

Assuring health and environmental safety of herbicides

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Summary

The development of a new herbicide is extremely costly and time consuming. Research and development may take 10 years and cost \$50-70 million. Safety is the over-riding consideration – a major portion of the time and expense is utilized in determining that the product is effective and poses no threat to health or the environment under intended use conditions.

Once a candidate herbicidal product has been identified by Monsanto, it undergoes a preliminary assessment of safety and environmental compatibility. If it passes this initial screen, efficacy, toxicology and environmental testing continue concurrently. The product may fail to reach commercialization due to adverse findings in any of these facets of testing. A product is subjected to more than 120 separate tests to ensure it will not present any health or environmental concerns.

Health and environmental safety testing is designed to meet the requirements

of laws and regulations world-wide, which mandate strict standards that must be met before herbicides can be marketed.

The development of a new herbicide is extremely costly and time consuming. Moving a herbicide from the discovery stage to the marketplace, for example, may take 10 years of research and development and cost upwards of \$50 million. This cost does not include the tens of millions of dollars that may be needed to design and build a production facility.

Part of the research and development cost is associated with assessing the efficacy of the product. A product must not just be effective but must be determined to be cost-effective. It must work effectively against target weeds at a cost that is balanced or exceeded by the benefits. These benefits may be such things as increased crop yield or reduced disease incidence from control of pest hosts.

However, determining the cost effectiveness is only part of the research and development budget. Safety is the over-riding consideration in pesticide research and development. The major portion of the \$50 million is spent in determining that the product poses no threat to health or the environment under intended use conditions.

Health and environmental safety testing begins as soon as a candidate product is identified in the laboratory. Once a promising herbicide has been identified by Monsanto, it undergoes a preliminary assessment of safety and environmental compatibility based on available information on itself or similar chemicals, together with the results of preliminary testing by Monsanto.

The safety profile of the candidate product is as important as its efficacy in any decision to continue its development. If it passes this initial screening, efficacy, toxicology and environmental testing continue concurrently.

A promising herbicide which passes initial efficacy and safety screening is moved from the laboratory and greenhouse to expanded testing in field studies which document the performance of the product under actual use conditions. At the same time, potential environmental effects are assessed, such as persistence and dissipation. Meanwhile, in the laboratory, the physico-chemical profile is established and toxicology studies continue.

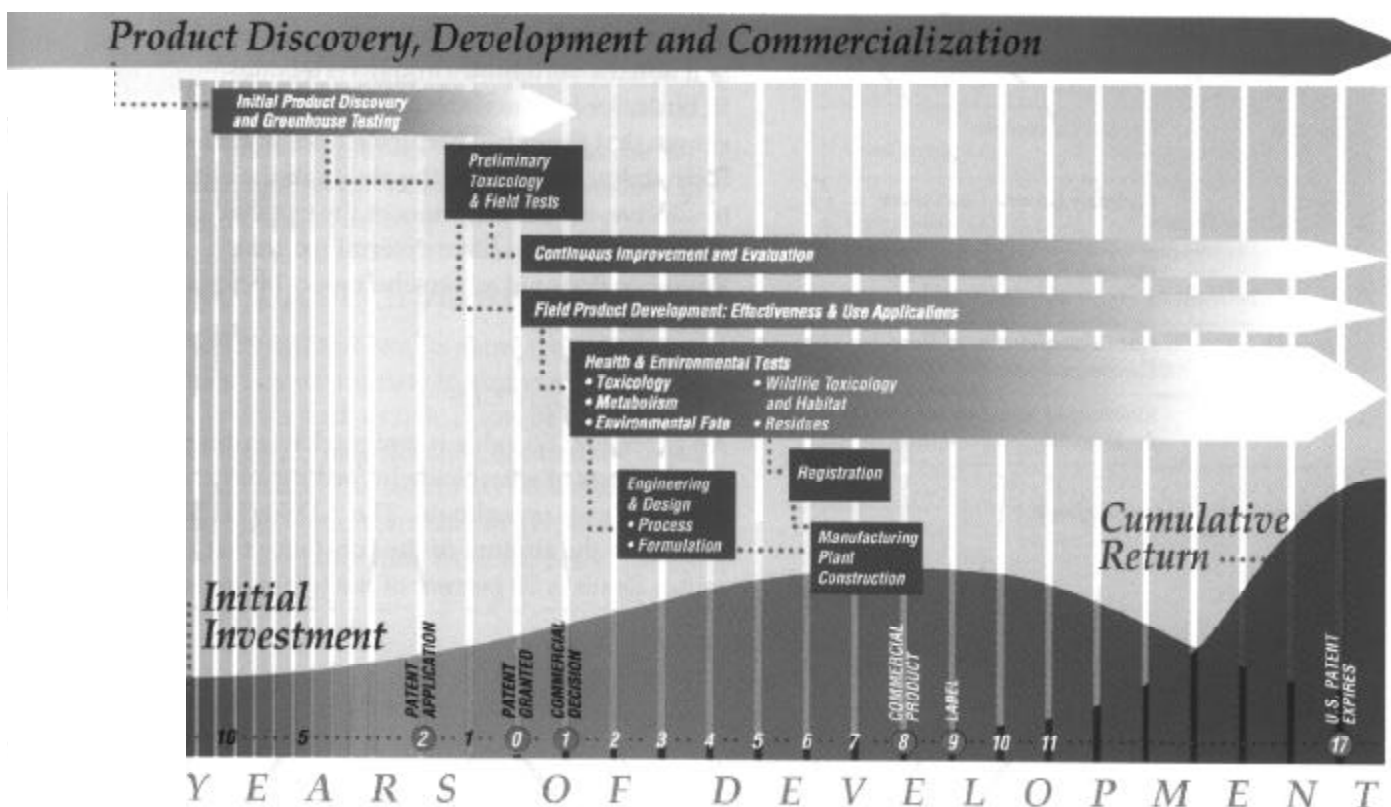


Figure 1. Health and environmental safety are integrated into the research and development process for a new herbicide. Safety is the over-riding consideration in the decision to commercialize a product.

The product may fail to reach commercialization due to adverse findings in any of these facets of testing. A product is subjected to more than 120 separate tests to ensure it will not present any health or environmental concerns.

Health and environmental safety testing is designed to meet the requirements of laws and regulations world-wide, which mandate strict standards which must be met before a pesticide product can be sold. A range of studies, which represent best science, must be conducted and information from them submitted for evaluation by scientific experts appointed by government authorities.

Research studies include those related to:

Physico-chemical properties

- active constituent
- formulated product

Toxicity testing in animals

- acute effects of single doses
- chronic effects of lifetime exposures
- effects on reproduction
- mutagenic effects on genes and inherited traits
- carcinogenic effects during lifetime exposures

Metabolism

- breakdown in animals
- breakdown in plants

Residues in food and animal feed

- raw crops
- processed food
- animal products – meat, milk, eggs
- animal feed

Environmental fate

- breakdown in soil, water, air, plants
- movement by run-off, leaching, spray drift

Ecological effects

- birds – acute and chronic toxicity
- fish – acute and chronic toxicity
- invertebrate – acute and chronic toxicity
- non-target plants – short and long-term effects

Efficacy

- performance under a wide range of conditions
- safety to crops

All these studies are conducted according to strict standards, designed to ensure the quality and integrity of the research data. It may take up to eight years from the initial screening of a candidate herbicide until the studies are completed and ready for submission to regulatory authorities. The authorities then take another one to two years to complete a thorough review of the data. When regulatory approval is finally granted, the product can be used with confidence, knowing that it has been comprehensively tested and checked to assure it is safe and effective when used according to the label directions.

Regulatory perspectives of agricultural chemicals

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Paper not submitted.