

IS THE SECTION 5 REVIEW PERIOD FIXED OR FLEXIBLE IN NEW TSCA?

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New TSCA fundamentally changes EPA's approach to evaluating and managing industrial chemicals. The body of changes, the careful balancing of competing needs and interests, and artful drafting yield a statute that has been greatly strengthened and addresses virtually all of the deficiencies that have impeded the effective implementation of TSCA over the years.

Among its other requirements and authorities, Section 5 of new TSCA generally requires that a company timely submit to EPA a notice of its intent to manufacture or process a new chemical or significant new use (NC/SNU). EPA is then required to conduct a review of the Section 5(a)(1) notice and make a determination on the NC/SNU and take required additional actions. Questions have been raised as to whether the review period is fixed and requires that EPA determinations and actions be completed within that period, or if the statute can be read to permit a more flexible review period along the lines of how it was interpreted and applied in old TSCA with the use of voluntary suspensions. This article analyzes that question.

Background

Under old TSCA, when EPA identified concerns that indicated a possible need for a consent order under Section 5(e) to allow for needed regulatory requirements to be applied (e.g., to control exposure or releases, preclude certain uses, and/or to require that the notifier conduct needed testing), EPA would typically obtain the agreement from the notifier to "voluntarily suspend" the notice period. *See* 40 C.F.R. Section 720.75(b). This was typically done around day 80–85 of the review period and was intended to provide the time needed to allow for the issues to be sorted out and for EPA and the notifier to agree on the terms of a negotiated consent order specifying needed controls or testing requirements.

New TSCA Requirements

Section 5(a)(1)(B) specifies that to manufacture or process a NC/SNU, the person must submit a notice of its intention to manufacture or process a NC/SNU to EPA *at least 90 days before* such manufacture or processing. Emphasis is added where relevant. The person must comply with any applicable requirements under Sections 5(b), (e), or (f).

Section 5(a)(3) requires that "within the applicable review period" EPA "shall review such notice" and make a determination. The available determinations at Section 5(a)(3) are the NC/SNU presents an unreasonable risk, the "information available is insufficient to permit a reasoned evaluation of the health or environmental effects," or in the absence of sufficient information to make such an evaluation, the NC/SNU may present an unreasonable risk, or the NC/SNU has substantial production and substantial or significant exposure, or the NC/SNU is not likely to present an unreasonable risk. Under the first two determinations, EPA is required to regulate the NC/SNU.

Section 5(c) states that EPA "may for good cause extend for additional periods (*not to exceed in the aggregate 90 days*) the period, *prescribed* by subsection (a) or (b)." The section goes on to require that "such an extension and the reasons therefor *shall be published* in the *Federal Register* and shall constitute a final agency action subject to judicial review."

Section 5(d)(1) states that the notice required by Section 5(a) shall include certain information as described in the section. Section 5(d)(3)(A) requires that EPA, at the beginning of each month, "*shall publish*" a list in the *Federal Register* of the chemicals for which notice has been received under Section 5(a) "*and for which the applicable review period has not expired, and (B) each chemical for which such period has expired since the last publication.*"

Section 5(e) is used to implement control actions on cases found by EPA to satisfy a determination under Section 5(a)(3)(B). In such cases, per Section 5(e)(1)(A)(i), EPA “shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit...” Section 5(e)(1)(B) goes on to state that

[a]n order may not be issued under subparagraph (A) respecting a chemical substance – (i) *later than 45 days before the expiration of the applicable review period*, and (ii) *unless [EPA] has, on or before the issuance of the order*, notified, in writing each manufacturer or processor, as the case may be, of the substance of the determination which underlies such order.

Section 5(f) describes the regulatory procedure for cases meeting the Section 5(a)(3)(A) determination, which, in general, parallels but differs in specifics from that in Section 5(e), including that EPA “may” issue an immediately effective proposed Section 6(a) rule or a Section 5(f) order. The provisions of Section 5(e)(1)(B) concerning the need to issue the action 45 days before the expiration of the applicable review period apply in the case of the order but not for the proposed rule.

Section 5(g) requires that in the case of a determination under Section 5(a)(3)(C) that a NC/SNU is not likely to present an unreasonable risk, “then *notwithstanding any remaining portion of the applicable review period*, the submitter of the notice may commence manufacture or processing.” EPA is also required to “make public” a statement of its finding that “shall be submitted for publication” in the *Federal Register* “*as soon as practicable before the expiration of such period.*” Note that publication of the statement “is not a prerequisite to” manufacture or processing.

Section 5(i) defines applicable review period as follows:

(3) For purposes of this section, the *term*

‘applicable review period’ means the period starting on the date [EPA] receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

Analysis and Conclusions

A first observation is that if Congress did not want to change the current understanding, it could have retained the language in old TSCA. The fact that Congress changed the language and defined a new term *applicable review period* presumably reflects congressional intent at a minimum to clarify the concept that had been described as the “notification period” in old TSCA. Or, as is our view, Congress’s intent was to change the interpretation of this concept regarding the effective operation of the old TSCA Section 5 review period against the calendar.

We note in this regard that it can be argued EPA overinterpreted the flexibility in “notification period” and the other provisions in old Section 5 that related to the review period. Although the use of voluntary suspensions has been codified in 40 C.F.R. Section 720.75(b), there is not a provision in old or new TSCA that speaks to such suspensions.

We note also the use of “prescribed” in old and new TSCA Section 5(c) and in old TSCA Section 5(d)((3)(A). In the dictionary, “prescribed” is defined as “to lay down, in writing or otherwise, as a rule or a course of action to be followed” and, in addition, “enjoin,” which has a particular legal denotation, is offered as a synonym. No challenge was made of the interpretation that allowed voluntary suspensions. The practice was subsequently codified, and, of course, is now widely used. Thus, despite the efforts of congressional drafters to, in our view, change the meaning, the bottom line may be that someone has to make a legal challenge to EPA’s interpretation of *applicable review period* if it includes voluntary suspensions in its implementation approach going forward under the new law.

We recognize that this is an issue that industry stakeholders will need to consider carefully. We

believe, however, that a good argument can be made that applying the new TSCA Section 5 notice review process within a defined period brings a clarity and certainty that perhaps may be beneficial to all involved. Perhaps recognizing the benefits of clarity on this issue, Congress may have endeavored to restate the requirements in terms of an *applicable review period* to make clearer what was intended to apply.

While we recognize and understand the desire of notifiers not to be “the nail that sticks out,” an unintended consequence of the informal voluntary suspension in lieu of a “due process” approach under old TSCA Section 5 is that EPA reviewers and new chemical submitters grew unaccustomed to engaging in the push and pull that characterizes other environmental issues. Perhaps as a consequence, they did not have the benefit of constructive, albeit sometimes adversarial, dialogue as scientific, legal, and policy peers over the substance and conclusions of EPA’s evaluations and its proposed control remedies, respectively. We believe such dialogue is essential and strengthens the process by providing clarity while also producing more broadly and mutually acceptable outcomes. The U.S. regulatory system is premised on legal requirements and their application to specific factual settings. Conflict over the interpretation or application of legal authorities to specific situations can result in the need for judicial recourse, and the clarity that judicial resolution provides can be helpful as an alternative to accepting what may be an unacceptable status quo.

The starting point for our analysis is to consider the definition of *applicable review period*, provided above. “Date” is defined in the dictionary as “a particular month, day, and year at which some event happened or will happen.” The review period thus starts on a particular day and ends 90 days after that particular day, or on “such date” provided for under a Section 5(c) extension that allows EPA for good cause to extend the period for additional periods, not to exceed an additional 90 days in the aggregate. By our reading, the net effect is to stipulate that, e.g., a premanufacture notifica-

tion’s 90-day review starts on the day and month received, ends 90 days after that date but can be extended in the aggregate to no more than 180 days after that date of receipt. The use of “date” puts a peg into the calendar and, it can be argued, affords no discretion to add “voluntary suspension” days to the allowed period because in so doing, the resulting period would violate the requirement that the *applicable review period* begins on a specific date (day/month/year) and ends no later than the date (day/month/year) that is 90 or 180 days later.

While this argument alone may suffice to resolve the question, there is additional support within new TSCA Section 5, as follows:

- The new law uses the phrase “within the applicable review period” in Section 5(a)(1)(B)(ii)(II) concerning the requirements on EPA in reviewing and making determinations on NC/SNUs and at Section 5(a)(3) concerning the requirement that EPA “shall review such notice and determine.” The relevant provisions read as follows (emphasis added):

Section 5(a)(1)(B). A person may take the actions described in subparagraph (A) if— (i) . . . ; and (ii) the Administrator— (I) conducts a review of the notice; and (II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph *within the applicable review period*.

Section 5(a)(3). REVIEW AND DETERMINATION.—*Within the applicable review period*, subject to section 18, the Administrator shall review *such* notice and determine—(A). . . ;(B). . . ; or (C). . . .

The dictionary definition meaning of “within” in the context of time is as follows: “in the course or period of, as in

time: within the year.” Other meanings include: “in the compass or limits of; not beyond: within view; to live within one’s income.” Thus, one meaning of the phrase is that “in the course or period of time of the applicable review period,” EPA shall, respectively among the two provisions cited, take the actions required or shall review such notice and determine (A), (B), or (C).

- The “such notice” language at Section 5(a)(3) seems to require that EPA review what was submitted and could be read to limit, if not preclude, the ability to amend informally the notice after its submission. This question needs more consideration but in the context of a “fixed review period” analysis, it may be intended to take away the flexibility that could contribute to EPA not being able to complete a timely review. This could result, for example, from the need to re-review multiple notice iterations and account for the changes in revising the EPA exposure and risk assessments. Such changes could then set up a ripple effect altering and further delaying EPA’s determination and decisions regarding the need for and nature of the control actions.
- The Section 5(d)(3)(A) and (B) requirement to publish the monthly report on Section 5 notices received, as structured, seems to add to the perspective that the *applicable review period* is fixed. This can be inferred in the way it requires that EPA report on the cases for which (A) this period has not expired and (B) those cases for which the period has expired. We note that one could also read the original TSCA Section 5(d) to have a similar effect, although the use of the term *applicable review period* gives a “date-oriented” emphasis to the meaning which was less evident in TSCA (redlining shows changes from old TSCA):

(3) At the beginning of each month EPA

shall publish a list in the *Federal Register* of “(A) each chemical substance for which notice has been received under subsection (a) and for which the applicable review notification period [i.e., a certain day/date/month] ~~prescribed by subsection (a), (b), or (c)~~ has not expired, and (B) each chemical substance for which such ~~notification~~ period has expired” [i.e., the day/date/month 90 or 180 days later] since the last publication in the *Federal Register* of such list.

- Section 5(e) and Section 5(f) orders are required to take effect “on the expiration of the applicable review period,” i.e., on the day/date/month that, e.g., after using a Section 5(c) extension, is 180 days after the date on which the notice was received.
- The use in Section 5(g) of “notwithstanding any remaining portion of the applicable review period” loses its meaning if EPA can voluntarily suspend, for example, to allow it to complete the (C) determination by, as it were, “pretending” not to go beyond day 90 through the artifice of stopping the review clock while the calendar days continue to pass. Admittedly, EPA could achieve this outcome by issuing a Section 5(c) extension but it would, nonetheless, have to provide an explanation of the need for the extension.

By our reading, new TSCA arguably applies a fixed review period to the completion by EPA of its review and determination and needed actions on a NC/SNU submitted to the Agency. Whether this reading will apply, however, as was the case in old TSCA, may turn on whether EPA, in light of the revised statutory text, takes this view and, if not, on whether a notifier legally challenges the use of an informal voluntary suspension approach. At the same time, we note that submitters could obtain this outcome, even in the presence of a voluntary suspension approach, by declining a request to allow for a voluntary suspension,

thereby compelling EPA to proceed with issuance of a Section 5(c) notice to extend the review period and to otherwise meet the deadlines in new TSCA. Such an approach would require that EPA issue the order or explain the substance of its determination in writing to the notifier by day 135 of the review period. Having acknowledged this requirement, however, we see no reason why EPA's discussions with the notifier could not continue during some portion of the additional 90-day period to produce a negotiated order acceptable to both EPA and the notifier. *See* EPA, EPA Actions to Reduce Risk for New Chemicals under TSCA, *available at* <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-actions-reduce-risk-new#section%205> ("Most TSCA section 5(e) orders issued by EPA are Consent Orders that are negotiated with the submitter of the PMN."). Hard deadlines can be helpful in more promptly producing clarity and agreement if both parties bring a demonstrable willingness to find common ground to the table.

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