FROM THE CHAIR
Keith A. Matthews

This edition of the committee newsletter marks the final issue for American Bar Association (ABA) year 2016–2017. This has been quite an eventful year for the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee. As is typical, we have had some great speakers for our Friday Forums, including Bill Jordan, Wendy Cleland-Hamnett, and (upcoming) Susan Dudley. Our events programming similarly has excelled with panels on implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the great collaboration with Croplife America’s Law Committee on our annual program on pesticides law and policy issues, the recent panel on Endangered Species Act (ESA)-Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) integration, and, of course, our annual summer reception for summer associates. We produced an outstanding Year in Review volume on what, in 2016, was a very active and eventful area of environmental law; and, as always, our newsletter brimmed with topical, insightful, informative, and thought-provoking content.

It has been a pleasure for me working with our vice chairs, and I am looking forward to next year as we embark on a new co-chair leadership model with Larry Culleen and me working together to serve the committee as co-chairs. Larry, of course, has been a vice chair for Programming for a number of years. Larry embodies the selfless ethos of volunteerism that is a fundamental characteristic of our committee.

Finally, on a positive note, I must say that I am optimistic about new developments in pesticides and chemicals regulation in 2017 and beyond. As one who has a particular interest in genetic technologies, I have hope that the new administration will bring a more science-based and risk-based approach to the regulation of agricultural biotechnologies. It often comes as a surprise to people that the learned scientific consensus on the safety of foods produced utilizing techniques of genetic engineering (GE) is even more overwhelming than is the scientific consensus on the causes and potential impacts of global warming. And the consensus on both is indisputable. A paper recently published in the journal Economics of Disasters and Climate Change by Mekbib Haile and Joachim von Braun of the Center for Developmental Research, Bonn University, projects that climate change impacts could result in decreases in global crop production of 9 percent in the 2030s, and 23 percent in the 2050s—i.e., during a period when the global human population is predicted to increase by a third. Given the potentially tragic implications of these trends, a regulatory approach to agricultural biotechnology that rests on a foundation of science-based risk assessment would be a welcome advance. The adoption of GE agritechnologies

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Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter
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Lynn L. Bergeson, Editor

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worldwide has been calculated to have significantly reduced the use of conventional chemical pesticides during the period 1996 to 2015, and, in 2015, to have facilitated agricultural practices such as no-tillage farming that resulted in decreases of greenhouse gas emissions equivalent to removing 11.9 million cars from the roads of the 26 countries where GE crops are grown. G. Brookes & P. Barfoot, *Environmental Impacts of Genetically Modified (GM) Crop Use 1996–2015: Impacts on Pesticide Use and Carbon Emissions*, 8 GM Crops & Food 117–47 (2017). It will be imperative that the benefits of agricultural biotechnology continue to be realized, given the challenges of climate change and increased human populations.

The PCRRTK Committee strives to bring information and informed discussion to our members and guests in a myriad of ways to help facilitate reasonable and effective regulation of chemical products. Please do not hesitate to contact me or one of our vice chairs with any suggestions on how we can continue to do so.

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The U.S. Environmental Protection Agency (EPA) announced in May a 90-day extension of the effective date of its Toxic Substances Control Act (TSCA) section 8(a) information-gathering rule for chemical substances manufactured or processed as nanoscale materials. The final rule was among a number of TSCA regulatory actions published during the final days of the Obama administration. The agency also announced the publication of draft guidance for the nanoscale materials rule and opened a 30-day comment period to allow stakeholders and the public to comment on EPA’s draft guidance. The guidance is intended to shed light on uncertainties in the final rule, such as the definition of a reportable nanoscale chemical substance, and the steps that processors of nanoscale materials must take to comply with the rule. Open questions about the rule are likely to remain, however, and stakeholders are likely to encourage EPA to further delay the effective date of this rule until these questions are addressed.

EPA Draft Guidance

EPA issued its long-awaited draft guidance for this rule on May 16, 2017. The guidance is primarily focused on three areas of uncertainty: (1) what substances are reportable; (2) who is required to report; and (3) what information is required to be reported.

(1) Reportable substances. The guidance provides greater insight into the factors that make a substance reportable under the final rule. It reveals that manufacturing or processing a substance that exhibits one or more unique properties as a result of its size (therefore bringing it into this rule’s definition of covered nanoscale materials) requires an element of intent—i.e., a manufacturer must not only manufacture a substance that has unique properties because of its size, the manufacturer must also manufacture the substance in that size because of the unique properties. This suggests that a nanoscale substance that would otherwise appear to be covered by this rule might be excluded from reporting if its small size is incidental. This also suggests that a substance that has unique properties because of its small size also might not be reportable if the manufacturer has no intent to take advantage of the specific properties of the substance that only appear when it is produced on a nanoscale. The element of “intent” raises questions about the compliance responsibilities of a manufacturer that, for example, manufactured nanoscale substances without the intent required for those substances to be covered by this rule but later determines that the nanoscale substances have one or more unique or novel properties that benefit the manufacturer, or a processor/user who also is a customer of the manufacturer.

The guidance offers several other clarifications with respect to the substances covered by this rule. First, it confirms that a unique or novel optical property, e.g., a change in color, is sufficient to trigger the requirements of this rule. EPA also clarifies that a manufacturer or processor’s
new use of an existing chemical substance, for which reporting under this rule had already been completed, would not initiate a new reporting requirement under this rule so long as the new use did not require a new discrete form of the nanoscale substance. Finally, EPA clarified the status of mixtures under this rule: as with other TSCA reporting regulations, mixtures are not reportable, however, the components of a mixture that is covered by this rule are considered to be reportable.

(2) Who must report. EPA also offered additional guidance on the kinds of companies that are covered by this rule, and the steps they will be expected to take to comply with the rule. First, the EPA guidance confirms that importers of chemical substances with nanoscale particles are covered by this rule even if the nanoscale particles are incorporated into a formulation (such as ink toner) prior to being imported into the United States. Similarly, companies that manufacture reportable substances in the United States solely for export are also covered by this rule. Second, EPA’s guidance clarifies where in the supply chain the reporting requirements of this rule cease to be applicable. If an article will be manufactured that will contain a covered nanoscale substance, each manufacturer and processor of the nanoscale substance in the supply chain that creates the article is required to report until the point at which the substance is incorporated into the article. A company that merely purchases a covered nanoscale substance in a formulation solely for the company’s own use (and does not change or modify the substance or the formulation containing the substance) need not report the covered substance. EPA has a history of defining “processing” to include “use” of a substance as a chemical intermediate. Importers of a covered nanoscale substance, including in a formulation (mixture), are considered to be manufacturers that must report, even if the importer does not intend chemically to change or physically modify the imported substance or mixture.

(3) What must be reported. EPA’s draft guidance offered some clarifications on the information that covered entities will be required to report. The final rule requires covered entities to report requested information to the extent it is known or reasonably ascertainable by the reporting entity. In its response to comments to the proposed rule, EPA confirmed that information is considered “reasonably ascertainable” for a processor if it could be collected through a request to the manufacturer. EPA reiterated this statement in its guidance. The agency also outlined additional steps that covered manufacturers and processors are required to take to ensure that they have gathered all “reasonably ascertainable” relevant information, including reviewing existing customer surveys, requesting information from employees (including those not in supervisory positions) who research, develop, manufacture, or market a covered chemical substance, and reviewing customers’ websites to fill gaps in a manufacturer’s or processor’s knowledge about the uses of a covered substance. EPA confirmed, however, that processors are not required to conduct their own materials analysis or other forms of testing to determine if materials it receives from a supplier are subject to the rule, and manufacturers and processors are not required to conduct new, comprehensive customer surveys to ascertain the uses of a covered substance. Most notably, and potentially of concern for entities covered by this rulemaking, EPA’s guidance states that it “expects in most cases” that the information needed for an entity to comply with this rule will be known or reasonably ascertainable to that entity.

Next Steps

Although EPA’s guidance provides some welcome clarity on a number of uncertainties in its final nanoscale materials rule, stakeholders are likely to raise additional questions about the rule during the 30-day comment period. Given the new administration’s sensitivity to what are perceived to be burdensome regulations, it remains possible that features of the final rule could be delayed past the current August 2017 effective date. Nevertheless, entities that are likely to be affected by the final rule should begin making preparations to comply with the current effective date.

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EPA’s Evaluation and Determination of Epidemiological Data for Chlorpyrifos
Lisa M. Campbell, Timothy D. Backstrom, and James V. Aidala

Among the many legal, regulatory, and policy issues being watched closely by pesticide registrants as the U.S. Environmental Protection Agency’s (EPA) long and contentious review of chlorpyrifos registrations continues is the controversy concerning when EPA may appropriately apply a tenfold uncertainty factor pursuant to the Food Quality Protection Act (FQPA 10X). This issue centers around EPA’s novel and unprecedented use of epidemiological data and the statutory requirements that govern EPA’s determination that sufficient uncertainty exists to warrant applying the FQPA 10X, not only to chlorpyrifos itself, but to all organophosphate (OP) pesticide products. This issue has drawn much attention and concern from pesticide registrants, and from other interested parties. The issues directly affecting chlorpyrifos have played out not only in EPA’s registration review process for chlorpyrifos, but also in a court challenge to EPA’s decision.

By way of brief background, FQPA establishes a default 10X safety factor for infants and children, but allows EPA to reduce or eliminate this default factor if EPA determines it will be safe for women and children based on “the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue,” and “the nature of the toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies.” In the past, EPA had repeatedly eliminated the default FQPA safety factor for particular OP pesticides based on extensive data that establish the levels at which OP pesticides inhibit acetylcholinesterase (AChE). In a September 15, 2015, document entitled “Literature Review on Neurodevelopmental Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides” (2015 Literature Review), EPA determined a new FQPA safety factor for all OP pesticides based on several epidemiology studies that EPA asserted show an association between purported neurodevelopmental effects and exposures to chlorpyrifos (an OP pesticide) at levels below the threshold for AChE inhibition. Pesticide registrants criticized the scientific and legal rationale supporting this revised FQPA determination. Among the comments made were that EPA did not identify any potential Mode of Action (MOA) for the purported neurodevelopmental effects of chlorpyrifos at levels that do not inhibit AChE or demonstrate that other OP pesticides would share a similar MOA, and that EPA did not resolve critical questions concerning the absence of replication in similar epidemiology studies, the presence of potential confounding exposures, or the likely role of methodological biases. Moreover, industry stakeholders commented that EPA did not have access to the underlying data for these studies, even though the research in question was partially funded by EPA. At bottom, industry stakeholders were concerned that EPA’s use of epidemiological data in making this determination ignored FQPA legal requirements and effectively established an unattainable standard for determining whether there is sufficient uncertainty to warrant retention of the FQPA 10X safety factor.

EPA’s use of epidemiological data for the chlorpyrifos risk assessment has been the subject of several Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) meetings, with the most recent of these held after EPA’s issuance of the 2015 Literature Review. The SAP’s focus in this meeting was on an EPA proposal to use one of the epidemiology studies to establish a quantitative point of departure for the chlorpyrifos risk assessment, rather than on EPA’s decision to utilize the 10X uncertainty factor. Nevertheless, the SAP review of the EPA proposal highlighted the unresolved scientific issues raised by EPA’s reliance on the epidemiology studies for chlorpyrifos and fueled the concerns of industry stakeholders about the erosion of the FQPA standard governing when
there is sufficient uncertainty to warrant use of the FQPA 10X safety factor. Although the subsequent SAP report criticized EPA’s proposal to use a chlorpyrifos epidemiology study to establish a point of departure for risk assessment, during the waning days of the Obama administration, EPA seemed firmly committed to its assessment of the epidemiological data for chlorpyrifos and to its interpretation of the FQPA requirements concerning application of the FQPA 10X.

The arrival of the Trump administration seemed to bring material changes in EPA policy. On March 29, 2017, EPA Administrator Pruitt signed an order denying a September 12, 2007, petition of the Pesticide Action Network North America (PANNA) and the Natural Resources Defense Council (NRDC) requesting that EPA revoke all tolerances and cancel all registrations for chlorpyrifos. This petition and the petitioners’ contention that EPA had too long delayed its response have also been the subject of protracted judicial review in the Ninth Circuit Court of Appeals. The most recent case requesting a writ of mandamus was filed on September 10, 2014.

In the order denying the chlorpyrifos decision, Administrator Pruitt made a number of statements that are relevant to EPA’s use of epidemiological data for chlorpyrifos risk assessment. With respect to EPA’s determination of “whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA’s existing regulatory standard (10% cholinesterase inhibition),” the order states that “Congress has provided that EPA must complete registration review by October 1, 2022,” and that EPA has “concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution” concerning potential neurodevelopmental effects in children. The order further states that the “science addressing neurodevelopmental effects remains unresolved,” and “further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos.” For these reasons, EPA explains in the order that, given an August 12, 2016, order by the Ninth Circuit that “made clear” that no further extension of the March 31, 2017, deadline for responding to the petition would be granted, EPA decided to deny the petition.

This decision concerning the pending chlorpyrifos petition effectively kicked the can down the road to some extent on the key scientific issue—whether EPA has appropriately evaluated and utilized the epidemiology studies that report an association between exposure to chlorpyrifos and adverse neurological impacts on infants and children. The order language has been debated with regard to whether it also reflects any type of new EPA direction on the FQPA 10X issue. In any event, EPA’s decision to deny the petition led to charges by critics of “politics over science,” but in responding to the court-ordered deadline of March 31, 2017, EPA declared that it needs more time to resolve difficult science issues, time that would be afforded by the standard registration review process. EPA effectively stated that, if it must make a decision concerning these issues now, there is not an adequate scientific consensus to support regulatory action.

The controversy over EPA’s use of epidemiological data and its chlorpyrifos decision generally continues in numerous venues. Petitioners in the Ninth Circuit case on April 5, 2017, filed a motion asking the court to “grant further mandamus relief [for EPA] to act on its findings that chlorpyrifos exposures are unsafe and to establish deadlines for the next steps in the revocation and cancellation processes for chlorpyrifos.” A request from Congress to EPA’s inspector general (IG) requesting that the IG address questions specifically targeting the rationale, communications, and consideration that Administrator Pruitt took prior to reaching the decision was submitted on April 27, 2017. On
June 5, 2017, an administrative appeal was filed by the attorneys general for California, Maine, Maryland, Massachusetts, New York, Vermont, and Washington that submits legal objections and requests immediate agency action to vacate the March order and revoke the chlorpyrifos tolerances; and a petition for review of the March order was filed in the Ninth Circuit on June 5, 2017.

A significant new development in this ongoing battle occurred on May 25, 2017, when EPA placed in the public dockets for certain OP pesticides an “update” of the September 15, 2015, Literature Review and FQPA determination, along with a response to comments on the original document. These newly disclosed documents were signed by EPA scientists on December 29, 2016. The documents attempt to rebut the various criticisms of EPA’s assessment of the epidemiology studies for chlorpyrifos and the original FQPA safety factor determination for OP pesticides, and they reaffirm the policy embodied in the original Literature Review. Because these documents were signed in the last days of the Obama administration, they are likely to be viewed by industry stakeholders as an effort by some at EPA to “lock in” the prior policy concerning OP pesticides before the arrival of the Trump administration.

The legal and policy issues posed by EPA’s evaluation of the epidemiological data for chlorpyrifos and by EPA’s determination that these data create sufficient uncertainty to warrant retention of the FQPA 10X safety factor for all OP pesticides will be a continued source of controversy, and will be watched with interest by all stakeholders.

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**New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation**

Lynn L. Bergeson and Charles M. Auer, Editors

May 2017, 367 pages, Paperback or eBook

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**State-of-the-art guide to the dramatic changes to TSCA**

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On May 30, 2017, the U.S. Court of Appeals for the Ninth Circuit responded to two petitions for review of the U.S. Environmental Protection Agency’s (EPA) conditional registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of a nanosilver pesticide product and vacated that conditional registration. **NRDC v. EPA**, No. 15-72308. The Natural Resources Defense Council (NRDC), the Center for Food Safety (CFS), and the International Center for Technology Assessment (ICTA) filed petitions in 2015 asking the court to set aside EPA’s final order granting a conditional registration for a nanosilver-containing antimicrobial pesticide product named NSPW-L30SWS (NSPW). The court vacated the conditional registration because, according to the court, “EPA failed to support its finding that NSPW was in the public interest.”

**Background**

On May 19, 2015, EPA issued a conditional registration for NSPW-L30SWS. According to EPA’s Office of Pesticide Programs, the product would be used as a non-food-contact preservative to protect plastics and textiles from odor- and stain-causing bacteria, fungi, mold, and mildew. Items to be treated included household items, electronics, sports gear, hospital equipment, bathroom fixtures, and accessories. EPA based its decision “on its evaluation of the hazard of nanosilver after reviewing exposure data and other information on nanosilver from the applicant, as well as data from the scientific literature.” EPA stated that these data show that treated plastics and textiles release “exceedingly small amounts of silver.” Based on this evaluation, EPA “determined that NSPW-L30SS will not cause unreasonable adverse effects on people, including children, or the environment and that it would be beneficial because it will introduce less silver into the environment than competing products.” EPA noted that it is requiring the company “to generate additional data to refine the Agency’s exposure estimates.”

On July 27, 2015, NRDC filed a petition in the U.S. Court of Appeals for the Ninth Circuit (Case Number 15-72308), and CFS and ICTA filed a second petition (Case Number 15-72312). Both petitions asked the court to set aside EPA’s final order granting a conditional registration for NSPW.

NRDC had previously challenged EPA’s first decision to grant a conditional registration for a product characterized as a nanosilver product, which was granted to HeiQ in 2011. On November 7, 2013, the U.S. Court of Appeals for the Ninth Circuit granted in part and denied in part NRDC’s petition for review of HeiQ AGS-20 and AGS-20 U (collectively, AGS-20). The court held that “substantial evidence” supported EPA’s decision to use the characteristics of toddlers rather than infants in determining whether AGS-20 placed consumers at risk. The court vacated EPA’s decision “insofar as it concluded that there was no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface-coated with AGS-20.”

**Issue before the Court**

When EPA granted another conditional registration for NSPW, EPA found that granting it was in the public interest. EPA made this finding on the basis that NSPW had a lower application rate and a lower mobility rate when compared to conventional (non-nano)-silver pesticides, and thus had the potential to reduce environmental loading and risk caused by the release of silver into the environment. Petitioners disputed these facts. EPA also found that the registrant had insufficient time to generate the data required for unconditional registration. Petitioners also challenged this finding, but the court reached a decision without considering this argument.
Court’s Decision

The court stated that it was unaware of any prior decision considering the public interest requirement under FIFRA section 3(c)(7)(C). The court reviewed the statutory background of the provision and then considered whether EPA had supported its public interest finding for NSPW with substantial evidence. The court stated that, under FIFRA section 3(c)(7)(C):

[EPA] may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the [EPA] first imposed the data requirement) on the condition that by the end of such period the [EPA] receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the [EPA] may prescribe. A conditional registration under this subparagraph shall be granted only if the [EPA] determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest. [Emphasis added.]

According to the court, the public interest requirement reflects an important distinction between conditional registration and unconditional registration. EPA can temporarily register a pesticide “with less-than-complete risk data so long as the EPA, among other additional requirements, determines ‘that use of the pesticide is in the public interest.’” The court reviewed the legislative history of the public interest requirement, stating that Senator Leahy, “who sponsored the bill that created the conditional registration provision, stated that the Senate committee carefully considered the statutory requirements so conditional registration ‘would be reserved to the truly exceptional case.’” The court also noted the testimony of former EPA Administrator Douglas Costle, who stated that there “may be a real need for use of the pesticide to avoid pest outbreaks. It is our opinion that in some of these cases it would be proper to allow conditional registration . . . if the public interest would be served by issuance of a conditional registration, bearing in mind the benefits as well as the likely scope of the risk. Although we think that the exercise of this conditional registration authority for new chemicals would be rare, we feel that it should be available in appropriate cases.”

When considering the registration application, EPA found that use of NSPW is in the public interest because it has the “potential” to reduce the amount of silver released into the environment. The petitioners challenged the factual premises underlying EPA’s public interest finding:

(1) That NSPW has a lower application rate (i.e., it uses less silver) than conventional-silver pesticides;

(2) That NSPW has a lower mobility rate (i.e., it is less likely to release silver into the environment in detectable quantities); and

(3) That current users of conventional-silver pesticides will switch to NSPW and/or that NSPW will not be incorporated into new products.

While the court found that substantial evidence supports EPA’s findings that NSPW has lower application and mobility rates, the court agreed that the third premise, that current users of conventional-silver pesticides will switch to NSPW and/or that NSPW will not be incorporated into new products, “impermissibly relies on unsubstantiated assumptions.” According to the court, EPA cited no evidence in the record to support its assumption that current users of conventional-silver pesticides will switch to NSPW (“the substitution assumption”), but contends that it will occur as a “logical matter.” The court stated that the lack of evidence supporting the substitution assumption is problematic in light of EPA’s other
unsupported assumption, that there will be no
new products. The court noted that EPA assumes
current users of conventional-silver pesticides will
switch to NSPW because of its benefits, but that
these same benefits will not prompt manufacturers
to incorporate NSPW into new products. EPA
could have proved these assumptions, but without
evidence in the record to support the assumptions,
the court stated that it “cannot find that the EPA’s
public-interest finding is supported by substantial
evidence as required by FIFRA.” According to the
court, the public interest finding is an “essential
prerequisite to conditional registration,” and
EPA failed to support that finding for NSPW
with substantial evidence. The court vacated the
conditional registration in whole, and did not
consider the remaining issues raised by petitioners.

Discussion

While the court’s 2013 decision regarding the
conditional registration for AGS-20 was decided
on a very narrow, case-specific issue, this decision
is broader in scope and could have significance for
EPA’s issuance of conditional registrations under
FIFRA. In 2013, the court vacated EPA’s decision
granting a conditional registration to HeiQ “insofar
as it concluded that there was no risk concern
requiring mitigation for short- and intermediate-
term aggregate oral and dermal exposure to textiles
that are surface-coated with AGS-20.” Here,
the court reviewed the statutory background of
the public interest provision and ruled that EPA
failed to provide sufficient evidence to support its
finding that granting a conditional registration for
NSPW was in the public interest. The briefs were
filed and the case was argued under the Obama
administration, and it remains to be seen how the
Trump administration will respond.

Because the court vacated the registration for
NSPW, pending further review by EPA on remand,
EPA would consider continued commercial sale
and distribution of NSPW unlawful. To effectuate
the court’s decision, EPA will need to devise an
orderly process for removing stocks of NSPW from
channels of trade. This may involve issuance of a
Stop Sale, Use, and Removal Order under FIFRA
section 13.

The decision’s broadest application is a logical
outgrowth of the policy decision that EPA made
years ago that it will classify the nanosilver in each “new” product formulation as a new
active ingredient, rather than presuming that all
nanosilver contained in any registered pesticide
is a single active ingredient. EPA also has not yet
determined whether it will classify the colloidal
elemental silver contained in many existing
registered pesticides as nanosilver, although it
appears to satisfy the EPA definition.

EPA’s decision to classify each new nanosilver
product as a new active ingredient means that EPA
must satisfy the more stringent “public interest”
criterion to grant a conditional registration for each
and every new nanosilver product. This significant
threshold requirement may well discourage
applicants to register innovative new nanosilver
products, even where such products would supplant
existing nanosilver or conventional silver products
that may entail greater human or environmental
exposures. Stakeholders may wish to consider
urging EPA to reconsider its policy of classifying
each new nanosilver formulation as a new active
ingredient or otherwise to amend its current
position to ensure innovation is not impeded.

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With his characteristic humility, President Trump declared the orders would yield “the largest ever cut by far in terms of regulations.” Dave Boyer, Trump Signs Order to Cut Red Tape for Businesses, WASH. TIMES (Jan. 30, 2017). Indeed, they do reflect a dramatic shift in regulatory practice, though the ultimate outcome of this shift may not be visible for years. Cf. John F. Cooney, Federal Regulations During President Trump’s First 100 Days, ADMINISTRATIVE & REGULATORY LAW NEWS (Winter 2017).

E.O. 13771: “Reducing Regulation and Controlling Regulatory Costs”

Though E.O. 13771 refers to a “budgeting process,” it does not call for a strict regulatory budget comparable to the fiscal budget, where the government would have to quantify the costs of existing regulations (an insurmountable task). See Susan E. Dudley, Can Fiscal Budget Concepts Improve Regulation?, 19 N.Y.U. J. LEGIS. & PUB. POL’Y 259, 268 (2016). Instead, it imposes two separate constraints. First, it requires agencies to eliminate two regulations for every new one they issue (what the administration is calling a “one-in-two-out”). Second, it sets a cap on incremental regulatory costs.

This incremental cost cap is likely to be the more binding of these constraints. In fiscal year 2017, the E.O. sets the cap at zero, so that for every dollar of cost imposed by new regulations, agencies would have to find offsets of an equal dollar amount by eliminating or modifying existing regulations. In future years, the order charges the director of the Office of Management and Budget (OMB) to establish an incremental cost allowance for each agency.

E.O. 13777: “Enforcing the Regulatory Reform Agenda”

President Trump’s second crosscutting regulatory executive order is not as dramatic as the first. E.O. 13777 establishes mechanisms and provides direction for implementing the previous order. In particular, it requires heads of regulatory agencies to 1) designate an agency official to be the Regulatory Reform Officer responsible for overseeing implementation of regulatory reform initiatives and policies; and 2) form a Regulatory Reform Task Force to make recommendations for agency regulatory reforms.
The task forces have until the end of May to report to their respective agency heads on the progress of their efforts to identify regulations for repeal, replacement, or modification and to improve how regulatory reform initiatives and policies are implemented in general. Thereafter, each agency head is responsible for setting deadlines for progress reports.

What role does benefit-cost analysis play?

In response to E.O. 13771’s requirement that the OMB director develop implementation guidance for agencies, OMB issued a memorandum in early April after seeking comment on “interim guidance.” OFFICE OF MGMT. & BUDGET, MEMORANDUM: IMPLEMENTING EXECUTIVE ORDER 13771, TITLED “REDUCING REGULATION AND CONTROLLING REGULATORY COSTS” (April 5, 2017), https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementingexecutive-order-13771-titledreducing-regulation. Importantly, the guidance makes clear that the requirements of E.O. 13771 do not supplant longstanding bipartisan requirements for agencies to analyze the benefits and costs of regulations, and that such analysis will be an important element in ensuring that agencies achieve regulatory objectives. E.O. 13777 also references President Clinton’s 1996 E.O. 12866 and President Obama’s 2010 E.O. 13563, both of which call for analysis of regulatory benefits and costs and retrospective review of regulatory impacts.

In comments to OMB on the interim guidance, my colleagues and I suggest that the guidance be explicit that an assessment of the net benefits remains the best way to distinguish a good rule from a bad rule (one that does more harm than good), and for optimizing the level of a standard or otherwise fine-tuning the details of a regulation’s content. Susan E. Dudley et al., Public Interest Comment on The Office of Management and Budget’s Interim Guidance Implementing Section 2 of the Executive Order on January 30, 2017, Titled “Reducing Regulation and Controlling Regulatory Costs,” THE GEORGE WASHINGTON UNIV. REG. STUDIES CTR., Feb. 10, 2017. Indeed, recent Supreme Court decisions have indicated that it would be unreasonable for agencies not to consider benefits and costs in making regulatory decisions. See, e.g., Michigan v. EPA, 135 S. Ct. 2699, 2707 (2015). Rather than replacing the benefit-cost test, the new orders should be viewed as guiding the agencies as they allocate their resources and set priorities.

What regulations and costs will be covered by the orders?

E.O. 13771 provides a more sweeping definition of “regulation” than previous orders have, and could have been interpreted to encompass guidance documents or even compliance letters. Sofie E. Miller & Susan E. Dudley, The Devil is in the Details of President Trump’s Regulatory Executive Order, THE GEORGE WASHINGTON UNIV. REG. STUDIES CTR. (Feb. 1, 2017), https://regulatorystudies.columbian.gwu.edu/devil-details-presidenttrump%E2%80%99s-regulatory-executive-order. However, the guidance narrows the definition of “E.O. 13771 regulatory action” to “significant” regulations and guidance documents issued by executive branch agencies, which limits the new actions subject to the offset requirements to those projected to have the largest effects on the economy and on the law. On the other hand, the April guidance defines “E.O. 13771 deregulatory actions”—those available to use as offsets for new actions—to include any action expected to result in cost savings.

Each agency’s Regulatory Reform Task Force will be responsible for evaluating existing regulations and recommending rules that should be repealed, replaced, or modified pursuant to E.O. 13771. Consistent with the president’s focus on jobs, E.O. 13777 directs the task forces to prioritize review of regulations that “eliminate jobs, or inhibit job creation.” It also directs them to identify regulations that “are outdated, unnecessary, or ineffective; impose costs that exceed benefits; [or] create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies.”
E.O. 13777 directs agency task forces to look particularly at “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility,” which may be aimed at Environmental Protection Agency regulations that have long frustrated the regulated community. It also focuses the task forces’ attention on rules that “derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.” This language may be aimed at regulations developed in response to President Obama’s orders regarding immigration, gender discrimination, and worker pay.

On the critical question of how agencies should measure the cost of offsets and new rules, OMB’s guidance appropriately instructs them to calculate “opportunity cost,” which is a broad measure of social welfare that best captures the diverse impacts of federal regulation on the public. Marcus Peacock, Implementing a Two-for-One Regulatory Requirement in the U.S., THE GEORGE WASHINGTON UNIV. REG. STUDIES CTR. (Dec. 6, 2016), https://regulatorystudies.columbian.gwu.edu/implementingtwo-one-regulatory-requirement-us.

What outcomes should we expect from these orders?

Despite the sweeping nature of these executive orders, do not expect to see changes in the first 100 days or even the first year. Removing or revising existing regulations takes at least as much time and effort as developing new regulations. Indeed, the E.O.s effectively direct agencies to reallocate their internal resources away from creating new burdens and towards relieving existing ones. Agencies will have to follow the steps dictated by the Administrative Procedure Act and prepare a justification to support each change. Susan E. Dudley, Regulatory Reset: How Easy is it to Undo Regulation?, THE GEORGE WASHINGTON UNIV. REG. STUDIES CTR. (Nov. 30, 2016), https://regulatorystudies.columbian.gwu.edu/regulatory-resethow-easy-it-undo-regulation. They then must seek and respond to public comment before they issue a final rule to rescind or modify an existing rule. The final rule, of course, would be subject to litigation.

Presidents for the last 40 years have called upon agencies to analyze the benefits and costs of new regulations before they are issued. While this is still an important requirement, it hasn’t constrained the scope and reach of regulation. As Michael Mandel and Diana Carew of the Progressive Policy Institute note, like pebbles tossed in a stream, each individual regulation may do little economic harm, but eventually the pebbles accumulate and like a dam, block economic growth and innovation. Michael Mandel & Diana G. Carew, Regulatory Improvement Commission: A Politically-Viable Approach to U.S. Regulatory Reform, PROGRESSIVE POLICY INSTITUTE (May 2013), http://www.progressivepolicy.org/wp-content/uploads/2013/05/05.2013-Mandel-Carew Regulatory-Improvement-Commission_A-Politically-Viable-Approach-to-US-Regulatory-Reform.pdf.

Back in 1980, President Jimmy Carter’s Economic Report of the President observed that “tools like the regulatory budget may have to be developed” to “make certain that the first problems addressed are those in which regulations are likely to bring the greatest social benefits.”

While the details of President Trump’s executive order have yet to be worked out, it has the potential to impose some discipline on regulatory agencies, generate a constructive debate on the real impacts of regulations, and ultimately lead to more cost-effective achievement of public priorities.

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