

**National Pollution Prevention and Toxics Advisory Committee (NPPTAC)  
Recommendation to the EPA Administrator and Deputy Administrator on  
Incorporating the Functional Use Approach into OPPT Activities  
January 26, 2006**

**Introduction**

Since laws were introduced in the 1970s to control chemicals in commerce, EPA approaches to chemical risk management have evolved to include greater consideration of a substance's life cycle and the functions that a chemical or group of chemicals may perform. This shift has allowed for a more holistic view of risk management and encouraged greater stakeholder participation in EPA's risk management work. With the recent increase in chemical information available to EPA and the public, additional substances may become of interest to the Agency from a risk management perspective.

While the traditional approach to managing chemical risks has been to focus on specific substances, risk managers and other stakeholders have begun to adopt a functional use approach, which focuses on the functions that a chemical or group of chemicals may perform. For example, Design for Environment (DfE), an Office of Pollution Prevention and Toxics (OPPT) program focused on potentially safer alternatives to existing chemicals and formulations, has taken a functional use approach when looking at flame retardants. Pentabromodiphenyl ether became of interest to the Agency and, in response, OPPT formed a DfE multi-stakeholder partnership to look at potential alternatives from a functional use perspective. The result has been a novel combination of regulatory actions under TSCA and voluntary pollution prevention (P2) efforts to help manage or reduce risks in the future, while maintaining the important functionality of flame retardancy. Participants in the process note that the regulatory and voluntary aspects complement one another and have led to a stronger risk reduction approach.

The functional use approach can allow EPA to reduce risks, accomplish pollution prevention objectives, and encourage the use of greener chemistries and cleaner technologies. The starting point is consideration of the function that is desired. The functional use approach provides an opportunity to take a systematic look at the chemical or non-chemical alternatives that could provide the desired function. Issues such as downstream effects, activity patterns that might lead to exposure, and end of life management need to be considered. If the desired function can be delivered with improved environmental performance, the functional use approach can provide an opportunity for chemical or non-chemical alternatives with positive attributes to receive greater consideration.

The functional use approach can be applied in making initial product design decisions or used to improve product performance and/or enhance environmental profile. While function is only one of many factors that industry considers when making a product design decision, looking at the function provided by a chemical is what sets the functional use approach apart from traditional EPA risk management approaches. This approach examines the range of chemical and non-chemical alternatives that may be used to provide the function, rather than examining only the currently-used chemical that has become "of concern." It can enhance substitution activities, but

it should be noted that substitution is not a foregone conclusion. The functional use approach creates a more level playing field among the chemical of interest<sup>1</sup> and potential chemical and non-chemical alternatives to it by asking the following questions:

- What function(s) is/are the chemical/substance performing (in the formulation, product, article, etc.) and what benefit(s) does it provide? In instances where the function(s) is/are broad (e.g., chemical solvency), it may be useful to narrow the focus to specific market applications or use categories (e.g., degreasing).
- How extensively is the chemical used to perform the function(s) (e.g., is it used only in specialty applications and products, or is it used broadly in a variety of applications and products)?
- Can the hazard and/or risk be mitigated through some other mechanism (e.g., engineering controls, manufacturing process changes, etc.)?
- Can the function(s) be filled by something else?
  - Must the function(s) be filled by a chemical, or is some other non-chemical approach acceptable (e.g., rather than chemical flame retardants incorporated into foam, could flame retardant barriers, fabrics, and alternative furniture designs, such as designs that do not contain foam, be used)?
  - What information is available or is needed in order to assess potential alternatives on key attributes such as toxicity, physical/chemical properties, performance, cost/benefit, availability, exposure, use and disposal methods, as well as functionality?
  - What criteria will be used to evaluate and compare the possible options?

In instances where a chemical of interest is one with positive attributes that could merit broader application, the functional use approach can provide an opportunity for such a chemical to receive consideration.

The functional use approach applies basic principles of commercial design. Industry chemists, engineers, and product designers apply the approach in their formulation, engineering, and design decisions. EPA has used the functional use approach to complement voluntary pollution prevention programs and/or regulatory actions, either as part of a multi-stakeholder partnership or independently. EPA could also apply the functional use approach outside of a multi-stakeholder partnership, for example in discussions with a single company, in their internal discussions about the function of specific chemicals in the marketplace, in multi-stakeholder forums such as federal advisory committees and negotiated rulemakings or in proposals offered via notice-and-comment rulemaking. The inclusion of multiple perspectives helps to ensure that a chemical's function and the associated economic, environmental, and social consequences of any action will be fully explored and evaluated. There are likely a number of places within

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<sup>1</sup> Chemical of Interest can include any chemical managed by OPPT under TSCA. Chemicals of interest for P2 approaches can rise to OPPT's attention through a number of routes. They may pose a concern or provide a potential alternative to address a concern.

OPPT's chemical review processes where use of the approach can help shape more creative and collaborative outcomes.

### **Incorporating the Functional Use Approach into OPPT Activities**

OPPT's risk assessment and management activities that consider chemical function can lead to voluntary and regulatory actions that are better focused on the issues of concern. It is useful to OPPT whenever there is a basis for concluding that a chemical should be removed from commerce or that potential exposures to the chemical should be reduced due to risks to human health or the environment. It could also be an important tool for furthering the Agency's obligations under the Pollution Prevention Act, which requires EPA to incorporate P2 across the broad range of Agency activities. The functional use approach may identify P2 strategies that reduce the risks that a chemical of interest poses, but it may also identify opportunities to encourage greater use of greener chemistries and cleaner technologies.

With regard to risk assessment, TSCA provides OPPT with tools to acquire information about chemicals and to manage risks associated with certain substances.<sup>2</sup> It is worth noting that, in addition to the information that EPA can acquire through its TSCA authorities, the Agency will soon receive additional data on hazard and exposure for high-volume chemicals through the HPV Challenge Program and the Inventory Update Rule Amendments.<sup>3</sup> Review of these data may lead to actions that would lend themselves to a functional use approach (e.g., relying on the use information under the Inventory Update Rule). In addition, the hazard information made available through the HPV Challenge Program will provide some of the information necessary for comparing possible substitute chemistries when the functional use approach is applied. Use of this information in a multi-stakeholder application would help to widely inform diverse audiences of the existence of valuable EPA data resources.

The functional use approach can be used during the risk management process to help select which uses of a chemical of interest are appropriate for which type of risk management actions. For example, a chemical of interest may have several different uses. Instead of, or in addition to establishing controls, pursuing an all-out ban under TSCA Section 6, or referring regulation to

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<sup>2</sup> For example, TSCA Section 8 gives EPA the authority to require the submission of data on use, exposure, health and safety, and significant adverse reactions. If EPA determines that a chemical may present an unreasonable risk, or it is produced in substantial quantities and it enters/may enter the environment in substantial quantities, or there is/may be significant or substantial human exposure, it can require companies to conduct toxicity and environmental fate testing under TSCA Section 4. EPA also receives information related to use and exposure under TSCA Section 5, which pertains to new chemicals.

<sup>3</sup> The Inventory Update Rule Amendments (IURA) update the TSCA chemical substances inventory by collecting facility and chemical identity, chemical production volume, and other information from manufacturers and importers of certain chemicals listed on the TSCA chemical substances inventory. The IUR Amendments add manufacturing and use exposure-related elements to the collection, adjust the exemptions to the rule, and make certain confidential business information (CBI) changes. They also raise the reporting threshold from 10,000 to 25,000 pounds per year per producer, and propose to lengthen the interval between reporting periods from four to five years." The first submission period under the IURA will occur in 2006. See <http://www.epa.gov/oppt/iur/iurafinalrulefactsheet.htm> for more information. As 2006 will be the first year of reporting under the IURA, it is suggested that the Agency evaluate the information it receives to assess its quality and to determine what value it may have in helping to set priorities for exposure assessment or use evaluation.

another Agency under Section 9, OPPT could employ a functional use approach to identify the uses that cannot be satisfied otherwise and uses appropriate for risk management actions. In the process of identifying potential risk management actions, the functional use approach can help to identify voluntary risk management measures that manufacturers and/or users might take to reduce exposure, as well as possible regulatory options.

With regard to pollution prevention, the functional use approach (for example, used in a multi-stakeholder partnership) can help to highlight specific P2 tools and approaches that may be well-suited for a particular chemical of interest (e.g., as part of the “P2 Option Review” called for in the NPPTAC’s June 2005 recommendation to EPA on institutionalizing P2 Across EPA and within OPPT). Furthermore, the approach requires OPPT staff to seek information from new sources; thus it can also be used as a vehicle to build and improve coordination within OPPT divisions and branches as called for in the NPPTAC recommendation referenced above.

### **Benefits of OPPT’s Application of a Functional Use Approach**

A priority area for EPA, expressed by the Administrator, is to enhance collaboration with stakeholders. The functional use approach provides a prompt for Agency staff to seek input on chemicals of interest from outside stakeholders. OPPT’s use of multi-stakeholder dialogues has demonstrated their value for gaining a common understanding along the relevant supply chain on the scope of the problem to be addressed, the range of possible solutions, the approach to information gathering or data generation, and the criteria upon which decisions will be based. For example, participants in the Furniture Flame Retardancy Partnership have indicated that a key element of their success to date has been the recognition on the part of the end user that a change is necessary, and a commitment on the part of the producer to develop more acceptable alternatives. Thus, the functional use approach can also be pursued in a voluntary framework, applying TSCA as necessary to support information gathering, testing, use restrictions, and to ensure that inappropriate uses of chemicals do not arise.

As noted previously, the functional use approach can also help to spur consideration of all potential TSCA and P2 tools that can be applied to a chemical of interest, thus helping to integrate the two. As described above, the functional use approach complements the risk assessment and management processes because it considers the function the chemical of interest is performing, its hazard information and exposure potential, and other important attributes. By looking at the intended functional use, it may be possible to seek alternative ways to fulfill the function through chemistry, engineering, design, or other means. In cases where the functional use can only be fulfilled by the chemical of interest, risk management decision-making should be employed.

### **Summary**

Functional use is a holistic approach to examine and consider a broad range of chemical and non-chemical options which provide a particular function. The approach can be used to encourage use of greener chemistries and cleaner technologies or as a complement to traditional OPPT risk management procedures. It shows promise and supports publicly stated Agency goals of more

actively engaging stakeholders. Further, it complements OPPT's existing risk assessment and management tools, both regulatory and voluntary, and contributes to the integration of P2 within OPPT and across EPA. In addition, the approach will make use of the hazard, use, and exposure information that OPPT has or will soon have available on many chemicals

## **Recommendation**

The NPPTAC recommends that OPPT broaden and strengthen its application of the functional use approach when exploring potential options for managing risks from a chemical of interest. The approach can also assist OPPT when encouraging the use of greener chemistries and cleaner technologies. Doing so would require OPPT to systematically consider questions such as the following to implement the functional use approach:

- What function(s) is/are the chemical/substance performing (in the formulation, product, article, etc.) and what benefit(s) does it provide? In instances where the function(s) is/are broad (e.g., chemical solvency), it may be useful to narrow the focus to specific market applications or use categories (e.g., degreasing).
- How extensively is the chemical used to perform the function(s) (e.g., is it used only in specialty applications and products, or is it used broadly in a variety of applications and products)?
- Can the hazard and/or risk be mitigated through some other mechanism (e.g., engineering controls, manufacturing process changes, etc.)?
- Can the function(s) be filled by something else?
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  - What information is available or is needed in order to assess potential alternatives on key attributes such as toxicity, physical/chemical properties, performance, cost/benefit, availability, exposure, use and disposal methods, as well as functionality?
  - What criteria will be used to evaluate and compare the possible options?

In instances where a chemical of interest is one with positive attributes that could merit broader application, the functional use approach can provide an opportunity for such a chemical to receive consideration.

Once broader use of the functional use approach is underway, OPPT is requested to work with the NPPTAC to conduct an evaluation of the functional use approach, including the development and use of appropriate metrics. In addition, OPPT is requested to report back to NPPTAC on efforts to implement this recommendation within one year, and periodically to the public. At that time the Committee will consider if further advice is appropriate.