Senate EPW Committee Hearing on the Nomination of Michael Dourson – EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention

Wednesday, October 4, 2017, 10:00 AM, Room 406 of the Dirksen Senate Office Building

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Preserving the risk-based regulatory model

Dr. Dourson: As you know, the U.S. follows a risk-based model in registration of pesticides – which we also see in the General Agreement on Tariffs and Trade (GATT) – which has proven to be the gold standard for much of the world. However, the European Union has been trending toward hazard-based regulation, in spite of its commitments in GATT and a consensus that the risk-based model is more science-based and protective of human health and the environment. To cite one example, the U.S. has refused to issue a ban on the use of neonicotinoid pesticides (neonics), while the European Commission continues to move in that direction and proposed earlier this year to ban neonics for all applications except greenhouses. To cite another example, the European Commission has taken an approach to registering pesticides (Regulation (EC) No. 1107/2009) that establishes several hazard-based "cut-off" criteria that essentially exclude certain categories of products from consideration, without performing a risk assessment. As you know, such a process is entirely contradictory to the risk-based model that is used in the United States?

Since EPA is the agency responsible for protecting the gold-standard of risk-based rulemaking, please provide your thoughts on how you, as the head of the EPA office that regulates pesticides, will defend that risk-based approach inherent in the agency's regulatory decisions, domestically as well as on the international stage.

Process fouls, regulation by letter

EPA in recent past has imposed new requirements (for instance, additional label language relating to pollinators) through processes not authorized in the statute – Under your leadership, in what ways can we expect EPA to more strictly follow the law as written by Congress? And if substantial changes are warranted, will you tell us in Congress so WE can change the law, not bureaucrats?

FIFRA sufficiency

After a registrant spends tens of millions (or >100 m) on development, many millions on safety data, submits often times over one hundred studies on the safety of the product, AND goes through FQPA rulemaking (special examination of children's risks, aggregate risk assessment, etc.) - can EPA actually communicate to the public that this pesticide product will not result in any unreasonable effects to the environment and human health? The Federal Food, Drug and Cosmetic Act says food must be "safe" but EPA seems reluctant to say the word – how will you ensure that EPA appropriately defends Agency decisions?

PRIA/OPP Funding Question

The Pesticide Registration Improvement Act (PRIA) was first enacted in 2003 and established a fee schedule for pesticide registration requests. It lists specific decision time periods for EPA to make a regulatory decision on

pesticide registration and tolerance actions submitted to the Agency. The goal of PRIA was to create a more predictable and effective evaluation system for affected pesticide decisions and couple the collection of individual fees with specific decision review periods. It also promoted shorter decision review periods for reduced-risk applications.

It has been tremendously successful, providing hundreds of millions of dollars in funding to EPA and providing product developers with clarity on timelines for agency actions and facilitating investment in research and development of new products. Importantly, it also has provided $1 million annually in worker protection and pesticide safety training, funded by industry fees.

PRIA has been reauthorized twice since it was first enacted – in 2007 and 2012 – each time by unanimous consent. It has been supported by large and small manufacturers of agricultural and non-agricultural products, antimicrobial products, biotech companies, and biopesticides, as well as labor and environmental advocates. The current law expires on September 30, 2017. HR 1029, the Pesticide Registration Enhancement Act, which would reauthorize these authorities passed the House on March 20, 2017 and was reported by the Senate Agriculture Committee on June 29, 2017.

What would the impact be to worker protection programs if PRIA is not reauthorized?

Answer:

- The $1 million annually that goes to program funding for worker protection safety and training – largely in cooperation with State Departments of Agriculture and Cooperative Extension Service -- would cease. Therefore those programs would either have to be funded with other EPA funds (difficult in a time of shrinking budgets), funded by our state partners, or terminated.

What would the impact be to EPA if PRIA is not reauthorized?

Answer:

- The loss of maintenance and registration fees would result in the elimination of 200 full-time-equivalent positions in EPA's Office of Pesticide Programs.
- The authority to collect product maintenance fees expires on 9/30/2017, resulting in an annual loss of resources of $27.8 million. However, EPA's obligation to conduct registration review continues. Without additional resources, it will be impossible for EPA to comply with the 2022 review deadline.
- New registration applications submitted after 9/30/2017 have no completion deadlines. Companies will face tremendous uncertainty about whether to make new R&D investment in new products.

Pollinators

Science magazine described studies (February 5, 2016 issue) which finally confirmed what beekeepers and the United States Department of Agriculture (USDA) scientists had known for some time; that an invasive Asian bee parasite, which was first found in the U.S in 1987 is considered to be the "single most detrimental pest of honey bees and can magnify the role of viruses in bee health" according to USDA scientists. More evidence turned up when tests were done in Australia, the only major land mass that had not been invaded by those destructor mites. Australian farmers used a wide range of pesticides just like those in the U.S. and yet Australian bee

colonies were healthy and on the rise. Scientists finally figured out how these invasive destructor mite impacted bees. Given the importance of pollinators to agricultural production, Dr. Dourson, will you work to develop policies to control and eventually eradicate the invasive Asian Varroa destructor mites so as to protect the efforts of farmers and beekeepers?

(WICKER) Agriculture is vital to the economy and people of Mississippi. With farming comes crop pests and disease that must be managed. To do that, we need crop protection tools and I regularly hear from farmers that the access to new and innovative products has become more restrictive. Many of these delays and restrictions are due to concerns about honeybees even when the crops are wind pollinated (e.g. corn, cotton, sorghum, soybeans) and bees are not present. This policy is overly precautionary and not risk vs. benefit and has broken down a system of collaboration and friendship between beekeepers and farmers many of which have been in place for decades.

Will you commit to re-evaluating this policy put in place in the last Administration and bring balance and appropriate risk vs. benefit consideration back to the registration process?

ESA

Action is needed to minimize the threat to EPA's pesticide program posed by the federal government's inability so far to effectively integrate the requirements of the Federal Fungicide, Insecticide and Rodenticide Act and the Endangered Species Act. As it stands, the failure to reconcile these two statutes is a threat to US agriculture and is of no benefit to listed species or their habitats. What opportunities do you believe exist to improve these issues and allow the registration of pesticides while simultaneously protecting endangered species and their habitat?

Agricultural productivity

What is the appropriate role for EPA in improving the efficiency of American agriculture and the competitiveness of American agricultural products in world markets?

Public engagement & education on 'Risk'

The characterization of hazards and risks to human health and the environment can be very frightening and confusing for the American public, as well as policy makers. What can EPA do to improve the public understanding of the relative risks of the technologies it is called on to regulate?

Transparency

Transparency is essential to maintaining public trust in the EPA's review and regulation of chemical products. Whether EPA ultimately decides to authorize use of a chemical product or not, it is imperative that Agency decisions be based on sound science and that the review process is as transparent as possible. As Assistant

Administrator, how will you commit to basing regulatory decisions on studies and information that have been made available to the public?

NPDES

(FISCHER) I continue to be concerned about NPDES permit requirements for the application of pesticides to, over and near water. NPDES permits are duplicative and do not add any additional environmental protection beyond those provided via the EPA registration process. To the contrary, NPDES permits negatively impact the ability to protect people from mosquitoes that can vector the Zika Virus and other viruses, to control invasive aquatic plants that contribute to flooding, impede navigation and impact public safety, and many other important uses. As Assistant Administrator will you uphold the rigorous FIFRA pesticide registration process and work with Congress to eliminate these costly and duplicative permits?