intentions expressed in this Agreement and its implementing mechanisms. The decision to withdraw will, of course, take the failure's nature and duration into account.

Kodak will be given notice and a reasonable opportunity to remedy any "substantial failure" before EPA's withdrawal. If there is a disagreement between the parties over whether a "substantial failure" exists, the parties will use the dispute resolution mechanism identified in Section X of this Agreement. EPA retains its discretion to use existing enforcement authorities, including withdrawal or termination of this Project, as appropriate. Kodak retains any existing rights or abilities to defend themselves against any enforcement actions, in accordance with applicable procedures.

## **B. Procedures**

The parties agree that the following procedures will be used to withdraw from or terminate the Project before expiration of the Project term. They also agree that the implementing mechanism(s) will provide for withdrawal or termination consistent with these procedures.

1. Any party that wants to terminate or withdraw from the Project is expected to provide written notice to the other parties at least sixty (60) days before the withdrawal or termination.

2. If requested by any party during the sixty (60) day period noted above, the dispute resolution proceedings described in this Agreement may be initiated to resolve any dispute relating to the intended withdrawal or termination. If, following any dispute resolution or informal discussion, a party still desires to withdraw or terminate, that party will provide written notice of final withdrawal or termination to the other parties.
3. The procedures described in this Section apply only to the decision to withdraw or terminate participation in this Agreement. Procedures to be used in modifying or rescinding any legal implementing mechanisms will be governed by the terms of those legal mechanisms and applicable law. It may be necessary to invoke the implementing mechanism's provisions that end authorization for the Project (called "sunset provisions") in the event of withdrawal or termination.

## **XII. COMPLIANCE AFTER THE PROJECT IS OVER**

The parties intend that there be an orderly return to compliance upon completion, withdrawal from, or termination of the Project, as follows:

### **A. Orderly Return to Compliance with Otherwise Applicable Regulations, if the Project Term is Completed**

If, after an evaluation, the Project is terminated because the term has ended, Kodak will return to compliance with all applicable requirements by the end of the Project term, unless the Project is amended or modified in accordance with Section VIII of this Agreement (Amendments or Modifications). Kodak is expected to anticipate and plan for all activities to return to compliance sufficiently in advance of the end of the Project term. Kodak may request a meeting with EPA to discuss the timing and nature of any actions that Kodak will be required to take. The parties should meet within thirty days of receipt of Kodak's written request for such a discussion. At and following such a meeting, the parties should discuss in reasonable, good faith, which of the requirements deferred under this Project will apply after termination of the Project.

### **B. Orderly Return to Compliance with Otherwise Applicable Regulations in the Event of Early Withdrawal or Termination**

In the event of a withdrawal or termination not based on the end of the Project term and where Kodak has made efforts in good faith, the parties to the Agreement will determine an interim compliance period to provide sufficient time for Kodak to return to compliance with any regulations deferred under the Project, as soon as is practicable. The interim compliance period will extend from the date on which EPA or Kodak provides written notice of final withdrawal or termination of the Project, in accordance with Section XI of this Project Agreement. By the end of the interim compliance period, Kodak will comply with any applicable standards set forth in 40 CFR part 723.50. During the interim compliance period, EPA may issue an order, permit, or other legally enforceable mechanism establishing a schedule for Kodak to return to compliance with otherwise applicable regulations as soon as practicable.

This schedule cannot extend beyond 6 months from the date of withdrawal or termination.

**XIII. SIGNATORIES AND EFFECTIVE DATE**

We, the undersigned, pledge our support for the continued success of the Kodak Pollution Prevention Project XL and the furtherance of an effective partnership between EPA and Eastman Kodak Company.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

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Susan H. Wayland  
EPA Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances

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Date

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R. Hays Bell,  
Director, Health, Safety and Environment  
Vice President  
Eastman Kodak Company

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Date

## Appendix A

### P2 Framework Models

Model	Endpoints Addressed	Inputs Needed	Availability
Models to Estimate Physical-Chemical Properties			
EPI Suite*	Melting and Boiling Points, Vapor Pressure	CAS RN or Chemical Structure in SMILES notation	These methods were developed by Syracuse Research Corporation (SRC). Some methods were developed under contract to US EPA, OPPT in support of Section 5 of TSCA. EPIWIN is available from SRC, Syracuse, N.Y.
	Octanol / water partition coefficient		
	Water solubility from log Kow		
	Soil organic carbon partition coefficient		
	Henry's law constant: VP/WS		
	Bioconcentration factor		
Models to Estimate Environmental Fate			
EPI Suite*	Atmospheric oxidation potential	CAS RN or Chemical Structure in SMILES notation	These methods were developed by SRC. Some methods were developed under contract to US EPA, OPPT in support of Sec. 5 of TSCA. EPIWIN is available from SRC, Syracuse, N.Y.
	Biodegradation rate		
	Hydrolysis rate		
	Percent removal in POTW		
Models to Estimate Human Health and Environmental Hazards			
OncoLogic	Cancer hazard potential	Chemical structure	Developed by LogiChem under a cooperative agreement with USEPA, OPPT in support of Sec. 5 of TSCA. OncoLogic is available from LogiChem Inc., Boyertown, PA.
ECOSAR*	Aquatic toxicity to fish, invertebrates, algae	CAS RN or Chemical Structure in SMILES notation	Download at no cost from <a href="http://www.epa.gov/oppt/newchems/21ecosar.htm">http://www.epa.gov/oppt/newchems/21ecosar.htm</a>
Models to Estimate Exposure and / or Risk			
E-FAST	Surface water ingestion, fish ingestion, ground water ingestion, ambient air inhalation, indoor air inhalation, dermal exposure, aquatic environment exposure/risk	Physical / chemical properties, fate properties, release amounts, release medium, release location, aquatic concentration of concern, NPDES number	Download at no cost from <a href="http://www.epa.gov/opptintr/exposure">http://www.epa.gov/opptintr/exposure</a>
ReachScan	Impact of surface water discharges on drinking water facilities, i.e., chemical concentration downstream at drinking water intake point	Facility location (NPDES number), release data	Contact Tom Brennan at <a href="mailto:brennan.thomas@epa.gov">brennan.thomas@epa.gov</a> for a free copy
Occupational Exposure Spreadsheets^	Vapor generation rates and worker exposure to vapors during filling, sampling, and to open liquid pools; and during degreasing operations; Water releases and worker exposures to powders during textile dyeing	Molecular weight, vapor pressure, operation hrs/day, worker exposure hrs/day; if applicable, volume of degreasing solvent or dye used, dye exhaustion rate	Contact Scott Prothero at <a href="mailto:prothero.scott@epa.gov">prothero.scott@epa.gov</a> for a free copy
^ "ChemSTEER", a comprehensive Windows®-based tool containing methods from these spreadsheets and many other methods for estimating workplace exposures and environmental releases from industrial and commercial operations, is currently under development.			

July 2000

DISCLAIMERS: Mention of trade names or commercial products, or services does not convey, and should not be interpreted as conveying official USEPA approval, endorsement, or recommendation.

The models presented in OPPT's P2 Framework have been developed over a period of more than 20 years by OPPT, EPA contractors and/or grantees or others in the scientific and technical community, to screen chemicals in the absence of data. Through the P2 Framework, OPPT is presenting these screening models to industry and other stakeholders in the hopes that use of these models early in the research and development process will result in safer chemicals entering commerce. The P2 Framework models should be used for priority setting and to provide additional information so that choices can be made on the chemicals being evaluated.

Other chemical screening methodologies have been developed and are in use by chemical companies and other stakeholders. The Agency recognizes that other models are available and that these models can also be of value in chemical screening efforts.

CAUTION: Screening models predict data with an inherent degree of uncertainty, and should *never* be used to replace measured data from well designed studies. Measured data are always preferred over predicted data. If measured data are not available, measured data on close analogs can be used. If no analog data are available, screening level models, such as those in the P2 Framework, may be used for priority setting and to predict values that can be used to indicate which chemicals may need further testing or evaluation.



*Minutes of Meeting with EPA, Kodak and PPG  
July 12<sup>th</sup>, 2000*

**Topic:** Mechanics of Simultaneous Submissions of TME's and PMN's

**Present on the Call:** Kodak: Gary Katz, Frank Amato, PPG: Jean Chung, Jim Schlesberg  
EPA: Lisa Reiter, Ken Moss, Bill Waugh, Becky Cool, Maggie Wilson, Janet Murray.

The purpose of the call was to discuss the mechanics of the process for both Project XL participants, PPG and Kodak, submitting simultaneous TME (test marketing exemptions) and PMN's (premanufacturing notices) which is not currently done, but will be allowed for purposes of this XL project.

Ken Moss explained that the two companies will include with their PMN submissions, a cover letter which will clarify that the company is submitting a PMN along with a request for a test marketing exemption, and that the company is doing so as part of Project XL. Since there is no standard form for TME's, the company may use the PMN form or other format and justify the activities to be undertaken as genuine test marketing, including such information as the estimated volume they intend to manufacture, the time period for test marketing, the numbers of people estimated to be exposed, and generally distinguish this from full scale commercialization, in accordance with 40 CFR 720.38. Ken said that he would send along specific language (see below) so that the companies know exactly what is expected of them and what language needs to be inserted into the submission. Bill Waugh stated that the companies will also have to include supporting documentation which came from using the models in the P2 Framework process, i.e., the copies of the model runs that they did using the computer software, or a written report summarizing the results of the info they found using the computer models - as verification.

The question was asked, at what point is it clear that they are switching over from the PMN to the TME? Bill's and Ken's response was that, when they apply for the initial TME exemption, the company needs to state up front what they think the test market time period and production volume will be, and when they will stop manufacturing under the TME and begin manufacture under the PMN. Both companies were concerned about the potential for violation if they were to cross outside of the appropriate dates. Bill suggested that this would not be a problem as long as the test marketing dates or production volumes are estimated in the TME notices to allow for maximum flexibility for the company, and the company kept appropriate records that clearly distinguished between the two types of production activities.

**I. Suggested language to include with XL TME notices:**

The company has developed this new chemical substance using the pollution prevention hierarchy as articulated in the Pollution Prevention Act of 1990 and EPA's Pollution Prevention Strategy (56 Federal Register 7849, February 26, 1991). In this Strategy, the Agency ranks source reduction as the first preference in methods of controlling chemical risks.

The company has addressed source reduction through the application of SAR and risk screening methodologies that comprise EPA's Pollution Prevention (P2) Framework. The P2 Framework is

designed to evaluate potential chemical risk or hazards based on an analysis of chemical structure and other factors. This represents a unique approach to product development in the industrial chemical sector and constitutes a significant departure from standard practice in new product development. Standard practice typically does not include P2, SAR, and other risk screening approaches in early product development. This approach to product development may result in the selection of a material to be commercialized that is different from a material which might have been selected based on more traditional approaches to product development (i.e., based primarily on cost, efficacy, yield, performance, etc.).

The new chemical will be used as a component in a product. The company plans to test market the new chemical that was developed with this unique P2-based product development paradigm to ensure acceptability of the product in the marketplace. During the test marketing period, the company plans to do the following activities as part of an effort to evaluate the acceptability of the product based on the new chemical:

(Companies would list test marketing activities - here are some examples)

- For a period of six months, the company will judge the marketability of a currently sold product which now uses a new isolated intermediate (the TME substance) in the manufacturing process for that existing product. The TME substance will be distributed and consumed by two Divisions within our company, but the final product's market will be unchanged.
- For a period of 45 days to one year, we will judge market acceptance of a "new and improved" general consumer coating that includes the TME material as a new component. Production is estimated at 150,000 kg and the TME substance will be distributed in this coating in commerce to a very large general consumer customer base.
- For a period of \_\_\_\_\_, we will judge market acceptance of a TME material used as a dye coupler in general photographic applications. The TME substance will be distributed in film to 1000's of consumer photographic supply outlets.
- ....to judge the market acceptance of a TME material used in manufacturing adhesives for automotive glass.

As a result, we believe that this test marketing of the product developed using the P2 Framework satisfies the requirement to distinguish this test marketing activity from full-scale commercial production and research and development, as required under 40 CFR 720.38(b)(5).

## **II. Suggested language for a cover letter with the joint TME/PMN submission**

Enclosed are two separate TSCA section 5 submissions for the same new chemical substance, one a TME and one a PMN. These notices are being submitted in accordance with a Final Project Agreement signed by (Kodak/PPG) and EPA under the Agency's XL Program.