BNA Insights

CHEMICALS

TSCA

President Barack Obama signed into law amendments to the Toxic Substances Control Act on June 22. The amendments bring sweeping changes to the nation's primary chemicals law. In this Bloomberg BNA Insights, Charles M. Auer and Lynn L. Bergeson look specifically at the role of ''conditions of use'' in Sections 5 and 6 under the amended law and other chemical exposure considerations.

Role of 'Conditions of Use' Under Sections 5 and 6 of Amended Toxics Law

BY CHARLES M. AUER AND LYNN L. BERGESON

The concept of ''*conditions of use*'' plays an important role in the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. In this paper, the amended TSCA statute (Pub. L. No. 114-182) is referred to as ''new TSCA,'' versus ''old TSCA'' (Pub. L. No. 94-469). *Conditions of use* is a centralizing concept under which the U.S. Environmental Protection Agency (EPA) determines how a chemical is made, processed, used and disposed. The term is defined in Section 3 and also appears one or more times in the following Sections: 5, 6, 9, 14, 18, 21 and 26. The term is not used in Sections 4 and 8. This paper explores the use and application of the term *conditions of use* under new TSCA Sections 5 and 6, and provides insights into the implications of what may be its unusual use in Section 5 in comparison to Section 6.

Background

Conditions of use is defined in new TSCA Section 3(4) as follows: the term ''*conditions of use*'' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of. This definition lays out an EPA role in determining the circumstances involved in a chemical's *conditions of use* wherever the term appears. ''Intended'' seems applicable in the case of new chemicals or Significant New Uses (NC/SNU) under Section 5 given the premanufacture status of such chemicals and uses. ''Known'' seems to fit best in Section 6 where the *conditions of use* would be informed by reporting or other information obtained by EPA. ''Reasonably foreseen'' may be defined disparately. *Black's Law Dictionary* defines ''reasonable'' to mean ''agreeable to reason; just; proper'' and ''foreseeability'' as the ''ability to see or know in advance; the reasonable anticipation that harm or injury is a likely result from certain acts or omissions.'' ''Reasonably foreseen conditions of use'' might be interpreted to mean ''*conditions of use* that are known in advance.''

Charles M. Auer is a senior regulatory policy adviser with Bergeson & Campbell PC. Auer, a chemist by training, was formerly the director of the Environmental Protection Agency's office of pollution prevention and toxics (EPA/OPPT).

Lynn L. Bergeson is managing partner of B&C and practices extensively in all matters involving the Toxic Substances Control Act and related global chemical notification programs.

Section 5. Manufacture and Processing Notices. Under Section 5(a), companies are required to submit premanufacture notifications (PMN) to EPA for new chemicals or Significant New Use Notifications (SNUN) for chemicals that are subject to notification based on a EPA SNU Rule (SNUR). As amended, Section 5 retains much of old TSCA, but makes changes that strengthen the regulation of new chemicals. EPA must review all NC/SNUs and make one of three TSCA Section 5(a)(3) determinations (henceforth referred to as ''initial determinations'') concerning the potential risks or other issues relating to a NC/SNU. EPA must then take required regulatory actions resulting from that initial determination. EPA also has authority under Section 5(h) to grant exemptions. The role of *conditions of use* is outlined below.

Section 5(a). Section 5(a)(3) initial determinations that include the concept of *conditions of use* consist of those at subsections (A) and (C) (emphasis added to highlight the use of *conditions of use*):

- The Section 5(a)(3)(A) determination (referred to as an ''(A) initial determination'') is relevant when EPA determines that a NC/SNU ''present[s] an unreasonable risk. . .without consideration of costs or other nonrisk factors, *including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA] under the conditions of use*'' (PESS/COU); and
- The Section 5(a)(3)(C) determination (''(C) initial determination'') is relevant when EPA determines that a NC/SNU is ''not likely to present an unreasonable risk. . .without consideration of costs or other nonrisk factors, *including an unreasonable risk to a [PESS/COU]*.''

Conditions of use does not appear in the initial determinations under Section 5(a)(3)(B) (''(B) initial determination''), including the following initial determinations (emphasis added; note that these provisions are not quoted):

> (i) That the information available to EPA *is insufficient to permit a reasoned evaluation of the health and environmental effects* of the NC/SNU (an ''insufficient information initial determination''); *or*
>
> (ii)(I) That in the absence of sufficient information to make ''such an evaluation,'' the NC/SNU *may present an unreasonable risk*, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by EPA (a ''may present initial determination''), *or*
>
> (ii)(II) That the chemical will be produced in *substantial quantities* and it either enters or may be anticipated to *enter the environment in substantial quantities* or there is or may be *significant or substantial human exposure* (an ''exposure-based initial determination'').

If EPA makes the (A) initial determination, it must regulate under Section 5(f). If EPA makes any of the three (B) initial determinations, it must regulate under Section 5(e). For both (A) and (B) initial determinations, EPA is required to consider the need for a SNUR, or to publish reasons for deciding otherwise. If EPA makes the (C) initial determination, the notifier can commence manufacture or processing under Section 5(g) ''notwithstanding any remaining portion of the applicable review period'' and EPA is required to publish its finding.

Section 5(e). Section 5(e)(1)(A) involves two steps. The first concerns the initial determination and the second concerns decisions as to the ''extent necessary'' control measures that are needed to protect against unreasonable risk. Interestingly, PESS/COU is included in the may present determination at Section 5(e)(1)(A)(ii)(I) (but not in the Section 5(e) determinations for ''insufficient information'' and ''exposure-based'') and in the ''extent necessary'' regulatory decision. Section 5(e)(1)(A) reads as follows regarding the use of ''*conditions of use*''):

> If the Administrator determines that—
>
> (i) [insufficient information determination]; or
>
> (ii)(I) in the absence of sufficient information. . . the manufacture, processing, distribution in commerce, use, or disposal of such substance. . . may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, *including an unreasonable risk to a [PESS/COU]*; or
>
> (II) [exposure-based determination],
>
> [EPA] shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal. . . to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors,*including an unreasonable risk to a [PESS/COU]*, and the submitter of the notice may commence. . . manufacture or processing. . . including while any required information is being developed, only in compliance with the order.

While it does not play a role in the (B) initial determinations, *conditions of use* is included in the ''5(e) 'may present' determination'' and in EPA's ''5(e) 'extent necessary' regulatory decision.'' In both cases, *conditions of use* modifies the meaning of ''unreasonable risk'' by clarifying that it includes an unreasonable risk to a PESS/COU, thus reaffirming the application of *conditions of use* in EPA's 5(e) decisions regarding the ''extent necessary'' control measures for ''may present'' cases. As structured, it also applies to EPA decisions regarding the control measures for cases involving insufficient information and exposure-based Section 5(e) determinations.

Section 5(f). Section 5(f)(1) involves a determination that the NC/SNU presents an unreasonable risk (''5(f) determination'') and an ''extent necessary'' decision (''5(f) 'extent necessary' regulatory decision''). This section references *conditions of use* in the 5(f) determination. The term is cross-referenced in the ''extent necessary'' regulatory decision. Section 5(f)(1) reads (emphasis added):

> If the Administrator determines that a [NC/SNU] presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a *[PESS/COU]*, [EPA] shall. . . take the action authorized by paragraph (2) or (3) to the extent necessary to protect against *such* risk.

Section 5(f)(2) describes how EPA can issue an immediately effective proposed rule under Section 6(a) while Section 5(f)(3) provides order authority. *Conditions of use* does not appear in either provision.

Section 5(h). This provision concerns exemptions and has references to *conditions of use* at Section 5(h)(1) concerning test marketing exemptions and at Section 5(h)(4) concerning exemptions that notifiers can request from EPA. Interestingly, the relevant wording is different in the two provisions: subsection (4) uses a PESS/COU formulation similar to that discussed above, but does not include the ''as relevant'' phrase; subsection (1) speaks to ''*specific* conditions of use *identified in the application*'' (emphasis added). Other than substituting ''information'' for ''data'' where it appears, these were the only changes to this TSCA section.

In summary, under Section 5, *conditions of use* is relevant to the initial determinations for (A) ''presents'' and (C) ''not likely to present an unreasonable risk.''

  DEN ISSN 1060-2976

The term is not relevant to the (B) initial determinations. *Conditions of use* is, however, a relevant consideration in the risk management provisions at Sections 5(e) and (f) regarding unreasonable risks to potentially exposed or susceptible subpopulations, although its role in the former is varying and complex, as discussed above. The term is relevant to consideration of unreasonable risks to a PESS/COU in Section 5(h). A final point to note is that while *conditions of use* can be relevant to evaluating exposures and health risks to potentially exposed or susceptible subpopulations in Section 5, the statute is silent on the application of the concept of *conditions of use* to environmental organisms and to human exposures that do not involve potentially exposed or susceptible subpopulations and, thus, the concept (and its ''reasonably foreseen'' aspect) is not relevant when conducting exposure and risk assessments for environmental organisms or general population exposures, or in determining control measures needed to protect such organisms/populations from unreasonable risks.

See Table 1, summarizing the use in Sections 5(e) and (f) of *conditions of use*.

Section. 6. Prioritization, Risk Evaluation, and Regulation of Hazardous Chemical Substances and Mixtures. New TSCA revises Section 6 by adding prioritization and risk evaluation stages, deleting the ''least burdensome requirement,'' and including timelines for completion of the key steps, including prioritizations, risk evaluations and control actions. *Conditions of use* appears in Section 6(b) concerning prioritization and risk evaluations, Section 6(c) concerning consideration of alternatives when taking a control action that ''substantially prevents a specific condition of use,'' Section 6(g) concerning the granting of exemptions from a Section 6(a) requirement for a ''specific condition of use,'' and in Section 6(h) concerning expedited action on certain Persistent, Bioaccumulative, and Toxic (PBT) chemicals. In these instances, *conditions of use* appears to be relevant to human and environmental aspects of the various stages. *Conditions of use* does not appear in Section 6(a) concerning the scope of regulation. Its use in Section 6 is outlined below.

Section 6(b)(1). This section concerns prioritization for risk evaluation and includes several references to *conditions of use*, including (emphasis added):

- In the rulemaking required to establish the prioritization process, EPA is to include consideration of ''the *conditions of use or significant changes in the conditions of use*'' of the chemical; and
- Concerning identification of high-priority substances, EPA is required to designate as high-priority chemicals that EPA concludes, without consideration of cost and other nonrisk factors, ''*may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use,* including an unreasonable risk to a potentially exposed or susceptible subpopulation'' that EPA identifies as relevant.
- *Conditions of use* is included in the determination that EPA makes in identifying low-priority chemicals by the cross reference to the Section 6(b)(1)(B)(i) standard on designating high-priority chemicals.

Section 6(b)(4). This section concerns the risk evaluation process and deadlines and has several references to *conditions of use*, including the following (emphasis added):

- In conducting risk evaluations, EPA shall determine whether a chemical substance ''*presents an unreasonable risk of injury to health or the environment*, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by [EPA], *under the conditions of use*.''
- In publishing the scope of the risk evaluation six months after its initiation, EPA must include ''the hazards, exposures, *conditions of use*, and the potentially exposed or susceptible subpopulations [EPA] expects to consider.''

In conducting a risk evaluation EPA shall, among others:

- *Integrate and assess available information on hazards and exposures for the conditions of use* of the chemical substance;
- *Describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use* were considered, and the basis for that consideration; and
- *Take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use* of the chemical substance.

Section 6(c)(2)(C). This provision requires that EPA consider ''to the extent practicable, whether technically and economically feasible alternatives. . . will be reasonably available as a substitute'' when actions that ''prohibit or restrict in a manner that *substantially prevents a specific condition of use* of a chemical'' take effect.

Section 6(g), regarding the criteria for exemptions, states that EPA may by rule grant an exemption from a Section 6(a) rule requirement concerning a ''specific *condition of use*'' if EPA makes any of several findings that are available for granting such an exemption.

Section 6(h)(1), concerning expedited action on PBT chemicals, requires that EPA shall propose Section 6(a) rules not later than three years after enactment for certain PBT chemicals on the 2014 update of the TSCA Work Plan for which ''*exposure. . . under the conditions of use is likely* to the general population or to a potentially exposed or susceptible subpopulation identified by [EPA], or the environment.''

In summary, under Section 6, *conditions of use* is relevant to the prioritization and risk evaluation stages of the new TSCA Section 6 process. Unlike the situation in Section 5 where *conditions of use* was relevant to evaluating exposures and unreasonable risks to potentially exposed or susceptible subpopulations in certain provisions, in Section 6 *conditions of use* is relevant to both human and environmental aspects of exposures and risks in the prioritization and risk evaluation stages, including in the latter with regard to ''aggregate or sentinel exposures'' and the ''duration, intensity, frequency, and number of exposures.'' When taking risk management actions involving ''specific conditions of use,''

EPA is required to consider the availability of technically and economically feasible alternatives when deciding whether a ban or phase-out action should be taken. The concept of ''specific conditions of use'' also appears in Section 6(g) concerning the granting of exemptions from ban or phase-out actions. Finally, Section 6(h) requires that EPA, in taking expedited action against certain PBT chemicals, consider *conditions of use* regarding exposure of such PBT chemicals to the general population, to a potentially exposed or susceptible subpopulation, or to the environment.

See Table 1 for a tabular summary of the use of *conditions of use* in Section 6, and in relation to Section 5.

Table 1. General Summation of Key Provisions in Sections 5 and 6 of New TSCA and the Relevance to each of *Conditions of Use (COU) per se*, Potentially Exposed or Susceptible Subpopulation (PESS*) per se, and* Potentially Exposed or Susceptible Subpopulation Under the COU [a.] (PESS/COU).

Relevant Section of New TSCA	COU	PESS	PESS/COU
Section 5			
Determinations at Section 5(a)(3)			
(A) ''presents an unreasonable risk'' (UR)	. . .	. . .	**X**
(B)(i) ''insufficient information''	. . .	. . .	. . .
(B)(ii)(I) ''may present an UR''	. . .	**X**	. . .
(B)(ii)(II) ''exposure based''	. . .	. . .	. . .
(C) ''not likely to present an UR''	. . .	. . .	**X**
Section 5(e)			
5(e) determinations (Section 5(e)(1)(A))			
(i) ''insufficient information''	. . .	. . .	. . .
(ii)(I) ''may present an UR''	. . .	. . .	**X**
(ii)(II) ''exposure based''	. . .	. . .	. . .
5(e) extent necessary regulatory decision	. . .	. . .	**X**
Section 5(f)			
5(f) determination	. . .	. . .	**X**
5(f) extent necessary regulatory decision	. . .	. . .	**X**
Section 6			
Section 6(b)(1)(A) Establishment of prioritization process	**X**	**X**	. . .
Section 6(b)(1)(B) Identification of priorities			
High-priority	**X**	**X**	. . .
Low-priority	**X**	**X**	. . .
Section 6(b)(4)(A) Risk evaluation (RE) process	**X**	**X**	
Section 6(b)(4)(D) Scope of RE	**X**	**X**	. . .
Section 6(b)(4)(F) RE requirements[b.]	**X**	**X**	. . .
Section 6(h)(1)(B) Expedited action on PBTs[c.]	**X**	**X**	. . .

[a.] The wording differs amongst the provisions where this concept is relevant and the actual text should be consulted.

[b.] The following concepts are included under *COU* in this subsection: aggregate or sentinel exposure and likely duration, intensity, frequency, and number of exposures.

[c.] Exposure ''under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by [EPA], or the environment.''

Discussion

Conditions of use appears to play a distinctly different, narrower and more complex role in Section 5 of new TSCA as compared to its much broader use in Section 6. Under Section 6(b) EPA's determination of the *conditions of use* for both human and environmental aspects is directly tied to EPA's prioritization determinations of ''may present an unreasonable risk'' in regards to both high- and low-priority designations and to the ''presents an unreasonable risk'' determination that applies in conducting a risk evaluation. Section 6(b)(4) concerning the risk evaluation process includes several additional references to *conditions of use* that make clear how central the concept is to this process. Specifically, EPA must:

- Include *conditions of use* in its risk evaluation scope document;
- Integrate and assess the available information on ''hazards and exposures for the conditions of use'';

  DEN ISSN 1060-2976

- Discuss the need to describe whether ''aggregate or sentinel exposures'' to a chemical under the *conditions of use* were considered, and the basis for that consideration; and
- ''Take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use.''

At Sections 6(c) and 6(g), the term is used in the context of the need to consider the availability of alternatives when evaluating ban and phase-out control actions and possible exemptions from those actions, respectively. The term also appears in Section 6(h) concerning PBTs where EPA is required to consider whether exposure of the PBT chemical under the *conditions of use* is likely to the general population, to a potentially exposed or susceptible subpopulation, or to the environment.

In contrast, while *conditions of use* appears multiple times in Section 5, it is not consistently applied in the initial determination provisions at Section 5(a)(3). When used in the (A) and (C) initial determinations (''presents'' and ''not likely to present,'' respectively), the term is narrowly applied and does not include consideration of environmental organism or general population exposure and risk aspects, but is limited to considerations revolving around potentially exposed or susceptible subpopulations. This general approach is continued elsewhere in Section 5 where the concept of PESS/COU is considered in unreasonable risk determinations made under Sections 5(e) and (f), in the risk management ''extent necessary'' regulatory decision made under Section 5(e) and (f) and in granting exemptions under Sections 5(h)(1) and (4) (the particulars differ in each of these four areas). The term does not appear at all in the three (B) initial determinations.

What are we to make of the distinctly different use of *conditions of use* in Section 5 versus Section 6? While Section 6 clearly envisions and requires that EPA determine and apply *conditions of use* as such in its human and environmental organism prioritization and risk evaluation analyses and in subsequent stages as discussed above, the situation is very different in Section 5 where *conditions of use* is, at best, inconsistently applied.

Hints that may help to illuminate what may be going on can be found in the chapeau to Section 5(a)(3) which requires that EPA ''shall review *such* notice and determine. . .[(A), (B), or (C)]'' (emphasis added). The ''such notice'' provision can be interpreted as potentially limiting EPA's flexibility in considering information beyond that in the notice except possibly as allowed in those provisions that include the concept of *conditions of use* and, thereby, the ''reasonably foreseen'' aspect included in the term's definition. This limitation would not apply in the case of the (A) and (C) initial determinations, for which an unreasonable risk to a PESS/COU and its ''reasonably foreseen'' consideration is applicable. Read this way, ''such notice'' might apply a *de facto conditions of use* concept that does not envision an EPA *conditions of use* role in such a determination regarding environmental organism and general population exposures and risks in making (A) and (C) initial determinations, and all aspects of the (B) initial determinations. Rather, under this reading, it is the submitter that determines the uses and exposures to be reviewed based on what is actually reported in the PMN/SNUN (we use the term ''submitter's *de facto conditions of use*'' when referring to this concept). Thus, in making a (B) initial determination, EPA would be limited to reviewing the uses, releases, and exposures reported in the notice. When making (A) or (C) initial determinations, on the other hand, EPA would also consider *conditions of use* as they relate to a potentially exposed or susceptible subpopulation that would bring ''reasonably foreseen'' uses and exposures into that aspect of the human exposure and risk assessment elements of the determination. This same submitter's *de facto conditions of use* aspect would apply generally in Section 5(a)(3) initial determinations in the case of human exposure and risk assessment aspects that did not involve PESS/COU, an example of which is general population exposure.

The next steps of the Section 5 process raise the question of how the concepts of *conditions of use* and ''such notice'' play through to the required risk management actions under Sections 5(e) and (f). This aspect is also complicated, particularly with regard to Section 5(e), but seems to operate as follows:

Section 5(e)

- In the case of Section 5(e) control actions to protect environmental organisms such as fish or to limit human general population exposures that do not involve potentially exposed or susceptible subpopulations, it appears that EPA can consider and regulate only the uses and exposures reported in the PMN/SNUN. To the extent other possible uses beyond those in the notice raise concerns, such uses could be addressed subsequently as appropriate through a SNUR, after considering the factors contained in Section 5(a)(2)(A-D). Further, it appears that this SNUR aspect could apply, depending on the specifics under all of the (B) initial determinations.
- In the case of control actions triggered by the initial determinations concerning ''insufficient information'' and ''exposure-based'' cases, because they do not involve an unreasonable risk, these determinations appear to flow directly through to the ''extent necessary'' regulatory provision in Section 5(e). EPA is required under this section to regulate to protect against an unreasonable risk, including an unreasonable risk to a PESS/COU. Insofar as EPA has earlier determined (unless it makes multiple initial determinations under Section 5(a)(3)(B)) that the chemical does not satisfy the ''may present'' initial determination, the regulatory actions are expected to be limited possibly to requiring the testing needed to permit a reasoned evaluation or, for the ''exposure-based'' initial determination, to develop test data such as that which EPA has required historically for such new chemical cases (*see* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5e-exposure-based). As part of the 5(e) ''extent necessary'' regulatory decision on such cases, if EPA identifies an unreasonable risk to a PESS/COU, it appears EPA can take additional regulatory actions to the extent necessary to protect against that unreasonable risk.
- In the case of control actions triggered by the ''may present'' initial determination, EPA was lim-

ited in making the (B) initial determination to considering the uses and exposures reported in the NC/SNU, including risks to a potentially exposed or susceptible subpopulation. In making the 5(e) determination and the 5(e) ''extent necessary'' regulatory decision, however, EPA is required to consider unreasonable risks to a PESS/COU. These two steps, with their reference to *conditions of use*, appear to inject ''reasonably foreseen'' circumstances of exposures (involving such a subpopulation identified as relevant by EPA) into these determinations. This suggests that the control action could extend to include ''reasonably foreseen'' uses that present an unreasonable risk to such a potentially exposed or susceptible subpopulation.

On the other hand, when determining the controls needed to protect adequately against such ''may present'' risks to environmental organisms and to the general population, EPA appears to be limited to controlling the uses and exposures that were reported in the PMN/SNUN. To the extent other possible uses of the NC/SNU raise potential issues in such cases, they could be addressed subsequently as appropriate through a SNUR, as discussed above.

Section 5(f)

- In the case of Section 5(f) control actions to protect environmental organisms or to limit general population exposures that do not involve potentially exposed or susceptible subpopulations, EPA appears to be limited to considering and regulating the uses and exposures reported in the PMN/SNUN.
- For Section 5(f) actions that include an unreasonable risk involving potentially exposed or susceptible subpopulations identified as relevant by EPA under the *conditions of use*, EPA could consider and take actions to prohibit or limit reasonably foreseen exposures and uses to the extent necessary to protect adequately against the unreasonable risk.

In the case of the (C) initial determination of ''not likely to present an unreasonable risk,'' the notifier can commence commercialization once the determination has been made. To the extent EPA believes there may be other uses and exposures beyond those described in the PMN/SNUN that may warrant future notifications, however, EPA can determine whether a SNUR is needed to ensure that EPA has a chance to review such uses and exposures, if they arise in the future. EPA could possibly use the so-called ''non-5(e) SNUR'' procedure at 40 C.F.R. § 721.170 in such cases. The regulatory text at subsection (a) of this procedure makes clear that it applies in cases ''if EPA determines that activities other than those described'' in the notice may result in significant changes in exposure or release.

Examples of New Chemicals Under Section 5

The following examples illustrate how the points discussed above might operate in the case of initial determinations under Section 5(a)(3) and 5(e) determinations, and in the case of 5(e) ''extent necessary'' regulatory decisions on NCs submitted as PMNs.

- EPA's review indicates low health concerns, but moderate environmental toxicity concerns are identified. Production and use of the new chemical as reported in the PMN do not include environmental releases, however. On this basis, the NC is determined ''not likely to present an unreasonable risk.'' Production and use of the NC by other companies could involve environmental releases, however, and, based on structurally related NCs previously reviewed by EPA, there are possible future uses of the NC that could involve environmental release. The likely outcome is that the notifier can commence manufacture once the initial determination is made and a SNUR, including a non-5e SNUR, could be used as needed, to allow future consideration of production/uses involving environmental releases.
- EPA's review indicates that insufficient information is available to support a reasoned evaluation of the environmental hazards, while EPA considers the NC to present a low concern for health effects. The case receives an initial determination of ''insufficient information'' and is referred for regulatory action under Section 5(e). In considering the 5(e) ''extent necessary'' regulatory decision, EPA does not consider possible PESS/COU issues because the low health concern indicates that health risks are likely to be low. The control action involves screening level ecotoxicity and environmental fate testing needed to provide a reasoned evaluation of the NC's environmental effects. The notifier can commence manufacture at the end of the applicable review period in compliance with the consent order. EPA will also need to consider whether a SNUR is needed. Based on the experience of one of the authors while serving as EPA's OPPT Office Director, under old TSCA EPA would typically not implement a SNUR on cases involving a Section 5(e) ''exposure based'' consent agreement but would consider the need for a SNUR after the required testing was received by the agency. Such an approach may be merited here.
- EPA's review of the NC leads to identification of a possibly significant health concern for inhalation exposure to fine particulates of the NC based on structurally analogous PMN cases, but low concern for environmental toxicity. The NC is manufactured and used strictly as a liquid suspension and the use and exposure information in the PMN indicates no potential for human exposure to fine particulates. These lead to an initial determination of (C) ''not likely to present an unreasonable risk.'' EPA, however, identifies that there are reasonably foreseen uses of the NC that could involve fine particulate worker exposure (a possible PESS/COU) and this precludes satisfying the (C) initial determination. EPA considers possible (B) initial determinations that could be relevant and believes that the insufficient information initial determination best fits the case. EPA proceeds to take up Section 5(e) and, when making the 5(e) determination, considers the PESS/COU issues identified previously. After considering these aspects, EPA concludes that it can meet the 5(e) determination regarding ''may present an unreasonable risk'' to PESS/COU, but not otherwise. EPA proceeds to

  DEN ISSN 1060-2976

the 5(e) ''extent necessary'' regulatory determination and decides to require that the NC be manufactured and used as a liquid suspension, and to require testing to understand better the inhalation hazards and the dose/response. Alternatively or in addition, EPA might require an exposure screening study to provide information on inadvertent worker exposures to particulates of the NC. EPA thus requires testing in the Section 5(e) order and that the NC be manufactured/used as a liquid suspension. EPA subsequently decides to issue a ''5(e) SNUR'' for manufacture/processing/use other than as a liquid suspension (*e.g.*, uses involving powders or fine particulates). The notifier can commence manufacture at the end of the applicable review period in compliance with the order.