Hazard vs Risk

RISK = HAZARD × 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

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

LOW RISK

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 **formaldehyde** *(100µg/kg)*

BUT
Formaldehyde
can be deadly if consumed at high concentrations.

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

[1] Medical 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.

ecpa.eu
@cropprotection

European Crop Protection

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**.

...TESTING SCALES UP SIGNIFICANTLY IN THE DEVELOPMENT PHASE

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

PESTICIDE AND BIOPESTICIDE: FROM RESEARCH TO APPROVAL UP TO **11** YEARS

Reviews and Controls

ONGOING

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.

BETWEEN **2005-2008** the cost of discovery and development of a substance was up to **€189 million**

BETWEEN **2010-2014** this cost increased to up to **€215 million**

AN **11.7%** INCREASE

Source:

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