TESTIMONY OF DR. STEVEN BRADBURY
DIRECTOR, OFFICE OF PESTICIDE PROGRAMS
U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE
SUBCOMMITTEE ON NUTRITION AND HORTICULTURE
OF THE AGRICULTURE COMMITTEE
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Introduction

Good afternoon Chairwoman Schmidt and Chairman Gibbs, Ranking Members Baca and Bishop, as well as other Members of the Subcommittees. My name is Steven Bradbury and I serve as the Director of the Office of Pesticide Programs (OPP) in the U.S. Environmental Protection Agency (EPA). I am pleased to appear before you today to discuss how EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to protect our nation's water resources. I will begin by describing our commitment to the principles of transparency and using the best available, peer-reviewed science. These principles undergird the two major components of EPA's program for regulating pesticides – the initial registration of pesticide products and the ongoing reevaluation of past decisions.

EPA's Programs for Regulating Pesticides

EPA's Office of Pesticide Programs is charged with administering FIFRA, under which we must ensure that use of a pesticide does not cause "unreasonable adverse effects on the environment." When used properly, pesticides provide significant benefits to society, such as

controlling disease causing organisms, protecting the environment from invasive species, and fostering a safe and abundant food supply. FIFRA's safety standard requires EPA to weigh these types of benefits against any potential harm to human health and the environment that might result from using a pesticide. The Agency has broad authority to restrict the way a pesticide may be used in order to lower its risks, and EPA may allow use of the pesticide only if we think the benefits outweigh the remaining risks.

Over the last 30 years EPA has developed a highly regarded program for evaluating pesticide safety and making regulatory decisions. EPA's reputation rests on our world renowned expertise in pesticide risk assessment. Our approach to decision making is also widely considered to be a model for transparency and openness. Using this approach, the Agency makes decisions consistent with scientific information and protective of public health and the environment.

Initial Registration and Ongoing Reevaluation of Pesticides

FIFRA generally requires that, before any pesticide may be sold or distributed in the United States, EPA must license its sale through a process called "registration." During registration EPA has examined every pesticide product that is being lawfully marketed in our country. In addition, FIFRA also requires EPA to reexamine previously approved pesticides against current scientific and safety standards. A major effort to revaluate old pesticides occurred from 1988 to 2008 through a program called "reregistration," and, as required by law, EPA is now systematically revisiting all of its past pesticide registration decisions through a new program called "registration review." Any restrictions on the use of a pesticide identified

through registration, reregistration, or registration review as necessary for safe use appear on product labels. State lead agencies enforce proper use of pesticides.

Both the registration and reevaluation programs for evaluating the safety of pesticides rest on the same two fundamental principles: basing decisions on the best available, peer-reviewed science and making our decisions through a process that is transparent and open to everyone.

Quality Scientific Assessments

EPA holds itself accountable to the public for ensuring the quality of its scientific risk assessments. EPA looks at all available scientific data from every source – whether from pesticide companies, other governments, or the published literature, and we look closely at every study. EPA reaches its conclusions through a systematic, objective evaluation of all relevant information that uses scientifically peer reviewed, documented procedures at each step.

Under FIFRA, the pesticide companies shoulder the cost of performing safety studies on pesticides they request to be registered. EPA regulations establish a rigorous battery of tests necessary to gain approval for a pesticide. A typical new agricultural pesticide must undergo over 100 different tests to characterize its potential risks. This data set provides, among other things: detailed information on where and how the pesticide will be used; a full battery of animal models studies to assess human health toxicity; data on the fate of the pesticide in the aquatic and terrestrial environments; and a suite of toxicity studies representing broad categories of wildlife and plants – birds, mammals, fish, terrestrial and aquatic plants, algae, insects, and other

invertebrates. The pesticide companies submit these studies for review, and we use these and other scientific data to develop detailed risk assessments for every use of each pesticide. If a test is not scientifically sound or if EPA needs more information, EPA may require a company to conduct additional studies. Further, because of the critical role that scientific data play in EPA decision making, FIFRA requires registrants to report in an ongoing fashion all information relating to the potential adverse effects of their products on human health or the environment, for example, new research.

Our first question is whether the results are scientifically sound. To assist in this review, EPA has issued both guidelines that provide instruction about how to conduct different types of studies and Good Laboratory Practice (GLP) regulations that describe procedures to ensure high quality data from laboratory studies. The reviewer double checks the analysis reported in a study and compares results from one test with other studies to detect inconsistencies. It is not unusual that EPA will disagree with the conclusions reached by an individual researcher. Then, following EPA risk assessment guidelines, we integrate the data to evaluate whether the pesticide poses potential risks to humans or the environment.

To ensure we reach the sound scientific conclusions, study reviews and risk assessments undergo scientific peer review. When we encounter a significant scientific controversy, we turn to the FIFRA Scientific Advisory Panel (SAP) for independent, external, expert scientific peer review. The SAP is a federal advisory committee and, thus, must comply with requirements for balance, objectivity, openness, and transparency. The Government Accountability Office commended the procedures used by the FIFRA SAP to assure balance and the absence of any

conflicts of interest among the people who serve on panels.. The Office of Government Ethics has also reviewed and commended highly the operations of the SAP.

An Open and Transparent Process

EPA believes in an open and transparent process. By "open" we mean that every member of the public – whether from a stakeholder group or simply an interested citizen – can, at any time, provide information for consideration, and everyone may comment on our proposed decisions and the reasons for them. To make comment opportunities meaningful, our process must be transparent. By "transparent" we mean that all of the information we have considered, and the way we analyze the data, is available to the fullest extent permitted by law.

Our regulatory processes typically provide several opportunities for comment. During registration review, for example, there are chances to comment on: a preliminary workplan on how the Agency will conduct the reevaluation; a preliminary assessment of the pesticide's risks; a written response to public comments on the preliminary risk assessment; and a revised risk assessment. We also invite comment on what measures are needed to address any risk concerns. We may hold public meetings for interested stakeholders to explain our positions and to receive input. Finally, we present our conclusions in a Registration Review Final Decision or similar documents. These documents contain our final risk assessment, our conclusions regarding whether the pesticide meets the statutory standard for reregistration, and if not, what regulatory measures would be necessary to mitigate identified risks. Similarly, we announce receipt of applications for registration of pesticide products containing new active ingredients and invite

public comments. Then, before we decide whether to register such products, we publish and take comment on our risk assessment and proposed decision.

In fact, whether we are dealing with issues concerning a specific pesticide or broader policy development, we actively reach out to and work closely with Congress, our state and federal regulatory partners, the agricultural community, nongovernmental organizations, the general public, and all of our stakeholders.

Risk Assessment

EPA uses peer reviewed procedures to analyze data to produce risk assessments, covering a wide range of potential effects on both humans and the environment. Although the data and models used will differ depending on what type of effect we are evaluating, the broad purpose of our risk assessments is to determine what levels of a pesticide will remain in the environment after use and how those levels compare with doses that could harm humans or the environment.

For example, we follow the framework set out in the EPA-wide Ecological Risk Assessment Guidelines when assessing potential for a pesticide to cause adverse effects on the environment. The basic approach to ecological risk assessment has two components, a hazard evaluation and an exposure estimate. Toxicity studies in twenty or more different species generate data that permit EPA to determine levels for both short term and long term exposures which would be unlikely to harm wildlife and plants. Using these studies, EPA has developed and made publicly available “aquatic life benchmarks” for over 200 pesticide active ingredients and their degradates. Our benchmark values are estimates of the levels of residue in water below

which the chemicals are not expected to harm aquatic life and aquatic ecosystems as a result of either short term or chronic exposure. The public and state and federal agencies can use these values to assess the risks posed by any levels of pesticide found by monitoring programs.

EPA also calculates exposure estimates using peer-reviewed models and scientific data on the persistence and mobility of each pesticide. A key value is an estimate of the concentrations of pesticide residues that may be present in surface waters as a result of direct application, runoff, or drift. EPA uses these values both in assessing risks to humans from consumption of drinking water, as well as in the evaluation of risks to aquatic ecosystems. The models employ data in such a way that the resulting estimates represent the amounts of pesticide that more highly exposed humans, wildlife, and non-target plants will likely receive. EPA then compares the toxicity of the pesticide with the expected environmental exposure to assess whether there is a potential risk.

Risk Management

The risk assessment then goes to EPA's risk managers to consider whether regulatory actions may be appropriate to mitigate the potential risks. Under FIFRA the Agency can impose a variety of risk mitigation measures – ranging, for example, from changes to how the pesticide is used to prohibition of specific uses or cancellation of all products containing a particular active ingredient – that ensure the use of the pesticide will not cause unreasonable adverse effects on the environment. When we are concerned about the risks arising from pesticides in water, we may require a reduction in application frequency or rates, a prohibition of certain application methods, the establishment of no-spray buffer zones around waterbodies, a requirement that

limits use only to trained and certified applicators, or other restrictions. These measures are typically national in scope, applying to all users throughout the country, but increasingly, we are designing protective restrictions that apply in specific geographic areas to address risks arising from local conditions. These requirements are communicated to users through the labeling of the pesticide product. The use directions and restrictions in labeling are enforceable under FIFRA section 12(a)(2)(G), which makes it unlawful to use a registered pesticide in a manner inconsistent with its labeling.

Pesticide Reevaluation

In addition to requiring an initial review of every pesticide product through the registration program, FIFRA allows EPA to take regulatory actions as necessary to revise the restrictions on the use of a pesticide and directs EPA to periodically revisit past regulatory decisions on previously registered pesticides through the reregistration and registration review programs.

The reregistration program was conducted from 1988 to 2008 during which EPA reexamined all pesticide products containing an active ingredient that was initially registered before 1984. Reregistration evaluated 613 different pesticide active ingredients / active ingredient groups, using contemporary scientific and regulatory standards. Reregistration led to extensive changes in the way pesticides are allowed to be used that has significantly reduced risks to human health and the environment. As a result of reregistration, EPA cancelled all products containing 229 different pesticide active ingredients and imposed many changes on the ways that most of the other 384 pesticide active ingredients are used.

Changes in science, public policy, and pesticide use practices continue to occur, meaning that prior regulatory decisions can become outdated over time. In 1996, Congress unanimously passed the Food Quality Protection Act (FQPA), which among other things, mandated a new, ongoing program: "registration review." Under the registration review program, we 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 new 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 statutory standard of no unreasonable adverse effects.

As one part of the registration review program, EPA has worked with state regulatory officials to develop a process for the voluntary submission of state and tribal surface and ground water quality data for consideration in exposure characterizations for ecological risk assessments and in risk management decisions. EPA will review these data to identify any pesticides that are being found in ground or surface water, as a result of lawful use, at levels which exceed existing human health or environmental safety benchmarks. If ongoing monitoring or other information indicates that there are unsafe levels of pesticide residue in water, EPA will impose additional risk mitigation measures, as needed to ensure the pesticide meets the statutory standard.

Conclusion

The regulatory restrictions imposed by EPA under FIFRA directly control the amount of pesticide available for transport to surface waters, either by reducing the absolute amount of pesticide applied, or by changing application conditions to make transport of applied pesticide less likely. In sum, EPA uses its full regulatory authority under FIFRA to ensure that pesticides

do not cause unreasonable adverse effects on human health or the environment, including our nation’s water resources.