FROM THE CO-CHAIR
Lawrence E. Culleen

Welcome to the spring edition of the Pesticides, Chemical Regulation, and Right-to-Know (PCRTK) Committee Newsletter. The committee was busy during the fall, offering programming inclusive of informative Friday Fora and with our members as active participants in the Section of Environment, Energy, and Resources (SEER) Fall Conference in Baltimore, Maryland. As co-chairs, Keith and I are looking forward to an exciting spring in which the committee will offer more exciting programs and our members will again take on very visible roles in programs scheduled at the Spring Meeting in Orlando. (Vice chair Lynn Bergeson will be among the many noteworthy speakers at the spring conference.)

Among the noteworthy programs being scheduled for the spring is the return of an annual favorite in which our committee will collaborate with CropLife America on a full-day event covering a panoply of hot topics and legal developments affecting pesticides. PCRTK benefits considerably from the leadership of our programming vice chair, Sara Beth Watson, who is actively planning and organizing that event in coordination with CropLife General Counsel Rachel Lattimore.

Of note: Lynn has recently organized PCRTK members who are busy compiling information that will form the basis of several papers that will better inform our American Bar Association colleagues seeking information on the intersection of chemical regulatory requirements, cannabis cultivation, and marketing in the United States. As our programming vice chair, Irene Hantman has been busy organizing a program for later this spring addressing cannabis-related legal issues and related topics.

Regulatory developments will ensure spring will be a busy time for practitioners in our field. We can expect to be active reviewing and assisting clients in responding to a variety of recently released regulatory actions, including the Toxic Substances Control Act (TSCA) fees rule. Risk evaluations are officially under way on the group of the first ten substances identified for review following the 2016 amendments to TSCA, and exposure assessments are likely to start to take shape on five persistent and bioaccumulative substances likely to be the target of “expedited” action under the U.S. Environmental Protection Agency’s (EPA) new TSCA section 6(h) authority.

Litigation also appears certain to keep “chemicals and pesticides” lawyers busy whether we work at EPA, in the nongovernmental organization (NGO) community, or in the private bar. The agency seems destined to be the target of new lawsuits at every turn, from Endangered Species Act claims to alleged violations of the Administrative Procedure Act, and ongoing challenges testing EPA’s...
Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter
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Lynn L. Bergeson, Editor

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discretion on how it responds to TSCA section 21 petitions. EPA, in turn, has begun to show signs of activity in the enforcement space.

Keith and I are pleased to be part of a very active and able PCRR TK Committee with members who enjoy keeping one another informed and educated through sharing information and encouraging a collegial approach in an otherwise competitive field. Please feel free to reach out to Keith or to me, or any of our talented vice chairs, with your contributions, thoughts, and ideas concerning ways to ensure our members are getting everything we all hope to gain through our membership in the PCRR TK Committee.

Lawrence E. Culleen is a partner in the environmental practice group at Arnold & Porter.

### Global Chemical Control Handbook: A Guide to Chemical Management Programs

Lynn L. Bergeson

List Price: $149.95
Section Member: $119.95
ISBN: 978-1-62722-739-1
Product Code: 5350252
(c) 2014, paperback

Global Chemical Control Handbook keeps practitioners abreast of these important developments—what they are, on what segment of the global supply chain they apply, and when and how these measures impact the business of chemicals. Providing a broad overview of key chemical management programs in the United States, Europe, Asia, and Central and South America, this book describes the key laws and their regulatory implementation in these jurisdictions. The authors provide a basic understanding of each law and help practitioners identify key business issues of concern.

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### MOST RECENT ANALYSES BY EPA AND BfR CONCLUDE, AGAIN, THATGlyphosate SHOULD NOT BE CLASSIFIED AS CARCINOGENIC TO HUMANS

Keith A. Matthews

In 2015, the International Agency for Research on Cancer (IARC) issued a monograph finding that the widely used herbicide glyphosate is a probable human carcinogen. Since IARC released its glyphosate monograph, there has been a veritable Texas flood of global independent regulatory determinations that existing data and information do not support a finding that glyphosate should be classified as carcinogenic to humans. The latest such regulatory assessments are by the U.S. Environmental Protection Agency (EPA) and the German Federal Institute for Risk Assessment (BfR).

On February 27, 2018, EPA released for public comment a draft glyphosate human health risk assessment in which it finds that glyphosate is “not likely to be carcinogenic to humans” (https://www.regulations.gov/searchResults?rpp=25&po=0&s=EPA-HQ-OPP-2009-0361&fp=true&ns=true). Similarly, BfR recently analyzed a new study, published in the November 9, 2017, issue of the *Journal of the National Cancer Institute* (JNCI) that examined data from the U.S. Agricultural Health Study (AHS), an epidemiological study of over 89,000 farmers and their spouses in Iowa and North Carolina. The AHS, which started in 1993, prospectively evaluates the incidence of cancers and other health outcomes in pesticide applicators and those in close contact with them. The study published in the JNCI concluded that AHS data collected to date do not support a finding of a statistical association between glyphosate exposure and the occurrence of any types of cancers (http://www.bfr.bund.de/cm/349/glyphosate-new-epidemiological-study-finds-no-connection-between-cases-of-cancer-and-use-of-plant-protection-products-containing-glyphosate.pdf).

EPA opened a 60-day public comment period on its draft glyphosate human health risk assessment,
which included a comprehensive evaluation of the
existing data relevant to the determination of the
carcinogenic potential of glyphosate. This included
an assessment of existing epidemiological data,
animal carcinogenicity studies, and genotoxicity
studies related to glyphosate. In addition, EPA
considered the comments of the 2016 Federal
Insecticide, Fungicide, and Rodenticide Act
(FIFRA) Scientific Advisory Panel (SAP) that
evaluated charge questions regarding potential
human health effects of glyphosate. Based on its
weight-of-the-evidence evaluation, EPA concluded
that glyphosate should be classified as “not
likely to be carcinogenic to humans.” The draft
glyphosate human health risk assessment is part of
the regular pesticides registration review process.
EPA has stated that it will publish its proposed
glyphosate registration review decision in 2019.

On December 22, 2017, BfR released
Communication No. 036/2017, titled “Glyphosate:
New Epidemiological Study Finds No Connection
between Cases of Cancer and Use of Plant
Protection Products Containing Glyphosate,”
that is based on BfR’s assessment of a new study
published in the JNCI (http://doi.org/10.1093/
jnci/djx233), which evaluates data generated by
the AHS. Based on the updated analysis of AHS
epidemiological data, the study published in the
JNCI concludes that no statistical association could
be recorded between the use of plant protection
products containing glyphosate, according to users’
own information, and the occurrence of cancers
in general or leukemias, including non-Hodgkin
lymphomas (NHL) and multiple myeloma, in
particular. BfR concluded that the study results are
reliable based on the large number of participants,
all participants are active users of pesticides and
plant protection products, the study adjusted for
confounding factors such as age, smoking, alcohol
use, familial cancer history, use of other pesticides/plant protection products, and the temporal length
of the long-term AHS.

BfR’s 2017 assessment follows a communication
that BfR released shortly after the 2015 IARC
report, in which BfR noted that IARC’s
classification of glyphosate as a probable human
carcinogen “comes as a surprise,” because
numerous earlier evaluations by risk assessment
authorities worldwide had reached a differing
conclusion. BfR specifically cited previous
evaluations by the United Nations Food and
Agriculture Organization (FAO)—World Health
Organization (WHO) Panel of the Joint Meeting
on Pesticide Residues (JMPR) in 2004, and by
national regulatory agencies such as EPA—
which had long concluded that glyphosate is
not carcinogenic. In its 2015 statement, BfR
noted that the IARC glyphosate carcinogenicity
classification is based on “limited evidence” in
humans. The classification is primarily based
on three epidemiological studies in the United
States, Canada, and Sweden in which a statistical
correlation was determined to exist between
exposure to glyphosate and an increased risk of
NHL. A correlation between glyphosate exposure
and NHL, however, has not been otherwise
confirmed, including by analyzing the U.S. AHS
large cohort study, or in other studies. BfR noted
that, as Germany is the rapporteur Member State
in the ongoing reevaluation process of glyphosate
in the European Union (EU), it has compiled
a database of hundreds of toxicity studies on
glyphosate and thousands of references from the
open literature—which is presumably the most
comprehensive toxicological database anywhere
devoted to glyphosate. Given this extensive
glyphosate toxicological database, BfR suggested
that the entire database must be taken into account
for toxicological evaluation and risk assessment
of a substance “and not merely a more or less
arbitrary selection of studies.” The March 23, 2015,
BfR communication is posted at http://www.bfr.
bund.de/cm/349/does-glyphosate-cause-cancer.pdf.

In addition to the EPA and BfR glyphosate
carcinogenicity assessments, numerous
regulatory bodies worldwide have assessed the
potential carcinogenicity of glyphosate. All have
reached conclusions inconsistent with the IARC
classification. Some, but not all, of these regulatory
assessments are summarized below.

On April 28, 2017, Health Canada released a
regulatory determination that glyphosate products,
when used according to label directions, are not
a concern to human health and the environment.
Specifically, Health Canada concluded that, inter alia, glyphosate is not genotoxic and is unlikely to pose a human cancer risk; dietary exposure associated with the use of glyphosate is not expected to pose a risk of concern to human health; and occupational and residential risks associated with the use of glyphosate are not of concern, provided that updated label instructions are followed (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/registration-decision/2017/glyphosate-rvd-2017-01.html).

On March 15, 2017, the European Chemicals Agency’s (ECHA) Committee for Risk Assessment (RAC) released a report concluding that “[t]he available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction” (https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa).

In May 2016, the JMPR again considered glyphosate and concluded that glyphosate is “unlikely to be genotoxic” at anticipated dietary exposures and that it is “unlikely to pose a carcinogenic risk to humans from exposure through the diet” (http://www.who.int/foodsafety/jmprsummary2016.pdf). On November 12, 2015, the EU European Food Safety Authority (EFSA), following a specific mandate from the European Commission to consider the IARC findings regarding the potential carcinogenicity of glyphosate, concluded that (1) glyphosate is unlikely to pose a carcinogenic hazard to humans and (2) the evidence does not support classification of glyphosate with regard to carcinogenic potential. In support of this conclusion, EFSA noted that all the Member State experts but one agreed that neither the human epidemiological data nor the evidence from animal studies demonstrated causality between exposure to glyphosate and the development of cancer in humans (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf).

The numerous and consistent findings by expert regulatory bodies that existing data do not support a finding that glyphosate is carcinogenic finally appear to be having an effect in glyphosate-related litigation. On February 26, 2018, an injunction was issued in the U.S. District Court for the Eastern District of California enjoining the state of California from requiring Proposition 65 (Prop 65) warnings related to glyphosate. Nat’l Ass’n of Wheat Growers et al. v. Lauren Zeise, Director of the Office of Environmental Health Hazard Assessment, Civ. No. 2:17-2401 (E.D. Cal. Feb. 26, 2018). The district court ruled that requiring a Prop 65 warning related to glyphosate-containing products would be compelled commercial speech and would fail the first prong of the test articulated by the Supreme Court in Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio (471 U.S. 626, 651 (1985)) in that such compelled warning would be neither factual nor uncontroversial. The required Prop 65 warning as to glyphosate would not be factually accurate and uncontroversial because it “conveys the message that glyphosate’s carcinogenicity is an undisputed fact, when almost all other regulators have concluded that there is insufficient evidence that glyphosate causes cancer.” Nat’l Ass’n of Wheat Growers et al. at 15 (citing regulatory assessments by EPA, EFSA, ECHA, BfR, WHO, and, interestingly, the Office of Environmental Health Hazard Assessment). While this is only a decision on a motion for a preliminary injunction, the court necessarily found that plaintiffs are likely to succeed on the merits of their First Amendment argument.

Still to be seen is whether the growing scientific and regulatory consensus that existing data do not support a finding that glyphosate is a human carcinogen will be properly accorded due weight and found to be dispositive in the ongoing multidistrict glyphosate products liability litigation in the U.S. District Court for the Northern District of California, where hundreds of cases have been consolidated that allege a causal connection between exposure to glyphosate and development of various cancers. For the sake of science-based and evidence-based judicial decision-making, hopefully the distinction between Sacramento and San Francisco, at least jurisprudentially, is indistinguishable.

Keith A. Matthews is of counsel with Wiley Rein LLP.
On February 14, 2018, the U.S. Environmental Protection Agency (EPA) and Amazon Services LLC (Amazon) entered into a consent agreement and final order (https://www.epa.gov/enforcement/amazon-services-llc-consent-agreement-and-final-order), whereby Amazon agreed to pay $1,215,700 in civil penalties for approximately 4,000 alleged violations under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the distribution of unregistered pesticide products. Amazon neither admitted nor denied the specific factual allegations, which included:

1. Between January 1, 2013, and November 1, 2015, Amazon distributed, held for distribution, held for shipment, or shipped two unregistered pesticide products called “3pcs Cockroach Cockroaches Bugs Ants Roach Kills Chalk” and “Miraculous Insecticide Chalk” on multiple occasions in the United States.


Amazon also agreed to implement a supplemental environmental project (SEP) consisting of the development, deployment, and operation of a publicly available eLearning course, downloadable educational materials, and test on FIFRA requirements and associated regulations (eLearning Project). Although no monetary amount was specified for the implementation of the SEP, the eLearning Project will be a significant undertaking, as the materials will be available in three languages (English, Spanish, and Chinese) and Amazon will require all of its Amazon.com sellers to complete the eLearning course and pass an associated test prior to allowing such Amazon.com sellers to sell products identified as pesticides. The only circumstance when this requirement will not apply to Amazon.com sellers is when a seller can “demonstrate that the seller’s existing compliance program is sufficient to ensure products sold via Amazon.com comply with FIFRA.”

This settlement agreement is noteworthy not only because of the size of the agreed penalty amount and the breadth of the training program that Amazon has agreed to develop and implement, but also because it highlights a number of issues with regard to illegally imported pesticides about which some in the regulated community have long voiced concern. EPA issued two stop sale, use, or removal orders (SSURO) to Amazon based on Amazon’s distribution of the illegal pesticides, which were sold by third parties, because Amazon provided the online marketing platform for those third-party sellers. Specifically, EPA states that Amazon “offers a service called “Fulfillment by Amazon” (“FBA”) whereby products are posted on the Amazon.com website for sale by the third-party sellers, stored in Amazon’s fulfillment centers, and Amazon packs, ships, and/or provides logistics services for these products.” The term “distribute or sell” under FIFRA is quite broadly defined and includes holding for shipment, delivering for shipment, releasing for shipment, receiving and delivering or offering to deliver a pesticide, so it is not surprising that EPA pursued Amazon with regard to these issues. Some have commented, however, that it is puzzling that this platform was not the subject of close enforcement scrutiny and significant enforcement action well before now.

Also of note is Amazon’s reaction to EPA’s SSUROs. The first was issued in August 2015 and focused on a chalk type of pesticide product that EPA stated could “easily be mistaken for
black-board or side-walk chalk, especially by children”; the second followed only a few months later, in January 2016, and focused on certain bait products. Following receipt of the second SSURO, EPA’s press release (https://www.epa.gov/newsreleases/epa-settles-amazon-distributions-illegal-pesticides) notes that among other actions, Amazon “prohibited foreign sellers from selling pesticides,” and then “created a robust compliance program comprised of a sophisticated computer-based screening system backed-up by numerous, trained staff.” In addition, EPA’s press release states that Amazon “notified all customers who purchased the illegal pesticides between 2013 and 2016 to communicate safety concerns with these products and urge disposal.” Further, Amazon “refunded those customers the cost of the products, approximately $130,000.” These actions may set a high bar for future enforcement actions involving online sales.

Lisa M. Campbell is a partner with Bergeson & Campbell, P.C. Lisa R. Burchi is of counsel with Bergeson & Campbell, P.C.
The proposed rule provides a description of proposed TSCA fees and fee categories for FYs 2019, 2020, and 2021, and explains the methodology by which the proposed TSCA user fees were determined and would be determined for subsequent FYs. In proposing the new TSCA user fees, EPA also proposes amending long-standing user fee regulations governing the review of section 5 premanufacture notices (PMN), exemption applications and notices, and significant new use notices (SNUN). After implementation of final TSCA user fees regulations, certain manufacturers and processors would be required to pay a prescribed fee for each section 5 notice or exemption application, section 4 testing action, or section 6 risk evaluation for EPA to recover certain costs associated with carrying out certain work under TSCA. EPA did not propose specific fees for submission of confidential business information (CBI).

The proposed rule would apply fees to manufacturers and importers of chemicals subject to section 4 actions, section 5 notices and exemptions, and section 6 risk evaluations, including manufacturer-requested risk evaluations. EPA would apply fees to processors that submit section 5 SNUNs or when a section 4 activity is tied to a SNUN submission by a processor. EPA based this approach on what it saw as the difficulty in identifying processors for the other fee-triggering actions and discussed its expectation that manufacturers would pass some of the fee costs downstream. EPA requests comment on the proposed user fee approach and amounts, and on the methodology used for determining the amounts. EPA is also proposing and taking comment on standards for determining which persons qualify as small business concerns and thus would be subject to lower fee payments.

Who Will Be Charged Fees

EPA notes that although it has the authority to collect fees from both manufacturers and processors, it is proposing to focus fee collection on manufacturers. EPA proposes to collect fees from processors only when processors submit a SNUN under section 5 or when a section 4 activity is tied to a SNUN submission by a processor. EPA “feels the effort of trying to identify a representative group of processors for the other three fee-triggering actions would be overly burdensome and expects many processors would be missed.” EPA states that it expects that manufacturers required to pay user fees will have a better sense of the universe of processors and will pass some of the costs on to them. EPA seeks public comment on this approach.

While fee payers will self-identify for certain actions, such as making a section 5 new chemical submission to EPA, for other actions, such as TSCA section 6 risk evaluations, EPA proposes to use Chemical Data Reporting (CDR) data to identify a preliminary list of companies. EPA seeks comment on whether to adopt a process that would allow time for public input for adding to that preliminary list before it is issued in final. EPA states that it is also interested in comments on using other sources to identify those subject to payment of fees, sources including information reported to the Toxics Release Inventory, notice of commencement, submissions under EPA’s TSCA New Chemicals Review Program, and information reported under the TSCA Inventory active/inactive notification rule.

How EPA Calculated the Proposed User Fees

EPA states that it believes that assigning fees across TSCA sections 4, 5, and 6 is the most equitable and efficient approach for allocating costs. EPA intends its proposed fee methodology to recover fully the amount specified in the statute per TSCA section 26(b)(4)(F). According to EPA, the estimated annual costs of carrying out TSCA sections 4, 5, 6, and 14, without including the costs associated with manufacturer-requested chemical risk evaluations, are approximately $80.2 million. Based on these cost estimates, EPA anticipates collecting approximately $20.05 million in fees each year. EPA intends to collect fees from manufacturers to recover a portion of costs incurred by EPA in
conducting chemical risk evaluations requested by manufacturers. EPA expects this fee amount will be $1.3 million per chemical for chemicals on the Work Plan and $2.6 million per chemical for chemicals not on the Work Plan.

EPA states that it determined the anticipated costs associated with TSCA sections 4, 5, 6, and 14 activities, including both program costs and indirect costs. For FYs 2019 through 2021, EPA estimated these costs to be approximately $80.2 million per year, as detailed in the table below:

<table>
<thead>
<tr>
<th></th>
<th>Direct Program Costs</th>
<th>Indirect Costs</th>
<th>Annual Costs</th>
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<td>TSCA Section 5</td>
<td>$22,375,000</td>
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<td>TSCA Section 6</td>
<td>$34,073,000</td>
<td>$9,545,000</td>
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<td>TSCA Section 14</td>
<td>$3,531,000</td>
<td>$814,000</td>
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<td><strong>Total</strong></td>
<td><strong>$62,744,000</strong></td>
<td><strong>$17,425,000</strong></td>
<td><strong>$80,178,000</strong></td>
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*Note: Numbers may not add due to rounding. The indirect cost rate for Office of Chemical Safety and Pollution Prevention is estimated at 28.14 percent for the purposes of this analysis.*

After EPA estimated the annual costs of administering TSCA sections 4, 5, 6, and 14, EPA had to determine how the costs would be allocated over the narrower set of activities under TSCA sections 4, 5, and 6 that trigger a fee. EPA states that it took an approach to determining user fees that parsed the fees based on the type of submission or fee-triggering event, allowing costs to be more equitably allocated among the submissions and their related costs.

Under the proposed rule, EPA would require payment of fees for most types of fee-triggering events under TSCA sections 4, 5, and 6. This includes the requirement to submit information to comply with a test order, test rule, or ECA under TSCA section 4. EPA would also require payment for the following TSCA section 5 notices and exemptions: PMNs and consolidated PMNs, SNUNs, microbial commercial activity notices (MCAN) and consolidated MCANs, test marketing exemptions (TME), low releases and low exposures (LoREX), low volume exemptions (LVE), Tier II, film article exemptions, and TSCA experimental release applications (TERA). Payment would also be required for chemicals undergoing both EPA-initiated and manufacturer-requested risk evaluations under TSCA section 6.

For TSCA section 4 activities for existing chemicals, EPA is proposing three fee categories. The proposed fee associated with a test order is $10,000. The proposed fee associated with a test rule is $32,000, and the fee proposed for an ECA is $25,000. EPA states that it expects these fees will be paid by consortia, assuming that multiple companies manufacture the same chemical, and is requesting that consortia assign comparatively lower fees for small businesses than for large businesses in the consortia. Consistent with comments previously received, EPA is proposing to provide flexibility to manufacturers to form consortia to allocate these fees amongst those
members involved in each submission activity.
EPA estimated that, on average, it will annually undertake work on ten test orders, one test rule, and one ECA.

EPA proposes two categories of fees, with different fee amounts, for TSCA section 5 submissions. According to the proposed rule, EPA “chose to lump activities with similar Agency costs together” to develop a simple fee structure. The fee proposed for each PMN, SNUN, and MCAN is $16,000. The fee proposed for each LoREX, LVE, TME, Tier II, film article, and TERA is $4,700. EPA proposes to continue the practice of allowing consolidation of PMNs, consolidation of MCANs, and, in some cases, consolidation of a synthetic sequence for up to six closely similar chemical substances with similar use, structure, and probable toxicology at the same time and for the same fee as a single chemical substance. According to EPA, consolidated PMNs (and MCANs) benefit submitters by reducing the administrative burden of developing multiple section 5 submission forms for manufacture of two or more structurally related new chemical substances that have similar use, exposure, environmental release, and test data. EPA notes that its review process is also better facilitated by reviewing similar substances simultaneously. EPA also proposes to eliminate the currently available “intermediate PMN” fee class, arguing that each intermediate in a sequence takes about as much time to review as does the final product that is sold or used commercially.

EPA is not proposing to assess greater fees for submissions with CBI claims, an important consideration for section 5 notices, given the frequency of CBI claims for new chemicals. Also, in an important nod that recognizes the continued importance of the Sustainable Futures program, EPA is proposing to waive the TME fee for submission from companies that have graduated from this program.

For risk evaluations, EPA is proposing a slightly different fee amount ($1.35 million versus $1.3 million) for EPA-initiated risk evaluations and for manufacturer-requested risk evaluations for Work Plan chemicals, while the fees would approximately double for manufacturer-requested risk evaluations on non-Work Plan chemicals. The one size approach is curious. While $1 million plus may be appropriate for high volume or high value chemicals, many if not most existing chemicals share neither of these attributes.

The fee amounts being proposed are summarized in the top table on the following page.

**Small Business Concerns**

EPA proposes reduced fees for small businesses, as summarized in the bottom table on the following page.

EPA set the proposed small business fees at an 80 percent reduction compared to the proposed base fee for each category. EPA notes that in one case, for PMN and related actions, the proposed small business fee reduction is 82.5 percent.

EPA proposes to revise the size standard used to identify businesses that can qualify as a “small business concern” under TSCA for the purposes of fee collection. In 1988, EPA promulgated a regulatory definition for a small business that makes a submission under TSCA section 5, based on the annual sales value of the business’ parent company. EPA states that the definition provided in 40 C.F.R. § 700.43 currently states: “Small business concern means any person whose total annual sales in the person’s fiscal year preceding the date of the submission of the applicable section 5 notice, when combined with those of the parent company (if any), are less than $40 million.” EPA proposes several changes to this definition. Consistent with the definition of small manufacturer or importer at 40 C.F.R. § 704.3, EPA proposes to increase the current revenue threshold of $40 million using the Producer Price Index (PPI) for Chemicals and Allied Products, as compiled by the U.S. Bureau of Labor Statistics. Using a base year of 1988 and inflating to 2015 dollars results in a value of approximately $91 million.
### Proposed TSCA User Fees

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<tr>
<th>PROPOSED FEE CATEGORY</th>
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<td>PMN and consolidated PMN</td>
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<td>SNUM</td>
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<td>MCAN and consolidated MCAN</td>
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<td>LVE</td>
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<td>TME*</td>
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<td>Tier II exemption</td>
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<td>TERA</td>
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<td>Film Articles</td>
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<td><strong>TSCA Section 6</strong></td>
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<tr>
<td>EPA-initiated risk evaluation</td>
<td>$1,350,000</td>
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<td>Manufacturer-requested risk evaluation on a chemical included in the Work Plan</td>
<td>$1,300,000</td>
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<td>Manufacturer-requested risk evaluation on a chemical <em>not</em> included in the Work Plan</td>
<td>$2,600,000</td>
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*EPA is proposing to waive the TME fee for submissions from companies that have graduated from EPA’s Sustainable Futures program.

### Proposed TSCA User Fees for Small Businesses

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<tr>
<th>PROPOSED FEE CATEGORY</th>
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<td><strong>TSCA Section 5</strong></td>
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<tr>
<td>PMN and consolidated PMN</td>
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<td>SNUM</td>
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<td>MCAN and consolidated MCAN</td>
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<td>LoREX</td>
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<td>LVE</td>
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<td>TME</td>
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<td>Tier II exemption</td>
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<td>TERA</td>
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<td><strong>TSCA Section 6</strong></td>
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<td>EPA-initiated risk evaluation</td>
<td>$270,000</td>
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<tr>
<td>Manufacturer-requested risk evaluation on a chemical included in the Work Plan</td>
<td>$1,300,000</td>
</tr>
<tr>
<td>Manufacturer-requested risk evaluation on a chemical <em>not</em> included in the Work Plan</td>
<td>$2,600,000</td>
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Pursuant to 13 C.F.R. § 121.903(a)(1)(ii), EPA also proposes to change the time frame over which annual sales values are used when accounting for a business’ revenue. Instead of using just one year preceding the date of submission, EPA proposes to average annual sales values over the three years preceding the submission. EPA proposes to apply this updated definition—adjusted for inflation and averaging sales revenue over three years—to not only TSCA section 5 submissions, but also to TSCA sections 4 and 6 submissions as well.

**Timing of Fee Payment**

EPA proposes to collect lump sum payment of the entire user fee for section 5 notices prior to reviewing each submission or undertaking the activity associated with the fee. EPA proposes to require fee payment at the time a TSCA section 5 notice (including an exemption) is submitted.

EPA proposes to allow fee submitters for test orders, test rules, ECAs, and EPA-initiated chemical risk evaluations time to associate with a consortium and work out fee payments within that consortium. Payment for fee categories under TSCA section 4 (i.e., test orders, test rules, and ECAs) is due within 60 days of the effective date of the order or rule, or 60 days upon signing of an ECA. For EPA-initiated risk evaluations, full payment is due within 60 days of EPA publishing the final scope of a chemical risk evaluation. EPA states that it believes this provides sufficient time for manufacturers to associate as a consortium, if they so choose, and to decide on the partial fee payments each member of the consortium will be responsible for. EPA notes that manufacturers will have ample warning that a risk evaluation is under way, well before the final scope is published in the *Federal Register*.

For manufacturer-requested risk evaluations, EPA proposes to collect a fee when it grants the request to conduct the evaluation. Payment will be required within 30 days of EPA providing such notice.

EPA proposes that user fees will begin to be incurred starting on October 1, 2018. EPA states that it will not collect any fees until the final user fee rule is effective. Instead, EPA intends to record actions that would be expected to trigger payment of fees and once the rule is final, send invoices to the affected parties. The invoices would reflect timing for payments and amounts based on the final rule.

**Circumstances under Which EPA Will Refund Payments**

EPA states that it will continue to refund any fee paid for a section 5 notice whenever it determines that the notice or fee was not required. TSCA section 26(b)(4)(G) permits EPA to refund fees, or a portion of fees, for notices submitted under TSCA section 5 that are later withdrawn and for which EPA conducts no substantive work unless it determines that the submitter unduly delayed the process. EPA proposes to refund a consistent 75 percent of the user fee to the submitter if the notice is withdrawn within ten business days. Beyond ten business days, EPA states that it is likely to have already conducted substantial review work that qualifies as substantive work for which no refund is authorized under TSCA section 26(b)(4)(G). According to EPA, up to three significant milestones of the PMN review process can take place within ten business days: the Chemical Review/Search Strategy Meeting occurs between days 8 and 12; the Structure Activity Team Meeting occurs between days 9 and 13; and Development of Exposure/Release Assessments occurs between days 10 and 19. EPA states that it “feels that tying the refund time period to a certain number of days is a simpler and more efficient approach than tying it to a specific milestone of the review process.” EPA does not have authority to, and therefore will not, provide refunds under any other circumstances.

**Consequences of Failing to Pay a Fee**

The proposed rule states that failure to comply with any requirement of a rule promulgated under
TSCA is a prohibited act under TSCA section 15 and is subject to penalties under TSCA section 16. When the final rule is promulgated, failure to pay the appropriate fee at the required time would subject each manufacturer and processor who is subject to the fee payment to penalties of as much as the maximum statutory amount per day ($38,114 as of January 2017) until the required fee is paid. Each person subject to fees would be subject to such penalties regardless of whether they intend to pay independently, as a joint submitter, or through consortia. Specifically, each member of a consortium, and each joint submitter, is individually responsible for payment of the fee, and subject to penalties for non-payment, until the fee is actually paid.

Compliance Date

EPA proposes to start collecting fees the day after the final TSCA user fees rule is published in the Federal Register.

Other Proposed Amendments

EPA proposes minor changes to several of its regulations that cross-reference the part 700 fees regulations, specifically parts 720, 723, 725, 790, and 791. Amending the regulatory text in these parts will ensure that existing regulations appropriately reference the regulatory text being proposed. EPA proposes minor updates for implementing the fee requirements for TMEs at section 720.38; PMN regulations at section 720.45(a)(5); instant photographic and peel-apart film articles exemptions at section 723.175; amendments to regulations covering MCANs and exemption requests at sections 725.25 and 725.33; minor amendments at sections 790.45 and 790.59; and a modification to the general provisions for data reimbursement found at section 791.39.

Discussion

EPA reached an important milestone in issuing the proposed user fees rule. The proposal is generally well constructed and thoughtful, particularly with regard to its approach to processors, the limited fees on section 4 actions, and continued flexibility in fees for certain section 5 notices, for example, consolidated cases, and Sustainable Futures-related submissions. Additional careful thought needs to be given by stakeholders to the implications of EPA’s proposal to not include the “intermediate PMN” approach and the “one size fits all” fees for section 6 risk evaluations in the case of low value, low volume, or categories of existing chemicals.

EPA properly requests comment on many key issues and it should expect to receive many comments. The Environmental Defense Fund, for example, has already expressed its view that the fee calculation methodology is flawed and that EPA has underestimated its costs in conducting TSCA activities. Other TSCA stakeholders can be expected to comment extensively on the proposal.

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The Trump administration is no stranger to challenges from environmental nongovernmental organizations (NGO) to its environmental policies; the lawsuits have become so commonplace that organizations like the Center for Biological Diversity have even dedicated web pages to tracking the number of lawsuits they have filed against the Trump administration. The U.S. Environmental Protection Agency’s (EPA) Toxic Substances Control Act (TSCA) activities have not been immune to these challenges. In addition to litigation filed concerning the agency’s “framework rules,” which establish processes for the administration of the key features of the 2016 amendments to TSCA, EPA is in the throes of a lawsuit brought by a number of environmental NGOs related to the agency’s denial of a citizen petition under TSCA section 21. The petitioners are led by Food & Water Watch, and joined by the Fluoride Action Network, the American Academy of Environmental Medicine, the International Academy of Oral Medicine & Toxicology, and Moms Against Fluoridation, who have become the first litigants to challenge a section 21 petition denied following the 2016 amendments.

TSCA section 21 permits citizens to request EPA to issue, amend, or repeal a rule or order issued pursuant to TSCA sections 4 (testing of chemical substances and mixtures), 5 (manufacturing and processing notices), 6 (prioritization, risk evaluation, and regulation of chemical substances and mixtures), and 8 (reporting and retention of information). EPA must respond to a section 21 petition within 90 days of receipt. If EPA denies the petition, or fails to act on the petition within the 90-day period, the petitioner may seek judicial review of his section 21 petition by a district court. The district court reviews the petition in a “de novo proceeding.” For section 21 petitions seeking the issuance of a rule under TSCA section 6 to restrict or prohibit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, the district court is charged with determining whether the petitioner has proven, by a preponderance of the evidence, that the chemical substance targeted by the petition poses an unreasonable risk to human health or the environment. If the district court finds that the petitioner has proven an unreasonable risk of harm by a preponderance of the evidence, the court may order EPA to initiate a rulemaking under TSCA section 6(a) to restrict or prohibit the use of a chemical substance.

The litigants originally filed their section 21 petition in November 2016. This petition was the first received by EPA following the amendment of TSCA in June 2016. The petition called for EPA to “ban[] the addition of fluoridation chemicals to water.” The petition was accompanied by over 300 exhibits, including studies purported to demonstrate adverse effects of fluoridation chemicals on human health. The petitioners allege that the addition of fluoridation chemicals to water may cause neurotoxicity, and that the current EPA maximum contaminant level goal for fluoride, established pursuant to the Safe Drinking Water Act, does not reasonably protect against neurotoxicity. The petition further alleges that addition of fluoridation chemicals to water is exactly the “type of unreasonable risk” that EPA is authorized to address using its authority under section 6(a) of amended TSCA. The petitioners called upon EPA to prohibit the addition of fluoridation chemicals to water.

In February 2017, EPA denied the section 21 petition, finding that the petition did not sufficiently establish that “persons have suffered neurotoxic harm” as a result of exposure to fluoridation chemicals from water. EPA further explained that it was denying the petition because the petitioners failed to explain why it was appropriate to regulate fluorination chemicals as a category, rather than to regulate each fluorination chemical individually. On April 18, 2017,
petitioners filed a complaint for declaratory relief in the Northern District of California, seeking a declaration from the court that they had shown that the addition of fluoridation chemicals to water poses an “unreasonable risk” and ordering EPA to initiate a TSCA section 6(a) rulemaking to prohibit the artificial fluoridation of water. In September 2017, EPA moved to dismiss the petitioners’ complaint on the grounds that (1) the petition only addressed one condition of use of fluorination chemicals: the addition of fluorination chemicals to water; (2) the petition did not sufficiently identify the fluorination chemicals it targeted; and (3) the petition did not sufficiently explain why fluorination chemicals should be targeted as a category of chemicals. In late December 2017, the Northern District of California denied EPA’s motion to dismiss.

Basis for Denying Motion to Dismiss

In denying the agency’s motion to dismiss, the court relied first on an interpretation of the statute drawn in part from the preamble of one of EPA’s recently issued final “framework” rules, “Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act” (Risk Evaluation Rule). The court rejected EPA’s claim that the petitioners were required to discuss all conditions of use of fluorination chemicals in their petition. The court first explained that, on its face, TSCA only requires section 21 petitioners to prove that a chemical substance poses an unreasonable risk to human health or the environment. This requirement is satisfied so long as petitioners show that one condition of use of a substance poses an unreasonable risk to human health or the environment. The court also looked to revisions the agency made to the proposed Risk Evaluation Rule in the course of issuing the final Risk Evaluation Rule. In the proposed Risk Evaluation Rule, EPA stated that a risk evaluation of a chemical substance under TSCA section 6(b) should cover all conditions of use of the substance. In the final rule, however, EPA determined that section 6(b) risk evaluations could cover only certain conditions of a use of a substance, focusing on conditions of use most likely to pose an unreasonable risk.

Second, the court rejected EPA’s argument that the petitioners did not adequately identify the chemical substances at issue. EPA had argued that the petition focused on unspecified fluorination chemicals, and therefore EPA did not have sufficient information about the chemical substances at issue to determine whether they would pose an unreasonable risk to human health or the environment. The court rejected this argument because EPA had not denied the petitioners’ request on the basis that the agency did not have sufficient information to evaluate the request—EPA had rejected the petition on the merits. The court also noted that the section 21 petition did identify specific fluorination chemicals, and that EPA’s denial of the section 21 petition contained references to these specific fluorination chemicals.

Finally, the court also rejected EPA’s argument that the petition did not sufficiently establish why fluorination chemicals should be regulated as a category of chemicals. The court noted that the petitioners had discussed that these chemicals are used for a similar purpose, and have a similar “mode of entrance into the human body,” because all of the fluorination chemicals targeted by the petition were added to water. The petitioners also alleged that all of the fluorination chemicals targeted by the petition posed a similar risk of harm. The court found that, at most, EPA had raised questions about whether petitioners could meet their burden of showing by a preponderance of the evidence that fluorination chemicals in water pose an unreasonable risk to human health or the environment, but noted that this question was more appropriately addressed on summary judgment.

EPA Unsuccessfully Moves to Limit Discovery and Scope of Judicial Review

In February 2018, the court rejected a separate motion filed by EPA requesting that its review of the TSCA section 21 petition should be limited
to the administrative record, and that plaintiffs not be allowed to conduct discovery. The court rejected EPA’s argument that, because section 21 petitions must include evidence that could support a rulemaking under TSCA section 6(a), petitioners could not introduce additional evidence during a district court’s review of a section 21 petition, and should not be entitled to discovery. The court also rejected EPA’s argument that the statutory text allowing petitioners, following the denial of a section 21 petition by EPA, to request a de novo proceeding to review “such petition” limited the district court’s scope of review to the plaintiffs’ petition and EPA’s denial. The court noted that, taking the statutory text on its face, it would only be able to conduct de novo review of the petition itself, and would not be able to review EPA’s denial of the petition. The court therefore determined that Congress did not intend the statute to be read so literally.

The court also focused its analysis heavily on the term “de novo proceeding” in TSCA section 21. This term, the court held, differed from the term “de novo review.” The term “proceeding” suggested that the court was not limited to review of the administrative record, and that it could consider additional evidence introduced by the parties. The court rejected EPA’s argument that allowing the scope of review to expand beyond the administrative record could cause plaintiffs to withhold evidence supporting their petition until they are in front of the district court. The court found that plaintiffs had no incentive to withhold evidence because plaintiffs will likely prefer to give EPA all of the available evidence in support of their petition in hopes that EPA will grant the petition and the parties could avoid litigation. Additionally, the court held that courts still have discretion to prevent petitioners from introducing certain evidence if they find that the petition did not give reasonable notice that such evidence would be introduced, and may prevent discovery that is not relevant or “proportional to the needs of the case.” This is a somewhat less stringent standard than that imposed by the Southern District of Texas in what appears to be the only other federal court decision addressing this issue in the context of a TSCA section 21 petition. In *Walker v. EPA*, 802 F. Supp. 1568 (S.D. Tex. 1992), the court held that the plaintiffs would only be allowed to proceed with “extra-record discovery” if they sufficiently demonstrated “improper behavior or bad faith by EPA.”

In light of the Northern District of California’s ruling on EPA’s motion to limit discovery and to limit review to the administrative record, the parties are likely to proceed to discovery, and subsequently motions for summary judgment, following the entry of a case management order. The outcome of the litigation and the opportunity to gain a de novo judicial review of an EPA determination with respect to a chemical’s safety for a particular use can be expected to encourage NGOs, avowed combatants of the current administration, to file more section 21 petitions. Such petitions will likely call for EPA to take action on a particular chemical and use combination, and if the response is a denial, to seek judicial review of the denial of such petitions. The section 21 petition process could provide organizations unhappy with the current direction of EPA’s chemical substances policies another potential forum in which to challenge those policies and seek judicial redress outside of the restrictions of the Administrative Procedure Act. Companies that import, manufacture, and process chemical substances that are among those of specific concern to the NGO community should monitor section 21 petitions and any resulting litigation to be prepared to intervene in litigation if needed.

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