



INTERNATIONAL STATEMENT ON AGRICULTURAL APPLICATIONS OF PRECISION BIOTECHNOLOGY

COMMUNICATION FROM ARGENTINA, AUSTRALIA, BRAZIL, CANADA, THE DOMINICAN REPUBLIC,
GUATEMALA, HONDURAS, PARAGUAY, PHILIPPINES, THE UNITED STATES OF AMERICA
AND URUGUAY

Revision

The following communication, received on 26 October 2018, is being circulated at the request of the delegations of Argentina, Australia, Brazil, Canada, the Dominican Republic, Guatemala, Honduras, Paraguay, Philippines, the United States of America and Uruguay.

1 OVERVIEW

1.1. Precision biotechnology techniques, as a whole, constitute an essential tool for agricultural innovation. Their use provides farmers with access to products that increase productivity while preserving environmental sustainability.

1.2. Global environmental challenges, pest and disease pressures, food insecurity, and changes in consumer preferences, among other factors, have made the use and fostering of tools such as precision biotechnology vital for increasing the production of safe food.

1.3. In this light, in April 2018, the countries participating in the "Seminar on Genome Editing for Regulators", organized by the Inter-American Institute for Cooperation on Agriculture (IICA), shared a draft statement on the applications of precision biotechnology.

1.4. The primary objective is to coordinate efforts to ensure that the regulatory approaches for these techniques, which include gene editing, are scientifically based and internationally harmonized.

1.5. The final text of the international statement is non-binding on supporting countries, but provides the necessary guidelines for preventing regulatory asymmetries and, in turn, potential trade disruption.

2 TEXT OF THE "INTERNATIONAL STATEMENT ON AGRICULTURAL APPLICATIONS OF PRECISION BIOTECHNOLOGY"

2.1. Agricultural innovation has played an essential role in increasing yields and productivity in support of growing, prosperous civilizations. Innovations in precision biotechnology, such as gene editing, have brought the promise of major improvements in terms of the ease and precision of introducing desirable traits into agricultural organisms, as compared to other breeding methods. Farmers continually need to broaden access to new tools to improve productivity, plant and animal health, and environmental sustainability, and need to help address global challenges such as climate change, pest and disease pressures, and the safety and security of worldwide food supplies, as well as meet consumer preferences and demands for healthier, higher quality foods at affordable prices. Government policies must continue to foster innovation, including in the public sector and by small

and medium-sized enterprises (SMEs), and mitigate unintended, unnecessary barriers to the entry of agricultural products.

2.2. In some cases, precision biotechnology, such as gene editing, may generate organisms with characteristics similar to those obtainable through conventional breeding. In other cases, the organisms generated may have characteristics similar to those introduced into organisms using recombinant-DNA technologies. In either case, the food, animal, and environmental safety of such products can be adequately addressed by existing regulatory frameworks for agricultural products and existing safety standards based on the characteristics of the product or organism.

2.3. Governments are engaging in policy discussions on regulatory frameworks and global regulatory compatibility to encourage cross-border research collaboration and minimize potential disruptions to trade. 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. Recognizing the potential positive contributions of precision biotechnology to global agriculture, and emphasizing the importance of early action to identify avenues to minimize the trade impacts of differing regulatory approaches, the undersigned governments acknowledge that:

- Precision biotechnology products have the potential to play a critical role in addressing the challenges facing agricultural production, including by contributing to increasing the supply of foods and other agricultural products, in a sustainable way;
 - Collaborative research efforts and the ability to introduce useful products into the market, especially by SMEs and public sector researchers, are necessary to fully realize the potential of precision biotechnology;
 - Given the differences internationally in approaches used to assess agricultural biotechnology, due consideration should be exercised by governments to avoid arbitrary and unjustifiable distinctions between end products derived from precision biotechnology and similar end products obtained through other production methods;
 - To ensure appropriate science- and risk-based approaches consistent with the protection of human, animal and plant health and the environment, due consideration should be given to available scientific and technical information when updating existing regulatory frameworks or applying these frameworks to products of precision biotechnology, and when using available flexibility within existing regulatory frameworks for agricultural products;
 - Regulatory approaches necessary to help ensure safety (of humans, animals, plants, and the environment) in respect of products derived from precision biotechnology should be science- and risk-based, transparent, predictable, timely, and consistent with relevant international trade obligations;
 - Cooperative work by governments to minimize unnecessary barriers to trade related to the regulatory oversight of products of precision biotechnology, including the exploring of opportunities for regulatory and policy alignment, should be pursued where possible;
 - This collaborative work should promote constructive dialogue with trading partners and agricultural stakeholders on potential trade issues related to precision biotechnology, so as to support open and fair trade and encourage research and innovation;
 - Public communication efforts can build trust in regulatory frameworks and improve the acceptability of future agricultural innovations that will help farmers address global challenges with a view to the production of abundant, safe and affordable food, feed, fibres, and energy in the 21st century.
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