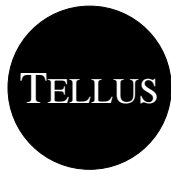


**Design for Competitive Advantage:
The Business Benefits of the
EPA Pollution Prevention
Assessment Framework
In New Product Development**

**Thomas J. Votta
Allen L. White, Ph.D.**

**Submitted to:
Eastman Kodak Company
and
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics**

August 25, 2000



INSTITUTE

Resource and Environmental Strategies

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Any errors in fact or interpretation of information used to conduct this report are the sole responsibility of the authors.

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EXECUTIVE SUMMARY

Every manager involved in the development of new chemicals perennially faces a complex business decision: how do I choose a new product among the multitude of candidates so as to minimize time to market while, at the same time, minimizing development and manufacturing costs?

Managers in all industries, of course, face this same product development challenge. However, for chemical makers, especially those in technology-based industries, the challenge is particularly daunting. Unlike most materials, new chemicals are strictly regulated by EPA under the Toxic Substances Control Act (TSCA). Each year, between 1,500 and 2,500 applications for the manufacture of new industrial chemicals are received by EPA. Of this number, approximately 10 percent are either voluntarily withdrawn by the submitter or restricted by EPA. In either case, significant costs are incurred by firms who sink substantial resources into new product development before seeking EPA approval. Moreover, chemical product developers are well aware of the realities of downstream costs and risks associated with worker exposure, reporting, testing, recalls and product liability risks.

Thus, any early warning to managers signaling a potential “bad actor” represents a potentially strong competitive edge. Sharper decision-making among chemical candidates, avoidance of regulatory delays, faster time to market and reduced manufacturing costs are benefits which might be expected to arise from such an early warning system.

Based on results of a recent pilot effort, EPA’s Pollution Prevention Assessment Framework (P2 Framework) offers such a system. Evolved over two decades of assessing chemicals based on chemical structure, the set of

evaluation tools comprising the Framework have recently been evaluated by a number of companies within their own product development processes.

The premise of this pilot effort was straightforward: provide companies for internal use the same tools EPA uses to assess new chemicals. By using these tools to evaluate potential new products, companies gain insights into risk concerns. Companies can use this information to identify environmentally preferable products. Advance screening for risk will maximize the prospects for expeditious TSCA review and approval of those chemicals that eventually reach EPA. If this can be achieved, both the environment and the submitting company win—the former through use of safer substances in commerce and the latter through a more rapid product development process.

What is the specific nature of such business advantages? The answer lies primarily in early detection of problematic product attributes beginning in the earliest stages of the product life cycle, starting with concept development and extending through technology development, production design, manufacture, and use. The ability to detect problematic materials even before a new chemical is synthesized or formulated represents a substantial cost avoidance and shortens time to market of successful candidates. The converse is also true: the longer problematic chemicals survive in the product development cycle, the larger the accumulated and irrecoverable costs incurred once the chemical is abandoned. Figure ES-1 (below) illustrates this relationship between retention of a problematic chemical and cumulative, at-risk resources.

Timely application of the P2 Framework offers a substantial degree of protection against at-risk product development costs. Competitive advantage may also materialize in two other areas: product development speed and production costs for full-scale manufacturing. Benefits in all three areas are summarized in Table ES-1 (overleaf).

The benefit side is compelling. But what about the cost of acquiring and using the P2 Framework? The answer is that the acquisition costs are minimal. For any medium to large firm in the business of new chemical product development, the P2 Framework is affordable. Up-front costs are in the range of \$2,000 to \$27,000 depending on which methods are purchased, plus an estimated \$5,000 to train each user. Each application of one of the methods to one chemical candidate requires about 15-60 minutes. Compared to the benefits of avoided product development costs and accelerated time to market, these costs are relatively trivial. They represent an up-front investment in software and staff capacity which yields a stream of benefits over many years of repeated application.

Use of the P2 Framework is, in the end, about a cost-effective method of obtaining better and earlier information that leads to greater certainty, quicker decisions, and smarter product design. While product development processes vary across companies, all managers grapple with the common challenge of quickly and continuously developing new products and rapidly commercializing them to establish marketplace advantage. While the quality of a company's existing screening practices and historical experience with chemical assessments affects the net benefits of the P2 Framework, it is highly probable that the framework is a source of value-added to virtually any firm — large or small — engaged in the chemical product design, development, manufacture and use.

Figure ES-1: Accumulated Resources Spend on a Single Chemical Candidate in New Product Development

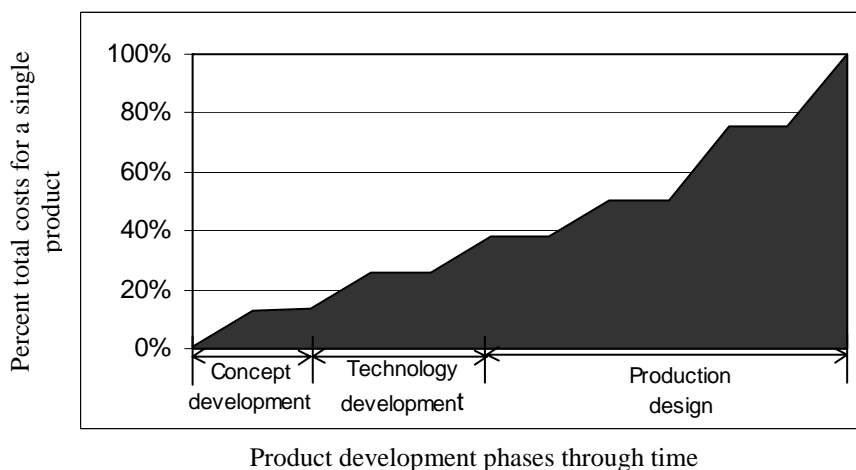


Table ES-1: Summary of Benefits of the P2 Framework

LOWER PRODUCT DEVELOPMENT COSTS FOR NEW CHEMICALS AND INTERMEDIATES	
Quantitative Benefits	<ul style="list-style-type: none"> • Reduced (avoided) costs spent on technical development and R&D of new chemicals. • Decreased resources spent on laboratory tests for human health and environmental testing.
Qualitative Benefits	<ul style="list-style-type: none"> • A greater number of product combinations and product alternatives can be evaluated early in concept development. This allows for greater technology innovation and is due to the quick and cost-effective nature of the P2 Framework. • Better and earlier information on environmental and health (E&H) impacts allows the product development team to focus resources on technical performance. Knowing the E&H profile early allows the team to anticipate any additional E&H lab testing that may be required for PMN submittal to EPA. Such information may also alert the team to a chemical candidate that it wants to abandon based on E&H concerns before significant resources have been spent on investigating its technical performance. • Better information allows companies to compare competing product alternatives and helps them identify environmentally sound technologies. • Greater awareness of “green design”.
REDUCED TIME TO MARKET FOR NEW PRODUCTS/CHEMICALS TO MARKET	
Quantitative Benefits	<ul style="list-style-type: none"> • Faster time to market for new product introduction by minimizing the chances that a lead candidate will fall out of the product development process for health, environment, or safety concerns. • Avoid a 5(e) regulatory action for PMN review which may require additional information or testing, causing delays in getting EPA approval. • Minimize cycle time for PMN review by submitting an informed and complete application to EPA.
Qualitative Benefits	<ul style="list-style-type: none"> • Reduced probability that a candidate is dropped at an advanced development stage, delaying the product team as they evaluate another candidate.
LOWER PRODUCTION COSTS FOR FULL-SCALE MANUFACTURING OF NEW CHEMICALS	
Quantitative Benefits	<ul style="list-style-type: none"> • Decreased costs associated with using hazardous chemicals (e.g., environmental reporting, testing, employee training and personal protective equipment, waste treatment, disposal, handling spills). • Reduced probability the submitted chemical will be subject to 5(e) actions by EPA which may require either monitoring and tracking or more controls and treatment during manufacturing. • Decreased potential for downstream interventions such as product recalls or major changes to the manufacturing operation (related to unanticipated long-term toxicological effects of a product or technology).
Qualitative Benefits	<ul style="list-style-type: none"> • Improved performance of the health and environment team in supporting the overall product development process. • Enhanced ability to identify and drive P2 outcomes.

INTRODUCTION

Each year, the New Chemical Program at the US Environmental Protection Agency (EPA) receives an average of 2,000 applications for the manufacture of new industrial chemicals.¹ Under the Toxic Substances Control Act (TSCA), EPA's Office of Pollution Prevention and Toxics (OPPT) is responsible for ensuring new chemicals do not pose an "unreasonable risk" to workers, consumers, and the environment. As the chemicals are new products by definition, there are often no existing data with which EPA can adequately evaluate health or environmental risk. Moreover, TSCA does not require companies test new chemical substances prior to submission to EPA

With the implementation of TSCA requirements, EPA immediately saw the need for new predictive techniques that could be used to identify chemicals and chemical processes that could pose an "unreasonable" risk. A variety of screening tools have been developed over the years by EPA scientists and Agency support contractors to assist in characterizing the fate and hazard likely to arise from the manufacture, use, and disposal of new chemicals. Collectively known as the EPA Pollution Prevention Assessment Framework (P2 Framework), these methods include OPPT's most important computer-based methods developed to quickly evaluate chemicals when test data are lacking. Some methods help predict potential hazard based on chemical structure; others help anticipate human and environmental exposures; and still others help estimate fate and movement of chemicals in the environment. These tools reflect 20 years of concerted effort by OPPT to automate the process of evaluating chemicals based on chemical structure and standard scenarios.

¹ U.S. EPA Office of Pollution Prevention and Toxics, New Chemical Program

Bolstered by years of every-day use and refinement within the Agency, the methods were viewed as a potentially valuable resource that could be used by companies in developing new chemicals and processes. The premise was simple —companies sometimes choose which chemicals to develop without the benefit of hazard- and/or risk-related information. The OPPT recognized that the P2 Framework could serve as a resource for companies, allowing them to easily incorporate risk considerations early in the product development process. If the P2 Framework could be successfully employed in this way, , a win-win situation may result: reduced use and release of harmful substances into the environment, and reduced costs and risk to business.

The P2 Framework was viewed as a valuable resource that could be used by companies in developing new chemicals and processes.

Thus, EPA initiated an effort comprising distribution and technical support of the methods. A key component was the recruitment of an industry partner to participate in a technology transfer pilot project to help assess the P2 Framework's overall utility to industry. In 1994, Eastman Kodak agreed to participate in the technology transfer project.²

² For a more detailed account of the EPA/Kodak project, see "EPA-Developed Methodologies for the Fate and Hazard of Industrial Chemicals, A summary of Eastman Kodak Company's Experience with the Use and Applicability I Risk Assessment." Kodak Technology Transfer Team, May 13, 1996.

In addition, EPA hosted a number of regional three-day workshops to introduce and train a broader industry audience in the use of the P2 Framework. Successive workshops were held in San Jose, California; Durham, New Hampshire; and Chicago, Illinois. During the workshops participants listened to a presentation on each method describing how EPA uses the method, its development, limitations, inputs and outputs, and interpretation of results. Participants then received hands-on experience using the methods by working on examples and case studies provided in the P2 Framework Manual.

The 2-year EPA/Kodak collaboration yielded positive results for both sides. From EPA's standpoint, the project demonstrated a new and valuable application of fate and hazard assessment methods that previously had been used only for internal Agency purposes. From Kodak's perspective, these same methods, used in conjunction with professional judgement and effective internal communication, augmented existing procedures to evaluate new chemicals and processes. These methods allowed company scientists to make sound business decisions in the *very earliest* stages of R&D and product development.

This report assesses these business benefits gained by using the P2 Framework and provides a conceptual model which a broad industry audience can apply to their unique product development processes. Use of the P2 Framework methods, as we shall see, also presents opportunities for pollution prevention (P2) since information from the methods allows companies to utilize P2 approaches at the earliest possible stages of the product development process.

In constructing a model to illustrate these benefits, we first discuss chemical screening and evaluation, both in the context of the TSCA regulatory approval process and, more importantly, in the broader context of the product development process. A brief description of the P2 Framework is presented, followed by a discussion of the potential benefits, some quantitative and some qualitative, of the P2 Framework. Quantitative benefits from two discrete applications at Kodak are provided in the appendices.

THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

When TSCA was enacted in 1979 (40 CFR §700-799) chemicals were divided into two categories: existing and new. Existing chemicals, defined as those chemicals already in use prior to 1979, were listed on the TSCA Chemical Inventory. Any company can manufacture "existing" chemicals on the Inventory without notifying EPA. For such "existing" chemicals, the burden is on EPA to show an unreasonable risk exists before it can

act to restrict their production, distribution, or use.³

Any firm proposing to manufacture or import a new chemical or chemical intermediate not on the existing TSCA Chemical Inventory

³ This report provides a cursory review of the PMN process for new chemicals under TSCA. For a more detailed discussion of TSCA and New Chemical Review, visit the EPA OPPT New Chemical Program website at www.epa.gov/opptintr/newchms/. Specific questions can also be directed to the TSCA hotline at 202-554-1404.

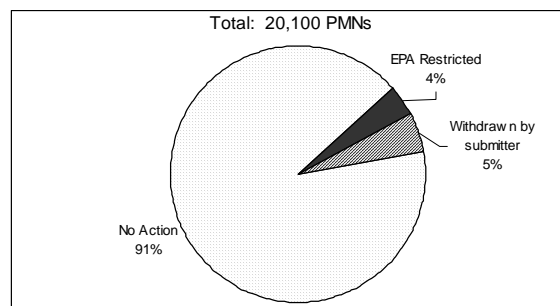
must notify EPA 90 days in advance. For any such new chemical, EPA must review potential risk and decide if the chemical should be allowed to enter commerce freely, or whether it should be controlled in some manner. The manufacturer or importer is not required to test the new substance or assess its expected health or environmental impacts. Instead, a company's premanufacture notification (PMN) must contain, only to the extent "reasonably ascertainable," the identity of the substance, its expected use and exposure, its expected production volume, and any *available* health, safety and environmental information.

If EPA concludes, within the 90-day review period, that the proposed chemical may pose an unreasonable risk and that further data are necessary to determine whether it does or does not, the Agency can restrict the manufacture and use of the chemical, pending the development of additional data. Restrictions, described in section 5(e) of TSCA, are called "5(e) orders." These orders generally involve a consent order specifying additional data, additional controls, restrictions on a chemical's manufacture and use, or other actions which mitigate potential risk. If EPA finds the chemical does indeed present an unreasonable risk, then EPA may issue an order to restrict or ban the chemical under Section 5(f). 5(f) actions occur much less frequently than 5(e) actions.

If EPA does not act to restrict the proposed new chemical during PMN review, the chemical can be manufactured or imported without restriction. Once a newly manufactured or imported chemical has successfully passed through the PMN process, the chemical may be commercialized. It is not placed on the TSCA Chemical Inventory until EPA receives a notice of commencement of manufacture/import (NOC) from the manufacturer signaling the chemical is in the marketplace.

Figure 1 displays the outcome of PMN review for 20,100 applications received by EPA between 1979-1993. During this time, the number of PMN applications averaged around 1,500 per year.⁴ The 1,500 PMN applications amount to roughly 7-8 new chemical notices per work day of the year. EPA has imposed Section 5(e) restrictions pending receipt of additional data on more than 4 percent of the PMNs reviewed between 1979 and 1993. Only four other PMNs were restricted as unreasonable risks under section 5(f). In addition, submitters withdrew an additional 5 percent of PMNs during the same period. The withdrawal usually occurs in the face of regulation. Thus, in total, nearly 10 percent of new chemicals have either been voluntarily withdrawn from PMN review or restricted by EPA.

Figure 1: TSCA PMN Outcomes (1979-1993)



Source: INFORM, 1995

Given the volume of PMN applications and the short review period specified under TSCA, EPA has spent considerable resources to develop methods and processes to fulfill its regulatory mandate—to ensure new chemicals that present an

⁴ The 1,500 per year PMN average as well as statistics for 5(e) and 5(f) actions between 1979 and 1993 are taken from "Toxic Watch 1995," INFORM, 1995. According to OPPT's New Chemical Division, the average number of PMN applications in recent years has grown to 2,000 per year while the combined average of 10% of PMN applications either withdrawn or restricted by EPA has remained essentially constant.

unreasonable risk are identified and do not enter commerce. The P2 Assessment Framework is an outgrowth of such efforts.

THE EPA P2 FRAMEWORK

The P2 Framework is a collection of computer-based methodologies that each assess a particular aspect of a chemical's potential impact on humans or the environment. The P2 Framework methods provide information in four general areas:

- physical/chemical properties,
- chemical fate in the environment,
- hazard to humans and the environment, and
- exposure and/or risk.

These methods, along with the outputs and required input, are shown in Table 1 (overleaf).⁵

Methods included in the P2 Framework are intended to provide information to help assess the risk posed by a chemical or group of chemicals. Most methods deal with two steps of the four-step risk assessment process: hazard identification and exposure assessment. (The complete risk assessment process also includes dose-response assessment and risk characterization.)

The original purpose of the P2 Framework was to contribute to more informed regulatory decision-making. These are screening level methodologies that are of most value when chemical-specific data are lacking. In cases where validated data are available for a given

endpoint from a well conducted test, they should be used in lieu of data predicted by the P2 Framework assessment method for that particular endpoint.

The methods are based largely on quantitative structure activity relationships (QSAR). QSARs are predictive methods which estimate the properties of an untested chemical (e.g., melting point, vapor pressure, toxicity and ecotoxicity) on the basis of the similarity of its structure to that of a tested chemical. In most cases the primary input required is the chemical structure of the substance being evaluated. In addition, the assessor needs an understanding of organic chemistry and ecotoxicity. Overall, the methods are user friendly and require minimal data input.

Exploring Business Applications

To learn if data generated by the P2 Framework could reduce developmental costs of new chemicals and processes and lead to development of environmentally preferable products, OPPT shared the P2 Framework with five major companies who frequently submit PMNs. OPPT wanted to learn if industry could use the P2 Framework to generate previously unavailable chemical-specific data. Initial results are encouraging. EPA found that the P2 Framework can substantially affect the way companies develop new chemicals and approaches to reformulating existing products.

⁵ For a more detailed discussion of the methods in the P2 Framework, see *The Pollution Prevention Assessment Framework*, US EPA, Office of Pollution Prevention and Toxics, October 1997.

Table 1: Inputs and Outputs of the P2 Assessment Framework Methodologies

Models to Estimate Physical/Chemical Properties			
<i>Model</i>	<i>Source</i>	<i>Output</i>	<i>Input</i>
MPBPVPPWIN	SRC	Melting point; boiling point; vapor pressure	Chemical structure
KOWWIN	SRC	Octanol-water partition coefficient	Chemical structure
WSKOWWIN	SRC	Water solubility	Chemical structure
PCKOCWIN	SRC	Soil organic carbon sorption coefficient	Chemical structure
HENRYWIN	SRC	Henry's law constant	Chemical structure
BCFWIN	SRC	Estimated bioconcentration factor	Log Kow
Models to Estimate Chemical Fate in the Environment			
<i>Model</i>	<i>Source</i>	<i>Output</i>	<i>Input</i>
AOPWIN	SRC	Atmospheric oxidation	Chemical structure
BIOWIN	SRC	Biodegradation	Chemical structure
HYDROWIN	SRC	Hydrolysis	Chemical structure
STP	EPA	Percent removal	Chemical properties
Models to Estimate Hazard to Humans and the Environment			
<i>Model</i>	<i>Source</i>	<i>Output</i>	<i>Input</i>
OncoLogic	LogiChem	Cancer hazard ranking	Chemical structure
ECOSAR	EPA	Ecotoxicity values (concentration of concern (COC), etc.)	Chemical structure, melting point, log Kow
Models to Estimate Exposure and/or Risk			
<i>Model</i>	<i>Source</i>	<i>Output</i>	<i>Input</i>
DERMAL*	EPA	Consumer dermal potential dose rate (PDR)	Weight fraction
SCIES*	EPA	Consumer inhalation PDRs	Molecular weight, vapor pressure, weight fraction
ReachScan*	EPA	Chemical concentration at the drinking water intake point	Facility location, concentration data
PDM3*	EPA	Days per year the COC is exceeded	Release quantity, COC
SEAS*	EPA	Stream concentration, Drinking water & fish ingestion PDRs	Flow data, release quantity, BCF
Occupational Spreadsheets**	EPA	Worker exposure to vapors	Molecular weight, vapor pressure, hrs/day of operation, hrs/day of worker exposure
<p>Notes: SRC = Syracuse Research Corporation, located in North Syracuse, NY. The SRC methods can be purchased in packages ranging in cost from \$1,500 to \$2,000 depending on which models are included. LogiChem is located in Boyertown, PA. OncoLogic costs \$25,000. All EPA models are available free of charge.</p> <p>* These exposure models are being integrated into a single windows-based model, E-FAST, which will allow for single data entry. ** This model is being upgraded into a windows-based model, ChemSTEER.</p>			
Source: USEPA, Pollution Prevention Assessment Framework Manual, October, 1997			

The following comments are a representative sample of industry perspectives and appear in no particular order:

“...The P2 Framework helps us understand potential risk-related concerns associated with new chemical substances under development.” (Shell)

“The methodologies 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.” (Eastman Kodak)

“Use of the P2 Framework gives us a sense for potential health and safety concerns early on in the product development cycle — a definite plus for Shell.” (Shell)

“...[The tools are] particularly useful when used to minimize the potential synthesis or generation of hazardous wastes and chemicals before production processes have been decided upon.” (Eastman Kodak)

“P&G found EPA’s environmental assessment methods of critical importance in the early stages of our R&D efforts.” (Procter & Gamble)

“...We regularly use the EPIWIN and ECOSAR software...to assess our products from an environmental standpoint.” (S.C. Johnson Wax)

“The P2 Framework provides a logical, consistent structure for comparing competing products and processes...” (Shell)

“...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.” (Eastman Kodak)

“As industry strives to achieve Sustainable Development, the kind of guidance these...methods provide will increase in importance.” (Procter & Gamble)

“The P2 Framework reduces uncertainty around health and environmental impact...we can manage or prevent risk as long as we know what it is early on in our process” (PPG)

“EPA ...may underestimate the true value of these tools.” (Procter & Gamble)

“...Other industries will benefit from use of the P2 Framework.” (Shell)

The P2 Framework also provides substantial benefits in instances where TSCA regulatory approval is not required.

A strength of the P2 Framework is both the ease and rapidity of individual methods. A general theme echoed by companies who have used the methods and EPA is that the most important economic and environmental benefits of the P2 Framework are realized when the methods are applied early in the product development cycle, before significant resources are spent on the leading chemical candidates.

The P2 Framework also provides substantial benefits in instances where TSCA regulatory approval is not required. This is often the case when a customer specifies a particular

chemical or specifies strict technical parameters that only one or a select group of chemicals can meet. Early risk-related information in this context allows the manufacturer to understand the true costs associated with producing the chemical. Regulatory reporting and monitoring, storage and transportation issues, cleaning during process shutdowns, personal protective equipment and handling waste are all recurring operational costs related to the toxicity of a chemical. Such costs directly affect the product's profitability. The P2 Framework can provide data to help a company incorporate estimates of such production costs into decision making.

Costs of Using the P2 Framework

The P2 Framework incorporates both EPA- and contractor-developed tools. Table 1 shows where individual methods in the P2 Framework can be obtained by indicating the source of the methods:

- The EPA developed methods in the P2 Framework that are available at zero cost to interested parties.
- The methods developed by the Syracuse Research Corporation can be purchased in packages for a cost of \$1,500-\$2,000, depending on which methods are purchased.

- The OncoLogic® program developed by LogiChem is more expensive, costing \$25,000. The total cost to purchase all the methods in Table 1 amounts to no more than \$27,000.

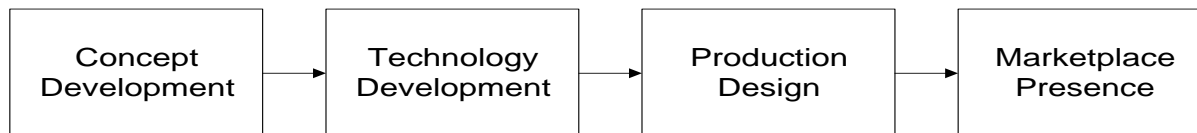
In addition to the purchase costs of the methods, resources are required to train assessors (who should have a good understanding of chemistry) in their use. Another resource required is the actual time to run the methods and analyze the results. Based on the experience of Eastman Kodak, it is estimated that the training costs no more than \$5,000 per person. Applying and analyzing the results from individual methods can take a trained assessor anywhere from 5 to 15 minutes depending on the complexity of the individual method. A more complete assessment, requiring output from several methods, may take up to an hour.

In sum, the initial up-front costs are up to \$27,000 for all the methods in the P2 Framework and most likely no more than \$5,000 to train each user. Each time the methods are applied, it will take the individual running the model between 5 minutes to one hour to complete an assessment.

THE PRODUCT DEVELOPMENT PROCESS

In general, any new chemical or new chemical intermediate is part of new product development or product redesign. If a TSCA PMN is required, the chemical must pass the test of not posing an "unreasonable risk" to health or the environment. Any chemical that does not meet this requirement will incur further development costs and the costs and competitive consequences resulting from a delay in getting to

market. In this context, screening chemical candidates early in the product development process for health and environmental hazard is the optimal point of application of the P2 Framework. An overview of a generic product development process can help demonstrate how the P2 Framework enhances chemical screening and evaluation.

Figure 2: Four Phases of a Generic Product Development Process

The Generic Product Development Process

Broadly speaking, the product development process is a sequence of steps employed to conceive, design and commercialize a product. The process typically involves the creation of a varied set of alternative product concepts and the subsequent narrowing of alternatives and increasing specification of the product until the product can be reliably and repeatedly manufactured in a cost-effective manner. Some organizations define and follow a precise and detailed process, while others may not even be able to describe their process (though all firms have one, even if by default). One thing is certain; every organization differs. Each has a process that is at least slightly different from every other organization.

Figure 2 depicts four phases common to most product development processes. Though there will be differences among companies on the detailed tasks under each of the four phases, chemical technologies are managed broadly as follows:

1. Concept Development. This phase is geared toward developing several alternative concepts that will meet the needs of the customer. With most chemical-related technologies, the product development team

will generally know what end result is desired. For example, they may want a chemical to perform a certain function, or to replace an existing chemical for other performance reasons. Experimentation and creativity are essential in this phase so the team can investigate a complete range of potential alternatives. During concept development, the team will also look at the feasibility of alternative technologies and often make and assess samples or prototypes. Once the team starts making prototypes or samples, the product development process transitions into the technology development phase.

2. Technology Development. This phase generally involves actually making the technologies conceived in concept development. Existing equipment and processes are used to determine the appropriate route to make the chemical. The goal is to select a technology that is most efficient to manufacture. Experimentation and iteration with work performed during the concept development phase is not uncommon during technology development. Testing and refinement of different chemical technologies are routinely performed. Typically at the end of this phase, the product development team selects a single or a select few chemical(s) to be brought through the final two phases.

- 3. **Production Design.** Producing the chemical on a larger volume scale is the focus of this phase. Chemical specifications defining acceptable performance, variability, and other criteria are finalized. Performance testing and further refining of the chemical technology also is a common activity of this phase.
- 4. **Marketplace Presence.** Production ramp-up usually marks the beginning of this phase. Workers are trained and any remaining problems are worked out. Oftentimes intensive testing continues during production ramp-up. Preferred customers may also be asked to use the product so the company can evaluate how well it meets their needs and how it performs. The transition from production-ramp up to full-scale production is usually gradual and continuous, culminating in the launch of the product in the marketplace.

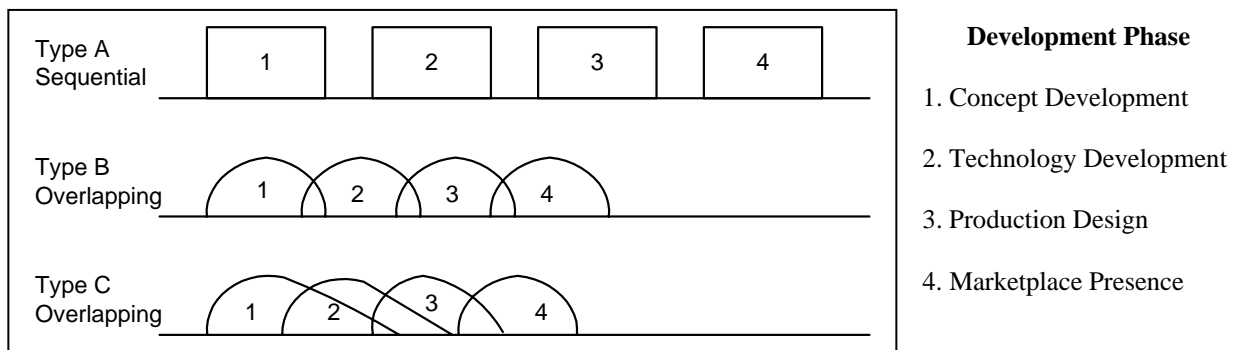
conducted. The top diagram, Type A, shows a strictly sequential process whereby work is passed on, like a baton in a relay race, at the end of each phase. The middle variant, Type B, depicts a process where activities are extended into the next phase. A highly active, integrated and iterative process is illustrated in the bottom variant, Type C. Which of these three internal procedures a manufacture uses is often dependent on the product being produced.

Significant time and resources are required to bring a new product through the four phases, with costs for chemical technologies accruing and increasing as one moves from concept development to marketplace presence. For product development processes that follow Types B and C processes, the distribution of spent resources differs from a sequential process. In general, the resources spent in technology development and production design occur early in the overall product development process. The magnitude and timing of these costs differs across firms, depending on the internal procedure used to bring the product development team through the four phases and the type of product being developed.

Though Figure 2 suggests a linear and sequential process, most organizations will have some level of overlap, iteration, or feedback loops among the different phases in their product development process. Figure 3 shows three variations of a generic product development process. Each has four phases in its development process but a different internal procedure by which the activities within each phase are

For example, an entirely new product requiring extensive research and new process design can be very expensive, taking years to develop. This type of product might follow a

Figure 3: Sequential and Overlapping Product Development Processes



Source: Adapted from "The New New Product Development Game", Takeuchi and Ikujiro, 1986

more overlapping product development process. In contrast, a product that builds off an existing technology, or chemicals that are intermediates of final chemicals produced, usually follows a sequential process and moves through the product development process quicker with less downstream impacts.

Regardless of whether total costs to bring a new or modified chemical are in the hundreds of thousands of dollars or the millions, streamlining the process is a high priority for any product development team. Each delay directly translates into potential lost profits and market share.

TSCA Review as Part of the Product Development Process

Submitting a PMN application under TSCA typically occurs in the middle to latter end of production design when the team is confident they have the best chemical candidate to manufacture and incorporate into a product. A company can expect three possible outcomes once it submits a PMN application: (1) no action is taken by EPA and the chemical can enter the market without restrictions; (2) the chemical may be regulated under a 5(e) consent order with some restrictions or; (3) the chemical is either banned by EPA or withdrawn by the manufacturer.

The financial consequences of a restriction or withdrawal of a PMN can be severe. Section 5 (e) restrictions can include consent orders requiring additional studies (such as long-term toxicity studies), worker protective clothing, emission controls or treatment technologies, and other forms of use restrictions. The magnitude of potential additional costs from a 5(e) restriction can easily be in the hundreds of thousands of dollars and sometimes reach several million should the manufacturer decide to comply with 5(e) restrictions and manufacture the chemical. Additional documentation and paperwork accompany most consent orders and their binding legal nature offers an additional

incentive for manufacturers to do their best to avoid them.

Opting to withdraw the PMN application is not necessarily a way to avoid costs for a potentially hazardous chemical. All the resources spent during conceptual development, technology development and production design are irrecoverable. Assuming the manufacturer is still interested in making the new product, another chemical candidate must be identified and brought back through the product development process. In this respect, costs for development, up to the point the potentially hazardous chemical is detected, can double.

It is in a company's interest to bring only one chemical candidate through the product development process and obtain PMN approval on the first try.

The additional costs incurred by withdrawing a chemical from the PMN process or manufacturing a restricted chemical are discussed in more detail in later sections of this report. It is safe to say that it is in a company's interest to bring only one chemical candidate through the product development process and obtain PMN approval on the first try. In doing so, the manufacturer is avoiding withdrawing the chemical after significant resources have been spent on its development, or manufacturing it with use restrictions. The best way to ensure no use restriction on a PMN application is to effectively screen out chemical candidates with undesirable human health or environmental impacts. The P2 Framework can help a company meet these objectives.

Chemical Evaluation and Screening in the Product Development Process

Many companies have developed internal systems for rapid, inexpensive chemical screening to help collect some hazard- and risk-related information on chemical candidates at earlier phases of product development.

The P2 Framework enhances these systems, in many cases significantly, because data that previously did not exist can be obtained rapidly, cost-effectively, and with minimum prior information on the chemical being evaluated. An examination of typical chemical screening and evaluation methods with and without the P2 Framework methodologies illustrates the value of early information.

Screening new chemicals is complex. The mere fact that a chemical is new means there are little or no existing data about its potential health or environmental impacts. Companies can use several approaches to try to learn about the health and environmental risks of a given chemical candidate:

- A company can undertake literature searches to see if a similar chemical is in the market or has been previously researched internally.
- Some companies have an internal group of specialists in health, safety, environmental, and regulatory issues to try to estimate health and environmental risk for a new chemical. Specialists generally rely on expert judgment and literature reviews to assess potential hazard. Such assessments will inevitably vary according to the prior experience and qualitative judgment of the assessors.
- Finally, environmental and health risk can be assessed through laboratory testing. Literature reviews and expert panels give at best a qualitative assessment while the results from laboratory testing are more quantitative in nature.

Recall that under TSCA, the manufacturer or importer is neither required to test the new substance nor proactively assess its expected health or environmental impacts when submitting a PMN. Instead, the PMN submission must contain, only to the extent “reasonably ascertainable,” the identity of the substance, its expected use and exposure, its expected production volume, and any available health and safety data. Presently, there are few positive incentives for a company to evaluate a PMN chemical early in the product development process. There are, however, significant disincentives in the form of financial resources and time required to thoroughly evaluate a chemical prior to a PMN submission.

Qualitative and quantitative assessments consume valuable financial resources. On the qualitative side, there is no guarantee of obtaining better information through literature reviews and convening internal experts even if the company is willing to commit the required resources. Quantitative laboratory tests do guarantee results, but can easily run in the tens of thousands of dollars for each candidate chemical. The larger the number of chemical alternatives under consideration, the higher the costs to gather quantitative data for chemicals or intermediates. Since numerous alternative candidate chemicals usually are identified early in the product development process, the resources and time required to perform qualitative assessments and/or laboratory tests on each candidate can become prohibitive. As development costs, including assessment and testing, are passed on to the consumer, the product may be put at a competitive disadvantage compared to a competitor’s product that did not undergo testing. In addition to the direct financial costs, testing of a chemical and subsequent data analysis takes time. Since a primary objective in any business is to get products to the market in the shortest time possible, adding time to the product development cycle also adds a strong disincentive.

However, delaying health and environmental information also carries business risks. First, postponing such information until later in the process (when the team is confident they have a viable candidate) increases the potential that regulatory barriers will be identified too late in the process after significant resources have been expended on the candidate's research and development. More importantly, risk-related information reduces uncertainty early in product development. This allows a company to better anticipate and manage business risk through more informed design of production processes and treatment controls. It also allows business managers to understand the true costs of a chemical's production—from measures to ensure worker safety, to environmental controls, to handling waste and byproducts. When decisions are made in the face of high uncertainty, such costs may not be factored into profitability projections. In some cases omissions can significantly alter conclusions regarding the financial viability of a new product or process. Thus comprehensive and timely health and environmental information support both regulatory concerns and business objectives.

Regulatory concerns and business objectives drive the need for comprehensive and timely health and environmental information.

The objective of the product development processes is to select the best possible candidate in the shortest time with the

least expense while minimizing health and environmental impacts. It is appropriate that technical performance (i.e., how well the chemical meets its intended function) is the primary focus of the product development team. While chemical and environmental information is viewed largely as a support function in the overall product development process, these kinds of data have enormous strategic value. When incorporated early in the product development process, such data can add significant economic and environmental benefit to the entire product development process.

The P2 Framework provides data that previously were not available in a cost-effective manner. Without the P2 Framework, health and environmental evaluation very early in the product development process can become very time and resource intensive.

Benefits from information provided by the P2 Framework impact three major areas:

1. Product development and process redesign
2. Product development speed and the impacts on the time to bring new chemicals and products to the marketplace
3. Production costs for the full-scale manufacturing of new *or* existing products

We consider the benefits as they apply to each of these areas in turn.

**BENEFITS OF THE P2 FRAMEWORK IN
PRODUCT DEVELOPMENT AND PROCESS REDESIGN**

The P2 Framework improves the overall product development process, and increases the value that the health, safety and environment function within a given company delivers to this process. The greatest opportunity for health and environmental screening to positively affect product development is in concept development, the earliest phase of product development. At this phase, insight into costly downstream health and environmental effects can quickly remove a candidate from the selection process.

The challenge for most companies is to determine the most timely and cost-effective

manner to gather and integrate health and environmental effects information into the product development process. On some level, the product development process is attempting to balance the timing and resources required to gather health and environmental hazard information with the value of this information.

Table 2 summarizes the key benefits of the P2 Framework associated with new product development and process redesign. More detailed discussion follows the table.

Table 2: Summary of Key Benefits to New Product Development and Process Redesign

LOWER PRODUCT DEVELOPMENT COSTS FOR NEW CHEMICALS AND INTERMEDIATES	
Quantitative Benefits	<ul style="list-style-type: none"> • Reduced (avoided) costs spent on technical development and R&D of new chemicals. • Decreased resources spent on laboratory tests for human health and environmental testing.
Qualitative Benefits	<ul style="list-style-type: none"> • A greater number of product combinations and product alternatives can be evaluated early in concept development. This allows for greater technology innovation and is due to the quick and cost-effective nature of the P2 Framework. • Better and early information on environmental and health (E&H) impacts allows the product development team to focus resources on technical performance. Knowing the E&H profile early allows the team to anticipate any additional E&H lab testing that may be required for PMN submittal to EPA. Such information may also alert the team to a chemical candidate that it wants to screen out from the selection process based on E&H concerns before significant resources have been spent on investigating its technical performance. • Better information allows companies to compare competing product alternatives and helps them identify environmentally sound technologies. • Greater awareness of “green design”.
Comments	The entire product development process is streamlined by better and earlier E&H information. The qualitative benefits all contribute to the potential realization of the two primary quantitative benefits.

Reduced Technical Development Expenses

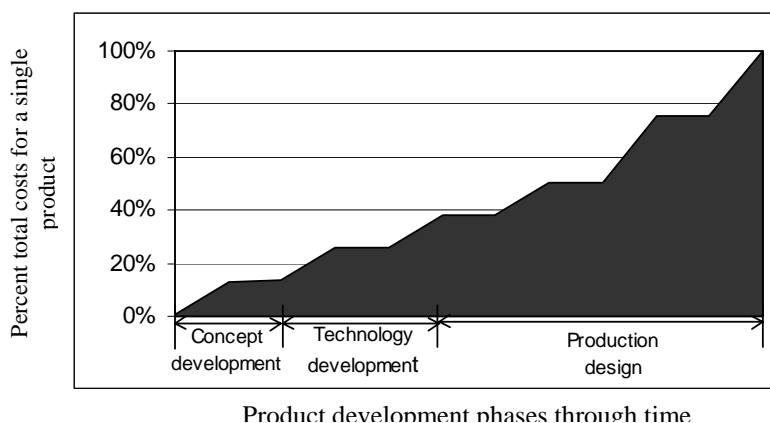
The benefit of having health and environmental data on alternative chemical candidates early in the product development process can have a major impact on the overall costs incurred in developing new chemical technologies. Though the benefits are probabilistic in nature, a closer look at the resources spent in the first three phases of product development points to the potential savings associated with using the P2 Framework as early as possible to screen out undesirable candidates. Figure 4 illustrates the cumulative resources spent on a single candidate as it goes through the first three phases of the product development cycle⁶. The activities under each of the three phases were discussed earlier in the product development process section of this report. The far right of the graph corresponds to the point a manufacturer typically submits a PMN notice.

A goal of the team is to have a lead candidate emerge from the pool of potential candidates identified in concept development. Any time a lead candidate is ruled out in one of

the later phases of product development, the team must start over with a new candidate back in the early phases of product development. Accordingly, all the money and time spent developing the lead candidate are irrecoverable - the team must start the process over from the beginning and commit resources to the next best lead candidate.

The graph shows how the percentage of total costs increases as a chemical progresses through the first three phases in the product development cycle. The distribution of costs follows a linear product development process. Companies that use a highly iterative and integrated process, where some activities in technology development and production design overlap earlier phases, will have a cost structure more front-loaded than that depicted in Figure 4. Each company, of course, operates differently. Thus, the average cost of bringing a chemical candidate through the process will vary. In general, the costs are substantial and may vary between hundreds of thousands of dollars to several million for each chemical (or process) evaluated.

Figure 4: Distribution of Cumulative Costs Spent in a Sequential Product Development Process



⁶ The distribution of costs approximate a typical linear product development process and is based in part on an example of the use of the methods at Eastman Kodak. This example is presented in Appendix B.

The graph illustrates how substantial savings lie in avoiding increased product development costs during the three phases of product development. Note that, normally, the majority of these costs are geared toward the technical aspects of a chemical's performance and its method of manufacture. As a technology gets further and further along in product development phases, the costs invested in a single candidate can be quite significant. Clearly, the earlier any adverse environmental and health effects are known about all candidates, the less likely a technology will progress into the later phases of product development. When a candidate is ruled out in later phases of product development, the team must select the next best alternative identified in concept development and invest time and resources in bringing it through the product development process. The further downstream the product development process an unfavorable candidate is discovered, the higher are lost product development costs.

The P2 Framework methods can help improve the company's chance that a viable

technical candidate will not be eliminated on environmental or human health grounds in later phases of product development. Ideally, the P2 Framework methods should be applied as early as possible in concept development to minimize resources spent on technical aspects of chemical candidates. Table 3 looks at the increased product development costs lost for each \$100,000 of total costs if the lead candidate must be dropped at progressive phases in the product development process. The magnitude of the irrecoverable costs will vary with where in the process the lead candidate was screened out. Based on the distribution of costs in Figure 4, the following rough estimates that can be made are shown in Table 3.

As an example, if a lead candidate requiring \$500,000 in total product development costs drops out at the beginning of production design, an estimated \$200,000-\$250,000 is lost. These lost costs translate into higher product development costs as the next best candidate is brought through the same set of activities costing another \$200,000-\$250,000.

Though these costs are rough estimates

Table 3: Product Development Costs Lost if Lead Candidate Must Be Dropped at Progressive Stages in Product Development

Scenario ...	Lost Cost per \$100,000 in Total Product Development Costs*
<ul style="list-style-type: none"> • Lead candidate drops out at the beginning of technology development 	\$15,000 - \$25,000
<ul style="list-style-type: none"> • Lead candidate drops out at the end of technology development 	\$25,000-\$35,000
<ul style="list-style-type: none"> • Lead candidate drops out at the beginning of production design 	\$40,000 - \$50,000
<ul style="list-style-type: none"> • Lead candidate drops out in the middle of production design 	\$60,000 - \$80,000
<ul style="list-style-type: none"> • Lead candidate drops out at the end of production design (does not get PMN approval) 	\$100,000
<p>*Distribution of costs for product development phases is based on Figure 5.</p>	

and variable, candidates historically have been dropped at all the phases listed in Table 3 for environmental or human health concerns. Recall that roughly 10% of all PMN submittals are either voluntarily withdrawn from PMN review or receive a 5(e) restriction by EPA. Assuming the manufacturer still intends to make the product, in either case they must now go back to the beginning of product development process and invest in resources in developing an alternative chemical. Such a scenario results in the greatest loss of product development cost to the submitter.

The P2 Framework doesn't eliminate product development costs but it does strengthen the team's ability to minimize them. From a business perspective, an organization wants to do everything possible to increase the probability that only one candidate needs to go through the latter phases of the product development cycle. In such a scenario, product development costs are kept at a minimum. Companies who employ some level of qualitative health and environmental evaluation early in the product development process may eliminate some undesirable candidates, but without quantitative data it is difficult for the company to be certain of their decision. Chemicals with undesirable health and environmental characteristics still make it to later phases of product development. No matter at what phase a candidate is dropped, some spent resources are irrecoverable, and are, in effect, wasted.

Some managers consider various failures and associated increases in product development costs as an expected part of the "cost of doing business" for the research and development of new products. The P2 Framework can help eliminate avoidable "failures" arising from health and environmental concerns.

Human Health and Environmental Testing Costs

Although there is no requirement that a company submit toxicological data under the TSCA PMN application process, many companies will conduct some level of testing if they suspect adverse health or environmental risk. Companies typically decide, on a case by case basis, what tests are needed to help meet regulatory approval or minimize risk in their operations, to their workers and to the environment

The level and extent of testing varies by company and by the chemical under consideration. Table 4 below provides typical costs for testing of substances using OECD Testing Guidelines and good laboratory practice. For human health, common tests may include acute oral, dermal, and inhalation toxicity. Based on data presented in Table 4, this would amount to \$21,650. Common tests for environmental effects might include acute toxicity to fish, acute toxicity to invertebrates (*Daphnia*), and aerobic aquatic degradation costing an additional \$28,000. Some companies may spend much larger amounts; following the Organization for Cooperation and Development (OECD) Guidelines the total cost for typical "base set" testing is between \$140,000 to \$200,000.⁷

In addition to TSCA regulatory approval, several companies who have used the P2 Framework expressed its utility for new chemical submission programs worldwide,⁸ notably in Canada and the European Union.

⁷ OECD, 1998.

⁸ Based on conversations with John Davis at Dow Chemical, Randi Henderson at PPG Chemical, and Chuck Ruffing at Eastman Kodak Company.

Table 4: Typical Costs for Testing of Substances (in US Dollars)

Mammalian Toxicity		Physical-Chemical Properties	
Acute oral toxicity	\$ 2,840	Melting point/melting range	\$ 440
Acute dermal toxicity	\$ 4,560	Boiling point/boiling range	\$ 490
Acute inhalation toxicity	\$ 14,250	Density/relative density	\$ 420
Repeated dose oral toxicity	\$ 51,840	Vapor pressure	\$ 2,140
Repeated dose oral toxicity with reproductive/developmental screen	\$ 154,930	Partition coefficient octanol/water	\$ 3,490
Reverse mutation assay	\$ 5,960	Water solubility	\$ 3,440
In vivo cytogenetics- micronucleus assay	\$ 34,820	Dissociation constant in water	\$ 1,450
In vitro mammalian cytogenetics	\$ 14,690	Soil adsorption/desorption isotherm	\$ 19,470
Developmental toxicity test	\$ 79,240	Ecotoxicity	
Reproduction and fertility effects	\$ 425,730	Fish acute toxicity	\$ 10,950
Chronic oral toxicity	\$ 324,600	Aquatic invertebrate acute (Daphnia)	\$ 7,230
Carcinogenicity	\$ 539,000	Algal toxicity	\$ 8,830
		Aquatic invertebrate chronic (Daphnia)	\$ 26,400
		Environmental Fate and Pathways	
		Hydrolysis as a function of pH	\$ 9,140
		Aerobic aquatic degradation	\$ 10,030

Source: Organization for Economic Co-operation and Development, 1998.

In addition to regulatory approval, need for chemical assessment is also driven by product recall, brand image, and competitor issues. To manage such risk, companies are presented with several alternatives: test all chemical candidates, test the most likely technical winners, or test only the best technical candidate.

Regardless of the total cost for testing, the P2 Framework can reduce environmental testing costs in two ways. First, in some cases, information from the P2 Framework methodologies will allow a company to avoid some tests altogether, thus lowering the amount of money spent on laboratory testing in the PMN submittal process. This is especially true for cases where a company may decide to test at an early point a particularly promising chemical candidate with highly uncertain health and environmental impacts. The second benefit is realized in those circumstances where the P2

Framework screens out a candidate that otherwise would have survived the entire product development process up through PMN submittal and ultimately be dropped. If the tests indicate that the chemical presents potential health and environmental effects and the company decides to withdraw the chemical and start the entire process from the beginning, a second chemical also will go through the product development process, including a similar series of tests.

Though these costs are insignificant compared to the costs spent on technical development of the second candidate, the money spent on testing the first candidate is irrecoverable. By using the P2 Framework, the team already has estimated the health and environmental characteristics of the new chemical and tests can be conducted to confirm these predictions. The P2 Framework greatly increases the probability that a company will test

only one candidate prior to submitting their PMN application.

The most significant testing cost may come if a new chemical receives a 5(e) action in the form of a consent order requiring additional toxicological data. For example health tests for reproductive and fertility effects, chronic oral toxicity and carcinogenicity all run in the hundreds of thousands of dollars. Note that a company can choose not to manufacture the chemical because of the consent order. This is not necessarily an attractive alternative from the standpoint of time or money—the company would still need to develop an alternative chemical.

A More Streamlined Product Development Process

Early and more definitive chemical screening will further streamline any company's product development process. The P2 Framework reduces uncertainty and allows the product development team to focus its resources on its core function – the technical performance of the new chemical in relation to the overall design criteria of the product being developed. In addition, timely and accurate information allows the team to better manage risk and can decrease time and resources spent on problem identification.

An important way in which the P2 Framework streamlines the product development process is that it allows the product development team to consider a larger number of chemical candidates. Without using the methods, narrowing down 12-15 chemicals to one or two in the early phase of product development can be a lengthy and costly process. This can be a daunting, or sometimes an impossible, task especially if the team must narrow the chemical candidates in a short period of time. The P2 Framework actually can reduce this burden because candidates can be screened quickly and inexpensively. More chemical candidates can be considered early in concept development by

using health and environmental concerns as a preliminary screen.

The P2 Framework allows the product development team to consider a larger number of chemical candidates.

There is a more subtle point to increasing the number of candidates evaluated—the product development team may find a much better candidate from the larger potential pool. The higher the number of candidates to choose from, the greater the chances that the best possible technical and environmentally preferable candidate will be selected. In getting down to a manageable number of candidates for more resource intensive evaluation, the product team does not falsely rule out some of the initial candidates due to uncertainty of their health and environmental impacts. Thus, in addition to screening out undesirable chemical candidates, the P2 Framework also will help prevent potential technically superior candidates from being ruled out due to uncertainty regarding their health and environmental characteristics.

In using the P2 Framework methodologies, EPA's process for review becomes more transparent to the applicant. An applicant also becomes a better judge of when a chemical may require additional information. In such cases, the applicant can perform the tests and submit the information as part of the TSCA PMN application. A more informed application greatly reduces the chance of an unfavorable action by the EPA.

The P2 Framework provides a logical framework for comparing chemical technologies and helps companies identify environmentally preferable products. Consistent, quantitative information gives the product development team the ability to rank, in a relative fashion, the leading candidates according to environmental and health hazard. Such rankings can be incorporated into other corporate efforts such as Design for the Environment, or can be used to help develop new environmentally preferable

product lines. Over time, the product development teams learn to design chemicals that effectively minimize environmental impacts yet satisfy all cost and performance goals. By making the use of health and environmental information standard business practice, use of the P2 Framework provides long-term and recurring benefits.

Together, the benefits of being able to evaluate more candidates and having consistent

and quantitative information can greatly strengthen a company's entire product development process. Put simply, better and earlier information leads to more certainty, quicker decisions, and smarter design. This is perhaps the greatest impact the P2 Framework has on product development in that it institutionalizes positive change to a company's evaluation component in new technology development.

BENEFITS OF THE P2 FRAMEWORK IN PRODUCT DEVELOPMENT SPEED

The P2 Framework has demonstrated a great potential for decreasing costs through streamlining the product development process and by increasing the probability that only one candidate will need to go through the latter phases of the product development cycle. However, these avoided costs only tell half the story of the possible benefits of the P2 Framework. For cases where the profitability of a new product is dependent on its introduction into the marketplace, the savings in the speed of new product development can be equally or perhaps more, important. Table 5 provides a

summary of the benefits of the P2 Framework as they relate to product development speed.

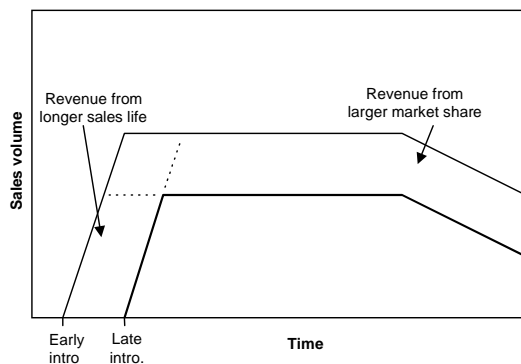
Figure 5 depicts potentially lost revenues when a new product does not meet its target date for market introduction. There are two situations contributing to potentially lost revenue. First is decreased market share from entering late into the market place. Second, a new product can lose revenue from a shorter sales life. Technology-based new products are susceptible to lost revenue from both types of situations. Aggregating lost revenue from slow introduction of all product poses serious risk to a

Table 5: Summary of Key Benefits to Product Development Speed

REDUCED TIME TO MARKET FOR NEW PRODUCTS/CHEMICALS TO MARKET	
Quantitative Benefits	<ul style="list-style-type: none"> • Faster time to market for new product introduction by minimizing the chances that a lead candidate will fall out of the product development process for health, environment, or safety concerns. • Avoid a 5(e) regulatory action for PMN review which may require additional information or testing, causing delays in getting EPA approval. • Minimize cycle time for PMN review by submitting an informed and complete application.
Qualitative Benefits	<ul style="list-style-type: none"> • Reduced probability that a candidate is dropped, delaying the product team as they evaluate another candidate.
Comments	<p>The magnitude of the benefits can be very large owing to increased revenues from a longer sales life and potentially larger market share for early or on-time market introduction. Benefits will vary from project to project and depend on factors such as missed product sales, volume for the delayed time period, product price and profit margin, and the overall competitive environment of the product.</p>

business's ability to compete.

Figure 5: Lost Revenue from Late Market Introduction of New Products



Source: adapted from *Product Innovation Pure and Simple* (Robert, 1995).

The P2 Framework can enhance the product development team's ability to meet their target market introduction schedule. Any time a candidate falls out of the product development process, the entire schedule is delayed as the product development team must start over with the next best candidate. The length of the delay will depend on exactly where in the product development process the candidate was screened from consideration. This can amount to weeks or months or in extreme cases greater than a year. The P2 Framework can eliminate such delays by providing information at the earliest phases of concept development.

Any chemical or intermediate that must go through New Chemical Review under TSCA is also susceptible to two types of delays:

1. Delays caused from a 5(e) action during PMN review. The length of delay will depend on the type of action. For example, demands for additional data or testing can involve several weeks or months for some types of laboratory testing and up to several years if long-term toxicity testing is required.
2. Delays from regulatory approval cycle time. Under TSCA, the EPA

can extend the review period from 90 days to 180 days with a showing of cause (e.g. concern may exist but there may not be enough information in the PMN application to make a conclusive determination in the 90-day review period). Conversely, manufacturers can shorten the 90-day review time under certain TSCA exemptions.⁹

Savings from reduced development time will depend largely on whether the sales volume is sensitive to the window of opportunity for product sales. This is often the case for new products and technologies where few existing products can compete or where the leading technology is highly dynamic. Computers and imaging technologies are examples. In such cases, meeting the target time for product introduction takes on a critical role as a driver of profitability.

Delayed introduction of a new product can result in huge financial losses, amounting to hundreds of thousands or millions of dollars. Technical, production-oriented and regulatory factors contribute to a new product reaching the market. Though a complex and dynamic process, the more control the product development team has over any of these factors, the better the chances of meeting the desired market introduction schedule. The P2 Framework helps ensure products with undesirable health and environmental impacts are screened out as early as possible. This helps avoid costly interventions where the product development team is forced to drop an undesirable candidate and re-start the examination of an alternative chemical candidate.

⁹ For further detail on extensions and exemptions, see the EPA OPPT New Chemical Program website at www.epa.gov/opptintr/newchms/. Specific questions can also be directed at the TSCA hotline at 202-554-1404.

BENEFITS OF THE P2 FRAMEWORK IN MANUFACTURING AND OPERATIONS

The focus of this report has been on new chemical development and chemical screening as part of product development. However, the P2 Framework also provides substantial benefits long after PMN submittal in downstream manufacturing operations. The benefits described in this section can also be realized for chemicals where a new chemical does not go through screening (there are no alternatives) or even for chemicals not subject to PMN approval under TSCA.¹⁰ While the same challenges associated with chemical screening do not exist, information from the P2

Framework provides strategic value relating to a chemical's production. Table 6 provides an overview of these benefits.

Early, quantitative information on health and environmental hazard allows companies to make more informed decisions that impact manufacturing operations. Usually, there is more than one technically feasible method for making any given chemical product. The challenge to companies is to find the most economical way, in order to compete effectively against others who may offer the same or similar product.

Table 6: Summary of Key Benefits to Ongoing Manufacturing and Operations

LOWER PRODUCTION COSTS FOR THE FULL-SCALE MANUFACTURING OF NEW CHEMICALS

<p>Quantitative Benefits</p>	<ul style="list-style-type: none"> • Decreased costs associated with using hazardous chemicals (e.g., environmental reporting, testing, employee training and personal protective equipment, waste treatment, disposal, handling spills). • Reduced probability the submitted chemical will be subject to 5(e) actions by EPA which may require either monitoring and tracking or more controls and treatment during manufacturing. • Decreased potential for downstream interventions such as product recalls or major changes to the manufacturing operation (related to unanticipated long-term toxicological effects of a product or technology).
<p>Qualitative Benefits</p>	<ul style="list-style-type: none"> • Improved performance of the health and environment team in supporting the overall product development process. • Enhanced ability to identify and drive P2 outcomes.
<p>Comment</p>	<p>Increased production costs typically result when environmental and health risk information is <i>unknown</i> or <i>unanticipated</i>. By providing this information <i>early</i> in product development, the team can make informed decisions about the tradeoffs in technical performance and the production costs related to using competing chemical candidates.</p>

¹⁰ The case study in Appendix B documents the benefits from estimating chemical properties of a chemical to determine safe handling procedures.

Sometimes there are significant differences in the health, environmental or safety considerations amongst alternative chemical inputs, synthetic routes or processes. Increasingly, chemical manufacturers must consider such factors in their choice of approach. As chemical facilities are one of the largest producers of toxic waste and the source of significant releases to the environment, the environmental stakes in these decisions are high. So are the financial stakes and the P2 Framework can help companies evaluate such considerations as a source of competitive advantage.

Consider the example when a customer submits a request for proposal (RfP) for the manufacturer of a specific chemical and there are no alternatives to consider. The P2 Framework can provide data to allow a manufacturer to accurately help capture costs associated with the manufacturing and management of byproducts from the specific chemical at the RfP stage. Early data can also be used during process design to look for cost savings opportunities (by reducing waste through P2, eliminating waste altogether, or finding more cost-effective ways to manage waste). The absence of health and environmental data increases the likelihood that significant costs will be overlooked or cost-saving opportunities will be missed—either one will negatively impact the bottom line. The P2 Framework can help provide such data quickly and at minimal cost.

Manufacturing chemicals by nature carries many additional, and often hidden, costs.¹¹ When considering any chemical manufacturing process, a company must specify correct personal protective equipment, process controls and proper safety guidelines. Sound waste management techniques also must be defined. Issues such as storing and transferring chemicals and cleaning during production

shutdowns all must be worked out. Once in the marketplace, a new chemical-based product may require hazard communications vehicles such as material safety data sheets and product labels. Communication on proper use may also be required so customers are properly informed. In addition, a company must be prepared to respond to customer inquires and concerns. All of these activities translate into additional costs or labor and are incurred throughout the production lifetime of the chemical. The magnitude of these costs is often related to the toxicity of a chemical. If they are not recognized or factored in to early decision making, they can greatly alter the profitability projections of a new product.

Manufacturing chemicals by nature carries many additional, and often hidden, costs.

For the case of new chemicals, many of these same costs can be triggered by a restriction under Section 5(e) of TSCA. In addition, many orders may require extensive monitoring and reporting. Whether the costs are driven by TSCA actions or a company's internal health, safety and environmental policy, it is crucial to understand the health and environmental impacts of proposed manufacturing as early as possible. The P2 Framework can strengthen the health and environmental team's capabilities in this area. By highlighting possible risk issues, a company can identify the otherwise unanticipated costs of production and management of toxic chemicals. This allows the entire product development team to make more informed decisions and to balance the technical performance of a chemical with its health and environmental impacts.

Better health and environmental information also decreases the potential for downstream interventions such as product recalls or major changes to the manufacturing operation (related to unanticipated long-term toxicological effects of a product or technology). While such occurrences are less frequent, the

¹¹ For a more detailed discussion on the full costs of chemical use in manufacturing processes, see Kauffman Johnson et al.

financial consequences can be enormous. Once a chemical is fully integrated into the economy, it becomes more difficult and costly to address than before it is introduced. PCBs in electronic equipment and other applications are a case in point. By knowing whether a chemical candidate is potentially hazardous early in the product

development process, the health and environmental team can avoid having these chemicals enter the marketplace and create unnecessary and unwanted financial risk for the company.

CONCLUSIONS

Competitive advantage in today's market is achieved and retained by a constant replenishment of new products and services. In technology-based companies, product development costs, time-to-market, and full-scale manufacturing costs are all key ingredients to achieving this competitive edge.

EPA's P2 Framework helps firms obtain a competitive edge by enriching health and environmental information early in the concept development phase of the product development process. Benefits from the P2 Framework vary across companies because product development processes and products themselves are highly diverse. For some applications, the primary benefits will be from reduced product development costs; in others, it may be reduced manufacturing costs; in yet another, it may be in meeting the target date to bring a new product to market.

In addition to these project-specific and predominantly economic benefits, there are less tangible benefits that will be realized every time the company uses the P2 Framework methods. These include the benefits associated with streamlining the product development process and improving the performance of the health, safety and environmental team. These benefits can greatly enhance a company's ability to proactively produce environmentally preferable products and design processes with distinct pollution prevention outcomes.

Given the project and company-specific nature of the benefits, this report attempts to provide a conceptual model that a company can apply to its unique context. Internal communications between the health, safety and environmental team with other members of the product development team are critical to the realization of the full benefit potential of the methods in the P2 Framework.

In thinking about how the P2 Framework may enhance a company's product development process, two considerations merit attention. First, it is important to describe the process a company currently uses to conduct health and environmental evaluations. In particular, at what stage in the product development process and at what level of detail is health and environmental screening currently performed? Do staff conduct literature reviews and try to assess a chemical candidate's health and environmental hazard early in the concept development phase? Are they able to screen candidates on health and environmental criteria early in the chemical process? Or does technical performance evaluation of new technologies predominantly guide the product development process with health and environmental issues investigated later in product development? Do staff rely predominantly on laboratory testing to assess health and environmental hazard? The answers to these questions will help determine the strategic potential of earlier, better, and more definitive health and environmental information provided by the P2 Framework.

The second consideration is the company's past experiences in product development with chemical technologies. What is the track record with submitting PMN applications under TSCA? How frequent are 5(e) actions? How much are they costing and how much did they delay product production? Have applications been withdrawn from the PMN process? Has it been discovered very late in the product development process that a chemical technology has unacceptable health and environmental characteristics? Have the environmental properties of any chemicals used in processes, or in products caused costly downstream interventions in the marketplace? In managing wastes? In protecting workers? In legal liability?

traditional lines between environmental concerns and core business functions are increasingly blurred. This, in turn, is another sign of the integration of environmental considerations into strategic decision-making.

A challenge in quantifying the benefits of the P2 Framework methods is that a company will never conduct a parallel "control" study to see what types of decisions *would have been made* if the methods were not used. However, looking at past experiences and associated product development costs provides a strong indication of the types and magnitude of costs the P2 Framework can help reduce or avoid. Product development processes can always be improved and the P2 Framework can greatly enhance health and environmental evaluation and screening capability by providing definitive data early in the process.

With a baseline of what constitutes health and environmental evaluation and screening protocol as well as knowledge of past experiences in product development, a company can use this conceptual model to see where and how certain methods can benefit the product development process. Since the costs of purchasing and training individuals to use the P2 Framework methods is relatively low and the methods can be used over and over again, their overall potential for continuous cost and environmental improvement is substantial.

Reflecting on the application of the P2 Framework in chemical-related product development, it is again made clear how the

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**Appendix A : Using the P2 Framework to Screen Chemicals Early in Design
A Case Study from Eastman Kodak**

USING THE P2 FRAMEWORK TO SCREEN CHEMICALS EARLY IN DESIGN - A CASE STUDY FROM EASTMAN KODAK

Application of the P2 Framework

The EPA P2 Assessment Framework (P2 Framework) was used to screen chemical candidates during the design of a new product—a reformulation of a chemical developer for one of Kodak’s major film lines. A major part of the reformulation involved replacing one of the chemical components, a lengthy and costly process as Kodak evaluates the technical performance of the replacement chemical. Since the reformulated developer has other chemical constituents, the compatibility of the replacement chemical is also part of the overall product development process. The process by nature is iterative. It entails taking anywhere from 5 to 20 or more potential chemical candidates, identifying “lead” candidates, and finally selecting a replacement ready for commercialization.

The reformulation in the proposed film line is significant because it affects all customers that process this type of film. Compared to many reformulation activities, it is also noteworthy because it involves actual chemical replacement rather than modification to an existing formulation.

The largest research costs incurred during product development are related to the technical evaluation of individual chemical candidates for their photographic properties. The product development team is encouraged to be innovative during the initial creation of chemical candidates. However, due to the high cost of technical evaluation for each and every candidate, Kodak will narrow the candidates to 4 or 5 lead candidates very early in the product development process. As it gets further in the product development cycle, the product development team will focus on a single “lead” candidate.

Narrowing the initial list of candidates to 1-2 lead candidates is accomplished through a series of screens on photographic performance, potential human health impacts and potential ecological hazard. In Kodak, as in most companies, the product development team’s primary focus is on the technical evaluation of a chemical’s photographic performance while Health and Environmental specialists provide support through the assessment of health and environmental risk. Since these chemicals by nature are new, there is limited information on their potential health and environmental impacts. Compiling such data through laboratory tests and controlled studies is a costly and sometimes lengthy process, often reserved for the later phases of product development when the team believes the “lead” chemical has satisfied technical performance criteria. With little health and environmental information, the product development team is often forced to screen the initial pool of chemical candidates down to a manageable 4-5 without knowing the risk tradeoffs amongst the 19 initial candidates.

The P2 Framework was designed to provide quantitative health and environmental data based on the chemical properties of a given chemical. Thus, the P2 Framework can provide timely information in a cost-effective manner so data can inform decisions made early in the product development process. Kodak’s Health, Safety, and Environment (HSE) department recognized an opportunity to enhance their knowledge of potential replacement candidates for this reformulated developer through use of the P2 Framework. In this case, the P2 Framework was aimed at enhancing ecological hazard information at the earliest possible point in the product development process. By screening out chemicals with undesirable ecological properties, the team could avoid expending resources on technical performance

tests and human health evaluation in later phases of the product development process. This case study highlights a primary benefit of using the EPA developed P2 Framework — to provide valuable, quantitative information early in the chemical design process.

Kodak relied primarily on two models within the EPA P2 Framework: ECOSAR, a model that estimates acute toxicity and, where available, chronic toxicity for fish, invertebrates, and algae; and KoW, a model that estimates a chemical's octanol/water partitioning coefficient. (ECOSAR requires limited input, including the octanol/water partitioning coefficient and the molecular weight of the substance.) The assessor needs a basic understanding of organic chemistry, ecotoxicity and structural activity relationships. He/she also needs to be familiar with the Simplified Molecular Line Entry System (SMILES) notation. SMILES is a system to translate a chemical's structure into a string of symbols that is easily understood by computer software. In summary, the P2 Framework, SMILES notation and molecular weight allow a user to estimate acute and chronic toxicity to aquatic organisms.¹²

Summary of key findings

Note that this case study compares the benefits of applying the EPA P2 Framework in the chemical selection process to a hypothetical "business as usual" (BAU) scenario where chemical selection is made without using the P2 Framework. When the EPA P2 Framework was actually applied, Kodak did not simultaneously perform a control study to try to make the exact same decision without the EPA P2 Framework. Consequently, the BAU scenario is based on the best estimates from those individuals directly

involved in the project on what *would have happened* if the EPA P2 Framework were *not* used.

The major benefits for this case are outlined below. Further discussion of each benefit can be found in the discussion following the summary.

- Between \$13,500 and \$100,000 of additional costs were avoided for each \$100,000 dollars Kodak spends in photographic testing for a new chemical candidate. The P2 Framework doesn't eliminate costs of photographic performance testing; rather, the P2 Framework strengthens the ability of the product development team to minimize them. Benefits are realized by reducing the probability that that such costs will be expended on a chemical candidate that will eventually be dropped from consideration on health or environmental grounds.

For example, assume it costs Kodak \$100,000 to bring a single candidate through photographic testing. If the lead chemical candidate drops out for health or environmental concerns after Kodak invests \$13,500 in time and resources, then this \$13,500 is irrecoverable. Kodak must begin again with the next best candidate with the goal of having it go through the entire process successfully at a cost of \$100,000. The total money spent if this second candidate makes it through the product development process is \$113,500 (\$13,500 on the first candidate that was dropped and \$100,000 for the second candidate that made it through the entire process). If an unacceptable candidate is discovered very late in the process then the amount of irrecoverable resources spent approaches the full cost of bringing a single candidate through photographic performance testing (in this case \$100,000). Similarly, the magnitude of savings from the P2 Framework increases if more than one candidate gets screened before resources are expended on photographic performance testing.

¹² At Kodak many employees already had the requisite skills and were aware of SMILES notation such that no additional resources were needed to train users in the SMILES system. This will likely be true at most large companies but may not be true at some smaller companies.

- The P2 Framework reduced Kodak's ecological evaluation costs by roughly 80% (\$100 per chemical with the P2 Framework compared to \$500 per chemical without the P2 Framework). Further, the P2 Framework provides quantitative estimates of ecological risk whereby assessments without the P2 Framework often must rely on the judgment and experience of internal experts. Note that the magnitude of the costs to obtain quantitative data with the P2 Framework is minimal compared to overall product development costs.
- The number of initial chemical candidates identified that could be investigated as potential replacement chemicals increased from 4-5 without the P2 Framework to 19 with it.

Discussion

A comparison of how chemical candidates are evaluated with and without the EPA methods is followed by a discussion of the benefits from using the P2 Framework.

Analyzing the Reformulation Components With and Without the EPA P2 Framework

The product development team initially identified 19 potential candidates as a replacement for the chemical in the reformulated developer. In general, the product development team is encouraged to be innovative in coming up with the initial pool of chemical candidates. The number of these initial 19 chemical candidates chosen for further investigation in a given product development scenario will depend on many project-specific factors, including: available information on any similar chemicals, available resources, and the target date to manufacture the new product. Time and resources, as always, dictate the overall number of initial candidates that can be more fully investigated.

The product development team's goal was to reduce the number of initial candidates

down to a manageable 4-5 "lead" candidates very early in the product development process. Screening was based on 3 criteria: 1) technical performance, 2) potential health impacts and 3) potential environmental hazard. A challenge for the product development team is minimizing the resources expended to gather data while getting enough data to make informed decisions on screening out the initial 19 candidates. On one hand, they do not want to expend significant resources on a chemical candidate that may be dropped early in the process as they narrow the initial 19 candidates down to 4-5. On the other hand, there is a risk in going forward with a select 4-5 chemicals when little is known about the potential health and environmental hazard; the risk being that a chemical could be dropped for unacceptable health and environmental reasons late in the product development process, after significant resources have been expended on evaluating its photographic performance.

Prior to the use of the P2 Assessment Framework, Kodak employed internal procedures and processes to estimate health and environmental risk of new chemicals. During the early phases of product development, when there are many potential chemical candidates, an internal group of specialists in health, safety, environmental, and regulatory issues would be used to estimate health and environmental risk for a given chemical. The group of specialists rely on expert judgment, literature reviews, and their past experience with similar chemicals to assess potential hazard. The assessments therefore vary according to the prior experience and qualitative judgment of the assessor.

Obtaining quantitative data on new chemicals typically is done through costly laboratory testing or long-term studies. Consequently, the team relies on the qualitative assessments an internal group of specialists during the early phases of product development. Because these qualitative assessments take time and resources, Kodak would have not have performed them on all of the initial 19 candidates. Therefore, the first screen going from the initial 19 candidates down to 4-5 lead candidates would have been based on known or

anticipated technical properties of each chemical.

Using the EPA P2 Framework, All 19 of these candidates were screened using ECOSAR which estimates the toxicity of a given chemical to aquatic organisms. Through the use of the EPA P2 Framework, these 19 candidates were reduced to five “leading” candidates based on estimated ecological toxicity. These five “leading” candidates then underwent initial technical performance and human health screening. Using ecological hazard information *as the first screen* represented a departure from the typical process of narrowing down the initial

The EPA P2 Framework augments the existing process by providing quantitative estimates for each chemical candidate based on its chemical structure.

19 candidates primarily on technical grounds.

Even with the EPA P2 Framework, Kodak continues to use its internal panel of experts to lend knowledge and help make decisions to screen chemicals with unacceptable human health or ecological risk. The EPA P2 Framework augments this process by providing quantitative estimates for each chemical candidate based on its chemical structure.

Without the use of the EPA P2 Framework, Kodak would not have been able to adequately consider all 19 of the originally identified candidates. The process of relying on literature reviews and expert judgment of internal specialists is a time consuming process. Further, even *if* Kodak judged it a valuable investment of time and resources, this qualitative process does not guarantee quantitative data on the ecological impacts of the chemical candidates. This is especially true if the new chemical is not similar to any known chemical and the literature search falls short. To get from

19 initial candidates down to these 4 or 5 “lead” candidates, preliminary evaluations are made with the “best available information” and often rely on an expert’s best judgment. Given the limited resources and high development costs of designing new chemicals, it is sometimes safer to be conservative and possibly rule out one candidate over another very early in the product development process simply because there is no ecological data or human health data.

In summary, the primary differences in Kodak’s chemical screening and evaluation process with and without the EPA P2 Framework in this case are:

1. The EPA P2 Framework allowed the team to evaluate more potential candidates (19 compared to 4-5)
2. The EPA P2 Framework provided quantitative data for each chemical candidate evaluated. Without the P2 Framework, the ability to gather quantitative ecological hazard information is often infeasible.
3. Better and more consistent data fundamentally changed Kodak’s chemical screening evaluation process. With the P2 Framework, Kodak was able to use ecological hazard screening as a primary screen, followed by more resource intensive screens of human health and technical performance. This is in contrast with simultaneous screening of human health, environmental and technical criteria under BAU.

Benefits of The EPA P2 Framework

Overall, the use of the EPA-developed P2 Framework aided in the development of a more complete and quantitative health and environmental assessment for this product reformulation. It provided Kodak with an understanding of the environmental effects for the new chemical and the feedstocks used in its

synthesis. This information was obtained in a cost-effective manner and was able to be used **early** in the product development process to allow for more informed preliminary screening decisions.

- Increased Number of Chemical Candidates can be Evaluated Early in the Product Development Process.

As mentioned above, the Kodak product development team was able to evaluate 19 candidates instead of 5 by using the P2 Framework. Increasing the throughput of candidates analyzed allowed the team to spend limited resources on a larger pool of candidates. The higher the population to choose from, the greater the chances that the best possible technical *and* environmentally preferable candidate will be selected and designed. Allowing a larger number of candidates also gives the product development team more flexibility to create innovative designs. In short, through the process of getting down to a manageable 4-5 candidates for more resource intensive evaluation, the product team did not falsely rule out some of the 19 candidates because of uncertainty in ecological impacts.

- Reduced Costs for Ecological Assessment of Chemical Candidates.

The P2 Framework reduced the costs for ecological evaluation. The estimated per candidate cost to perform literature reviews and conduct ecological assessments without the P2 Framework was between \$500 and \$1,000 per candidate. In using EPA's ECOSAR method, these costs are reduced to roughly \$100 per candidate. The cost estimate includes the labor cost associated with gathering input data, running the computer model, and evaluating the results. This amounts to an 80% reduction per candidate screened (from \$500 per candidate without the P2 Framework to \$100 per candidate with the P2 Framework). Looking at the overall costs to perform ecological evaluation, it costs

\$1,900¹³ to screen all 19 candidates with the methods compared to \$2,500 without them (5 candidates at the lower bound estimate of \$500 per candidate). Thus the overall savings amounts to \$600.

The monetary savings do not adequately capture the value the P2 Framework on ecological assessment. Consider that Kodak was able to assess more candidates with the P2 Framework at a lower cost. Further, the P2 Framework provided quantitative data while evaluation without the P2 Framework often leads to qualitative assessments based on limited available data. Together, the benefits of higher throughput and consistent and quantitative information have greatly strengthened Kodak's entire product development process. This is perhaps the most significant impact the P2 Framework has had in that it represents an institutionalized change to Kodak's evaluation component in new technology development.

The indirect benefits of the P2 Framework are strategic in nature – better information leads to more certainty, quicker decisions, and smarter design.

Ecological hazards screening savings, while the most quantifiable, are actually minor in comparison to indirect benefits. These indirect benefits are strategic in nature – *better information leads to more certainty, quicker decisions, and smarter design*. In this case, the P2 Framework provided quantitative estimates of acute and chronic toxicity to aquatic organisms for each candidate. Better information allows the expert panel to make decisions

¹³ This cost (\$100 per candidate for 19 candidates) represents the labor cost of using ECOSAR and KoW. The programs are free from EPA. It is also estimated that it costs \$5,000 to train each person on the entire P2 Assessment Framework. The one time training cost was not attributed to this single case study as the training will serve numerous uses and users of the P2 Frameworks.

quicker and with more certainty. Consistent, quantitative information allows the team to attempt to rank the leading candidates according to ecological hazard. A recommendation can then be made to the product development team as to which candidate should be chosen that will be the least likely to be eliminated for environmental reasons in later phases of development. This level of confidence allows the product development team to focus its resources on its core function – the technical performance of the new chemical in relation to the overall performance of the product being developed.

Of course these indirect benefits are difficult to quantify since they are probabilistic in nature. Recall that we are comparing decisions that were aided by use of the P2 Framework to some alternative decision we have to assume *would have occurred* if the P2 Framework were not used. Nevertheless, significant benefits of the P2 Framework are realized and can be more fully appreciated when viewed in the context of the overall product development process.

- Reduced Product Development Costs Related to Evaluation of the Technical Performance of New Chemicals.

The graph below illustrates the cumulative resources spent on a single candidate as it goes through the product development cycle. The product development cycle is broken into six stages representing activities done at Kodak to bring new chemicals to the market. These stages begin with initial synthesis and testing of chemical candidates and continue through manufacturing scale-up to clearance for chemical manufacturing. The six stages are:

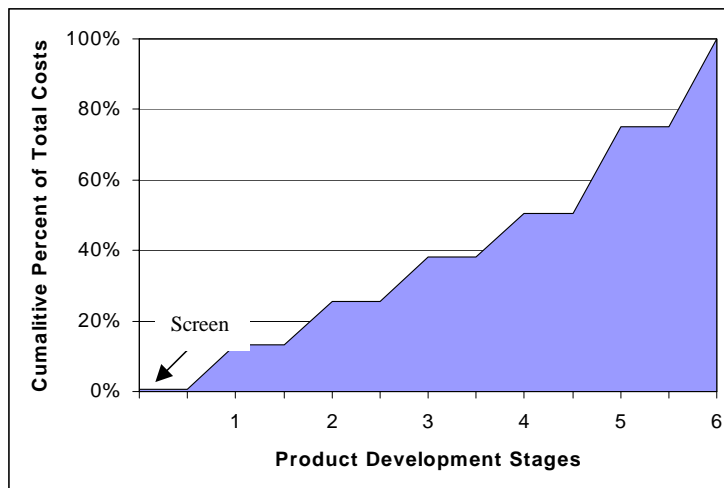
1. Initial synthesis of new chemical candidates and early testing and screening. The product team is encouraged to be innovative in this phase with the goal being to determine whether a given chemical or molecule can be made.

2. Analyze the most efficient “route” to make the chemical. The goal in this phase is to make the chemical or molecule in the fewest steps possible.
3. Analyze how to make chemical(s) on a larger volume scale. Up to this point, the team is working with small samples. During this phase, the team is concerned with the feasibility of manufacturing the chemical in larger volumes.
4. Develop chemical specifications (acceptable quality, variability in performance, etc.).
5. Extensive photographic performance testing and verification of chemical.
6. Final testing and chemical notification to EPA.

The graph shows the costs of each stage as a percent of the total costs for all six stages in Kodak’s product development process. Because details on the magnitude of the costs are strictly confidential information, we have illustrated the percent of total costs accumulated through each of the six stages. The total development cost per chemical at the end of all six stages is in the “hundreds of thousands of dollars”¹⁴.

¹⁴ The distribution costs are specific to Kodak’s process and represent an estimate of the average cost for the entire cycle assuming a relatively smooth product development process.

Figure A-1: Cumulative Resources Spent Over Six Stages in Kodak's Product Development Process



The six stages are shown as a linear process but in reality, some activities performed in later phases of product development are sometimes done much earlier. For example, some of the activities involved with designing chemical specification (phase 4) and performance testing (phase 5) are often done in the second or third phases. For the purposes of this case study, we assumed a linear process.

The far left of the diagram depicts when Kodak screens the 19 initial candidates down to a manageable 4-5. Normally, by stage 3, Kodak has selected a single lead candidate to bring through the rest of the process. Preliminary evaluations of potential human health and environmental impacts occur at the beginning and sometimes continue into the first stage of product development. They are revisited and usually confirmed with laboratory testing in the sixth stage of product development when Kodak submits a Premanufacture Notification to EPA.

Any time a lead candidate is ruled out in one of the six stages of product development, the team must start with a new candidate back in the early stages of product development. Accordingly, all the resources and time expended developing lead candidate(s) that are eliminated are irrecoverable as the team must start the process over from the beginning. In this case, Kodak found that by systematically

applying the P2 Framework and using the ecological information as a preliminary screen, they were able to greatly reduce the probability of having a chemical get dropped in later stages of the product development cycle.

The graph makes it readily apparent that the significant benefits of the P2 Framework lie in reduced product development costs. As a technology gets further and further along in the product development phases, the cumulative costs can be quite significant. Clearly, the earlier any environmental and health effects are known about all candidates, the less likely a technology will progress into later phases of product development. The further into the product development process an unfavorable candidate is discovered, the higher the irrecoverable product development costs.

The table below looks at the increased costs per \$100,000 of product development costs if a lead candidate drops out of the product development cycle in each of the six stages.

Though these costs are rough estimates and variable, candidates historically have been screened out at all these stages for environmental or human health concerns. However, it is more common for a candidate to get screened on health or environmental grounds immediately after stage one or at the very end of

the process in stage six. Thus, the avoided costs from using the EPA P2 Framework lies somewhere between \$13,500 and \$100,000 for each \$100,000 spent in total development costs. As the overall costs to bring a chemical through the product development process increases, so do the potential savings from the P2 Framework. For example, if it costs \$200,000 to bring a single candidate through all six stages of the process, than the avoided additional costs in the table below would double. Similarly, the magnitude of savings from the P2 Framework increases if, over the course of the project, more than one candidate gets screened before resources are expended on photographic performance testing.

The P2 Framework doesn't eliminate product development costs but it does strengthen the team's ability to minimize them. From a business perspective, an organization wants to do everything possible to increase the probability that only one candidate needs to go through all six stages of the product development cycle. In such a scenario, product development costs are kept at a minimum.

Kodak's entire evaluation process is set up with the goal of investigating only one lead candidate at a time during more resource intensive and time consuming stages of product development. The remaining lead candidates are generally preserved should the current lead candidate drop out for technical, human health or ecological reasons. When a lead candidate is excluded in a later stage of product development for technical or unforeseen environmental or

human health impacts, the team must start anew with the next best candidate. In such an instance the lost resources both in labor and in wasted time is considerable as all the resources expended up to that point are irrecoverable. Thus, the better the preliminary information on human health and ecological impacts of all candidates, the less likely a lead candidate will be excluded on these grounds in later phases of product development.

In Kodak's experience without the EPA P2 framework, it was extremely rare for the first lead candidate to make it through all six stages without dropping out for one reason or another. For the number of times chemicals are screened in a given year, it is estimated that on average at least one candidate will fall out in the first phase for each new chemical technology developed. This is not surprising given the high uncertainty and lack of data surrounding product development for new chemicals.

Given this past history of chemicals being eliminated in different stages of product development coupled with the success of ecological screening in this case, Kodak's team felt very confident in attributing savings of *at least* \$13,500 per \$100,000 spent in product development.

Additional Benefits

This case study exemplifies the business benefits the EPA P2 Framework has outside of the health, safety and environment function. The

Table A-1: Potential Costs Avoided by Using the P2 Framework

Scenario in which...	Avoided Additional cost per \$100,000 in Product Development Costs
<ul style="list-style-type: none"> • The first candidate drops out in stage 1 	\$13,500
<ul style="list-style-type: none"> • The first candidate drops out in stage 2 	\$26,000
<ul style="list-style-type: none"> • The first candidate drops out in stage 3 	\$38,500
<ul style="list-style-type: none"> • The first candidate drops out in stage 4 	\$51,000
<ul style="list-style-type: none"> • The first candidate drops out in stage 5 	\$76,000
<ul style="list-style-type: none"> • The first candidate drops out in stage 6 	\$100,000

main monetary benefits lie in reduced resources spent by the product development team through the technical research stages of the product development cycle. While reduced costs for early ecological evaluation is evident, the magnitude of the benefits are small in comparison to avoided increases in product development research costs. On a less quantitative level, the ability to make more informed decisions and evaluate a larger pool of candidates is also shown. Being able to consider a larger number of candidates and make more informed decisions early in the process also increases the probability that the best technical and environmental candidate emerges.

Taking a broader view, this case study exhibits benefits that are realized any time the EPA P2 Framework provides better or more quantitative information in the product development process. Although this case represents the use of two methods within the P2 Framework, it contributes to more strategic business and environmental objectives of any new product development case. These objectives can be stated simply as: find the best candidate in the fastest amount of time so the product can be brought to market. In this broader sense, this case study has the following additional benefits:

- A more streamlined product development process.

The use of the P2 Framework has greatly supplemented the way in which Kodak now performs chemical screening. In particular, they were able to use the ecological screen as a preliminary screen followed by human health and technical screening occurring in parallel. Prior to the use of the P2 Framework, all three screens happened simultaneously with any preliminary screening restricted by existing data (if any). Having more accurate information much earlier in the process benefits the entire product development team. Collectively, more informed decisions early in the product development cycle helps the team focus its resources on the technical research and testing aspects. Similarly, in using the EPA P2

Framework, the health, safety and environment function is able to give a higher level of service to their internal customers in the form of more

The objectives of the P2 Framework can be stated simply: find the best candidate in the least amount of time so the product can be brought to market.

complete and timely information. Overall, earlier screening with data provided by the EPA P2 Framework reduces the probability of numerous candidates going through later phases of product development.

- Faster time to market.

Any time a lead candidate is ruled out in one of the six phases of product development, the team must start with a new candidate back in the initial phase of product development. In addition to the money spent, the process also takes time as the team starts the process over from the beginning. Depending on the product line and the project schedule, the financial impacts of pushing back the time to market date can be enormous, especially for new products where being the first to market means increased market share. A product also can be delayed if it does not meet approval by EPA in their review process.

- A more informed application sent to EPA under the Toxic Substances Control Act.

In using the P2 framework P2 Framework, EPA's process for review becomes more transparent to the applicant. An applicant also becomes more aware of when a chemical may require additional information. In such cases, they can perform the tests and submit the information as part of the TSCA application. A more informed application greatly reduces the chance of an action by the EPA. Actions can take the form of an outright ban or more

commonly a consent order. Consent orders generally stipulate additional data, protective clothing or additional controls before a chemical is approved for manufacture. Any action by EPA on a submitted chemical increases the cost a manufacturer will face should they move forward with developing a product with the chemical in question. As discussed in the generic analysis, these costs can be quite significant depending on the course of action taken. In addition to costs to comply with a consent order, there is also a delay in getting the chemical manufactured. This in turn affects the products time to market.

- *Reduced ecological and human health testing.*

Though this case study clearly exhibits reduced chemical evaluation costs early in the screening process there is also the potential for reduced laboratory testing. Typically, Kodak will include 'standard' laboratory testing ranging from \$15,000 to \$60,000 as supporting data in their chemical notification application to EPA. If a chemical candidate gets ruled out at this final phase based on quantitative empirical data, Kodak will have to perform the same tests on the next candidate.

**Appendix B: Using the P2 Framework for Evaluation of a Chemical
Intermediate A Case Study from Eastman Kodak**

USING THE P2 FRAMEWORK FOR EVALUATION OF A CHEMICAL INTERMEDIATE

Application of the P2 Framework

The EPA P2 Framework methods were used in the evaluation of a chemical intermediate at Eastman Kodak. The chemical is an intermediate generated during the synthesis of a new chemical complex—a new coupler for use in photographic film. Couplers are generally a class of complex organic chemicals that are integrated into the film and ultimately react with developers to form color images on film and paper.

As with any new chemical, Kodak was concerned about potential health or environmental risks associated with the manufacture and use of the chemical. In this circumstance, chemical screening was not required—the intermediate was known and there were no alternatives being considered. Thus the P2 Framework was tested as a potentially valuable tool to remove uncertainty surrounding potential health and environmental impacts during manufacturing operations and to ensure pre-manufacture notification (PMN) approval of the chemical intermediate under TSCA. The EPA P2 Framework was used by Kodak with the following goals in mind:

- ◆ To better understand and manage risk and associated costs from the manufacture of the new intermediate,
- ◆ To minimize any potential occupational risk to their workers,
- ◆ To improve the design of the new chemical product or process by minimizing the generation of hazardous waste and associated cost,
- ◆ To establish guidelines for safe handling and disposal or treatment of the waste streams, and

- ◆ To support the TSCA application process and gain regulatory approval for manufacture.

The P2 Framework methodologies provided information through the use of removal estimation models, stream flow dilution models, and biodegradation potential models. Used together, several EPA methodologies greatly enhanced understanding of the predicted chemical loading to the environment by estimating the in-stream concentrations that would result when the reactors used for chemical synthesis are cleaned. The following methodologies were applied for this case study:

1. *PDM* - estimates how many days per year a chemical discharged in a plants effluent will exceed a concentration of concern in the receiving water
2. *ECOSAR* - estimates the aquatic toxicity of a compound
3. *BIODEG* - estimates aqueous biodegradation rates
4. *Kow* - estimates a chemicals octanol-water partitioning coefficient
5. *Henry* - estimates Henry's law constant, a relative measure of a compounds volatility from water
6. *STP* - estimates the percent removal of a compound from a waste water treatment plant
7. *SEAS* - estimates in-stream concentration of chemicals based on river flow information

Summary of key findings

Note that this case study compares the benefits of applying the EPA P2 Framework to a hypothetical “business as usual” (BAU) scenario where chemical evaluation is made without using the P2 Framework. When the EPA P2 Framework was actually applied, Kodak did not

simultaneously perform a control study to try to make the exact same decision without the EPA P2 Framework. Consequently, the BAU scenario is based on the best estimates from those individuals directly involved in the project on what *would have happened* if the EPA P2 Framework were *not* used.

The major benefits for this case are outlined below. Further discussion of each benefit can be found in the discussion following the summary.

- \$40,000 of hard savings in reduced ecological testing
- Reduced generation of hazardous waste; information from the methods lead Kodak to choose solvent recovery instead of discharging solvents to the sewer
- Reduced EPA application cycle time; information from the methods helped Kodak to decide to apply under the Low Environmental Release and Low Occupational Exposure (LOREX) exemption, requiring a maximum 30 day review by EPA compared to the typical 90 day review.
- Reduced probability of regulatory action; Kodak's use of the P2 Framework greatly informed their decision making process and reduced the chance of this intermediate receiving a consent order by EPA during the TSCA Premanufacturing Notification application. The *probabilistic* benefits from avoiding a consent order in this case can be summarized as:
 - An additional *potential* savings of \$750,000 to \$1,000,000 in long-term health studies on chronic effects if Kodak was forced into a consent order with EPA
 - Avoidance of a *potential* 1.5 to 2 year delay in manufacturing the chemical

Discussion

The benefits center around the role of the Health, Safety and Environment (HSE) function at Kodak — to provide guidance on human health and ecological risks as well as prepare documentation for the PMN application approval process. As is generally true for application of the methods, much of the benefits stem from obtaining quantitative ecological and human health information at the earliest phase possible.

The benefits for this case can be divided into two categories: 1) immediate and more quantifiable benefits, and 2) strategic but probabilistic benefits gained from having quantitative data much earlier in the process. For this case, the immediate bottom-line benefit of \$40,000 from avoided testing is straightforward. The tests avoided were toxicity to fish, Daphnia (acute) and biodegradation.

The more strategic but difficult to quantify benefits are best understood by considering how the P2 Framework enhanced HSE's performance in the clearance of a new chemical, a primary support function in the overall product development process. The common thread with all the methods used was that they provided quantitative information where none previously existed. This allows the product development team to evaluate all options based on best available information. More complete information in turn allows the team to take action **early and decisively** on design issues relating to the intermediate's use and manufacture.

The benefits of the P2 Framework are clearly shown in the decisions Kodak made. For ecological risk, the methods allowed Kodak to estimate the predicted chemical loading to the environment by estimating the in-stream concentrations that would result when the reactors used for chemical synthesis are cleaned. Using this information, Kodak could then run a variety of simulations to investigate the full range of potential wastewater conditions and the impact on the receiving water. Having

quantitative data of the chemical's ecological impacts led Kodak to investigate the possibility of submitting their PMN application under the Low Environmental Release and Low Occupational Exposure exemption (LOREX)¹⁵. To qualify for the LOREX exemption, the manufacturer must certify 1) that exposure to consumers, workers, and the general public meet certain restrictions and 2) that environmental exposure is kept below certain maximum levels in surface waters.

Kodak first investigated the feasibility of a more environmentally sound waste management technique — solvent recycling instead of sending waste to the sewer, and ultimately to a river. Solvent recycling would meet one of the LOREX criteria **and** it was found to be a more cost effective waste management option. Though the financial analysis for the two options was done apart from any work with the P2 Framework, the information from the methodologies was the impetus for Kodak to consider solvent recycling as an alternative¹⁶. This reinforces the adage that better information leads to smarter decisions.

Kodak then turned its attention to minimizing occupational exposure. Relying predominantly on their internal team of experts, Kodak was able to specify appropriate use guidelines and personal protective clothing to its workers. The personal protective clothing consisted of full hoods, supplied air and Tyvex suits, virtually eliminating occupational exposure. Thus, the early information concerning ecological impacts caused Kodak to consider the LOREX exemption which in turn

guided the decision to investigate further reducing potential occupational exposure.

The benefit to Kodak by taking steps to reduce exposure is two-fold. First, they reduce the typical TSCA review process by 60 days (the LOREX exemption takes 30 days compared to the typical 90 days for a regular TSCA application). Second, Kodak was able to avoid a *potential* EPA action. As discussed in the generic analysis, EPA actions can take numerous forms, ranging from an outright ban of the chemical to consent orders requiring long-term studies on toxicity or additional protective clothing and controls. Additional documentation and paperwork accompany most consent orders and their binding legal nature offers an additional incentive for manufacturers to do their best to avoid them. Once a consent order is issued, the manufacturer is at an undesirable fork in the road – they can choose not to make the product in question or they comply with the consent order. Either path is a costly one.

For this case study, The P2 Framework allowed Kodak to determine *early on* that they were likely dealing with a consent order intermediate. Thus they were able to choose whether to abandon the intermediate or try to design ways to minimize exposure. Kodak chose the latter and successfully applied for a LOREX exemption. The benefits of the methods in allowing Kodak to making this informed decision early in the process can not be understated. Consider a scenario in which they submitted their application without taking additional actions to minimize exposure. In Kodak's opinion, they probably would have been hit with a consent order mandating expensive long-term toxicity tests ranging in cost from \$750,000 to \$1,000,000¹⁷. In addition, Kodak would surely be delayed in bringing the product to the market as these tests typically take 1.5 to 2 years. Even if Kodak chose not to make the intermediate because the consent order was too onerous, they would have expended significant resources in developing this product

¹⁵ Chemicals approved under LOREX do not go onto the TSCA list and are only approved for site specific manufacture.

¹⁶ These savings are not included in this case study. However, according to Kodak, it was entirely possible that the team would have chosen the more expensive option of discharge to the sewer by virtue of not seeing the need or doing the cost analysis for comparing it to solvent recycling. Thus, a case could be made that information from the P2 Framework is responsible for these secondary benefits.

¹⁷ The expected tests include a 90-day bioassay as well as a possible 2-year cancer study.

only to abandon it in the very last phase of product development. The generic analysis and a second case study show such irrecoverable development costs in the hundreds of thousands of dollars. To reiterate, having quantitative information *early* can help companies steer clear of the undesirable “fork in the road” and avoid being stuck with two financially unattractive courses of action.

In all probability, Kodak believes they eventually would have come to the conclusion that the product was likely to incur a consent order even without the tools. However, it probably would have happened at the latter phases of product development and, as mentioned above, would have resulted in the potential loss of hundreds of thousands of dollars in product development costs. Having quantitative data on ecological impacts allowed them to act decisively and proactively on a course of action *at the earliest possible point*. In running numerous simulations with the methods, Kodak was confident that the steps they were taking would meet LOREX criteria. They were thus able to avoid the “fork in the road” and ultimately received approval under the LOREX exemption.

In summary, information from the P2 Framework greatly enhanced Kodak’s existing HSE capabilities and provided significant financial benefits. Specifically, the methodologies allowed Kodak to completely avoid \$40,000 in laboratory tests. The upside of the P2 Framework is enormous in that it helped Kodak make more environmentally sound decisions by minimizing exposure. By being able to predict surface water impacts at the earliest phases of process design, Kodak was able to understand and manage environmental risk (and associated costs) through solvent recycling. A more long term and recurring benefit shown in this case study is how the P2 Framework helps streamline Kodak’s internal processes. More quantitative information from the P2 Framework allows the entire product development team to make smarter choices about chemical design and the impacts of new products on human health and the environment.