International Seed Federation
Seed is Life

A CALL FOR POLICY ACTIONS TO FOSTER PLANT BREEDING INNOVATION

NOVEMBER 2024

A statement prepared by the International Seed Federation

The United Nations Sustainable Development Goals (SDGs) adopted by all UN member states, are a global framework of 17 interconnected objectives designed to address the world's most pressing challenges by 2030, including poverty, hunger, climate change, and environmental degradation (Source: UN Sustainable Development Goals). Achieving these ambitious and inspirational goals requires innovative approaches across various sectors, including agriculture. In 2021, the global seed industry formally committed to the UN SDGs and declared its engagement to help deliver solutions towards their achievement (Source: Seed Sector Declaration on UN SDGs, 2021).

Innovation in plant breeding plays a critical role in advancing the SDGs, particularly in areas like zero hunger, good health and well-being, and climate action. By developing crop varieties that are more resilient to climate change, more nutritious, and more productive, plant breeding innovation like genome editing can help ensure food security, promote sustainable agriculture, and improve livelihoods, all while reducing the environmental footprint of farming (Tripathi et al., 2022; von Braun et al., 2023; Seyi Adgebajo et al., 2024; Watson and Hayta, 2024). This innovation-driven approach is essential to building a more sustainable and equitable future for all.

Governments around the world have been updating their policies to support the deployment of plant breeding innovation like genome editing (see ISF Policy map, page 6). Despite the positive policy trends in many countries, plant breeders still encounter regulatory hurdles that hinder their ability to bring products of plant breeding innovation to farmers and consumers. The regulatory challenges are linked to pre- and post-market regulatory requirements, lack of policy flexibility and alignment for the expanding range of innovative breeding practices, as well as the resulting trade issues due to unharmonized global policies.

The ISF strongly believes that regulatory implementation challenges can be resolved by the adoption of enabling, globally harmonized and future-proof policies. These policies should support sustained investments in ongoing innovation in plant breeding to enable the successful uptake and integration of breeding innovations that deliver beneficial plant products to society (Source: ISF Future Proofing Policies Paper, 2022 ; Executive Summary, 2022).

Early developers' experiences: Proposed solutions to regulatory challenges

Policymakers are increasingly adopting holistic strategies that integrate three essential dimensions—healthy people, a healthy planet, and a healthy economy—to protect the well-being of current and future generations. The progress in plant breeding innovation policies is driven not only by the recognition that these innovations can play a crucial role in addressing global challenges like food security and the climate crisis, but also by the solid foundation of plant breeding's long-standing history of safety and success (Source: 100 Years of Plant Breeding Innovation – A statement by ISF, 2024). Common regulatory implementation challenges are identified below, along with examples of best practices by specific regulatory bodies that can guide the resolution of such challenges. Ultimately, raising awareness and sharing knowledge about innovations in plant breeding, genome editing and its benefits with society is essential.

Pre-Market Experience

Pre-market challenges encompass lack of early pipeline consultations, inconsistent data requirements, and the need for multiple regulatory status determinations for highly similar genome-edited products.

Early Regulatory Clarity: A Key to Cost, Timeline, and Market Success for Developers

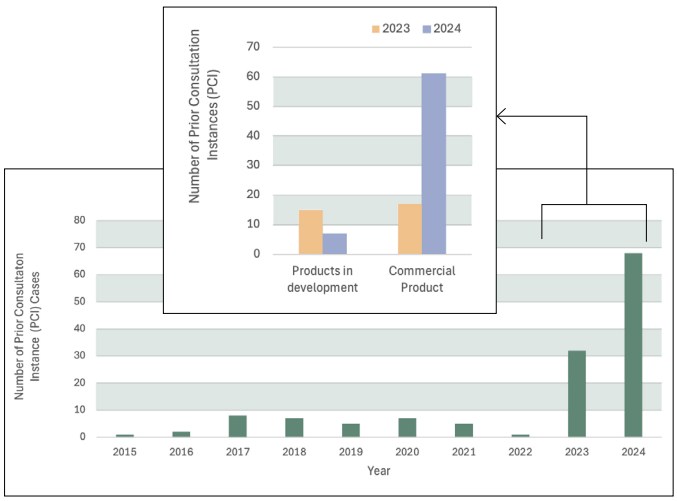
During the early stages of genome edited product development and field trials of new varieties, it is crucial for developers to have a clear understanding of the regulatory path to market through consultation with authorities. However, consultations may not always be possible as not all governments have such a process in place. One of the benefits of an early pre-market consultation is to determine the regulatory status early in the development process, such that field evaluations may take place efficiently. Furthermore, the costs of research and development work under Genetically Modified Organism (GMO) requirements are a substantial barrier for developers, especially when working in small markets and/or niche crops with longer developmental and/or harvest cycles. These challenges are exacerbated when consumer or market testing beyond the field is needed to confirm commercial viability of potential products, such as in fresh produce applications. Therefore, obtaining clarity on the regulatory status early on is essential for developers of all sizes, as well as for public institutions and allows for a realistic estimate of costs, timelines, and paths to market.

EARLY REGULATORY CLARITY ENABLES THE PATH TO R&D SUCCESS

Argentina stands out as an example of a country with a regulatory system that provides the possibility for early consultation – including for conceptual or early-stage research and development projects (Source: Argentinian Resolution 21/2021 ; Goberna et al., 2024). Through a Prior Consultation Instance (PCI) process, developers can obtain clarity on whether their product concept or product necessitates regulatory approval under the GMO framework or not. Since the implementation of the regulations in 2015, the number of PCIs has grown significantly, demonstrating the value this process brings for developers. Between April 2023 and March 2024, a total of 68 PCI applications were submitted with enquiries about seven conceptual and 61 actual products (Source: OECD Environmental directorate chemicals and biotechnology directorate, Series on the Safety of Novel Foods and Feeds, N° 38, 2024).

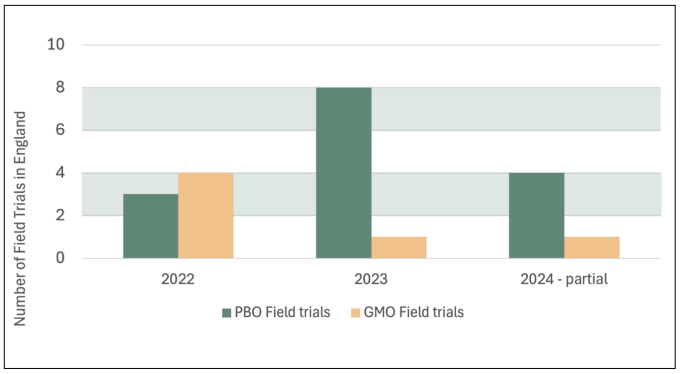
England's Department of Environment, Food, and Rural Affairs (DEFRA) notification system allows research trials for plants that could have been produced through traditional breeding (Source: DEFRA Guidance on using genetic technologies such as gene editing for making higher plants for research trials, 2023). This efficient approach helps to enable timely research and development.

Early regulatory consultations in Argentina over nearly a decade



The graphic illustrates the number of Prior Consultation Instances (PCI) submitted by various developers to the Argentinian government for products of NBTs (New Breeding Techniques - plants, animals, and microorganisms) in research and development or in commercial development, covering the period from 2015 to 2024. The products shown in the graphic were determined by CONABIA as conventional products. Data adapted and compiled by ISF from different sources: Whelan et al., 2022 and the OECD Series on the safety of Novel Foods and Feeds: Developments in delegations on the safety assessment of novel foods and feeds (2024, 2023, 2022).

A shift toward Precision Bred Crops in England's field trials



Notifications to release qualifying genetically modified higher plants (aka precision bred organisms - PBOs) compared to decisions granted to release genetically modified organisms (GMOs) for research purposes between the period of 2022 and 2024 in England. Over a three-year period, more field trials were conducted with precision bred (genome-edited) crops than with GMOs. This trend aligns with the introduction of the UK Bill on Precision Bred Organisms in 2023. Data sourced and compiled by ISF from Genetically modified organisms: applications, decisions and notifications - GOV.UK (www.gov.uk)

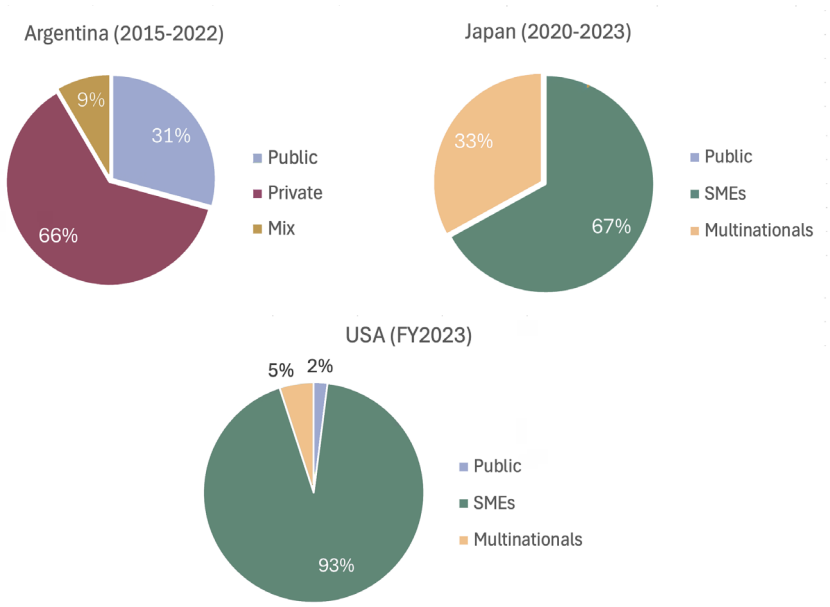
Consistent & risk-proportionate data requirements encourage innovation

Products developed with the use of plant breeding innovation and resulting in plant varieties that are indistinguishable from, or similar to, conventionally bred plants should be regulated similarly to conventionally bred plants (Schmidt et al., 2020; Jenkins et al., 2023). Therefore, the data or information required to demonstrate the plant is excluded or exempt from GMO regulatory oversight should be risk-proportionate. Specifically, genome edited products that could have been developed through conventional breeding or have characteristics of conventionally bred plants, should be evaluated in a similar way to avoid creation of substantial barriers to entry. Recent estimates indicate that the average global GMO regulatory costs are 37.6% of the total $115 million R&D and take 51.1% of the 16.5 years to complete. (Source: AgbioInvestor report, Time and Cost to Develop a New GM Trait, 2022). These lengthy, expensive processes neutralize the benefits and efficiency gains of these breeding innovations. Disproportionate GMO-like data requirements for regulatory status determination will discourage investment needed for innovation and limit the diversity of developers and products that could reach the market. Furthermore, certain governments mandate that companies must have an established local operation and be registered with the relevant local authorities before accepting a regulatory status request. This pre-requisite generates another limiting hurdle for applicants, particularly small and medium sized enterprises (SMEs). To effectively address the pressing challenges posed by food security and climate change, regulatory authorities must implement proportionate requirements and remove unnecessary barriers to innovation in plant breeding for a diverse set of stakeholders.

PROPORTIONATE PRE-MARKET REQUIREMENTS ENCOURAGE APPLICATIONS

Some countries have implemented clear and predetermined exemptions for specific plant breeding innovation products (e.g. Australia, USA). Other countries use voluntary (e.g. Canada) or mandatory notification systems with limited information or data requirements to enable pre-market determinations. Importantly, developers must provide data to demonstrate the absence of foreign DNA in the final product (e.g., Argentina, Brazil, Japan, Kenya, Nigeria, Philippines, Singapore, etc.). Such regulatory approaches demonstrate a practical and workable system to speed up the decision-making process. In Kenya, for example, no registration of a local entity with the regulatory agency is necessary to initiate a submission to the regulatory body (Source: Guidelines for determining the regulatory process of genome editing in Kenya, 2022).

Enabling proportionate pre-market data requirements boost evaluation requests from diverse developers



Applicants from diverse institutions—private, public, or a mix—ranging from small and medium-sized enterprises to multinational corporations, are requesting evaluations from CONABIA under the National Directorate of Bioeconomy in Argentina (upper right panel), the Japan Food Safety Agency (Ministry of Health, Labour and Welfare) (upper left panel) or for confirmation of exemption to the USDA (lower panel). The graphic highlights a significant increase in applications from SMEs across all three countries following changes in their regulations. It presents data on Argentina's PCI submissions from 2015 to 2022, the completed confirmation requests in the USA in 2023, and notifications by Japan's food safety authorities for genome-edited products from 2020 to 2023.

Source: USDA from presentation at meeting with stakeholders, 2023, Argentina from Whelan et al., 2022; Japan from Japan Food Safety Agency, mhlw.go.jp

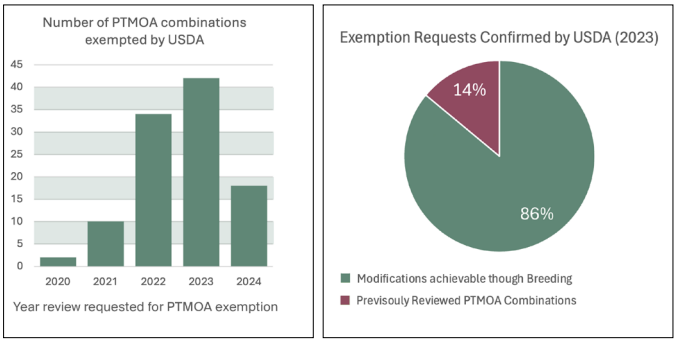
Streamlining requirements for highly similar products enables expanded product portfolios

Regulatory systems should aim to streamline processes and minimize redundant regulatory status evaluation requests for highly similar products such as edited plant varieties resulting in the same functional change (see box below). It is crucial that the decision scope of the original determination allows for seamless expansion of the product portfolio and developer activities without additional evaluations for products that fit within the scope of the original determination. Breeders endeavour to integrate essential characteristics, such as drought tolerance, nutritional improvements, and resistance to pests and diseases across a diverse range of varieties suited to different geographical and climatic conditions. Taking into account the considerable volume of newly registered and/or commercialized plant varieties on a yearly basis, the requirement to individually assess plants with identical functional changes, based on individual edits, only serves to intensify the regulatory burden.

USDA'S EXEMPTION PROCESS EMPOWERS EXPANSION OF PRODUCT PORTFOLIOS

The USDA system serves as a notable example of minimizing submissions for highly similar products. Exemptions are granted for categories of plants, determined through an assessment of factors such as plant species, mechanism of action, characteristics, ensuring a balanced regulatory approach (Source: USDA - Guide for Requesting a Confirmation of Exemption, 2022). The Confirmation of Exemption process is available to developers when a new product has the same plant - trait - mechanism of action (PTMOA) combination or meets exemption criteria, and therefore is exempt. USDA also acknowledges that "an exemption confirmed in one variety would be applicable to other varieties of the same crop, provided that the modification is the same in the subsequent varieties or is in the same gene and results in the same functional difference from the unmodified plant." (USDA Questions and Answers - Biotechnology and Regulatory Services).

The increasing regulatory experience by agencies can streamline the process for developers.



The graphics show the number of plant-trait-mechanism of action (PTMOA) combinations that have been determined by the USDA determined by the USDA to not be regulated under their updated Part 340 regulations, which entered into force in 2020 (left panel). When a PTMOA combination has previously been determined by USDA to not be regulated, a plant with this PTMOA combination qualifies for an exemption from the regulations. This exemption process is actively being used by developers (14%) in 2023 to streamline the development of their product, as indicated on the next graph (right panel). Data compiled and analyzed by ISF.

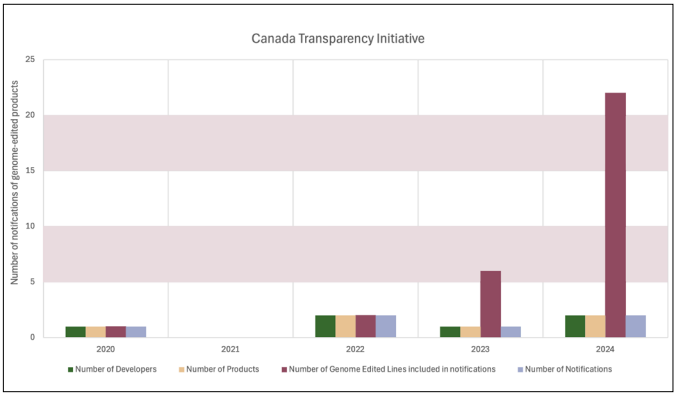
Post-Market Experience

Determining that a genome-edited product is not subject to, or is exempt from GMO regulations, while still imposing post-market requirements akin to GMOs, is another regulatory challenge that introduces substantial cost for investors, developers, growers, the supply chain and ultimately consumers. Imposing obligations, such as labelling, traceability, segregation, monitoring, and detectability needlessly creates a costly category of beneficial products that are less likely to reach the market. Therefore, exemption from GMO-based post-market requirements is a solution to deliver cost-effective transparency in the market.

CANADIAN TRANSPARENCY INITIATIVE INCENTIVIZES INNOVATION WITHOUT CREATING ENTRY BARRIERS

In Canada, genome edited plant products are not subject to pre-market risk assessment provided that the resulting characteristic(s) are not novel and the final product does not contain foreign DNA. This approach applies to all plant products developed using any breeding method, including genome editing. Health Canada established a voluntary Transparency Initiative (TI) process for developers to provide information about their genome edited product to Health Canada that subsequently is published on their website on a list of non-novel products, including conventional breeding products. This TI process was introduced by Health Canada to enable transparency on genome edited products that could be present in the Canadian food/feed supply. As a consequence, innovation is incentivized without creating additional entry barriers. (Source: CFIA - Directives 2009-09 ; Health Canada: Guidelines for the Safety Assessment of Novel Foods; Health Canada, Transparency initiative, list of non-novel products in plant-breeding for food use).

Published notifications of genome-edited products in Canada provide transparency for various stakeholders.



The graphic illustrates the number of genome-edited products voluntarily notified by developers to the Canadian government. These notifications pertain to genome-edited products and lines which are close to commercialization between 2020 and 2025, and classified as non-novel products of plant breeding for food use in Canada. Multiple lines within a single product are included in a single notification. Additionally, conventionally bred products are also recorded in the same database. Data compiled and analyzed by ISF from Health Canada, Transparency initiative, list of non-novel products in plant-breeding for food use. Data compiled and analyzed by ISF from Health Canada, Transparency initiative, list of non-novel products in plant-breeding for food use

Trade Experience

The global movement of seeds and agricultural commodities is governed by stringent regulations (e.g., WTO Sanitary and Phytosanitary regulations, OECD trade rules, ISTA seed testing, etc.). Undisrupted trade is essential for meeting the world's food, nutrition, and sustainability needs. The landscape of plant breeding, processing and commercialization is highly dependent on multiple countries and therefore is enabled by adequate multilateral frameworks. Multilateralism enhances trade efficiency by fostering cooperation, reducing barriers, promoting competition, and providing a framework for resolving disputes in the global trading system.

However, various regulatory challenges can interrupt trade. Lack of alignment between the regulatory approaches of different countries can result in differential regulation between trading partners (FAO report on Gene editing and agrifood systems, 2023; See ISF Policy Map, page 6). More than 14 WTO Parties in 2018 recognized that "differing domestic regulatory approaches for products derived from precision biotechnology may result not only in international asynchronicity in approvals, but also in asymmetry in regulatory approaches, and create potential trade issues that could impede innovation" (Source: G/SPS/GEN/1658/Rev.3, WTO, 2018).

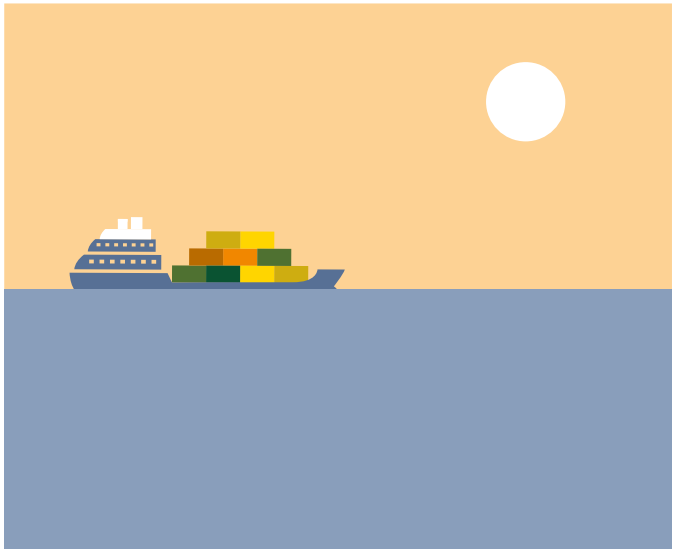
Examples of the impact of differential plant breeding innovation regulatory approaches on trade and seed movement include:

- When policies from trading partners for genome edited products create differing regulatory status for the same product. For example when a product is exempt or excluded from GMO regulation in an exporting country but is within the scope of the GMO regulations in an importing country. This situation poses challenges for product shipment, traceability, and fungibility.
- Asynchrony (i.e., difference in the timing) of regulatory status determinations due to varying data or information incongruencies or unclear timelines, or requiring determinations from other nations as a prerequisite to in-country regulatory application.
- Mandatory labelling and co-existence measures (see Post-Market challenges).

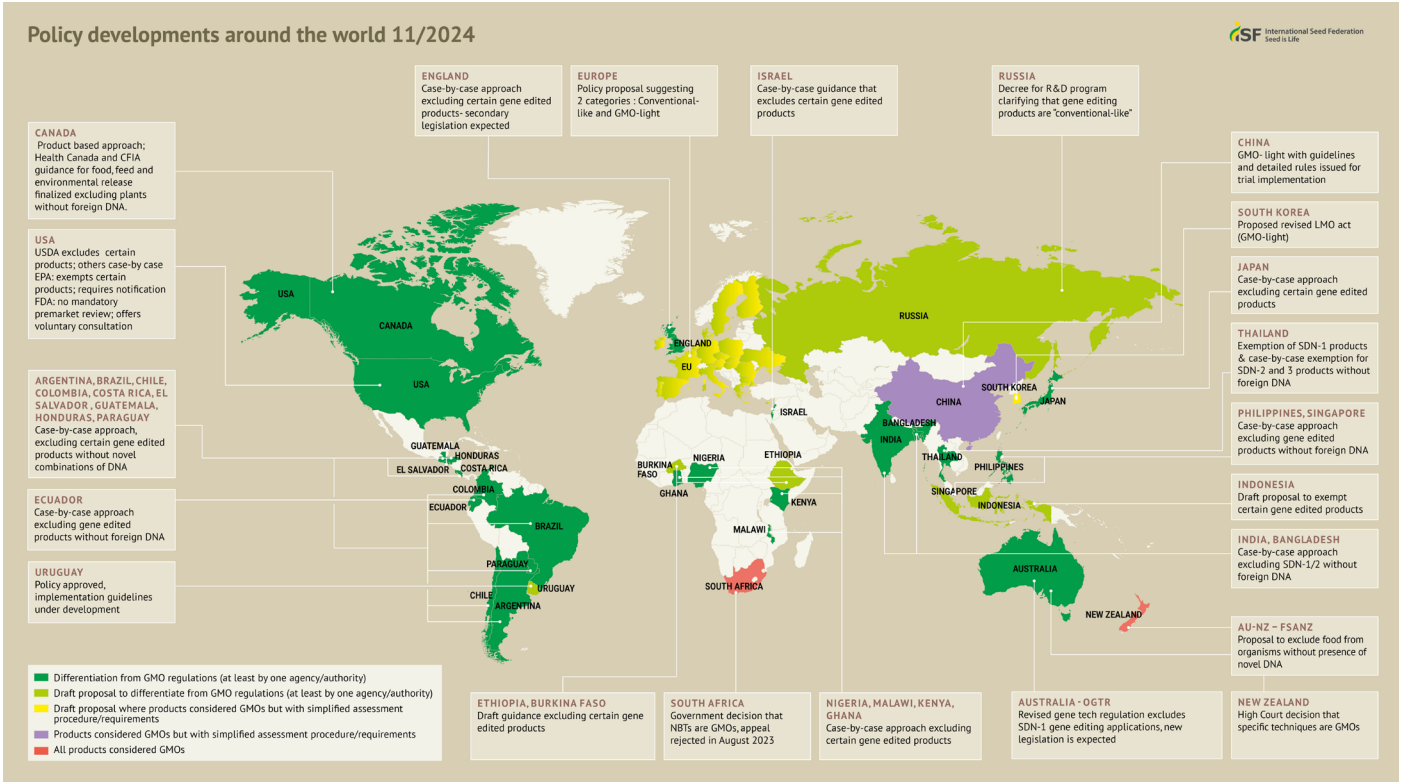
These regulatory challenges can create significant transactional cost and further disadvantage all developers in contributing to food security and delivering on the UN SDGs.

HARMONIZING REGULATORY APPROACHES BETWEEN COUNTRIES FACILITATES TRADE

In Honduras, the policy approach for genome editing explicitly notes Regional Harmonization of Criteria whereby the National Committee of Biotechnology and Biosafety (CNBBA) will cooperate with regional initiatives in order to harmonize the technical criteria, preserve the commercial interregional interchange and consider products in a similar way in the region (Source: Article 5, AGREEMENT C.D.-008-2019 HONDURAS REPUBLIC Tegucigalpa M.D.C. August 27, 2019). Furthermore, the Brazil-Argentina mutual recognition system for governing genome editing is a best practice that could be expanded multilaterally to mitigate trade challenges (Source: OECD Environmental directorate chemicals and biotechnology directorate, Series on the Safety of Novel Foods and Feeds, N° 38, 2024 ; ISF & CTNBio meeting, Brazil, March 2024).



Diverse global regulatory policy landscape for plant breeding innovation



This figure provides a global overview of the status of regulatory policy developments for plant breeding innovation around the world. For countries where policy developments are finalized or under development, the color indicates the domestic regulatory approach for product evaluation (Food or Feed or Cultivation). As reflected by the color diversity, regulatory approaches are diverse, which has the potential to lead to challenges for global trade.

Conclusion

The adoption of plant breeding innovation, such as genome editing, by plant breeders and developers depends on aligned implementation of clear, predictable and risk-proportionate regulations. This will enable the successful development of a wide range of potential products. The International Seed Federation (ISF) emphasizes the importance of governments to align and provide certainty for developers and end-users alike to enable plant breeding innovation to deliver on critically needed solutions to support the UN SDGs.

The shared examples cited above can be used as a practical guide to implement enabling and aligned policies and to facilitate the adoption of genome editing in plant breeding.

A Call to Action

The International Seed Federation (ISF) calls on governments to:

1. Recognize the equivalence of genome editing and conventional breeding outcomes and to incentivize innovation.

2. Enable clear and proportionate paths to market for genome-edited products that are indistinguishable from conventionally bred products.

3. Prioritize regulatory status determinations at early stages of research and development to enable product testing and reduce uncertainty.

4. Establish pre- and post-market requirements that minimize costs and burdens for genome-edited products that are equivalent to products of conventional breeding.

5. Expand the scope of regulatory status evaluation to include multiple varieties with similar edits that result in the same functional trait outcome.

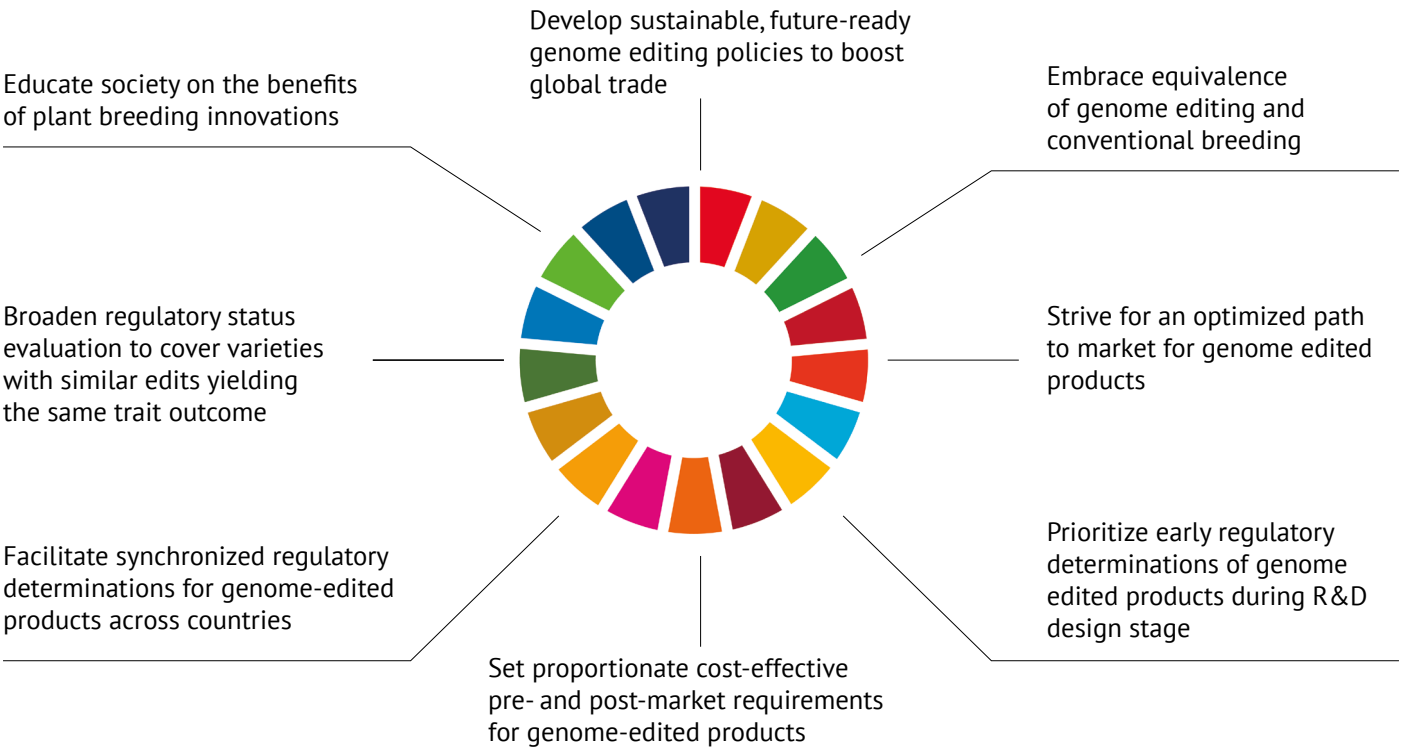
6. Strive for a synchronous approach among countries in regulatory status determinations or verifications of genome-edited products by harnessing the potential of digital tools.

7. Prepare sustainable and future-proofed policies to enhance global trade of genome-edited products.

8. Cultivate science-policy-society collaborations for enhanced awareness and education.

Regulatory systems that address these current challenges and embrace best practices enable plant breeding innovation to contribute to the achievement of the UN Sustainable Development Goals in addressing climate change, food insecurity and environmental challenges.

Plant Breeding Policy Solutions to Support UN Sustainable Development Goals



"Farmers urge governments to remove regulatory impediments and uncertainty to advance plant breeding solutions for rural communities, food security and sustainable development"

World Farmers Organization, Global Farmers Statement, 2023