ENVIRONMENTAL RISK ASSESSMENTS (ERAs)

CropLife INTERNATIONAL

With more than 25 years of experience, risk assessors have a wealth of data on safety to help them evaluate a range of genetically modified (GM) crops under various growing conditions.

Despite this, regulatory authorities are inconsistent around the world in both the data they ask for and their methodology of assessment.

It's time for a refined and harmonized approach to ERAs.

VITAL PROCESS

AGRICULTURE MADE UP 41%

of employment in Ghana in 2017.

OPPORTUNITIES COULD BE GAINED

$79 MILLION

The introduction of GM insect resistant cowpea could add $79 Million USD of economic benefit to the Ghanaian economy over the next 6 years.**

OPPORTUNITIES ARE LOST

In **China**, it is estimated that the economy lost $12 Billion USD per year between 2009 and 2019 due to delaying the introduction of GM insect resistant rice.*

25 YEARS

GM crops have been cultivated safely for more than 25 years.

IT'S TIME FOR DATA COHESION

Existing knowledge and experience with GM crops, traits and a history of safe use can be used to inform safety assessments and **streamline data requirements.**

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Harmonized requirements would also provide **consistent data** for regulators.

KNOWLEDGE IS POWER

Knowledge of GM crops that are popular today will inform the **GM crops** of the future:

POPULAR TODAY	IN THE FUTURE
Corn	Rice
Soybean	Cowpea
Cotton	Cassava
Canola	Banana
Papaya	Chickpea

*https://www.frontiersin.org/articles/10.3389/fpls.2019.01226/full
**Estimation from Dzanku et al (2019), IFPRI/STEPRI

ENVIRONMENTAL RISK ASSESSMENTS (ERAs)

Streamlining ERAs for genetically modified (GM) crops can maintain high standards for environmental safety and minimize the regulatory burden for developers.

The goal of all regulatory agencies globally is the same – to protect human/animal health and the environment.

Environmental risk assessments (ERAs) help regulators understand whether GM crops pose any risk to the environment, and if so, how these risks can be effectively managed. ERAs should be conducted using a science-based approach, which uses problem formulation to develop plausible scientific hypotheses on how the GM crop may result in environmental harm.

Risk assessors have more than 25 years of collective experience in assessing the safety of GM crops for cultivation. Despite this experience, problem formulation is not always used, and the collective underlying knowledge about GM crops is not leveraged as part of the risk assessment. As a result, the data that is required for cultivation approvals is not always warranted and assessment methods are not science-based.

Refining and harmonizing global ERA data requirements will add transparency and predictability for product commercialization.

Streamlined and predictable approaches to ERAs can encourage the development of new GM crops that enable new environmentally sustainable solutions to agricultural challenges. A few studies should be universally required to inform the ERAs for all crop and trait combinations. Additional data may be relevant in certain circumstances depending on the crop and trait.

- ERAs should ensure protection goals are met.
- The data that informs the risk assessment for any GM crop is limited. Any additional data should be required on a case-by-case basis if it informs the risk assessment for the specific crop and trait.
- Existing knowledge of GM crops and traits coupled with a history of safe use should be considered when structuring an ERA.
- Data transportability – where studies and/or safety conclusions from one country are leveraged to inform the safety assessment in another country – this contributes to the harmonization and streamlining of regulatory and data requirements.

Almost **370 events** have been approved for cultivation all around the world.

(ISAAA, 2018)

Relevant data for informing ERAs

Relevant for all crops and traits:

- Understanding the growing environment and basic biology of the crop.
- Comparing the agronomic similarities of the GM crop to its conventional counterpart.
- Understanding the intended trait of the GM plant and assessing whether it could lead to environmental harm.

Relevant on a case by case basis:

For crops:

- Assessing potential changes to agricultural practices.
- Generating additional agronomic data on features of the GM trait that may influence the ERA.

For the introduced pesticidal trait:

- Identifying potential harm to beneficial non-target organisms.
- Determining the environmental fate in soil, sediment, or surface water.

Examples of data that does not inform the ERA:

- Molecular characterization
- Composition
- Product efficacy

RISK = HAZARD X EXPOSURE

Risk only occurs when there is exposure to something hazardous

FOOD AND FEED SAFETY ASSESSMENT

CropLife INTERNATIONAL

Despite decades of safe consumption, the data requirements for regulatory approvals of genetically modified (GM) crops are inconsistent around the world.

It's time to unify around a streamlined, science-based approach to GM crop approvals.

A GLOBAL SUCCESS STORY

25 YEARS

GM crops have been **safely cultivated** worldwide for more than 25 years.*

$186bn

GM crops have provided global economic gain of $186 bn USD over 21 years.*

Since 1996, the global area planted with GM varieties has increased **more than*** **113-FOLD**

3,500

More than 3,500 food/feed safety evaluations passed, with **0 rejections** based on food/feed safety.*

SUSTAINABLE CAPABILITIES

27.1bn kg SAVING

The commercialization of GM plants led to a saving of 27.1bn kg in CO2 emissions in 2016, equivalent to taking **16.7 million cars** off the road for a year.**

A LACK IN GLOBAL CONSISTENCY LEADS TO:

REDUCED PRODUCT CHOICE

for farmers and consumers

DISRUPTIONS IN TRADE

and delays in commercial launches

ADDED COSTS

$4.9bn

USD in soybeans

HUGE POTENTIAL

A well-defined, consistent, and science-based approach to assessments would lead to:

- **greater innovation,**
- increased **commercialization** of beneficial GM crops and traits,
- a **streamlined** global review process with more efficient approvals.

With more timely GM plant approvals between **2018-2022**, major export countries could increase production by**:

$4.3bn

USD in corn

IT'S TIME FOR A NEW APPROACH

Safety assessments for GM crops should focus on characterizing risks

A new approach could look like this:

Core studies
to evaluate safety of GM crops.

Supplementary studies
in specific cases.

Supplementary studies
should be designed depending upon the crop, introduced trait and/or the intended use.

*ISAAA. (2017). Global status of commercialized biotech/GM crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years. In ISAAA brief (Vol. 53): ISAAA: Ithaca, NY. ISAAA. (2018). Global status of commercialized biotech/GM crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change. In ISAAA brief (Vol. 54). ISAAA: Ithaca, NY.
**Informa. (2018). The Impact of Delays in Chinese Approvals of Biotech Crops. In Informa Agribusiness Consulting Group Report.

FOOD AND FEED SAFETY ASSESSMENT FACT SHEET

CropLife INTERNATIONAL

Despite 25 years of safe use, the data requirements for regulatory approval of genetically modified (GM) crops are inconsistent from country to country resulting in added costs, less predictability and longer approval timelines.

In thousands of evaluations throughout those 25 years, GM crops have been repeatedly proven to be as safe as their conventional counterparts. Nonetheless, certain countries require data that does not add value to a safety assessment for humans and animals.

This results in significant delays to commercialization of GM crops, thereby hindering innovation.

It is time to evaluate how food/feed safety assessments are conducted for GM crops, and focus data requirements to address plausible risk.

Safety assessments should focus on a systematic approach to risk characterization.

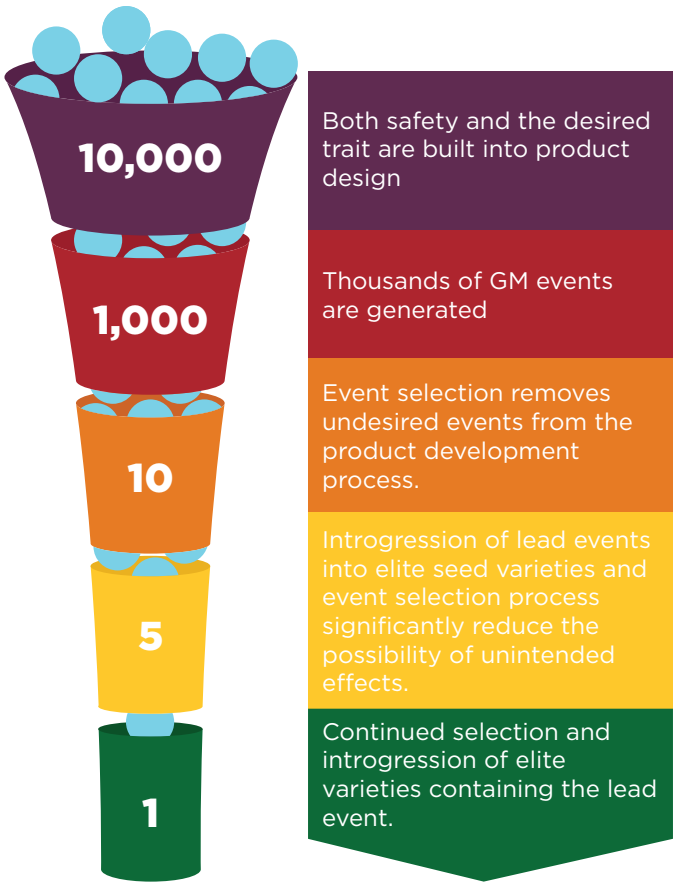
A problem formulation approach should be used to address any questions about product safety. This involves identification of hazard and/or exposure, which are components of risk. A stepwise, weight of evidence method should be followed when assessing the safety of newly expressed substances (protein or DNA) in alignment with Codex Alimentarius principles.

Something hazardous has the potential to cause harm — but only when there is exposure. In the case of GM crops, if there is no identified hazard scenario, there is no risk. As such, a set of core studies are recommended to evaluate safety.

In the absence of hazard, these core studies are sufficient to conclude that GM plants are as safe as their conventional counterpart. However, depending on the type of GM crop and potential for hazard scenarios, there may be a need for supplementary studies to fully characterize risk and assess safety.

Supplementary studies, if needed, should be designed using specific hypotheses around the crop, nature of the introduced trait and/or the intended use. This would help to streamline the review process across jurisdictions and provide a clear, consistent path to commercialization for developers.

The commercial development process for new GM varieties considers safety throughout.



Core studies:

- Molecular and protein characterization
- Safety assessment studies to evaluate hazard (encompassing toxicity and allergenicity)

Supplementary studies examples:

- Compositional analysis should be focused narrowly on components that may be affected by the trait (historically considered to be a Core Study)
- Dietary exposure assessment (DEA), as a lack of exposure would indicate no risk

GM CROPS - It's time for regulatory harmonization

CropLife INTERNATIONAL

Genetically modified (GM) crops have been consumed by people and animals for 25 years, with 0 confirmed health or safety issues.

However, regulations around the world are not always the same, which causes delays in commercialization for everyone from developers and farmers right down to consumers.

Let's explore why it's time to review how we regulate.

PROVEN TO BE SAFE

OVER 4000

approved events in 70 countries (1992-2018).*

$260 MILLION

North American consumers have eaten more than $260 million (118 million kg) of GM papayas since they were introduced to the market in 2003.***

ZERO REJECTIONS

based on safety concerns.

TRILLIONS OF MEALS

without a credible report of health or safety impacts to humans and animals.

LOST OPPORTUNITIES

$4-14 BILLION

China loses an estimated $4-14 billion USD annually to the overall economy each year it delays the commercialization of insect resistant maize.**

$115 MILLION

A **5-year** regulatory delay of new nitrogen efficient rice could cost the Ghanaian economy as much as $115 million USD.****

BUT REGULATION ISSUES CAUSE DELAYS

50%

The time and costs associated with regulation and registration have increased by 50% over the past decade.

13 YEARS

the average time it takes to get approval for a GM crop is 13 years – longer than new pharmaceuticals (12 years) and aircraft (8.5 years).

THE BENEFITS OF HARMONIZING GM CROP DATA REQUIREMENTS FOR:

Regulators
Provide a framework for future GM crop adoption, while freeing resources to focus on areas like training.

Consumers
Enjoy a safe, stable food supply, lower prices and access to biofortified foods that enhance nutrition and reduce food waste due to extended shelf life.

Farmers
Boost income through yield increases and access to sustainable practices, which preserve natural resources and combat climate change.

Developers
Allocate resources to research and development instead of duplicative regulatory dossiers.

*ISAAA. (2018). Global status of commercialized biotech/GM crops in 2018: Biotech Crops Continue to Help Meet the Challenges of Increased Population and Climate Change. In ISAAA brief (Vol. 54). ISAAA: Ithaca, NY. **Xie, W., Ali, T., Cui, Q., and Huang, J. (2017). Economic impacts of commercializing, insect-resistant GM maize in China. China Agric. Econ. Rev. 9 (3), 340-354. doi:10.1108/CAER-06-2017-0126 ***http://www.hawaiipapaya.com/#superhero-powers ****Estimation from Dzanku et. Al (2018), IFPRI/STEPRI

BENEFITS OF REGULATORY HARMONIZATION OF GM CROPS

Genetically modified (GM) crops have a long history of safety and offer a range of benefits.

The use of genetic engineering to introduce desired traits into plants was developed more than 25 years ago and first commercialized in 1994. GM crops offer a range of benefits to farmers, consumers and the environment by expressing traits such as herbicide tolerance, insect resistance or enhanced product quality. Every GM crop undergoes a thorough safety assessment before being approved for food, feed or cultivation.

To date, GM crops have been consumed for decades by people and animals without a single confirmed health or safety issue.

Innovation and consistency

Regulatory reviews (safety assessments), based on internationally accepted, science-based guidelines, are carried out to ensure product safety for humans, livestock and the environment. However, some regulatory agencies have diverged from the guidelines and increased their data requirements from crop developers seeking approvals.

This hinders innovation and creates regulatory uncertainty with no added safety benefit. More data does not increase the level of product safety for consumers or the environment.

After more than 25 years of safe use and numerous benefits to farmers, consumers and the environment, it's time to review and streamline the safety assessment process for GM crops. In fact, the international standard (Codex) on which most, if not all, regulatory systems for GM crops are built clearly states that **"where appropriate, the results of a risk assessment undertaken by other regulatory authorities may be used to [...] avoid the duplication of work."** Building on this statement and sharing science across geographies to harmonize global regulations and data requirements offers a solution to the challenges resulting from divergent regulatory requirements and asynchronous approvals.

It takes an average of **13 years** to get approval for a GM crop – longer than the **12 year** average it takes for new pharmaceutical medicines

(U.S. Farmers & Ranchers Alliance)

Benefits of harmonized data requirements for GM crops:

Regulators:

- Leverage extensive experience of existing safety assessments and data submissions.
- Free governmental resources to focus on other areas (e.g. training, knowledge sharing and inter/intra agency collaborations).
- Provide a framework for emerging regulatory systems in countries beginning to adopt GM crops.
- Help achieve the UN Sustainable Development Goals (SDGs).

Consumers:

- Enjoy national and local economic growth and stability from reductions in production costs and increased yields.
- Benefit from global food and nutrition security through lower food prices and a safe, stable, food supply.
- Purchase value-added products, such as biofortified foods and crops with extended shelf life, which can reduce food waste.
- Help to protect the environment by choosing products that are sustainably grown.

Farmers:

- Expedite farmer adoption of sustainable farming practices that benefit the environment and preserve natural resources, and help farmers adapt to and mitigate climate change.
- Increase in income for rural economies resulting from yield increases.
- Result in a larger variety of traits and/or crops being commercially available to farmers.

Developers:

- Reduce product development costs and timelines, which can enable smaller and public sector developers to bring diverse agricultural innovations to the marketplace.
- Lower cost barriers to working on new crops and traits.
- Make product launch timelines more predictable, enabling resource streamlining, patent protection, and better deployment/ allocation of resources.

STACKED TRAIT PRODUCTS

No stacked trait product has ever been denied approval due to safety concerns anywhere in the world.

So after decades of safe consumption, why haven't safety requirements been simplified or removed?

Some countries are beginning to do just that. Here's why others should follow.

CONSISTENTLY PROVEN

25 YEARS

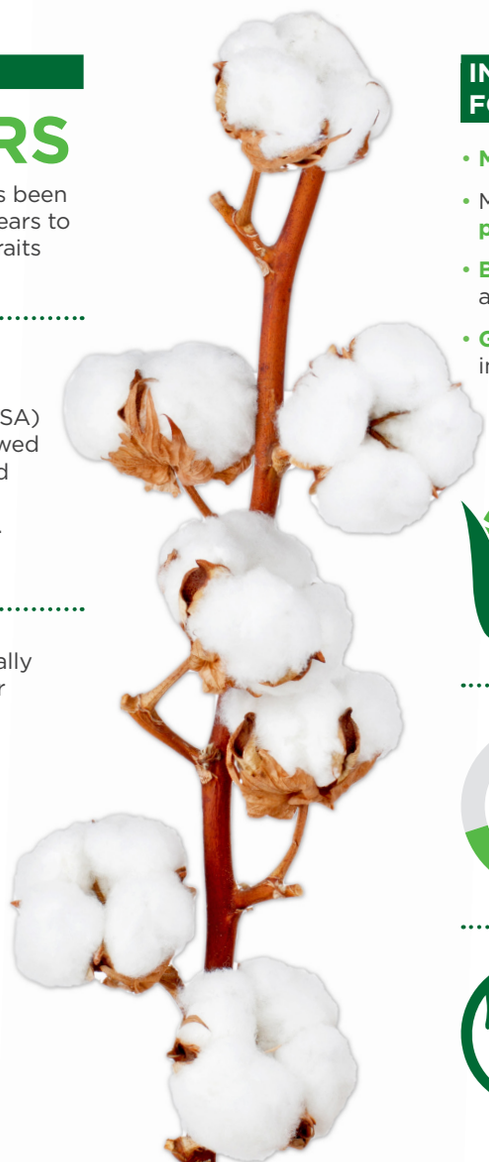
Genetic engineering has been used for more than 25 years to safely develop desired traits in plants.

100%

The **European Food Safety Authority** (EFSA) has extensively reviewed more than 30 stacked trait products – with a 100% approval rate.

Stacked trait products are not substantially different from their conventional counter parts or their **single-trait parents**, a view recognised by:

World Health Organization guidelines (1995)



INCREASINGLY VITAL FOR FARMERS

- **Multiple solutions** in one plant.
- More choice and enhanced **agronomic practices**.
- **Boost in fighting** problematic weeds and pests.
- **Greater productivity** means improved yield and nutrition.

80% OF CORN ACRES

were planted to stacked trait products in 2018 in the United States.

70%

That's a 70% increase in the last **15 years.**

115%

increase in global adoption in just **10 years.**

LEADING THE WAY

Since the 90s, stacked trait products in **Canada** and **Australia** have not required additional safety assessment if their single trait parents are approved. Recently, **Brazil** and **Argentina** followed suit.

Regulations for stacked trait products in **Japan** have also been simplified.

IT'S TIME TO WORK TOGETHER

Simplifying assessments for stacked trait products provides a consistent framework for innovation.

Consistency in regulating stacked trait products could greatly reduce:

- **out of sync** approvals and potential trade flow disruptions,
- **regulatory agency burden,**
- **unnecessary** costs and time for agencies and product developers.

STACKED TRAIT PRODUCTS FACT SHEET

Regulatory assessment of 'stacked trait' products is unnecessary when the single trait parents have been concluded as safe.

Stacked trait products contain multiple genetically modified (GM) traits, which have been brought together through conventional plant breeding. For example, different insect resistance traits can be stacked with one another to provide the crop with improved means of protecting itself against attack from multiple insects. This process also helps delay or avoid the development of resistance in the target pest populations.

Different traits (e.g. insect resistance, herbicide tolerance and product quality) can also be stacked together to improve yield and nutrition.

Stacked trait products are not substantially different from their single-trait parents. Therefore, they pose no greater risk to food or feed safety than products obtained from any other form of conventional breeding unless there is a plausible, testable hypothesis for the stacked traits to interact.

Multiple regulatory agencies have reviewed stacked trait products without any concerns. The European Food Safety Authority (EFSA) has extensively reviewed more than 30 stacked trait products, and determined them to be safe.

Is it time for regulatory overhaul?

Removing regulatory requirements for stacked trait products is scientifically justified and provides a consistent framework for innovation.

Differing regulatory requirements internationally for stacked trait products add unnecessary cost and time to the review process. Some countries (e.g. Brazil, Argentina) have recently significantly reduced or eliminated requirements if the single-trait parents have been approved, and Japan has continued to simplify their regulations for stacked trait products based on a history of safe use and familiarity.

Some countries have gone a step further and set a precedent for not even including stacked products in their regulation and only require a notification of commercialization (e.g. Australia and Canada).

Globally, no stacked trait product has **ever been denied approval** due to safety concerns.

Examples of benefits of stacked traits:

For farmers:

Ability to protect plants against multiple pests and diseases at once, giving farmers the necessary options to control insects, diseases, and weeds to optimize their operations.

For consumers:

Ability to combine multiple nutritional and other quality benefits at once (e.g. longer shelf life and enhanced nutrients).

For the environment:

Ability to enable no-till agriculture and water-efficiency in a single seed, allowing for use of best management practices that reduce tillage and conserve water.