



## Pesticides: Topical & Chemical Fact Sheets

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# Assessing Health Risks from Pesticides

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The Federal Government, in cooperation with the States, carefully regulates pesticides to ensure that they do not pose unreasonable risks to human health or the environment. As part of that effort, the Environmental Protection Agency (EPA) requires extensive test data from pesticide producers that demonstrate pesticide products can be used without posing harm to human health and the environment. EPA scientists and analysts carefully review these data to determine whether to register (license) a pesticide product or a use and whether specific restrictions are necessary. This fact sheet is a brief overview of EPA's process for assessing potential risks to human health when evaluating pesticide products.

### Questions on Pesticides?

- Contact the National Pesticide Information Center (NPIC) 1-800-858-7378

## Background

There are more than 1055 active ingredients registered as pesticides, which are formulated into thousands of pesticide products that are available in the marketplace.

EPA plays a critical role in evaluating these chemicals prior to registration, and in reevaluating older pesticides already on the market, to ensure that they can be used with a reasonable certainty of no harm. The process EPA uses for evaluating the health impacts of a pesticide is called risk assessment.

EPA uses the National Research Council's four-step process for human health risk assessment:

**Step One:** Hazard Identification

**Step Two:** Dose-Response Assessment

**Step Three:** Exposure Assessment

**Step Four:** Risk Characterization

## Step One: Hazard Identification (Toxicology)

The first step in the risk assessment process is to identify potential health effects that may occur from different types of pesticide exposure. EPA considers the full spectrum of a pesticide's potential health effects.

Generally, for human health risk assessments, many toxicity studies are conducted on animals by pesticide companies in independent laboratories and evaluated for acceptability by EPA scientists. EPA evaluates pesticides for a wide range of adverse effects, from eye and skin irritation to cancer and birth defects in laboratory animals. EPA may also consult the public literature or other sources of supporting information on any aspect of the chemical.

## Step Two: Dose-Response Assessment

Paracelsus, the Swiss physician and alchemist, the "father" of modern toxicology (1493-1541) said,

"The dose makes the poison."

In other words, **the amount of a substance a person is exposed to** is as important as **how toxic the chemical might be**. For example, small doses of aspirin can be beneficial to people, but at very high doses, this common medicine can be deadly. In some individuals, even at very low doses, aspirin may be deadly.

Dose-response assessment involves considering the dose levels at which adverse effects were observed in test animals, and using these dose levels to calculate an equal dose in humans.

### **Step Three: Exposure Assessment**

People can be exposed to pesticides in three ways:

1. Inhaling pesticides (inhalation exposure),
2. Absorbing pesticides through the skin (dermal exposure), and
3. Getting pesticides in their mouth or digestive tract (oral exposure).

Depending on the situation, pesticides could enter the body by any one or all of these routes. Typical sources of pesticide exposure include:

- **Food**  
Most of the foods we eat have been grown with the use of pesticides. Therefore, pesticide residues may be present inside or on the surfaces of these foods.
- **Home and Personal Use Pesticides**  
You might use pesticides in and around your home to control insects, weeds, mold, mildew, bacteria, lawn and garden pests and to protect your pets from pests such as fleas. Pesticides may also be used as insect repellants which are directly applied to the skin or clothing.
- **Pesticides in Drinking Water**  
Some pesticides that are applied to farmland or other land structures can make their way in small amounts to the ground water or surface water systems that feed drinking water supplies.
- **Worker Exposure to Pesticides**  
Pesticide applicators, vegetable and fruit pickers and others who work around pesticides can be exposed due to the nature of their jobs. To address the unique risks workers face from occupational exposure, EPA evaluates occupational exposure through a separate program. All pesticides registered by EPA have been shown to be safe when used properly.

### **Step Four: Risk Characterization**

Risk characterization is the final step in assessing human health risks from pesticides. It is the process of combining the hazard, dose-response and exposure assessments to describe the overall risk from a pesticide. It explains the assumptions used in assessing exposure as well as the uncertainties that are built into the dose-response assessment. The strength of the overall database is considered, and broad conclusions are made. EPA's role is to evaluate both toxicity and exposure and to determine the risk associated with use of the pesticide.

Simply put,

RISK = TOXICITY x EXPOSURE.

This means that the risk to human health from pesticide exposure depends on both the toxicity of the pesticide and the likelihood of people coming into contact with it. At least *some* exposure and *some* toxicity are required to result in a risk. For example, if the pesticide is very poisonous, but no people are exposed, there is no risk. Likewise, if there is ample exposure but the chemical is non-toxic, there is no risk. However, usually when pesticides are used, there is some toxicity and exposure, which results in a potential risk.

EPA recognizes that effects vary between animals of different species and from person to person. To account for this variability, *uncertainty factors* are built into the risk assessment. These uncertainty factors create an additional margin of safety for protecting people who may be exposed to the pesticides. FQPA requires EPA to use an extra 10-fold safety factor, if necessary, to protect infants and children from effects of the pesticide.

### **Types of Toxicity Tests EPA Requires for Human Health Risk Assessments**

EPA evaluates studies conducted over different periods of time and that measure specific types of effects. These tests are evaluated to screen for potential health effects in infants, children and adults.

**Acute Testing:** Short-term exposure; a single exposure (dose).

- Oral, dermal (skin), and inhalation exposure
- Eye irritation
- Skin irritation
- Skin sensitization
- Neurotoxicity

**Sub-chronic Testing:** Intermediate exposure; repeated exposure over a longer period of time (i.e., 30-90 days).

- Oral, dermal (skin), and inhalation
- Neurotoxicity (nerve system damage)

**Chronic Toxicity Testing:** Long-term exposure; repeated exposure lasting for most of the test animal's life span. Intended to determine the effects of a pesticide after prolonged and repeated exposures.

- Chronic effects (non-cancer)
- Carcinogenicity (cancer)

**Developmental and Reproductive Testing:** Identify effects in the fetus of an exposed pregnant female (birth defects) and how pesticide exposure affects the ability of a test animal to successfully reproduce.

**Mutagenicity Testing:** Assess a pesticide's potential to affect the cell's genetic components.

**Hormone Disruption:** Measure effects for their potential to disrupt the endocrine system. The endocrine system consists of a set of glands and the hormones they produce that help guide the development, growth, reproduction, and behavior of animals including humans.

### **Risk Management**

Once EPA completes the risk assessment process for a pesticide, we use this information to determine if (when used according to label directions), there is a reasonable certainty that the pesticide will not harm a person's health.

Using the conclusions of a risk assessment, EPA can then make a more informed decision regarding whether to approve a pesticide chemical or use, as proposed, or whether additional protective measures are necessary to limit occupational or non-occupational exposure to a pesticide. For example, EPA may prohibit a pesticide from being used on certain crops because consuming too much food treated with the pesticide may result in an unacceptable risk to consumers. Another example of protective measures is requiring workers to wear personal protective equipment (PPE) such as a respirator or chemical resistant gloves, or not allowing workers to enter treated crop fields until a specific period of time has passed.

If, after considering all appropriate risk reduction measures, the pesticide still does not meet EPA's safety standard, the Agency will not allow the proposed chemical or use. Regardless of the specific measures enforced, EPA's primary goal is to ensure that legal uses of the pesticide are protective of human health, especially the health of children, and the environment.

### **Human Health Risk Assessment and the Law**

Federal law requires detailed evaluation of pesticides to protect human health and the environment. In 1996, Congress made significant changes to strengthen pesticide laws through the Food Quality Protection Act (FQPA). Many of these changes are key elements of the current risk assessment process. FQPA required that EPA consider:

- **A New Safety Standard:** FQPA strengthened the safety standard that pesticides must meet before being approved for use. EPA must ensure with a reasonable certainty that no harm will result from the legal uses of the pesticide.
- **Exposure from All Sources:** In evaluating a pesticide, EPA must estimate the combined risk from that pesticide from all non-occupational sources, such as:
  - Food Sources
  - Drinking Water Sources
  - Residential Sources
- **Cumulative Risk:** EPA is required to evaluate pesticides in light of similar toxic effects that different pesticides may share, or "a common mechanism of toxicity." At this time, EPA is developing a methodology for this type of assessment.
- **Special Sensitivity of Children to Pesticides:** EPA must ascertain whether there is an increased susceptibility from exposure to the pesticide to infants and children. EPA must build an additional 10-fold safety factor into risk assessments to ensure the protection of infants and children, unless it is determined that a lesser margin of safety will be safe for infants and children.

### **For More Information**

If you would like more information about EPA's pesticide programs, contact the Communication Service Branch at (703) 305-5017 or visit the [Pesticides Web site](#).

For more information on specific pesticides, or to inquire about the symptoms of pesticide poisoning, call the National Pesticide Information Center (NPIC), a toll-free hotline information at: 1-800-858-7378, or visit their [Web site](#) [EXIT Disclaimer](#) .