

TESTIMONY OF
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BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
May 11, 2017

Good morning Chairman Roberts, Ranking Member Stabenow, and members of the committee. My name is Rick Keigwin and I serve as the Acting Director of the Office of Pesticide Programs in the U.S. Environmental Protection Agency.

Safe pesticide use makes an enormous contribution to our society, particularly in the production of U.S. food and fiber. Innovation in pesticide use has greatly increased U.S. agricultural productivity and contributed to a predictable food supply and stable food prices. The EPA estimates that pesticides used to control various pests such as insects, weeds, and fungus contribute billions of dollars per year to the U.S. economy, translating into a bolstered workforce of American jobs. Additionally, the pesticide industry— which is impacted by the EPA's decision making and assistance— accounts for various aspects of the U.S. economy: a dozen major pesticide producers; another 100 small producers; 1,700 pesticide formulators and 25,000 distributors; 23,000 commercial pest control firms; more than two million farms; and more than

88 million households.¹ There are more than 17,000 registered pesticide products containing more than 1,200 active ingredients, with uses ranging from insect repellents, household cleaners, lawn and garden chemicals, hospital disinfectants, biotech products and a wide range of agricultural chemicals used to provide an abundant food supply. These factors contribute greatly to the EPA's challenging and complex undertaking to run an efficient and equitable regulatory program.

Further, EPA Administrator Pruitt launched a "Back to Basics" agenda -- a formal plan to return the agency to its core mission of protecting the environment while engaging in cooperative federalism across a broad spectrum of interested parties. For example, as part of the Administration's regulatory reform effort, just last week the EPA held a public meeting to garner feedback on pesticide registration issues. This meeting, one of several regulatory reform meetings held by EPA program offices, allowed regional, local, agricultural, and other pesticides stakeholders to share their views on pesticide regulatory development, reform initiatives, evolving public policy and program implementation issues. These meetings highlight the current Administrator's commitment to all Americans in returning common sense, as well as transparent and peer reviewed science, to the pesticide registration process.

¹ EPA Pesticide Industry Sales and Usage: 2008-2012 Market Estimates

I would now like to provide an overview of how the EPA regulates pesticides to protect human health and the environment while making tools readily available to provide a safe and abundant food supply.

PESTICIDE REGULATION

The EPA's regulates pesticides under the authorities of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food Drug and Cosmetic Act (FFDCA); the Food Quality Protection Act of 1996; the Endangered Species Act (ESA); and the Pesticide Registration Improvement Renewal Act (PRIA).

The EPA has developed a highly regarded program for evaluating pesticide safety and making regulatory decisions. Our approach to decision making is based on a model of transparency. Using this approach, the agency makes decisions consistent with information that is peer-reviewed and protective of human health and the environment. Credibility is at the core of meeting the requirements of pesticide registration and reevaluation activities. The EPA has incorporated many processes that have integrated inherent efficiencies into our risk assessment process, enabling the agency to successfully meet the requirements of PRIA. We have done this in a collaborative manner with our regulatory partners and stakeholder community.

Under FIFRA, the EPA ensures that, when used properly, pesticides provide significant benefits to society, such as controlling disease causing organisms, protecting the environment

from invasive species, and fostering an affordable, safe and abundant food supply. FIFRA's safety standard requires the EPA to weigh these types of benefits against harm to human health and the environment that might result from using a pesticide.

FIFRA generally requires that before any pesticide may be sold or distributed in the United States, the EPA must license its sale through a process called "registration." During registration, the agency examines every pesticide product that is intended to be distributed or sold in our country. In addition, under FFDCFA, the EPA sets "tolerances" (maximum residue limits) for pesticides used on food or animal feed. The EPA may establish a tolerance or a tolerance exemption for a pesticide residue in food or feed only if the agency finds that there is a "reasonable certainty of no harm" from consumption of the pesticide treated food and from other non-occupational sources of exposure.

FIFRA also requires the EPA to reexamine previously approved pesticides every 15 years through a program called "registration review." Any changes to the use of a pesticide identified through registration or registration review, as necessary for safe use, appear on product labels.

In 2016, the EPA registered pesticides containing 20 new active ingredients, more than half were biopesticides or reduced-risk conventional chemicals, and approved products for 213 new uses. In addition, we approved hundreds of registration amendments and reviewed thousands of notifications of other minor changes to labels.

Some of the most dramatic examples of how pesticides can provide direct benefits occur under section 18 of FIFRA, where the EPA may respond to “emergency exemptions” requested by states to authorize the temporary use of an unregistered pesticide to address an unusual pest outbreak. Likewise, the EPA also approves special local need exemptions for states under section 24(c) of FIFRA. In 2016, to address serious pest threats, EPA completed 108 section 18 emergency decisions, including the use of antibiotics on citrus to combat citrus greening in Florida, which is devastating to the citrus industry. We also expedited registration of five chemicals for use on quinoa to be responsive to domestic grower’s needs, as well as Peruvian import needs.

Additionally, in response to the Zika virus crisis, four section 18 emergency exemptions were authorized to the Centers for Disease Control and Prevention to reduce populations of disease carrying mosquitoes in Puerto Rico, the United States Island Territories, and the continental United States. Authorizations were completed on all of the actions in less than 39 days and as little as eight days. The EPA also expedited 94 Zika fast track amendments with a turnaround time of two weeks or less, and expedited the approval of two unregistered sources to ensure adequate supplies of repellent to protect against Zika.

PESTICIDE REGISTRATION ENHANCEMENT ACT (PRIA 4)

The Pesticide Registration Enhancement Act (PRIA 4) is the third reauthorization of the Pesticide Registration Improvement Act (PRIA), which was signed into law in 2004. PRIA and its reauthorizations (hereafter collectively referred to as PRIA) provide examples for how user fees paid by the private sector can help support vital regulatory activities. The EPA's pesticide regulatory programs are funded by a combination of appropriations and user fees, with user fees consisting of a one-time registration service fees that accompany applications for covered activities under PRIA and annual maintenance fees to support continued registration of pesticide products.

Under PRIA, entities seeking the EPA's approval to sell or distribute pesticide products must, in most cases, pay a fee to process their applications. The amount of the fee depends on the type of application, complexity of the application, and the type of entity. For example, under PRIA, lower fees are charged for new pesticide products that are the same or similar to products already registered (known as "me too products"), than for entirely new pesticides. Small businesses pay reduced fees, and PRIA exempts government and government-supported organizations, like the USDA's Interregional Research Project No. 4 (IR-4), from application fees. PRIA registration service fees were intentionally set at levels that represent only a portion of the cost necessary for the EPA to complete its review – about 20 percent to 40 percent of total costs depending on the PRIA category.

PRIA was developed by a coalition of pesticide stakeholders representing seven different trade groups within the pesticide industry and public interest groups reflecting the environmental and farmworker safety communities. The result of this collaboration is that there are elements to the law important to all of the represented stakeholder entities in the coalition. The EPA serves in an advisory capacity to this coalition and has welcomed the opportunity to provide technical assistance.

For the pesticide industry, PRIA requires the EPA to make decisions on applications within mandated timeframes. PRIA was developed with the intention of providing additional resources to the EPA in order to achieve faster and more predictable registration decision time frames and in that respect has demonstrated success. The pesticide industry has actively sought to increase the number and types of registration actions covered under the fee for service programs from 90 categories in PRIA 1, to 140 categories in PRIA 2, 189 categories in PRIA 3, and now 212 proposed categories in the PRIA 4 legislation.

Before PRIA, because of limited resources, the agency could not process all of the applications it received in a timely fashion. Large backlogs developed, and applicants could not predict when the agency would make a decision. Pesticide companies had to establish priorities for which of their applications the EPA would review first. With the additional resources provided by PRIA, the agency can now process new applications in a timelier manner. The EPA has approved more than 20,000 decisions since PRIA went into effect in 2004, meeting the

timeframes for more than 98 percent of those actions. With this kind of consistency in the EPA's review of registrations, pesticide companies can develop more accurate business plans for marketing their products.

Pesticide users also benefit from the more rapid approval of more new pesticide products. Since PRIA became law, the agency has seen an increase in the approval of pesticides for "minor uses" to meet the pest control needs of farmers who grow minor crops – primarily fruits, vegetables, and nut crops. Further, under the law, some of the PRIA fees go to support improved safety standards for agricultural workers and to provide pesticide safety education for farm workers and farm worker families. Finally, PRIA sets aside a portion of the fees to increase funding for grants that improve understanding of integrated pest management and develop new tools to reduce pesticide use.

Society and the environment also benefit from PRIA. A number of the new pesticides receiving approval under PRIA are safer than the previously approved products that they can replace. Expedited review time frames under PRIA provide incentive for the development and submission of these reduced risk pesticides. In addition, PRIA reauthorized maintenance fees to support the EPA's registration review program. As mentioned earlier, under FIFRA, the EPA must reevaluate all previously registered pesticides at least every 15 years to make sure that products in the marketplace can still be used safely. The registration review program makes sure that, as the ability to assess risk evolves and as public policy and pesticide use practices change,

all registered pesticides continue to meet the FIFRA statutory standard of no unreasonable adverse effects.

Turning to PRIA 4, the House bill (H.R. 1029) reauthorizes PRIA for seven years and, consistent with previous authorizations, provides for two fee increases of five percent to be implemented in fiscal year 2019 and fiscal year 2021. With regard to maintenance fees collected under section 4 of FIFRA, PRIA 4 extends that provision for seven years, increases fees from \$27.8 million to \$31 million per year, and includes a provision allowing the EPA to average across years to correct for over or under collection within PRIA 4. An existing provision in FIFRA is removed that prevents the EPA from spending annual maintenance fee funds without exactly matching those funds from dollars appropriated in the same year. In recent years, the EPA has not been able to spend all of the maintenance fees collected from registrants due to this constraint. We are working expeditiously to resolve this issue and are in the process of developing a plan to ensure that these fees are utilized in a cost effective manner to meet our statutorily mandated responsibilities.

Also, an information technology (IT) set-aside of \$800,000 per year established under PRIA 3 is eliminated and replaced with a new set-aside of \$500,000 per year over five years to develop and finalize rulemaking and guidance for product performance data requirements for certain invertebrate pests of significant public importance. In addition, a second maintenance fee

set-aside of \$500,000 per year over seven years is established for Good Laboratory Practice (GLP) inspections.

As mentioned before, PRIA 4 expands covered applications to 212 categories, up from the 189 categories specified under PRIA 3. An example of category changes requested by the regulated community is the alignment of antimicrobial new chemical and new use categories to be consistent with Part 158W definitions. In general, new and amended categories reflect an effort to better align fees and time frame structures to the EPA resources necessary to review those actions. PRIA 4 also creates a financial incentive for registrants to develop and submit to the EPA reduced-risk pesticide applications, by raising fees for corresponding non-reduced risk categories within the conventional new chemical and new use fee tables. PRIA set-asides for worker protection, partnership grants, and pesticide safety education are extended. PRIA 4 directs the EPA to look for opportunities to streamline review processes for new chemical and new use applications, and to provide prompt feedback to applicant during process.

Additional reporting requirements specified by PRIA 4 include progress in meeting mandatory deadlines for development of product performance rulemaking and guidance for public health pests, the number of GLP inspections conducted under the set-aside, progress in priority review and approval of new pesticides to control vector borne public health pests for use in the United States, including territories and military bases globally, and the effectiveness of and engagement of stakeholders in worker protection, partnership grants and pesticide safety

education activities. Registration review reporting requirements are amended and reporting requirements remain for the unspent balance of the IT set-aside under PRIA 3.

CONCLUSION

The EPA has a history of working in strong collaboration with the grower community to address potential pesticide risks while still providing growers with the necessary tools to meet their pest management needs. Through meetings with the grower community, we will continue to gain the invaluable contributions that farmers make to our economy, the importance of working with them and the unique insights they provide. Under Administrator Pruitt's leadership, the EPA will double down on helping America through common sense regulations, including those in PRIA, allowing farmers to grow an abundant food supply and also grow the economy.

Thank you for the opportunity to testify today. I will be happy to answer any questions you and the other members may have.