More than 150 safety studies – designed and validated by regulatory authorities – are conducted on each potential crop protection product before its approval for commercial use. The studies are designed to evaluate all circumstances of human and environmental exposure.

Experts from regulatory authorities review the data and conduct risk assessments looking at the product’s toxicological profile and dose and exposure levels – to understand if the crop protection product can be used safely.

The authorities estimate how much exposure is likely to happen based on how the product will be used. They also set strict rules around potential residues. Generally a product is considered safe for use when the likely exposure is at least 100 times lower than the dose that causes no adverse effects in the studies.

Only the products that meet all stringent regulatory requirements are authorized.

The generation of regulatory data continues even after product authorizations have been granted.

There are several requirements for post-authorization data:

- Periodic review of authorizations
- Requests for post-commercial monitoring data or additional data on product safety
- Changes in regulatory systems
- Changes in regulatory systems

Our commitment to data transparency. Find out more at croplife.org/data-transparency

The pesticide authorization process is one of the most stringent product approval processes in the world.

The generation and use of safety studies

The studies provide data on:

- Health and environmental safety
- Efficacy and quality of the product

The studies are carried out in compliance with Good Laboratory Practice (GLP): an international framework for conducting safety tests that ensures quality and integrity of the data generated.

The cost and length of process

The crop protection industry spends an average $71m on toxicology and environmental safety tests for every product brought to the market. These tests help ensure that pesticides only receive regulatory approval if they are safe for human health and the environment.

The average time to take a product from discovery to commercial use is 11 years. Much of the increase is due to the rise in volume and complexity of data required by regulatory bodies to ensure products are safe and effective.

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