

QUALITY & INTEGRITY of our DATA



////////// is the foundation of product safety in agriculture

Before a *pesticide* or *GM plant* is approved for use on the market...



Numerous *safety studies* are conducted according to *scientific principles and quality standards* mandated by global regulatory agencies.

Regulatory bodies around the world protect and ensure the *health of people, animals* and the *environment*.

Did You Know? Up to **150¹** different safety studies are required per product to evaluate and demonstrate safety.



Overarching international *safety frameworks, supported by scientific principles*, define testing standards used in safety studies & are set by organizations such as Codex² and OECD³.

Did You Know? To bring a *pesticide* to market, it can take **11 years** & cost **\$286 million**; similarly, bringing a *GM plant* to market can take **13 years** & cost **\$136 million**. This represents the time and cost for research & development, required safety testing, and government approval processes.⁵

To gain product authorization, *country-specific safety and data requirements must also be met*. These are established by national regulatory agencies, like the EPA,⁶ EFSA and Health Canada.⁸

Did You Know? Biotech products have been approved in **60⁹ countries** for GM food, feed and cultivation & pesticides have been registered in **150⁺ countries**.

Standards Make Sense⁴

5000 years ago, the invention of the calendar (similar to ours today) helped to standardize agricultural practices - such as when to plant and harvest crops. This predictability allowed ancient farmers to coordinate trade.



In the 1800's, the first recorded instance of developing and implementing technical standards involved screw threads.

Before standardization, screw threads varied in quality (sizes, material used, etc.). Product *efficiency and consistency* resulted from adopting standards & by 1947, quality systems had been implemented, further securing *customer confidence*.



During the 20th century, as cities became more populated, national standardization was critical in ensuring the *safety* of city infrastructure. This is why fire safety equipment is *uniform and universally compatible*.



Today, standardization is commonplace for most products including cell phones, automobiles and computers.



References:

- 1 CropLife International - bit.ly/2B6JGxp
- 2 Codex Alimentarius Commission - bit.ly/2D1qvUJ
- 3 Organisation for Economic Co-operation and Development - bit.ly/2CsC4dq
- 4 American National Standards Institute - bit.ly/2Pdh5f
- 5 Phillips McDougall - bit.ly/2x0YCCB & bit.ly/2x2ZcaZ
- 6 Environmental Protection Agency - bit.ly/1N1W4bq
- 7 European Food and Safety Authority - bit.ly/2K4B1B8
- 8 Health Canada - bit.ly/2B2Tz7C
- 9 ISAAA - bit.ly/1pB8z3r

Is the *Data* Trustworthy?

Quality Systems are an integral component supporting the rigorous planning and execution of safety studies to ensure data is **reproducible, reliable, traceable and credible**.

REPRODUCIBLE

The resulting data can be independently replicated.

RELIABLE

Data collection is consistently performed by all personnel.

TRACEABLE

All raw data are maintained and can be retrieved for review & study reconstruction.

CREDIBLE

All personnel meet the requirements of proper education, training and/or experience to perform the tasks.

Quality Systems act as **checks and balances** to ensure the data is of high quality and integrity & minimize errors.

Our License to Operate as a business is completely dependent upon producing products that are **safe and valuable** to our customers.



Rigorous science strengthened by quality systems ensure products are **safe** for **people, animals** and the **environment**.

 Science for a **better life**

Quality Systems & Standards we follow:

Good Laboratory Practices (GLPs) Principles outlining how safety studies are planned, performed, monitored, recorded, archived and reported to maintain quality and integrity of study data that support regulated products.

In general, our studies are conducted under GLPs & these principles have been established in countries around the world. bit.ly/2MFgw1q



Facility inspections, audits and intense data reviews are performed randomly by regulatory authorities (like the EPA in the US) to ensure compliance & detect potential violations.

International Organization for Standardization

(ISO) Independent and internationally recognized standards that focus on process improvement to ensure quality, safety and efficiency.

ISO standards significantly contribute to a continuous evaluation of quality system management which includes identifying & implementing improvements. bit.ly/2tu1qpw



ISO certification is voluntary & an independent, 3rd party body provides certification that requirements are being met.

Bayer laboratories and manufacturing sites around the world have received this certification.

To Learn More:



Bayer - The Regulatory Process to Bring Pesticides to the Market bit.ly/2QUA2N9



Bayer (legacy Monsanto) - People, Processes and Regulations to Submit a Product for Regulatory Review bit.ly/2J2c9AP



Environmental Health Perspectives - Assessing the Reliability and Credibility of Industry Science and Scientists bit.ly/2z9p8Mz



Wired - Turn of the Century bit.ly/2pVOE3q



Bayer - Farm Meets Table: How to Meet a Mom's Safety Standards bit.ly/2pX4RVW



Bayer - Transparency Initiative bit.ly/2Hb9g1K