

# THE REGULATORY DATA BEHIND PESTICIDES

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

## THE GENERATION AND USE OF SAFETY STUDIES

# 150 STUDIES

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



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 studies provide data on:



Health and environmental safety



Efficacy and quality of the product

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



# 100 TIMES LOWER

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 COST AND LENGTH OF PROCESS

# \$71 MILLION

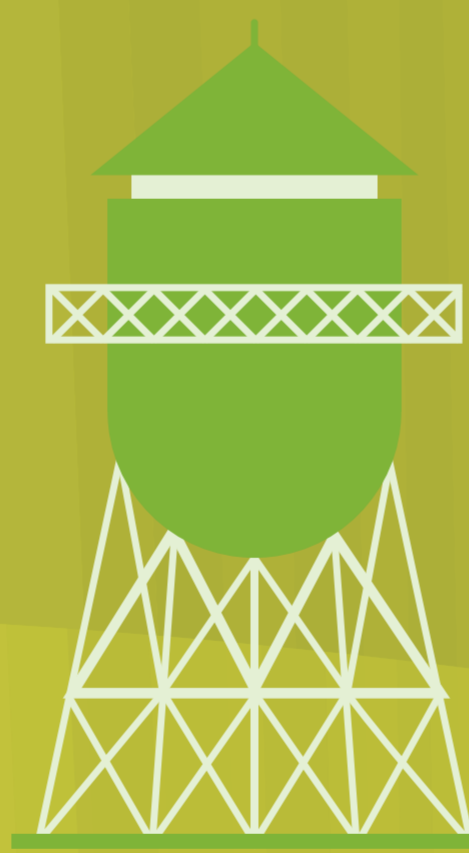
The crop protection industry spends an average \$71m on toxicology and environmental safety tests for every product brought to the market. These tests help ensure that pesticides only receive regulatory approval if they are safe for human health and the environment

# 11 YEARS

Average time to take a product from discovery to commercial use

# 55%

The increase in cost of bringing crop protection products to market since the turn of the century



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

## DATA GENERATION POST-AUTHORIZATION

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



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