

# Protecting the environment and



SwRI performs a variety of sophisticated tests on pesticide products.

Before reaching the marketplace, pesticides must meet tough regulations

by Gang Sun, Ph.D.

**A**s the federal government enforces new tougher regulations for registration of potentially hazardous pesticides, Southwest Research Institute (SwRI) is leveraging its 30 years of experience in pesticide research and environmental monitoring to provide technical and analytical support to pesticide manufacturers in meeting these stringent requirements.

To protect human health and the environment, the U.S. Environmental Protection Agency (EPA) requires manufacturers to register and test pesticides before they appear on the market.

A pesticide is any substance used to eradicate, deter or repel a pest. Pests include insects, weeds, rodents, fungi, worms and other microorganisms such as bacteria, viruses and mold.

By 2006, the EPA will review old pesticides to ensure that they meet new safety requirements.

## Pesticide registration

During the 1970s when concern about the effects of pesticides on the environment increased, the EPA assumed the responsibility of registering pesticides from the U.S. Department of Agriculture. This concern for environmental health and safety continues to grow as scientists learn more about the potential adverse effects of pesticides in wide use. Before granting registration to a pesticide, the EPA evaluates its potential health and environmental risks resulting from both short- and long-term exposures.

For these reasons, strict EPA registration procedures dictate the type of ingredients, application amounts, frequency of application, storage and disposal methods.

Four different types of pesticide registration exist under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The law requires all pesticides that are sold or distributed in the United States to be registered through the EPA. These include federal registration actions, experimental use permits, emergency exemptions and state-specific registrations. Along with national standards and requirements, many states have set



# human health

forth their own additional laws and guidelines concerning pesticide registration. SwRI primarily supports manufacturers in preparing the data for federal registration.

## Pesticide regulation

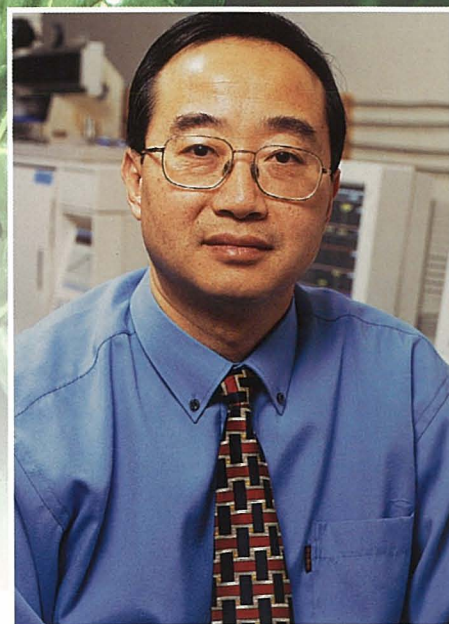
Chemistry studies must meet stringent EPA guidelines. The Institute's standard operating procedures were written using the EPA's laboratory practices guidelines and study protocols; a quality assurance officer assures strict adherence during all testing.

Federal regulations require the purity of the active ingredient and concentration of impurities be determined in technical grade active ingredients (TGAI) and end-use products. TGAI refers to a substance produced on a commercial scale that contains only the active ingredient and chemicals used for manufacture or purification. To support the pesticide registration under the above regulations, SwRI

performs preliminary analysis and characterizes the physical and chemical properties of the active ingredient and the final commercial product.

## Preliminary analysis

The first step in pesticide registration is a preliminary analysis of the TGAI percentage purity and identification of any impurity greater than 0.1 percent. For preliminary analysis, five samples representative of the product are tested using methods and test procedures developed by SwRI. Analyses are performed for both active ingredients and impurities using gas chromatography/mass spectrometry (GC/MS), high-performance liquid chromatography (HPLC) and liquid chromatography/mass spectrometry (LC/MS). Special attention and procedures are required to determine accurately the concentration of the relatively high

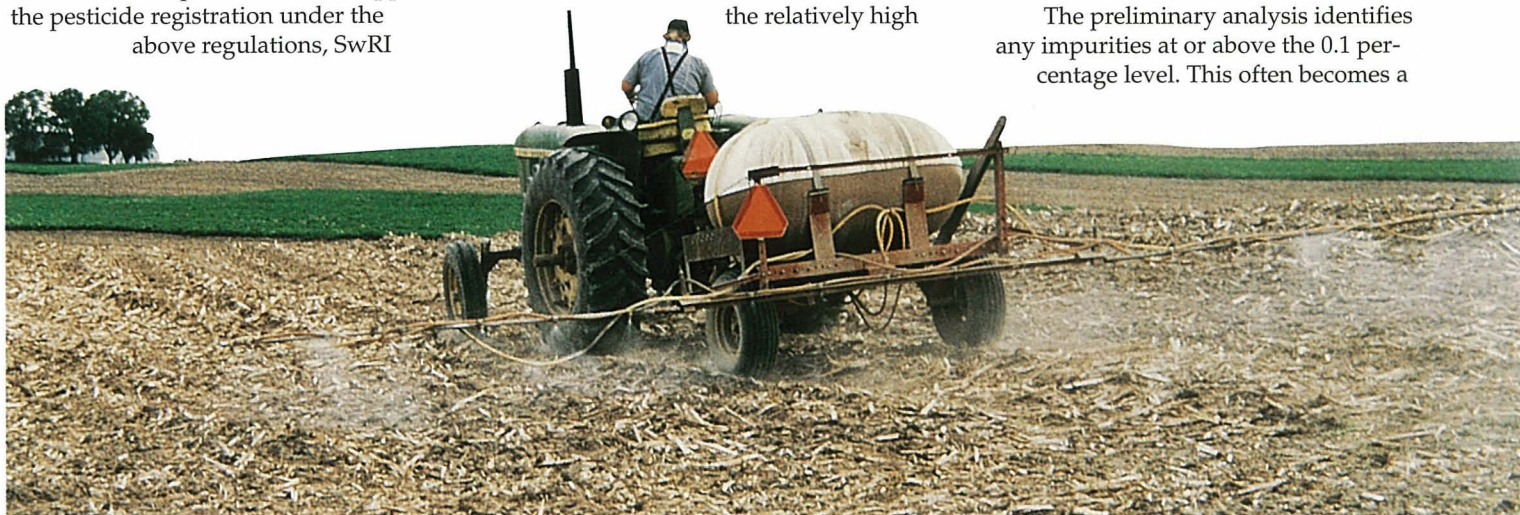


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percentage TGAI ingredients. Procedures normally used to perform trace level analysis are inadequate. Meticulous attention to detail is necessary during sample weighing, solution preparation and instrumental analysis to ensure accuracy in every step and in the final results.

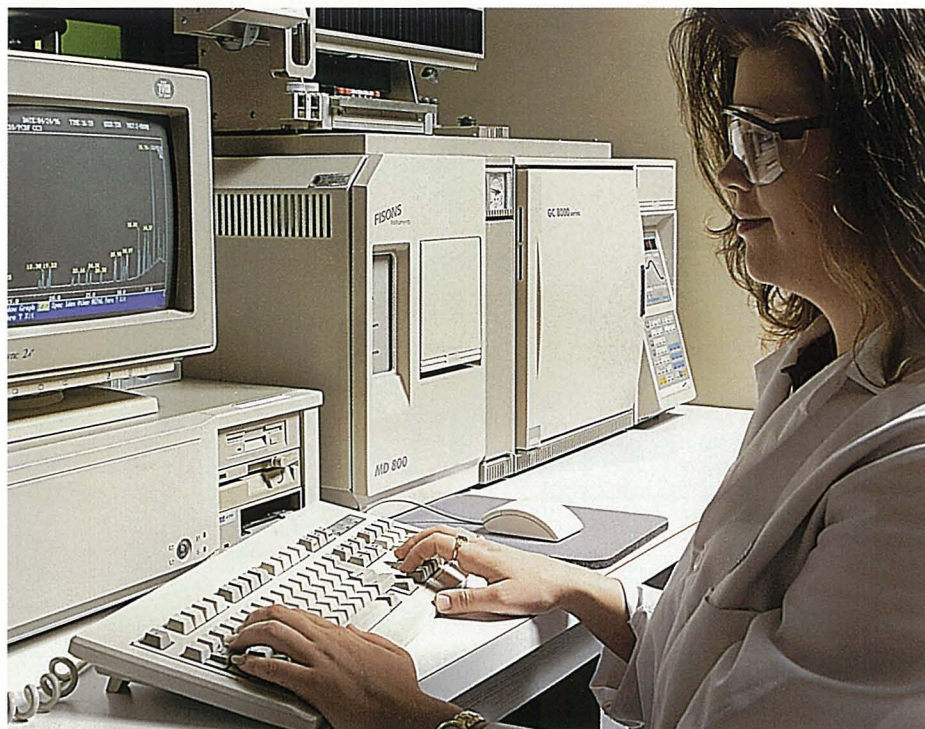
The preliminary analysis identifies any impurities at or above the 0.1 percentage level. This often becomes a



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*Sophisticated instruments that perform gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), and high performance liquid chromatography (HPLC) are powerful tools in the analysis of pesticide purity and impurity.*



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challenge during this phase of analysis, especially if the chemical is not known in advance.

SwRI uses knowledge of the synthesis process, GC/MS analysis and a computer library search program to interpret the mass spectra.

Data on the product composition are critical input to the registration process. For active ingredients found in the pesticide, EPA requires that the chemical and common name and the concentration level of the active ingredient be provided with the upper and lower certified limits. The concentration and certified upper limit of impurities with toxicological significance also must be identified in the product.

These impurities may come from raw materials, be an intermediate of a chemical reaction or be the product of a side reaction during the pesticide synthesis. Because some impurities can have an adverse impact on the environment or human health through food consumption, the EPA requires information on the identities and concentrations of the impurities in all pesticides. If they are seen in the analysis, highly toxic impurities must be quantified at levels even if they are less than 0.1 percent.

### Physical and chemical property characterization

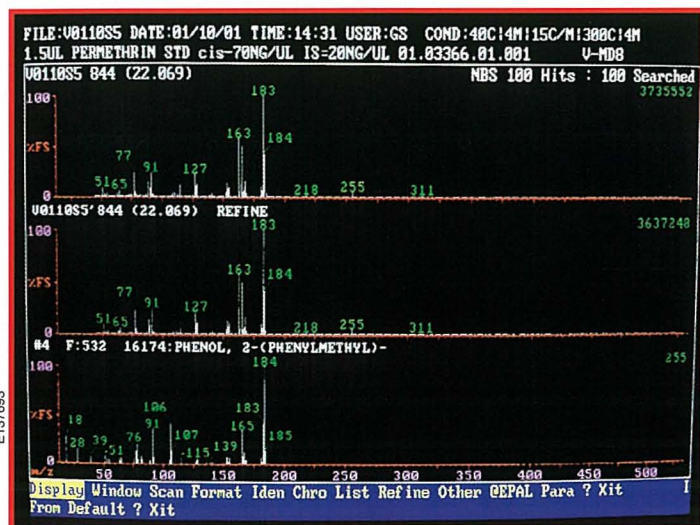
SwRI is one of a few organizations that can provide in its ability to provide all of the required physical and chemical properties tests for pesticide registration. The physical and chemical characteristics are determined with standard testing techniques. Other techniques can be used, but the EPA requires validation and specific test standards. With the Institute's 11 technical divisions, expertise can be drawn

from across the organization and all of the analyses can be performed at one location. Based on results of the physical and chemical properties tests, the EPA may require manufacturers to provide warnings on product labels. The results of the chemical studies also may cause the manufacturer to change directions for use, storage, transportation or disposal of the pesticide.

### Discussion

The EPA has set a high priority on registering safer pesticides. According to the EPA, more than 1 billion pounds of active pesticide ingredients are used in the United States each year. Americans are exposed to pesticides every day through food consumption, cleaning products and home and work environments. Because of the potential health effects of pesticide exposures, the EPA requires the highest level of quality assurance in the registration process. As the date for stricter federal regulations on pesticides approaches, SwRI has in place the strict quality assurance practices, the validated procedures and instrumentation to assist the pesticide manufacturers and formulators in meeting the strict requirements of the EPA registration or reregistration under FIFRA. SwRI also can provide trace level pesticide analytical support, method development and validation for water, air, soil, vegetable and fruit samples. ♦

*Comments about this article? Contact Sun at (210) 522-3954 or [gsun@swri.org](mailto:gsun@swri.org).*



*A mass spectrum library searching program is used for identification and confirmation of trace unknown impurity during GC/MS analysis.*