



May 15, 2017

U.S. Environmental Protection Agency  
Office of Regulatory Policy and Management  
1200 Pennsylvania Ave, N.W.  
Mail Code 1803A  
Washington, D.C. 20460-0001

Submitted via [www.regulations.gov](http://www.regulations.gov); Docket ID: EPA-HQ-OA-2017-0190

Re: Evaluation of Existing Regulations

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to submit these comments in response to the request for input, published in the Federal Register on April 13, 2017 by the United States Environmental Protection Agency (EPA or the Agency), seeking input on regulations that may be appropriate for repeal, replacement, or modification. The request for input references the February 24, 2017 Executive Order 13777, "Enforcing the Regulatory Reform Agenda."

CLA is the national trade association that represents the manufacturers, formulators and distributors of pesticides in the United States. CLA's member companies produce, sell and distribute virtually all the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners.

CLA recognizes the burden placed on American industry and agriculture by unnecessary, duplicative, or over-complicated regulations, no matter how well-intentioned. We support efforts to streamline and return common sense to the regulatory process. We also recognize, however, that the opportunities for reform are many and that a prudent approach to determining how best to meet these challenges will help us achieve our goals with minimum disruption to ongoing activities.

Many industries, including our own, depend on a predictable, science-based regulatory process to allow products to reach their intended customers – in our case, American farmers, ranchers and landowners – in a timely fashion. CLA's members' products must be registered (licensed) by the Agency, for use on food crops. This registration process must also establish "tolerances" for residues on those crops - regulations promulgated under the Federal Food, Drug, and Cosmetic Act (FFDCA). Our members support these regulatory actions, in part, through a user-fee program. American farmers and the entire food chain depend on this regulatory system to ensure that pesticides are used in a manner that is safe for food production and the environment.

**Background.** As the Agency is aware, pesticides protect the world's food supply, infrastructure, and public health from pests, weeds, and diseases. Farmers cannot grow enough food to feed the

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world's population on existing farmland without the ability to control weeds, plant diseases, insects, and other pests. Pesticides play important roles in public health and safety, as well. They protect the public from mosquito- and tick-borne illnesses, and antimicrobial pesticides protect against deadly microorganisms. More familiar to many consumers, pesticides protect homes and other structures from cockroaches and rodents, and keep yards, parks, and playgrounds free of weeds and other pests.

The Agency closely regulates the use of pesticides in the United States. No one may sell or distribute a pesticide product without first submitting a registration application to EPA's Office of Pesticide Programs (OPP). Following the industry investment in a decade or more of effort and hundreds of millions of dollars in research and development costs, OPP scientists evaluate each pesticide to ensure that it will not pose unreasonable adverse effects to human health or the environment, pursuant to its authority granted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As mentioned above, EPA grants a license or "registration" for pesticides that pass EPA's rigorous evaluations. The registration permits a pesticide product to be sold, distributed, and used in accordance with its EPA-approved label.

For pesticides used on food crops, the FFDCA also requires EPA to set tolerances through rulemaking for the legal limit of pesticide residue that may remain in or on each food or feed commodity harvested from a treated crop. In setting a tolerance, EPA makes a safety determination that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue ..." The FFDCA includes strong provisions for protecting infants and children, as well as other sensitive subpopulations.

A timely, predictable process for the pesticide registration process and tolerance rulemaking supports American manufacturing and agriculture by allowing growers predictable access to crop protection tools made by American companies. Registrations and tolerances help assure consumers in both the United States and other countries that food grown by American farmers is safe to eat.

Congress has repeatedly affirmed the need for a streamlined approval process for pesticide registrations funded in part by registration and user fees. The Pesticide Registration Improvement Act (PRIA) and subsequent iterations require that EPA make a registration determination on a manufacturer's pesticide application within the time specified in the PRIA statute. Similarly, for pesticides to be applied on food crops, PRIA sets timelines for EPA to make tolerance decisions.

**Comments.** We support the mission and purpose of OPP in its work on the processes outlined above. OPP serves as both a regulator and a licensing agency, whose goal is to fairly assess whether a given pesticide product can be properly labeled for its intended use with no unreasonable adverse effects. EPA's registration and label instructions represent the objective, risk-based standard that assures the public that lawful crop protection tools are available and meet the applicable standards.

Notwithstanding the regulated community's support for OPP's mission, the Agency is in serious need of reset to preserve risk-based regulation for pesticides based on sound science and a

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predictable regulatory process. Most urgently, CLA encourages the Administration to provide thorough, thoughtful review of OPP with scrutiny of departures from established policy, due process, and sound science that occurred in recent years. Lapses in EPA's risk assessment process (timing for registration and registration review) have threatened not only the effectiveness, but availability of a robust toolbox of crop protection products for American farmers, ranchers and landowners.

Resetting the process and science, and restoring transparency and predictability to the registration and review of pesticides, will resolve many product- and issue-specific concerns.

We also are very concerned about recent attempts to create policy without appropriate notice and public comment, using less formal and less transparent means instead.

Although not an exhaustive list, the following specific recommendations are deserving of action and oversight:

- **Reauthorize PRIA** - OPP is uniquely situated among the other offices within EPA in that it serves the critical function of reviewing and registering pesticides for the private sector – providing verification that a pesticide meets EPA's registration standards. To ensure a robust foundation for OPP's proper operation, CLA asks that the Administration support reauthorization of PRIA. This program is the private-sector-funded fee-for-service system that provides OPP a portion of the resources needed to complete timely pesticide registrations, and provides registrants business certainty and regulatory predictability, allowing proven and new technologies to reach pesticide users more quickly.
- **Develop Meaningful Endangered Species Act Reform** - We can do better when it comes to the proper implementation of the Endangered Species Act (ESA). The pervasive misapplication of the ESA across the regulated business spectrum and the ongoing dysfunctional working relationships among OPP, the Fish and Wildlife Service, and the National Marine Fisheries Service continue to frustrate the harmonization of ESA and FIFRA.
- **Restore Process and Science, Use Input Provided by the United States Department of Agriculture (USDA)** - Certain pending actions and recent policies are not consistent with the underlying science, or do not comply with the Agency's principles of transparency, or are otherwise not fully developed. These actions should be delayed until the policies are fully developed and the underlying science is determined to be reliable as the basis of decision-making. It is critically important that USDA's expertise and advice be meaningfully incorporated into all actions. An Executive Order that delays certain OPP actions until proper process and sound science are sorted out and restored could be helpful in this regard.
- **Zika Funding** - CLA urges the Administration to budget funding to states to support pest control operations and to support development of technology and products to deal with the Zika virus and its mosquito vectors. Surveillance and control of mosquitos is as important as vaccine development.

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Other issues of concern such as the Waters of the United States (WOTUS) Rule are outlined in comments to this docket made by the Pesticide Policy Coalition and the American Farm Bureau Federation, both of which we incorporate here by reference and fully support.

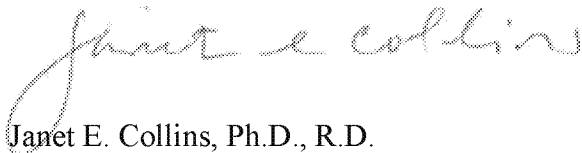
CropLife America believes that we can achieve our national environmental goals, including preservation and enhancement of biodiversity in agricultural landscapes, while maintaining and improving agricultural productivity, but to do so, we need effective, science-based federal policy.

The work done by OPP is critical to protect the environment, while serving the needs of America's farmers, ranchers, landowners, and consumers. CLA is proud to support that work. However, improvements can be made to provide greater clarity, greater reliance on sound science, and greater certainty for agriculture, the regulated community and other stakeholders. This will benefit farmers and ranchers across the country, as well as CLA's members with domestic manufacturing facilities. CLA would be pleased to provide greater detail on these issues and to discuss these matters more fully.

Should you have any questions or wish to discuss this matter, please contact me directly by email ([jcollins@croplifeamerica.org](mailto:jcollins@croplifeamerica.org)) or telephone (+ Ex. 6).

Thank you for your consideration of these comments.

Respectfully,



Janet E. Collins, Ph.D., R.D.  
Executive Vice President, Science and Regulatory Affairs

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