

Hazard vs Risk

$$\text{RISK} = \text{HAZARD} \times \text{EXPOSURE}$$

Hazard is not the same as risk.

There is often confusion between the terms hazard and risk, causing them to be used incorrectly. There is a fundamental difference between the two.

HERE'S AN EXAMPLE OF HAZARD VS RISK



HAZARD

Anything that can cause harm

LOW RISK



RISK

The likelihood of harm being done and the extent of that harm

HIGH RISK



The Importance of Dosage

— REMEMBER —

It's the dose that makes the poison

Many substances that are vital in small amounts can be lethal in large doses.

— HERE'S AN EXAMPLE —

The body needs
salt



BUT

57g

of salt is considered a fatal dose for a child.

Many fruits including
pears naturally contain



BUT

Formaldehyde

can be deadly if consumed at high concentrations.

formaldehyde
(100µg/kg)

Ingestion of as little as **30ml of a solution containing 37% formaldehyde** has been reported to cause death in adults.¹

¹Medical Management Guidelines for Formaldehyde

Animal Testing

Animal testing is required under EU law to ensure that pesticides, and other chemicals, **are safe for humans and the environment.**



The pesticides industry works hard to minimise animal testing

by applying **intelligent testing strategies**, in line with ECPA's commitment to the **"3 R's Principle"**:



1

REFINE

2

REDUCE

3

REPLACE

Pesticides and biopesticides

A guide to the stringent scientific testing required by EU Regulation



FROM
Research



TO
Approval

These substances are some of the most rigorously tested products in the world.

PHASE 1

Research

Each manufacturer has its own unique research strategy to find potentially suitable, safe substances.

To identify **ONE POTENTIALLY MARKETABLE PESTICIDE OR BIOPESTICIDE** an agrochemical company screens **HUNDREDS OF THOUSANDS OF SUBSTANCES**

TESTS

cover chemistry, biology, efficacy, toxicology and ecotoxicology

TESTING STARTS SMALL...

BY THE END OF THE RESEARCH PHASE, THERE IS A

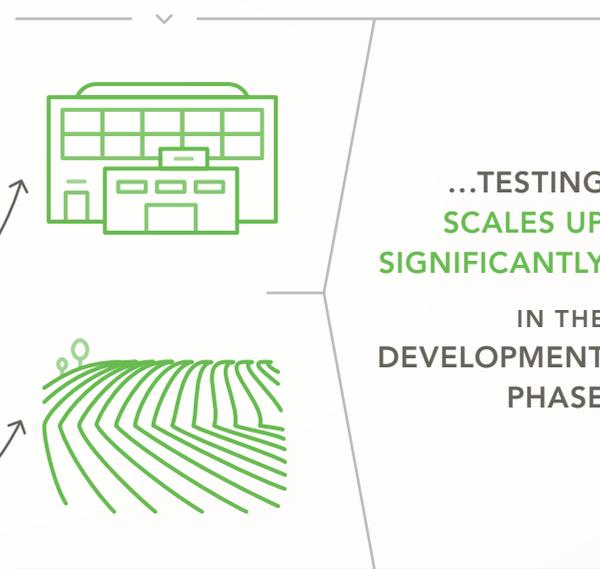
60% CHANCE

THAT THIS SUBSTANCE WILL BE BROUGHT TO THE MARKET

PHASE 2

Development

Much of the testing in this phase will consider the safety for humans, animals and the environment, it is often designed and conducted by independent bodies, adhering to international testing obligations as laid out by the OECD principles of **Good Laboratory Practice**.



GOOD LABORATORY PRACTICE

refers to a high quality system for research laboratories and organisations which allows regulatory authorities to independently assess the quality, reliability, integrity and reproducibility of testing.



PHASE 3

Approval and Registration

Before a substance is approved in the EU, more than 100 specific tests are conducted to ensure its safety.

A company submits test and study results to a designated national authority for approval



The evaluation is carried out by **one Member State**



Reviewed by **EFSA** and all the other Member States

European Commission submits a decision proposal to a Member States' Committee vote



Member States authorise and register products containing the substance for use on the national market

Reviews and Controls

A substance approval or product registration may be reviewed by authorities at any time in light of new scientific evidence.

A PERPETUAL REVIEW



Older products must be routinely reviewed by both the manufacturer and the authorities to ensure that they meet the most up to date safety standards.

ONGOING

PESTICIDE AND BIOPESTICIDE: FROM RESEARCH TO APPROVAL

UP TO **11**

YEARS

Source:

The Core of New Agrochemical Product Discovery, Development and Registration in 1995, 2005-8 and 2010 to 2014. Phillips McDougall. March 2016.