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**TESTIMONY OF
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**BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
OVERSIGHT, NUTRITION, AND FORESTRY
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES**

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INTRODUCTION

Good morning Mr. Chairman and members of the subcommittee. I am pleased to appear before you today to continue our discussion of the Environmental Protection Agency's (EPA) implementation of the Food Quality Protection Act (FQPA). In my testimony presented several weeks ago, I provided you and your subcommittee with a brief summary of the Agency's latest progress in implementing this new law.

This hearing shifts the focus of the discussion from agricultural pesticide uses to non-agricultural pesticide uses. Non-agricultural pesticides include a wide array of product types that play an important role in today's society. Non-agricultural pesticides include public health pesticides that serve a significant role in protecting the public's health from disease vectors, such as mosquitoes that transmit malaria and encephalitis, ticks that cause rocky mountain spotted fever and lyme disease, cockroaches and rats. Non-agricultural pesticides also include antimicrobial pesticides such as sterilants used in hospitals and disinfectants used in restaurants. The last major group of non-agricultural pesticides includes residential uses. Millions of people rely on these pesticides for everything from bathroom sanitizers to lawn care. Although the focus of FQPA is primarily on the dietary concerns from pesticide-treated food, non-agricultural pesticide uses contribute to our overall exposure to pesticides. Exposure from non-agricultural pesticide products can be significant.

FQPA's requirement that EPA consider the aggregate risks of all non-occupational exposures to a pesticide when reviewing tolerances -- including from agricultural and non-agricultural uses -- has placed greater emphasis on evaluating exposure from non-agricultural uses. This provision has greatly accelerated the development and use of new data and assessment methodologies for residential and other non-dietary exposures to more routinely incorporate consideration of these exposures in our risk assessments.

EPA'S APPROACH TO PUBLIC HEALTH PESTICIDES

Public health pesticides are defined in FQPA as “any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.” Because a pesticide can only qualify as a public health pesticide if it is a minor use pesticide, public health pesticides are afforded priority review and the other special considerations given to all minor use pesticides.

EPA is in the final stages of developing a Pesticide Registration notice (PR) outlining its policy with respect to public health pesticides. In addition to formalizing the list of public health pests required in FQPA, the PR notice will provide criteria for determining whether a pesticide use fits the statutory definition. One important criterion is that the pesticide is used in an organized vector control program. A public health pesticide is not simply a pesticide used against pests that have public health consequences; rather, a pesticide can only qualify as a public health pesticide if it is used predominantly in recognized public health programs for vector control or other public health purposes. For example, under this definition, an over-the-counter mosquito repellent would not be classified by the Agency as a “public health pesticide” even though it is used against a public health pest.

For any food use pesticide which also has public health uses, FQPA requires EPA to factor exposure from the public health use into our aggregate exposure assessments. There is concern by some public health professionals that this provision may lead to limits on some public health pesticide uses because registrants may choose to support more profitable food uses at the expense of public health uses.

When evaluating tolerances, consideration of the benefits of public health uses are limited to special circumstances, subject to the same restrictions in FQPA as all other pesticide uses. The important benefits of public health pesticides, however, would be considered by the Agency in determining how best to mitigate any unacceptable risks in order to bring aggregate exposures within safe levels. For example, if the aggregate risk of a pesticide were found to be unacceptable, EPA would consider the benefits associated with all the uses, and the availability of alternatives, when determining how to bring the risk down to an acceptable level.

EPA is sharing with DHHS all risk assessments for pesticides with public health uses at a stage well before any regulatory decisions may be made. Similar to our experience sharing preliminary risk assessments for food use pesticides with USDA, it is our hope that these early consultations will help us to significantly improve risk assessments for public health pesticide uses. To date, risk assessments for five public health OP insecticides have been shared with DHHS for comment. FQPA requires that EPA consult with DHHS and the Department of Agriculture (USDA) if the Agency were to conclude during this process that a non-food public health use may need to be limited or eliminated. Rather than relying solely on this requirement to ensure that public health uses are given appropriate consideration, EPA will continue to work with DHHS to improve risk assessments.

FQPA also included several other specific provisions that require EPA, DHHS, and USDA to work together when taking public health pesticides into consideration as we implement the law. EPA has selected a Public Health Coordinator to lead an internal Public Health Workgroup and to facilitate interagency communication and coordination. In particular, our Public Health Coordinator and internal workgroup have been working with the Office of Public Health and Science, the Center for Food Safety and Applied Nutrition, and the Centers for Disease Control to address the issues surrounding public health pesticides and how this group of products may be impacted by FQPA mandates. EPA and DHHS are in the beginning phases of designing a data development program for public health pesticides. We are working to put in place a Memorandum of Understanding to formalize this interagency cooperation to attain our common goals and are committed to maintaining a close, cooperative approach.

EPA'S APPROACH TO ESTIMATING RESIDENTIAL EXPOSURE

Background The Agency uses term "residential exposure" to cover a broad array of use scenarios. These may include use in the home and garden; use in schools, parks, playgrounds, and public buildings; use in swimming pools; use on pets; and many other non-dietary, non-occupational exposures.

Because tolerance determinations did not explicitly include a detailed assessment of residential exposures prior to enactment of FQPA, EPA's databases and exposure assessment methodologies in this area are less robust than for dietary exposures. We have, however, been working for a number of years to improve our understanding of these issues, and the explicit FQPA mandate to consider aggregate exposures is resulting in rapid development of more sophisticated, refined approaches to residential exposure assessments by EPA, the pesticide industry, and commercial users of residential pesticides.

We have used a number of tools -- including data call-in, voluntary cooperation with industry groups, and EPA supported research efforts -- to improve our data and risk assessment methodologies. The Agency has developed and published for public comment new Standard Operating Procedures for estimating exposure to pesticides resulting from residential use. We issued a data call-in requesting residential exposure data from the Outdoor Residential Exposure Task Force. EPA's Office of Research and Development (ORD) has conducted and otherwise supported new research on residential exposure, particularly focusing on children's exposures. And we are employing new methodologies to assess activity patterns that can result in residential pesticide exposures.

All these activities are helping to greatly improve our assessments of residential and other non-dietary exposures, allowing the Agency to more rigorously account for these exposures as required in FQPA.

Standard Operating Procedures As many of you are already aware, assessing the risks due to non-dietary, non-occupational exposure to pesticides was identified as one of the nine key

science policy issues by the Tolerance Reassessment Advisory Committee. In response, EPA published for comment Standard Operating Procedures (SOPs) for estimating pesticide exposure for over 40 activity scenarios in residential and similar settings. EPA brought these draft exposure models before the FIFRA Scientific Advisory Panel in 1997 and plans to present its latest work to the Panel this coming September. Our latest work will present new analysis of recent studies relating to key post application variables including percent dislodgeability of pesticides from turf, indoor surfaces and pets; dermal exposure methods; methods for estimating non-dietary ingestion; pesticide drift and contaminated house dust.

EPA is currently using these "Residential SOPs" to produce screening level assessments of residential pesticide exposure, using information derived from the pesticide labeling and other generally available data. Thus, SOPs are equally applicable to new products and products that are already in the marketplace. The SOPs represent conservative or screening level estimates of exposure and are used to identify those instances where there may be a potential for concern. If the screening assessments indicate that the risks from residential exposures is within acceptable limits, no further analysis is required. In the event, however, that the SOPs estimate potential exposures of concern, the Agency may seek additional information, determined on a case-by-case basis, to produce a more realistic estimate.

Exposure Methodology In estimating residential exposures for a given use scenario, consideration of two general factors is necessary: the amount of pesticide residues present that a person could come in contact with, and the behavior or "activity patterns" that could result in exposure.

To determine the amount of pesticide residues that may be available, EPA uses data on "dislodgeable residues" (the portion of the applied pesticide that can be physically removed during an activity) developed by pesticide registrants. This data, however, may not be available for all pesticides used in and around the home. In some cases, EPA may use assumptions, based on existing data, to estimate higher end exposures. For example, the Agency assumes that 20% of the applied pesticide can be removed from a treated lawn, and 50% of a pesticide can be removed from an indoor surface.

To reduce the need for such estimates, EPA issued a data call-in requesting residential exposure data from all registrants of lawn use chemicals. The Outdoor Residential Exposure Task Force, a consortium of companies which produce such pesticides, was formed to satisfy the data call-in. The 117 pesticides subject to this data call-in were divided into 2 groups based on their toxicity or usage. Data on chemicals in group I (chemicals of greater concern) are due by October 30, 1999. Data on group II (chemicals of less concern) are due by October 29, 2000. EPA will use these data to refine both pathway specific and aggregate exposure assessments for these pesticides.

In characterizing activity patterns, the Agency can use data from certain agricultural use settings to estimate exposures from similar residential activities. For example, working in a

home garden or lawn is similar to related agricultural activities. Data derived from fieldworker studies, then, can be extrapolated to help estimate exposure from these related residential activities.

The Agency uses other methods for estimating post-application exposures from other residential activity patterns. For example, EPA is using a method developed by the California Department of Pesticide Regulation that uses the Jazzercise® routine to predict exposures from certain residential activity patterns. Also, over the past few years, EPA has compiled a large database containing data on human activities in and around the home. This should prove useful in estimating pesticide exposures with increased confidence.

Research Because of FQPA's focus on the safety of infants and children, EPA is most concerned about children's exposures to pesticides in their homes, schools, day-care settings, and outdoor play areas. In addition to developing SOPs for estimating infants' and children's exposures to pesticides in these settings, EPA is conducting or otherwise supporting research to measure transfer of pesticide residues from residential surfaces to a child's body. Research in this area focuses on improving our understanding of exposures that infants and children receive in residential "microenvironments." Research objectives include (1) developing and demonstrating measurement methods and protocols for dislodgeable contaminant residues from lawns and indoor surfaces; (2) developing and demonstrating measurement methods to characterize residential dermal exposure and dermal-oral ingestion of contaminants, and (3) developing multipathway exposure - dose models to represent these exposures. Exposure measurement research is focusing on characterizing long-term exposures, biological markers of exposure, and associated activity patterns for two hundred fifty young children in both daycare and home settings. Another study is focused on residential pesticides exposures of children between the ages of three and twelve in Minnesota. EPA's ORD is also supporting research on transfer of residues from pets treated with pesticides. In addition, ORD's National Human Exposure Assessment Survey program (NHEXAS) is gathering valuable information on the distribution of human exposures to multiple chemicals via multiple pathways. In addition to ORD's exposure research activities, EPA can often adapt data from other sources in its residential exposure assessments. The Agency is examining use of exposure data from turf uses, spray drift studies and farm worker children studies. While not direct residential uses, analysis of these exposure scenarios may provide some important clues to assessing exposure in the residential environment.

FQPA has also challenged the research community. Behavioral studies and environmental exposure are newly emerging sciences within academia. Industry is also taking an active role. EPA is working closely with companies, users, and university researchers to design and implement appropriate and cost effective methods for gathering data for evaluating residential pesticides exposure. Not surprisingly, the pesticide chemical industry is committing substantial resources to this issue. Information acquired from research or from studies submitted in support of registration will help significantly improve the understanding of which exposure scenarios are of most concern.

Making Regulatory Decisions The use of available, scientifically sound data is essential for making any regulatory decision, including those that involve residential uses. Reliable data from all available sources (including modeling, direct measurement, and peer-reviewed literature studies) are used in an assessment. Where additional data may be useful in refining risk assessments, EPA will address on a case-by-case basis whether such data are reasonably required to support continuation of a tolerance.

Where a risk assessment indicates a potential concern, the Agency is conducting sensitivity analyses -- revisiting critical assumptions and data to determine what impact they may have on the risk determination. If these analyses suggest that key assumptions appear to lead to significant overestimates of risk, EPA may defer a decision until appropriate data are developed to refine the risk estimate. Conversely, if the sensitivity analysis suggests that assumptions are not critical to the assessment, EPA would be reasonably confident that even with the more refined data, mitigation measures may still be needed. Because of the Agency's responsibility to take prompt action to mitigate risk, EPA believes it would be inappropriate to delay decisions where available data are sufficient to reach a decision.

Residential Exposure to the OPs Because FQPA mandates priority reassessment of those pesticides that appear to pose the greatest risk, EPA has been focusing on evaluating exposures to and completing risk assessments of the organophosphate (OP) pesticides. Currently there are 17 OP pesticides with major residential uses.

We are fortunate that all 17 OPs with a potential for residential exposure have some level of actual data on which to base our assessments. For residential applicator exposure scenarios to the OPs (*i.e.*, the homeowner who is applying the pesticide), the Agency is reassessing previous (*i.e.*, pre-FQPA) conclusions with respect to use directions and the type of equipment used. For example, a homeowner, when applying an organophosphate insecticide may use a lawn spreader, hand held shaker can, or a sprayer attached to a garden hose. Each of these three methods of application results in different exposures.

In addition to the reassessments underway, EPA has also given priority to registering new, safer alternatives to existing pesticide uses that may pose greater risks. A good example of this is the recent registration of a new active ingredient for insect control. On June 30, EPA granted a registration for N-Methylneodecanamide (MNDA). MNDA will be used in the formulation of multi-purpose cleaner/insect repellent products to repel cockroaches and ants on household floors, walls, bathrooms, and other non-food contact surfaces. By placing a high priority on the registrations of these types of chemicals, we hope to stimulate development and registration of viable OP alternatives.

ANTIMICROBIAL PESTICIDES

As I stated earlier in my testimony, non-agricultural uses also include some very

important antimicrobial uses. FQPA fundamentally changed the way and rate at which EPA registers antimicrobials. FQPA reformed the antimicrobial registration process, with the goal of achieving significantly shorter EPA review times. It was in response to this mandate that EPA established the Antimicrobial Division (AD) within the Office of Pesticide Programs. In the past three years, AD has achieved a 98% reduction of backlog actions and has met all registration deadlines for submissions filed since November of 1996. In addition, the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA; P.L. 105-324) established EPA's jurisdiction over sanitizers used on semi-permanent and permanent food contact surfaces.

CONCLUSION

It is without question that non-agricultural pesticides play an important role--whether it be to control dandelions in the front yard, fleas on the dog, or disease vectors. However, along with these benefits comes exposures to these pesticides. These exposure pathways can be significant in some cases. Household pesticide uses (including lawn and garden) account for 17 percent of all pesticides sold in the United States. Non-agricultural professional sales, which include institutional uses (schools), and commercial uses (public buildings, golf courses), account for 13 percent (\$1.4 billion) of total U.S. sales. And a 1995 study conducted by the Centers for Disease Control and Prevention found a metabolite of a common household insecticide in the urine of 82% of the people monitored. As these numbers illustrate, food is by no means the only route of exposure.

The provisions in FQPA ensure protections not only from pesticides in our food, but also from pesticides in the air we breathe and the things we touch. And FQPA placed greater emphasis on non-agricultural pesticides. We are gathering new data and developing new methodologies in collaboration with pesticide users and producers and with our other government partners. By working in partnerships, we can meet the FQPA challenges and realize the better protections we all desire for our families and our children.

Thank you very much Mr. Chairman. I will be happy to answer any questions at this time.