

From **LAB** to **LABEL**




CropLife
CANADA

President's message

Canadians have access to one of the most abundant, safe and affordable food supplies in the world, thanks in part to the pesticides that farmers use to protect their crops from pest infestations. Left unchecked, insects, weeds and diseases would significantly reduce the amount of food farmers are able to produce. And if food production were to go down, overall food costs would be higher, making it more difficult for many Canadians to enjoy the fresh fruits, vegetables and whole grains they rely on for good health.

Increasing yields is also beneficial because it means more jobs are created, tax revenue is generated and our overall economy is strengthened by the export of Canadian crops to over 150 other countries.

Pesticides also help protect the environment. Pesticides help farmers grow more food on less land, which means that natural spaces, and the biodiversity within, are preserved. Pesticides – when used in conjunction with plant biotechnology – make it possible for farmers to practice conservation tillage, which reduces soil erosion and improves overall soil health by leaving plant material to deteriorate in place thereby adding valuable organic matter to this important resource.

Before a pesticide can be used or sold in Canada, however, it must first be evaluated. In Canada, pesticides are assessed by Health Canada's Pest Management Regulatory Agency to ensure they can be safely used.

The plant science industry is committed to safety. *From Lab to Label* explains how a pesticide makes it from the discovery phase to a registered product for use or sale in Canada.

CropLife Canada is proud of the products our members develop and our commitment to safety and stewardship. We hope you find this booklet informative.

Sincerely,



Lorne Hepworth
President, CropLife Canada

Pesticides are one of the most stringently regulated products in Canada. Before a new pesticide reaches the market, it has gone through a rigorous testing and assessment process similar to the process that prescription drugs undergo. This process takes an average of nearly 10 years and costs over \$256 million. In addition, all pesticides in Canada must be re-evaluated at least every 15 years to ensure they meet the latest health and environmental standards.

What are pesticides?

Pesticides – or pest control products, as they are also called – are tools that are used to control weeds, insects, plant diseases, bacteria and other pests such as ticks, rodents and slugs.

Pesticide is an umbrella term used to describe any pest control product. There are numerous uses for pesticides so products are often categorized by use. Some of the common categories include:

- **Herbicides:** any product used to control weeds or unwanted plants
- **Fungicides:** any product used to control plant diseases, such as rots or mildew, caused by fungi
- **Insecticides:** any product used to control potentially damaging or harmful insects
- **Rodenticides:** any product used to control rodents such as mice or rats
- **Antimicrobials/sanitizers:** products used to kill microorganisms such as bacteria and viruses



HOW ARE PESTICIDES REGULATED IN CANADA?

Federal regulation

Pesticides are one of the most stringently regulated products in Canada.

All pesticides are regulated by Health Canada's Pest Management Regulatory Agency (PMRA). PMRA employs over 300 scientists, including biologists, chemists, toxicologists, epidemiologists, plant pathologists, weed scientists and entomologists, for the sole purpose of evaluating pesticides.

Before a pesticide can be approved for use in Canada, PMRA requires that it undergo a thorough scientific review and safety assessment to ensure it meets Health Canada's standards. Only those products that meet the strict health and environmental standards can be registered by the PMRA for use or sale in Canada.

Additional details on the PMRA's role and the federal regulatory process are provided later in this document or you can visit their website at www.healthcanada.gc.ca for more information.

Provincial and territorial regulations in Canada

Provinces and territories may be involved in: issuing pesticide use permits; imposing additional restrictions on pesticide use; regulating the transportation, sale, storage and disposal of pesticides; regulating the training, certification and licensing of pesticide applicators and vendors; and responding to spills or accidents.

Municipal regulation

Some municipalities have chosen to enact bylaws restricting pesticide use in their jurisdictions. These regulations are not based on science and are unnecessary.

It is important to note that while both provincial and municipal governments may restrict pesticides within their jurisdictions none have the scientific expertise of Health Canada. As such, these restrictions are based on ideology rather than scientific evidence. In fact, no jurisdiction that has imposed restrictions has demonstrated a scientifically valid health or environmental rationale for doing so.



Why do we need pesticides?

Each pesticide is designed for a specific pest problem and is used by farmers, foresters, gardeners, homeowners, golf courses and many others to control weeds, disease or insect infestations. These infestations, if left unchecked, could have serious consequences for human health and the environment.



Farmers use pesticides to protect their crops from disease, weeds and insects. By controlling these threats, farmers are able to increase their yields. Without pesticides, farmers would lose a significant amount of their crops which, in turn, would have an effect on Canadians at the grocery store. For example, many fruits and vegetables would be in short supply and food prices would increase. Pesticides also allow farmers to deliver more food using less land and less fuel. They also enable farming practices that protect valuable top soil.

Pesticides are also used by:

- Power companies to prevent weed growth which, if left unchecked, could cause power outages.
- Road and rail crews to keep roadsides and rail lines clear of vegetation, which increases visibility and prolongs the lifespan of the infrastructure.
- People responsible for park and sports field maintenance who use the tools to protect healthy plants and preserve green spaces from pest and weed infestations. These green spaces help to reduce the impact of climate change, reduce exposure to allergens (such as ragweed pollen) and provide us with safe, healthy and sustainable sports and recreation areas.

Around the home pesticides are used in a variety of ways including to get rid of ants in patio stones, protect lawns from grub or chinch bug damage, control poison ivy or other weeds and to protect us from mosquitoes and other insects. Our swimming pools require pesticides to keep them clean from bacterial contamination. Even household items such as paints and caulking may contain fungicides to prevent mould growth.

These are just a few of the many ways pesticides are commonly used in daily life. Without effective pest control products, our ability to manage pests would be diminished, which would have a significant impact on our everyday lives.

FROM LAB: Research and testing of a pesticide

TRUSTWORTHY STUDIES

Pesticide developers are required by Canadian and international regulatory agencies to complete a specific set of tests on prospective pesticides and then submit the data to the PMRA for review. In order to ensure the veracity of these results and to determine whether the product is acceptable in terms of safety, merit and value, PMRA requires that the tests and data package submitted were conducted according to Good Laboratory Practice (GLP).

These international standards cover the organizational process and the conditions under which laboratory and field studies are planned, conducted, monitored, recorded and reported. The standards are intended to ensure the quality and validity of test data and to improve the international acceptance of data generated according to these principles.

Test guidelines and the principles of GLP were developed by the Organisation for Economic Co-operation and Development so that test data that meets the standards will be accepted in other countries that follow these guidelines.

RESEARCH AND SCREENING

Developing a new pesticide starts in the lab where thousands of chemicals are screened in hopes of finding a new solution to specific pest problems. Developing new pesticides is very expensive and scientifically demanding so very few chemicals will ever make it past the early screening process. In fact, less than one in every 140,000 will eventually make it into a pesticide.

The first steps are usually done by software that is designed to sort the chemicals for promising characteristics. The computers generate a shorter list of chemicals with potential that are then run through

hundreds of different tests to separate out ones that might present an unacceptable risk so researchers can focus on those that show the most promise.

The chemicals that make it past this step are then evaluated to ensure they do what they are designed to do against the intended target. They are also screened for potential negative effects on beneficial insects or plants before advancing to the next stage. Just a handful of chemicals make it even this far in the screening process – a process that takes several years.

The next step is to test the chemicals in a greenhouse, where real-world situations are simulated, giving researchers a chance to evaluate the potential product for its ability to control the intended pests. Even though they have shown promise up to this point, many chemicals fail at this stage for a variety of reasons, including insufficient effectiveness against the intended pest or negative impacts on the plant it is intended to protect. Only a few chemicals will pass this stage and advance to more detailed studies.

In the next stage, any chemicals that have made it this far are assessed in greater detail to determine the potential to cause adverse effects in humans, animals, or the environment. If necessary, the chemicals may be modified at this stage to reduce their potential to cause unintended effects in humans, animals or the environment.



SAFETY ASSESSMENT: HEALTH, ENVIRONMENT AND VALUE TESTS

Only one or two chemicals will advance to the next stages of testing, which can take several years to complete. During this phase, Health Canada's PMRA mandates that over 200 individual tests – designed to ensure the final products will not pose health or environmental concerns – are completed.

The required studies are all identified on PMRA's website and fall into three general categories: health, environment and value.

Health

Before any pesticide is approved, the chemical is subjected to a number of studies designed to determine whether varying exposure to a pesticide might cause adverse effects and – if so – what kinds and at what dose.

Health Canada dictates how the tests must be conducted and requires that Good Laboratory Practice (GLP) is followed so that results are valid, consistent and comparable.

Health tests must be completed to evaluate any potential risks to applicators or the public through exposure during mixing, use and entry into areas that have been treated. These studies must also identify at what dose level a problem may occur from exposure to a pest control product.

Tests are also completed to determine whether a given pesticide would be likely to remain as a residue on food if applied to a crop. The data from these residue studies then determines how a pesticide should be used to ensure that any remaining residues are at levels low enough to not pose health concerns.

The Canadian Food Inspection Agency (CFIA) monitors pesticide residues on foods. It released a report in 2012 that analyzed 3,078 samples of apples, small berries, leafy greens and tomatoes for over 400 different pesticide residues. According to the report, more than 99 per cent of tested food samples were below Health Canada limits for pesticide residues.



WHAT'S ON MY FOOD?

The Canadian Food Inspection Agency (CFIA) monitors pesticide residue levels on food. According to a report released in 2012, 99 per cent of the fruits and vegetables they tested complied with Health Canada's standards for pesticide residues on Canadian food products. In fact, most had no detectable levels whatsoever.



– According to 2009-2010 statistics

Environment

Environmental tests are used to identify any possible effects on mammals, species of birds, fish, insects and other plants that are not the intended target of the pesticide being tested. Tests are also done to determine what happens to the chemical in the environment. These studies, which are also called environmental fate studies, are used to determine how the product might break down and whether it will persist in the air, soil or water.

These studies include:

Persistence – how long the product remains in the environment

Mobility – can the chemical and its breakdown products move in the environment

Dissipation – how the product breaks down in soil and water

A breakdown product is the result of the pesticide breaking apart into other chemicals when exposed to sun, moisture or bacteria in the soil. Industry is

committed to full lifecycle responsibility so understanding how a product breaks down is an important part of the process. In addition, it is part of the PMRA's environmental assessment. If a product or one of its breakdown components might persist in the environment further studies will be done to ensure that they are not likely to be harmful. In many cases the chemical breaks down into harmless components like carbon dioxide and water.

Value

The evaluation process also requires a manufacturer to demonstrate that the new product has merit and value. After passing the greenhouse evaluations, products undergo field evaluation to ensure that earlier results can be replicated in the real world. This stage can take several years as researchers study how the chemicals perform on a variety of pests and under different soil and weather conditions. Researchers also continue to monitor for any undesirable effects. The data from these tests helps determine how the pesticide should be applied to make sure the final product does what it is supposed to do.

TO LABEL: Health Canada assessment

Pesticides are one of the most stringently regulated products in Canada; all pesticides are regulated by the PMRA, which employs over 300 scientists – including biologists, chemists, toxicologists, epidemiologists, plant pathologists, weed scientists and entomologists – for the sole purpose of evaluating pesticides.

Once the developers have completed the research and tests on a pesticide described in the previous section, they submit the data to the PMRA for independent assessment according to the Pest Control Products Act.

Evaluators at the PMRA cross-check the data against other research findings, including epidemiology studies published in peer-reviewed literature, when the information is available. PMRA also routinely consults with other international organizations that have conducted scientific reviews of the same product.

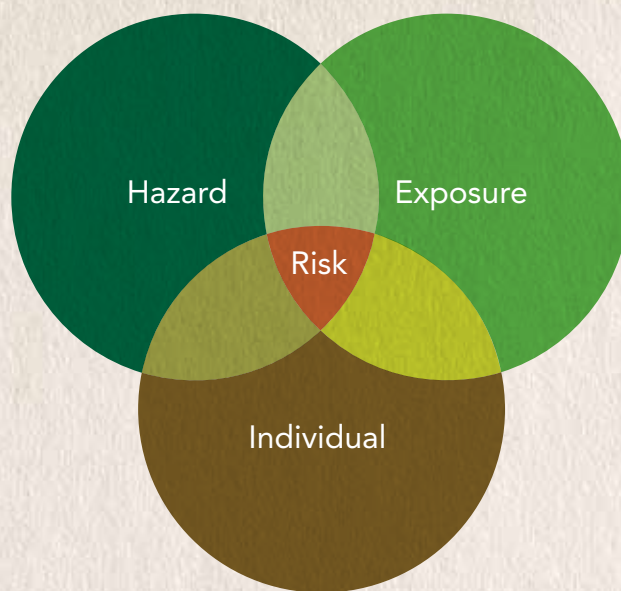
The registration process also involves a detailed risk assessment that draws from all of the research data. Potential risks from the use of pest control products are assessed according to the equation: $RISK = HAZARD \times EXPOSURE$.

THE PEST CONTROL PRODUCTS ACT

The responsibilities of the PMRA are mandated by the Pest Control Products Act (PCPA). The PCPA:

- Covers all pest control products, including those used in agriculture, forestry, industrial, public health and household applications
- Regulates all pest control products used, manufactured in or imported into Canada through a scientifically-based national registration system
- Minimizes health and environmental risks and encourages the development of innovative, sustainable pest management strategies
- Provides extensive transparency measures and public consultation requirements
- Provides additional safety factors for children and pregnant women and takes into account cumulative pesticide exposure from all sources, including food and water
- Requires that all pesticides be re-evaluated on a minimum 15-year cycle

RISK = HAZARD × EXPOSURE



Risk is a product of both hazard and exposure. As either the hazard or exposure changes, so too does the level of risk. For example, a hammer is a hazard to your thumb, but as long as the hammer is lying on the table, it is not a risk. However when you lift the hammer over your hand, it poses a risk.

Once the PMRA has finished its detailed review and risk assessment, it publishes a proposed decision on its website. Anyone can comment on the proposed decision and review the scientific research before PMRA makes its final decision about a product. The decision to register a pesticide is only made if the PMRA concludes that there is sufficient scientific evidence to show that the product does not pose an unacceptable risk to human health or the environment and that it serves a useful purpose.

THE PRECAUTIONARY PRINCIPLE

The use of precaution is the foundation for Canada's regulatory system. The primary objective of Health Canada's PMRA is *"...to prevent unacceptable risks to people and the environment from the use of pest control products."*

The precautionary principle is specifically enshrined in Canada's pesticide legislation to prevent negative health impacts or environmental issues.

The regulation process for pesticides is inherently precautionary with its required pre-market assessments and prevention of unacceptable risks. In fact, the PMRA uses highly precautionary assumptions of exposure and applies significant safety factors to address scientific uncertainty. As such, if PMRA scientists consider that the risks to human health or the environment are not acceptable, a registration will not be granted.



ALL COMPONENTS OF A PESTICIDE ARE REGULATED

Pesticides are generally composed of one or more active ingredients that are designed to affect a pest in combination with other ingredients. These additional ingredients are called formulants and they are also regulated by the PMRA.

According to the PMRA, a formulant is any substance, other than the active ingredient in a pesticide, that is intentionally added to a pest control product to improve its physical characteristics such as sprayability, solubility, spreadability and stability. Data on these chemicals is required to be submitted to the PMRA to be assessed as part of the pesticide evaluation process. The end use product, including all formulants, is evaluated by the PMRA to ensure the product as a whole meets health and safety standards.

RE-EVALUATION AND SPECIAL REVIEW

The PCPA makes it mandatory for all active ingredients to be re-evaluated at least every 15 years. In the meantime, the PMRA will keep track of any research on the products as well as decisions from other regulatory agencies on an on-going basis to ensure that products being used by Canadians continue to be safe for use. If at any time new information indicates that a pesticide could pose unacceptable risks, the information is evaluated and appropriate action is taken. After the re-evaluation is completed, a regulatory decision will be made based on the review of the data and the risk assessment. Any member of the public also has the right to request a special review on a product at any time if that person has scientific data that demonstrates a potential issue.

Re-evaluation or special reviews may lead to regulatory changes that range from minor changes to the product label or redefined conditions for use, all the

THE PESTICIDE LABEL

The pesticide label is a legal document that specifies the correct use of the product so that risks to human health and the environment are minimized. The label is required to include:

- The Pest Control Product registration number
- Name and concentration of the active ingredient
- Hazard statements and warning symbols
- Detailed instructions for use
- Instructions and warning labels about specific hazards, including First Aid information
- Protective clothing requirements
- Toxicological information including signs and symptoms of poisoning
- Product storage and container disposal instructions
- Time limits on re-entry to treated areas and pre-harvest intervals for treated crops
- Environmental precautions or warnings
- Any other information as deemed necessary to ensure safe and proper use

way to suspension or cancellation of the registration. This process ensures that all registered products meet current scientific and regulatory standards, perform within the limits of acceptable risk that protect the environment and general public and continue to provide their intended benefits.

Stewardship programs

CroLife Canada has developed many stewardship programs to complement existing laws and regulations for managing pesticides. These programs range from

research and discovery through to recycling or disposal of unwanted products. For more information on our stewardship activities, visit www.croplife.ca.

Conclusion

CroLife Canada is the trade association that represents the manufacturers, distributors and developers of plant science technologies, specifically pesticides and plant biotechnology. Our members work to provide Canadians with innovative products that protect the environment and contribute to a healthy food supply, a vibrant economy and well-maintained parks and recreational facilities.

Our industry invests heavily in research and development and is continually innovating to create newer, safer pesticides. The industry in Canada has developed

world-leading stewardship programs to properly manage its products along their entire lifecycle.

Canada has established a world-class process to evaluate pest control products. Based on sound scientific principles, this process evaluates the risk to human health, food safety and the environment of any product put forward for registration. This system of scientific and regulatory checks and balances assures that safeguards are in place for the protection of all Canadians and our environment throughout the full lifecycle of a pesticide.





www.croplife.ca