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PRODUCT STEWARDSHIP & SUSTAINABILITY REPORT

News and Analysis for Industry Marketers and Their Legal Counsel | June 2015

Responding to Stop Sale Orders—Preparation is the Key

By Tracy Heinzman

In the last 18 months, the U.S. Environmental Protection Agency (EPA) has stepped up its Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) enforcement activities and, especially, the use of its "Stop Sale, Use, or Removal Orders" (SSUROs) against alleged misbranded pesticides. These are pesticides that EPA believes or has determined are in violation of their respective confidential statements of formula, cancelled products, and products that are distributed in violation of EPA's supplemental distribution regulations. EPA's regional offices can issue these orders whenever they have reason to believe that a pesticide or device violates FIFRA, or has been or is intended to be distributed or sold in violation of FIFRA. SSUROs essentially prohibit any further movement, shipment, sale, distribution, or use of the suspect pesticide product. Most important, they typically are effective immediately.

ALSO IN THIS ISSUE

This means even the best companies that sell and distribute pesticides need to have response plans and procedures in place before a SSURO is received. The plan and procedures should address how the company will implement internal steps to respond to the order, take necessary corrective actions, and work with EPA to deal with the attendant enforcement action. In addition, a critical aspect of handling a SSURO is effectively communicating with key internal and external stakeholders, such as employees, distributors, and growers.

Many companies focus solely on dealing with the enforcement aspects of a SSURO, but the internal

continued on page 2

EPA Continues Enforcement Initiative on Imports of Recreational Vehicles

By Joseph S. Kakesh

In the last 18 months, EPA has posted for comment two dozen consent decrees, consent agreements, and administrative settlements of enforcement actions against manufacturers and importers of a wide range of nonroad equipment and engines. Several of the largest cases relate to imported recreational vehicles from China.[1] Most recently, EPA announced *In re: Geason Enterprises, LLC, et al.* It covers an American company that is the importer of record for recreational vehicles and a Chinese affiliate company that manufactured the vehicles in China.[2]

Foreign manufacturers and importers of recreational vehicles and other nonroad equipment should be aware that EPA continues to take Clean Air Act (CAA) violations regarding nonroad equipment and engines seriously.[3] Many of the alleged violations were likely identified at the border by Customs officials working in coordination with EPA. Penalties have ranged widely, but settlements have sometimes cost relatively small companies several

continued on page 6

No State Consumer Battery Stewardship Legislation This Year

By Saskia Mooney & George A. Kerchner

Four states—Connecticut, California, Texas, and New York—introduced consumer battery stewardship legislation this year. Initially, momentum for these proposals was generated from a battery stewardship forum in Connecticut (organized by the Product Stewardship Institute (PSI) and held in June 2014) and Vermont's scheduled implementation of the first U.S. mandatory primary battery collection and recycling law (on January 1, 2016). As another legislative year ends,

continued on page 6

implementation and communication aspects can be even more important. This article outlines good procedures that, if put in place before a crisis, will help a company to assure necessary compliance, get prompt EPA permission for corrective actions (such as retrieving affected products from distribution channels), and manage marketplace risks.

SSURO Basics

FIFRA Section 13 gives EPA the authority to issue SSUROs. It grants the agency the power to stop the sale, distribution, shipment, movement, use, or removal of any pesticide or device that EPA's believes has been or is intended to be distributed or sold in violation of the Act. EPA may issue a SSURO to any company or person that owns, controls, or has custody of an offending product. This could be the registrant or a distributor, or both.

Typically, SSUROSs are sent by certified mail, usually to the highest senior executive of the company, such as the President or CEO. They apply to all of the allegedly offending products under the recipient's ownership, control, or custody, wherever the product is located. This includes all sizes and quantities of the product, products marketed under alternate brand names, and any stocks returned to the company from its customers or other end-users. They also typically extend to all of the recipient's divisions, offices, and branches.

SSUROs immediately prohibit, upon receipt, any further movement, sale, shipping, distribution, and use of the offending product unless such activities are approved by EPA in writing. Thus, it is extremely important that once a SSURO is received, the company takes immediate steps to freeze and hold or block any further movement, shipment, or distribution of the subject product. Because it is a separate violation of FIFRA to violate a SSURO, failing to act promptly may subject the company to further enforcement exposure beyond just the alleged violation that triggered the SSURO.

SSUROs remain in effect indefinitely unless and until revoked, terminated, suspended, or modified in writing by EPA.

Elements of a Comprehensive Plan

Because SSUROs effectively stop any further commercial activities with respect to the products for which they are issued, they can have a huge, immediate impact on the supply chain. In most cases, therefore, it is imperative that a recipient take immediate action to evaluate the SSURO, correct any problems with the identified products, and get compliant product back into the channels as soon as possible, rather than seeking to assert legal defenses. Experience suggests that every pesticide registrant should have the steps outlined below in place before a SSURO is received.

1. Make Sure Likely Recipients Understand What SSUROs Are

As noted above, SSUROs usually are addressed to senior company executives. EPA expects the recipient to act as quickly as possible to implement the SSURO. It thus is vital that whoever screens their mail understands the significance of a SSURO and knows what to do when one is received. This may sound basic, but it is remarkable how often delays occur that have the effect of souring relationships with EPA and making resolution more difficult.

2. Have an Internal Team Ready to Act

A fundamental element of any plan for addressing a SSURO is identification of an internal team to assist in implementing necessary actions. This team should consist of representatives from legal, regulatory, logistics, and the commercial sides of the business. The legal representative is essential to the internal investigation of the allegations in the SSURO and to any compliance issues associated with the offending product. The regulatory representative is key to communicating with EPA's Office of Pesticide Programs and assisting with corrective actions, such as labeling, or other registration actions that require submission of amendments or notifications. Logistics come into play because the company will need to know how much of the affected product is still within its custody or control, how much is in the channels, where it is located, and eventually how it will be returned. Key people from sales/marketing need to be included to facilitate communications to the sales/marketing teams about the limitations set by the SSURO as well as external communications to distributors and end-users.

Ideally, this internal team should be designated ahead of time and be ready for activation if and when a SSURO is issued. At the very least, a single individual should be pre-identified as the person who will convene an appropriate team when events merit. All potential internal recipients of a SSURO (see point 1 above) should know at least who this person is, if not all the team members.

3. Find the Root Cause

As soon as the product is placed on hold, the internal team should start gathering facts and investigating the circumstances surrounding the SSURO. This process should be done under the direction of legal counsel. All SSUROs lay out the facts, the legal basis for EPA's determination that the product is in violation of FIFRA, and the specific, alleged violations that led EPA to issue the order. The first priority must be to determine whether the facts and conclusions in the order are accurate.

If the facts are accurate—and EPA has a pretty good record of getting facts correct—the next priority is to figure out how the violation occurred so that corrective actions can be implemented. The problem may extend beyond the product that is subject to the order, or may affect additional production runs for the same product. In either case,

continued on page 4

Little-Noticed Provision of National Pollinator Strategy May Lead to Most Impact

By David B. Weinberg

Many in the agricultural chemical industry greeted the Administration's May 19th "National Strategy to Promote the Health of Honey Bees and Other Pollinators" with relief, because it did not focus on pesticides until page 47 of a 53-page report. The measured nature of the Administration's approach indeed merits commendation. But buried in the document was announcement of an initiative that will trigger broad impacts far beyond recent attention to neonicotinoids. It is EPA's intention to restrict the use of 76 active ingredients considered "acutely toxic to bees." And with a May 29th *Federal Register* notice (80 Fed. Reg. 30644), the Agency opened a 30-day comment period on that initiative. That notice merits much wider attention than it has been receiving.

Most of the pesticide-related actions in the "National Strategy" and its appendices had been telegraphed by earlier EPA actions. For example, in August 2013, the Agency imposed new bee-protective language on neonicotonoid products. More recently, the Agency announced its intention not to grant label expansions of four neonicotinoid pesticides until new bee-impact assessments are completed. (The products are imidicaloprid, clothianidin, thiamethoxam, and dinotefuran.) And expansion (and thus necessarily delay) of registration review analyses to incorporate pollinator effects studies hardly comes as a shock.

But the new strategy also announced EPA's proposal to prohibit foliar application of "acutely toxic pesticide products during bloom for sites with bees on-site under contract." The May 29th *Federal Register* notice describes the affected products as those with an acutely lethal dose to 50% of bees tested of less than 11 micrograms per bee, based on acute contact toxicity testing. The more comprehensive document made available for comment identifies 76 active ingredients as meeting that test. *EPA's Proposal to Mitigate Exposure to Bees from Acutely Toxic Pesticide Products* at 17 (May 28, 2015). The list appears in the below table.

EPA's proposal is to require registrants of products containing these active ingredients to add a label prohibition of use "from onset of flowering until flowering is complete when bees are on-site under contract," except in limited cases. The approach harkens back to 15 to 20 years ago, when EPA requested that registrants "voluntarily" drop uses asserted to create unacceptable risks to children as part of the Agency's implementation of the Food Quality Protection Act (FQPA). That pressure resulted in a series of immediate cancellations and phase-outs, often documented in "memoranda of agreement" between the Agency and product registrant.

Many of the same issues that arose under FQPA are likely to arise here: questions about the validity of the pertinent testing, timing of label changes to avoid disadvantaging competitive products and—perhaps potentially most

continued on page 5

Appendix A – List of Registered Active Ingredients That Meet the Acute Toxicity Criteria

Abamectin	Acephate	Acetamiprid	Aldicarb	Alpha-cypermethrin	Amitraz
Arsenic acid	Azadirachtin	Bensulide	Beta-cyfluthrin	Bifenazate	Bifenthrin
Carbaryl	Carbofuran	Chlorethoxyfos	Chlorfenapyr	Chlorpyrifos	Chlorpyrifos Methyl
Clothianidin	Cyantraniliprole	Cyfluthrin	Cypermethrin	Cypenothrin	Deltamethrin
Diazinon	Dichlorvos	Dicrotophos	Dimethoate	Dinotefuran	Diuron
D-trans-allethrin	Emamectin benzoate	Endosulfan	Esfenvalerate	Ethoprop	Etofenprox
Fenazaquin	Fenitrothion	Fenpropathrin	Fipronil	Fluvalinate	Fosthiazate
Gamma-cyhalothrin	Imidacloprid	Imiprothrin	Indoxacarb	Lambda-cyhalothrin	Melathion
Metaflumizone	Methiocarb	Methomyl	Momfluorothrin	Naled	Oxamyl
Permethrin	Phenothrin	Phorate	Phosmet	Pirimiphos-methyl	Prallethrin
Profenofos	Propoxur	Pyrethrins	Pyridaben	Resmethrin	Rotenone
Sethoxydim	Spinetoram	Spinosad	Sulfoxaflor	Tefluthrin	Tetrachlorvinphos
Tetramethrin	Thiamethoxam	Tolfenpyrad	Zeta-cypermethrin		

deciding on appropriate corrective actions depends on figuring out how the problem occurred.

The investigation should also include gathering information to determine the scope of the problem, such as how much affected product remains within the control or custody of the company; how much product is in the distribution channel; and where the product is located. The company must have this information if it needs to move affected product for rework or disposal while the SSURO is in place, since Agency authorization may be required. **The first inclination of most companies is to retrieve affected product from the distribution channels, but this typically is not allowed under SSUROs.** Instead, the only way to remove product from the distribution channel after the SSURO is received is to get permission from EPA. Once again, failure to understand the rules in advance, and retrieving product without permission, can substantially increase a recipient's penalty exposure.

4. Take Steps to Implement the SSURO

Upon receipt of the SSURO, a company should immediately convene its internal team and take action to "freeze" in place all product within its ownership, custody, or control, wherever it is located. It is rarely in a recipient's interest to delay compliance while legal rights and obligations are assessed.

As an initial step, the product subject to the SSURO should be physically segregated from other products in inventory and marked to indicate that it is subject to an order and cannot be moved, shipped, or distributed until further notice. It is important that this happen immediately and effectively, because the SSURO is typically effective upon receipt and prohibits any movements, removal, sale, or distribution of the product from that point forward until the SSURO is lifted or EPA grants permission to move the product. The company's potential penalty exposure thus can be substantially increased if its procedures for implementing the SSURO allow product to get shipped or moved after the SSURO is in place.

Although it sounds like a simple exercise, there have been a number of situations where companies have failed to effectively place a timely hold on products subject to a SSURO, as a result of which further shipments were made. Because companies are required to keep all pesticide shipping and distribution records under FIFRA Section 8 and EPA's implementing regulations at 40 C.F.R. Part 169 for two (2) years, this activity will almost certainly come to light. Indeed, companies that intentionally ship or move product in violation of the SSURO are subject to potential criminal enforcement for "knowing" violations of FIFRA. Having a plan in place before an SSURO is received and implementing it in a timely manner should inoculate a recipient against such charges.

5. Develop a Strategy

If investigation shows the SSURO was issued on the basis of an error of fact, EPA must immediately be contacted and efforts initiated to have the order rescinded. In most cases, however, companies find that the facts and allegations in the SSURO are largely accurate. Thus, the internal team should develop a strategy for implementing corrective actions and lifting the order. If the violation involves misbranding, corrective actions will include correcting the labeling on all products that are packaged and labeled going forward. This may require simply ordering new labeling stock and packaging, and determining how to correct and work with existing labeling stock. In some situations, however, submission of a labeling amendment or notification to EPA may be required. In either case, all newly produced material should be labeled and packaged with the correct labeling, at a registered establishment, to avoid further allegations of violation.

A second part of the strategy must address existing product that is within the control and custody of the company and in distribution channels. Any relabeling, repackaging, or formulation adjustments must be done at an EPA establishment registered under FIFRA Section 7. Thus, even if the product can be reworked, it may need to be shipped to a registered establishment where the rework process will occur. This is another common area of confusion. **Doing any rework at a location that is not an EPA-registered establishment can create another violation and attendant enforcement issue. And, relabeling includes simple label corrections or restickering.** A number of companies have been subject to enforcement action for directing field personnel or distributors to make label corrections in the field. This generally is not allowed, unless the location where the labeling or restickering occurs is an EPA-registered establishment.

In addition, the EPA-registered establishment number for wherever labeling or repackaging occurs must be added to the label. EPA requires that the last EPA-registered establishment where the product was formulated, labeled, or packaged be the establishment listed on the labeling. This detail is often overlooked and has resulted in additional penalty assessments against some companies. In light of these considerations, in most cases the best strategy is to obtain EPA approval for shipping all existing product to an EPA-registered establishment designated by the company for relabeling or rework. This is often the same establishment that originally packaged and labeled the product. This process starts with a request to EPA's Office of Enforcement and Compliance Assurance (OECA). The request should be in writing and include (1) the purpose for which the movement is requested; (2) an accounting of the quantities of product to be moved, including location(s) and container sizes; (3)

continued on page 5

Responding to Stop Sale Orders—Preparation Is the Key *continued from page 4*

the destination location to which the product will be moved. OECA will review the request and determine whether to permit the movement of the product. If OECA grants the request, it will issue a letter or amended SSURO that provides for the movement of the product. **No product should be moved until the letter or amended SSURO is received from EPA.**

6. Implement a Communication Plan

One final aspect for effectively handling SSUROs is to develop a communication plan. This aspect is often overlooked but is equally as important as all the other elements noted above. The communication plan should have two tracks to be effective. The first should address internal communications to sales/marketing teams and others within the company that need to understand the SSURO, and how existing product in distributor's hands will be addressed. The second track should address external communications to distributors and growers/end-users.

For internal communications, there should be a coordinated message to the sales/marketing teams about the hold on further sales and distribution of the product. Employees who have regular contact with distributors should also be instructed on how to answer common questions likely to be received from distributors about the hold and when product will be available again. External communications should be focused on providing pertinent information to distributors and end-users/growers. Communications about the SSURO should be clear, factual, and not confusing. The company may need to implement a series of communications for the channel. Initially, the company will want to inform and educate regarding the product hold. Further communications will become necessary to inform the external stakeholders about returning existing product once the process for addressing the SSURO is further along and EPA has granted permission to retrieve product for rework or replacement. All communications should be reviewed by the internal team responsible for handling the SSURO and by the company's legal counsel before they are issued.

Understanding and implementing these elements and the other steps noted above will help to assure that the company handles a SSURO as effectively as possible and minimizes both its enforcement exposure and its marketplace risks.

For more information, please contact:

Tracy Heinzman
202.719.7106
theinzman@wileyrein.com

Little Noticed Provision of National Pollinator Strategy May Lead to Most Impact *continued from page 3*

disruptive commercially—possible decisions by some registrants who have taken a lead on product defense to finally throw in the towel.

Registrants and user groups thus should consider the implications of EPA's proposal carefully. Far more than consensus on appropriate label language (as to which EPA has requested comment) is at issue. For example, in some FQPA cases, user groups who failed to adequately explain to the Agency the vital need for particular products found a vital crop protection tool canceled. In others, market segmentation led to different views among registrants of the substantially similar products as to what limitations would be acceptable, or even whether continued registration remained economically viable. Some companies with dominant positions as to particular active ingredients, but patented alternatives in their portfolios, were inclined to enter into "phase out" agreements covering the older products, and negotiated draft agreements before only belated notice of impending changes was received by generic registrants. Even if such situations do not arise here, the inclusion of so many older products on the target list means that a generic registrant or set of generic registrants may have succeeded to the role of principal product steward, but may not be staffed adequately to evaluate or respond on a timely basis to this challenge.

In short, from the registrant's perspective, this proposal merits careful evaluation by both regulatory and commercial teams. Potential responses may differ among companies and, within individual companies, with regard to alternative products.

For more information, please contact:

David B. Weinberg
202.719.7102
dweinberg@wileyrein.com

No State Consumer Battery Stewardship Legislation This Year *continued from page 1*

however, three of these proposals are dead and one on life support.

Early Signs of Consensus

This result is surprising to many. At the end of last summer, it appeared that a consensus had been reached between rechargeable and non-rechargeable battery manufacturers, many marketers of battery-powered products, and activists within both state and local government agencies and non-governmental organizations. Based on that consensus, model legislation was drafted by the rechargeable and non-rechargeable segments of the consumer battery manufacturing industry, represented by PRBA-The Rechargeable Battery Association, National Electrical Manufacturers Association, The Corporation for Battery Recycling, and Call2Recycle, Inc. The model legislation mandates that every "producer" participate in a battery stewardship program. In turn, "producers" are broadly defined so that at least one entity in the distribution chain for every battery offered for sale—whether removable consumer batteries in products or stand-alone batteries—would be required to participate in a battery stewardship program. Most importantly, the model legislation establishes a mechanism for recovering from "free riders"— those battery producers selling batteries within the state but not complying with stewardship obligations — the costs of collecting and processing batteries, ensuring that collection costs are distributed equitably based on batteries sold within the state.

State Bills Proposed in 2015

Heading into 2015, Connecticut's proposed legislation appeared to be the most likely candidate for success. The state's Department of Energy and Environmental Protection (DEEP) had played a leading role in the PSI forum in June 2014 and initially supported legislation in 2015. But DEEP ultimately refused to support any bill that imposed even minimal regulatory obligations on its staff. While opposition also arose from several other industry segments (such as medical device manufacturers), it was DEEP's position that put the nail in the legislative coffin. In light of these issues, it seems very unlikely that Connecticut will have the stomach to pursue similar battery legislation in 2016.

Consumer battery stewardship bills in Texas and New York met a similar fate as Connecticut, although for different reasons. New York's bill may be revised next year, but the Texas legislature does not meet in 2016.

In California, an unusual sharps/primary battery stewardship bill was reported from the Assembly Committee on Natural Resources along with another bill mandating curbside battery collection programs. But faced with substantial opposition, the sharps/primary bill—sponsored by Assemblyman Richard Gordon—was turned into a "two-year" bill, which is tantamount to putting it on indefinite hold. The bill mandating curbside recycling also died.

Ironically, the only battery-related legislation that has succeeded this year is an exclusion for certain collectors of used lead-acid batteries from Utah's "metals theft prevention" law. That exclusion will exempt lead-acid battery retailers and wholesalers from registration and recordkeeping obligations otherwise applicable to collectors of used batteries. A New York legislative proposal also remains in play, with a bill moving forward in the State Senate. That proposal would remove New York's five-dollar cap on lead-acid battery deposits on new battery sales to encourage used battery returns for recycling. But there is strong opposition in the Assembly from a key committee chair, making passage in 2015 highly unlikely.

For more information, please contact:

George A. Kerchner
202.719.4109
gkerchner@wileyrein.com

Saskia Mooney
202.719.4107
smooney@wileyrein.com

EPA Continues Enforcement Initiative on Imports of Recreational Vehicles *continued from page 1*

hundreds of thousands of dollars. In addition, EPA has the authority to suspend or revoke the certificate of conformity for violating engines altogether, making it illegal to import or sell those engines or equipment containing those engines in the United States in the future.[4]

The basis for many alleged violations is an inconsistency between the information provided to EPA that supports the legal importation and sale of engines/equipment in the United States and the actual characteristics of the engines/equipment once they reach the border. This inconsistency may be identified by reviewing the certificate of conformity (COC) for the engines/equipment and the information contained in the application for the COC and comparing them against the characteristics of the products as they are actually imported. Below is a summary of the COC regulations and major issues with recreational vehicle COCs that EPA has identified in recent CAA enforcement actions.

Recreational Vehicle Engine Certificate of Conformity Basics

Under 40 C.F.R. § 1068.101, which is the general compliance provision for all nonroad engines and equipment, including ATVs and other recreational vehicles regulated under 40 C.F.R. Part 1051, no person

continued on page 8

U.S. Congress May Simplify TSCA Regulation of Articles

By Saskia Mooney

With similar House and Senate bills now referred out of committee for full floor votes, Congress is closer to amending key provisions of the Toxic Substances Control Act (TSCA) than at any other time in the statute's nearly 40-year history. These amendments could notably impact not just chemical manufacturers but also product manufacturers and importers, because both the House (H.R. 2576) and Senate (S. 697) bills, among other things, attempt to narrow EPA's authority to regulate products (referred to as "articles" under TSCA) containing chemicals on the TSCA inventory.

Overview

The core of TSCA has not been updated since it was first enacted in 1976. Its provisions are widely considered inadequate or otherwise inappropriate for protecting human health and the environment from current chemical hazards. After many years of unsuccessful attempts at reauthorization, it looks like there is a real chance that the law will be amended in 2015 or 2016. The similar House and Senate bills have been referred out of committees to the full House and Senate for vote, putting them only a few steps away from conference for harmonization. If passed by Congress, President Obama is expected to support the legislation.

This legislation has moved this year primarily because the pending bills have bipartisan support. This reflects the support of both the chemical industry and several major environmental interest groups. Product manufacturers also generally supported the reform.

In the past, companies that manufacture or import only articles containing TSCA-regulated chemicals sometimes have overlooked—to their detriment—that TSCA can and sometimes does apply to those articles, as well as to raw chemicals. Importantly, the pending bills would limit EPA's authority under TSCA to regulate chemicals contained in articles.

Bill History

On April 28th, the Senate Environment and Public Works Committee passed a markup version of the "Frank R. Lautenberg Chemical Safety for the 21st Century Act" (S. 697), sponsored by Tom Udall (D-NM) and David Vitter (R-LA). In the House, the "TSCA Modernization Act of 2015" was passed by the House Energy and Commerce Committee on June 3rd.

The House leadership has committed to bring H.R. 2576 to the floor for a vote in late June. Although the Senate has not yet publically committed to a floor vote, it may happen before the August recess. If so, time would remain in 2015 for a conference committee to reconcile the two bills and final legislation to be sent to the President for signature.

The overall goal of these bills is to revise EPA's authority to assess and regulate chemicals, making TSCA more similar to the framework of the European Commission's *Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals* (REACH).

The differences between the House and Senate bills are sufficient to assure a contentious conference. And there are not only differences between the bills; in addition, interest groups are unhappy with the parallel provisions in both bills. For example, some states are seeking to further narrow the state preemption language, even though a robust grandfather clause is already included for existing state rules. Other groups want to modify the House bill to make it easier for EPA to require chemical safety assessments for unstudied chemicals.

Safety Assessments and Regulation

Both the Senate and House bills would require EPA to conduct safety assessments for all new and existing chemicals in commerce, including the tens of thousands of substances that were grandfathered onto the "TSCA Inventory" in 1978. To prioritize review of these chemicals, EPA must identify higher priority substances, based on their potential hazard and exposure under the intended conditions of use. A certain subset of the high priority chemicals must be drawn from EPA's "TSCA Work Plan" chemicals list, with preference given to persistent and bioaccumulative toxic substances (PBTs). However, the House bill does not require "PBT" metals and metal compounds to be prioritized by EPA. The metals industry will seek to have the House version included in the final legislation.

If a substance fails to meet a safety standard by posing an unreasonable risk, EPA would impose corrective regulatory controls. The schedules for assessment and regulation are similar, but not identical, in the House and Senate bills. The agency would have the option to apply a range of controls, such as monitoring, labeling, restrictions on certain uses, or a total phase out. In deciding which restrictions to impose, EPA would be required to consider the costs and benefits of the proposed restriction and the availability of substitute chemicals. But the bills also would eliminate language under Section 6 of TSCA that currently requires EPA to use the "least burdensome" means

continued on page 9

may introduce an engine into commerce in the United States unless it is covered by a valid COC or else is covered by an exemption.[5] EPA reviews COC applications submitted by manufacturers to ensure that engines meet the relevant emission standards and contain sufficient information for EPA to determine that the engine family covered by the COC will meet those standards under normal operating conditions. Manufacturers must submit several pieces of information regarding emissions control systems and any other operating parameters or characteristics of the engine that may have an effect on regulated emissions. In addition, the application must indicate who manufactures the engines, and it must list all of the engine models to which the application applies.[6]

Once approved by EPA, the COC establishes the conditions under which an engine may be operated. Only those operating conditions described in the application and approved by EPA in the COC are allowed in order for the COC to be valid. EPA defines a "valid" COC as "one that applies for the same model year as the model year of the equipment..., covers the appropriate category of engines/equipment..., and conforms to all requirements specified" for that particular type of equipment.[7] EPA regulations state further that "[e]ngines/equipment are considered not covered by a certificate unless they are in a configuration described in the application for certification."[8] If any of the information contained in the application for the COC changes after EPA has issued the COC, manufacturers are required promptly to provide EPA with the updated information.

What EPA's COC regulations mean in practice is that manufacturers need to ensure that whatever information they submitted to EPA in support of their application for a COC is accurate and correct in every relevant particular at the time they sell or import the engine/equipment into the United States. Any variation from the information submitted may provide the basis for an enforcement action by the Agency.

Recent COC Enforcement Trends for Imported Recreational Vehicles

Recent CAFOs for recreational vehicles, including the *Geason* CAFO, have tended to focus on four main problems with the imported equipment.

1. Engine configuration different than in COC. Variations in the operating parameters and in the types of emissions control system configurations in the engines from those indicated in the COC were the source of many recent alleged violations. If an engine contains an adjustable operating parameter, for example (*e.g.*, injection timing or fuel rate), then the manufacturer must show that the engine meets emissions standards throughout the entire range of operation that is controlled by the adjustable parameter. Similarly, the composition, size, and configuration of emissions control devices, such as catalysts, must be identical to what is specified in the COC. Any variation in these devices could have a significant effect on the emissions profile of the engine and render the COC invalid.

2. Engine manufactured by different entity than in COC. Regardless of whether the engines are identical in all particulars to the configuration specified in the COC, it is a violation of the Part 1051 and Part 1068 regulations to use a different manufacturer than the one specified in the COC. Equipment manufacturers may want to rely on different engine manufacturers for a variety of commercial reasons, but any change must be communicated to EPA prior to the engines being introduced into commerce so that the certificate of conformity can be changed and, if necessary, the emissions profile of the engine updated to reflect the change.

3. Model names and numbers different than in COC. COCs are issued for broad engine "families," which may best be understood as a collection of engines that have very similar emissions profiles and operating characteristics but that need not be identical in every aspect. EPA regulations require manufacturers to specify which engine/equipment models are covered by the engine families that are included under the COC. Even if an engine/equipment model is identical in all particulars to the one listed on the COC, it is a violation if it is has a different model name when it is actually introduced into commerce.

4. Importation into the United States before or after the effective date of the COC. EPA issues COCs for a single model year. A "model year" for a new recreational vehicle engine is ordinarily defined as the calendar year.[9] This means that no matter when EPA actually issues a COC in response to an approved application, the engines/equipment covered by that COC may not be sold or imported prior to that date, even if their emissions profile is less polluting than the emissions standards of the earlier model year. In addition, the engines/equipment cannot be manufactured *after* the end of the model year (usually December 31) for which the certificate of conformity was issued.

Do Not Forget About the Labels

In addition alleging that engines did not conform to the configuration specified in the COC application, EPA alleged in *Geason* and other recent settlements that engine emissions labels could be removed with "minimal effort" and thus did not meet the requirement that the labels be "permanent" and not removable without being destroyed or defaced.[10] Problems with labels can often provide a hook for EPA and U.S. Customs to investigate shipments further to determine if there are other violations that are not readily apparent from visual inspection.

continued on page 9

of regulation. In the past, that language has constrained EPA's ability to impose restrictions.

Additionally, both of the proposed bills would provide EPA with broad authority to assess fees on industry to help EPA implement the law. Only the Senate bill, however, currently proposes to increase civil and criminal penalty ceilings (money and imprisonment) for TSCA violations.

New Approach to the Regulation of Articles

As noted above, TSCA also can be applied to articles containing chemicals, in addition to raw chemicals. Historical examples include PCB transformers and some asbestos-containing products.

More recently, articles produced with chemicals subject to some Significant New Use Rules (SNURs) under Section 5 of TSCA also have been regulated. For example, a final December 2014 rule covering certain dyes, phthalate plastic additives, and alkane lubricants did not include EPA's typical article exemption for importers. EPA also proposed last January to amend one of its existing chemical SNUR rules to remove the rule's exclusion for imported articles. Under both rules, importers of articles containing covered chemicals (such as carpets and non-stick pans) would be obligated to notify EPA at least 90 days prior to importation and give EPA the opportunity to consider regulation. With these rules, EPA is trying to level the playing field for domestic manufacturers as well as protect the American public from harmful chemicals in imported products.

Domestic manufacturers of articles also can be covered by current TSCA regulations as "processors" who incorporate regulated chemicals into products. For example, battery manufacturers have been subject to some SNURs due to their use of certain regulated nanocarbon chemicals.

The pending TSCA bills could significantly benefit article manufacturers and importers. For the first time, the Senate bill would establish parameters for EPA's TSCA authority to regulate chemicals contained in articles. EPA currently has poorly delineated (and thus arguably very broad) authority to regulate articles under Title I of the law. But the pending bills would limit EPA's authority, allowing regulation of articles only when a chemical of concern poses an exposure hazard in the article itself.

Furthermore, under Section 5 in the Senate bill, EPA would be precluded from using SNURs to regulate importation or processing of articles—even when a chemical substance in the article fails the safety standard—unless EPA finds by rule that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification." Moreover, the Senate bill would allow EPA to regulate articles "only to the extent necessary to address the identified risk." The committee-reported House bill contains similar limiting language.

Next Steps

It is never possible to predict whether this will finally be the year that TSCA reform legislation is adopted, but the stage has certainly been set.

For more information, please contact:

Saskia Mooney
202.719.4107
smooney@wileyrein.com

Conclusion

Foreign manufacturers of recreational and other non-road engines and equipment – and their U.S. counterparts responsible for importing the vehicles into the United States – need to be vigilant and ensure that all of the information they submit to EPA for a COC is in fact accurate at the time they import the machines. Problems with engine component suppliers, or the desire to change operating components or parameters for the purpose of manufacturing convenience or commercial advantage, can subject manufacturers to significant enforcement headache if they do not update or amend their COCs to reflect their products' true characteristics at the border.

For more information, please contact:

Joseph S. Kakesh
202.719.7435
jkakesh@wileyrein.com

[1] *See* 2014 Clean Air Act Vehicle and Engine Enforcement Cases and Resolutions, *available at* http://www2.epa.gov/enforcement/2014-clean-air-act-vehicle-and-engine-enforcement-case-resolutions; 2015 Clean Air Act Vehicle and Engine Enforcement Cases and Resolutions, *available at* http://www2.epa.gov/enforcement/2015-clean-air-act-vehicle-and-engine-enforcement-case-resolutions.

[2] *See* Consent Agreement and Final Order and Complaint for Hammerhead, *available at* http://www2.epa.gov/enforcement/consent-agreement-and-final-order-and-complaint-hammerhead. Under the Clean Air Act (CAA), both manufacturers and importers of record are considered to be "manufacturers" subject to enforcement for noncompliance. *See* 42 U.S.C. § 7550(1); 40 C.F.R. § 1051.801.

[3] General non-road equipment and engine requirements are in 40 C.F.R. Part 1068, and the emissions standard-setting, testing, and recordkeeping regulations for recreational vehicle engines are in 40 C.F.R. Part 1051.

[4] *See* 40 C.F.R. § 1051.255.

[5] *See id.* § 1068.101(a)(1)(i). Among others, exemptions include those for engines/equipment intended solely for export to countries with emission standards different than those in the United States or those intended solely for testing or display. *See* 40 C.F.R. Part 1068, Subpart C.

[6] *See, e.g.*, 40 C.F.R. § 1051.205 (information requirements for recreational vehicle engine COC applications).

[7] 40 C.F.R. § 1068.101(a)(1)(i).

[8] *Id.*

[9] *See id.* § 1051.801.

[10] *See id.* § 1068.45(a)(1).

Supreme Court Kills Pharma Stewardship Challenge

By David B. Weinberg

On May 26th, the Supreme Court of the United States declined to hear a challenge to *Pharmaceutical Research and Manufacturers of America* (*PhRMA) v. County of Alameda*. The case sought to overturn a Ninth Circuit Court of Appeals decision (768 F.3d 1037 (9th Cir. 2014)) upholding an ordinance requiring drug manufacturers to implement unwanted-drug take-back schemes. In a rare show of unity, the research and generic sides of the pharmaceutical industry had jointly filed suit against the county, arguing that the ordinance imposed an unconstitutional burden on interstate commerce. The "denial of certiorari" by the Supreme Court means that pending programs in Alameda County, San Francisco and San Mateo, California, and King County, Washington, will now proceed. These programs likely will create templates for similar programs in other cities and counties.

Product Stewardship/Sustainability Directory

Megan L. Brown	202.719.7579	mbrown@wileyrein.com
James N. Czaban	202.719.7411	jczaban@wileyrein.com
Tracy Heinzman	202.719.7106	theinzman@wileyrein.com
Joseph S. Kakesh	202.719.7435	jkakesh@wileyrein.com
George A. Kerchner*	202.719.4109	gkerchner@wileyrein.com
Roger H. Miksad	202.719.7193	rmiksad@wileyrein.com
Saskia Mooney*	202.719.4107	smooney@wileyrein.com
P. Nicholas Peterson	202.719.7466	npeterson@wileyrein.com
Steven Richardson	202.719.7489	rsrichardson@wileyrein.com
Maureen E. Thorson	202.719.7272	mthorson@wileyrein.com
David B. Weinberg	202.719.7102	dweinberg@wileyrein.com
Craig G. Fansler	202.719.7536	cfansler@wileyrein.com

*Senior Regulatory Analyst