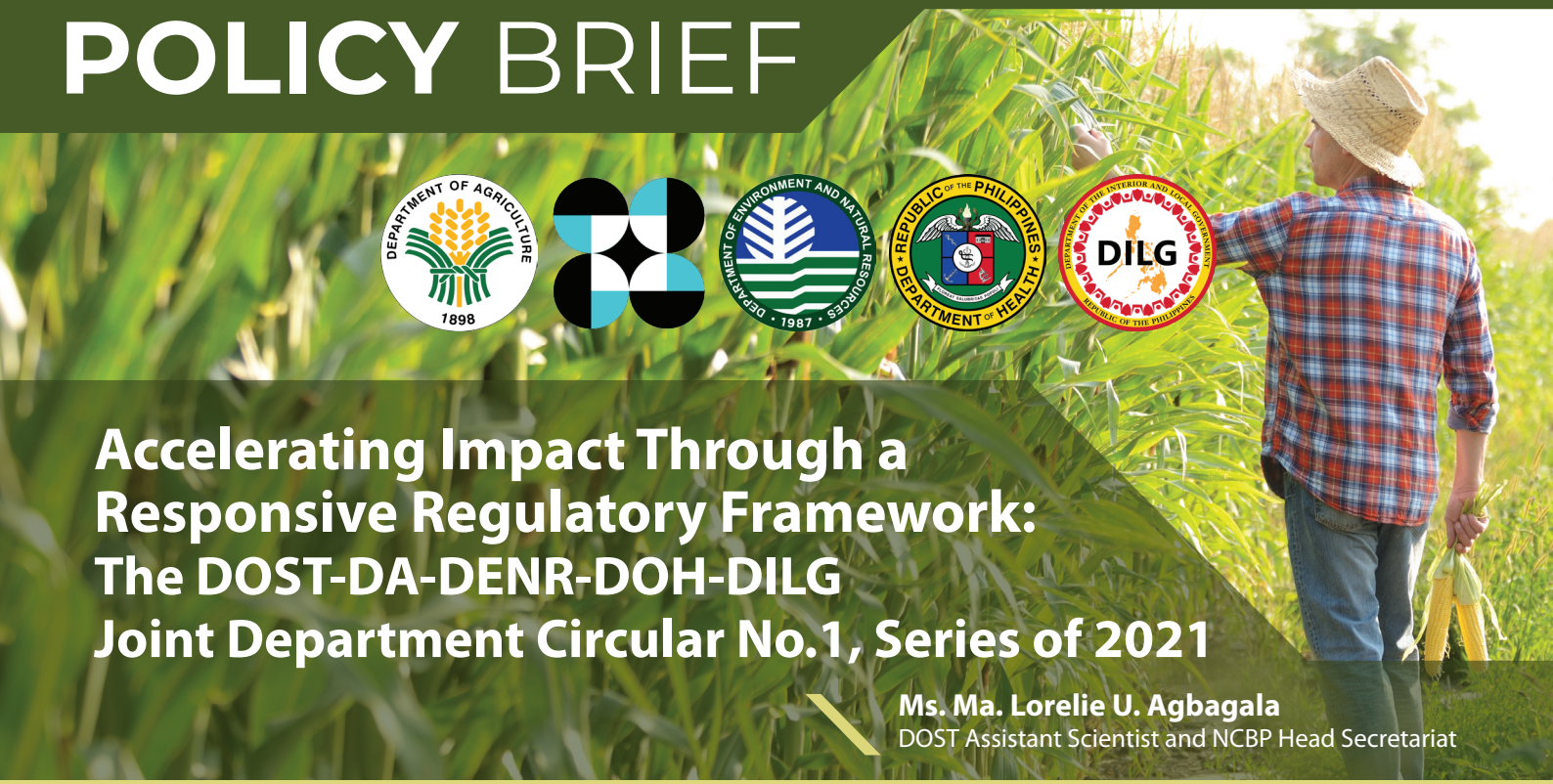
POLICY BRIEF



Accelerating Impact Through a Responsive Regulatory Framework: The DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021

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Policy Implications

The Philippines has policies and regulatory oversight in place to address issues of food safety, health, and environmental concerns. The regulation is continuously evaluated and modified to conform to internationally accepted standards and best practices including recourse and remedies in the event of non-compliance with the regulations.

The revised Joint Department Circular (JDC) aims to align and harmonize government regulations, address gaps, and clarify certain provisions. Thus, the 2021 JDC remains to be science-based, risk-proportionate, time-bound, and consistent with international guidelines. It is also a testament to the Philippines' dynamic and responsive biosafety guidelines and regulations.

Introduction

The Philippines is regarded as the leader of biotechnology in Southeast Asia – being the first country in the region to implement a regulatory framework on genetically engineered (GE) crops and approve cultivation for food and feed.

Its biotechnology regulatory system is governed by five departments: science and technology (DOST), agriculture (DA), environment and natural resources (DENR), health (DOH), and the interior and local government (DILG) through a Joint Department Circular (JDC). It sets out the rules and regulations for the research and development, handling and use, transboundary movement, release into the environment, and management of genetically modified plant and plant products derived from the use of modern biotechnology.

The JDC was first issued in 2016, as a response to the ruling of the Philippines' Supreme Court, declaring the DA Administrative Order (AO) No. 8, Series of 2002 (Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology) null and void on December 8, 2015, temporarily halting GE crop field testing and application "until a new administrative order is promulgated in accordance with the law". However, on July 26, 2016, the Supreme Court reversed its decision citing that it should have not acted on the constitutional question of the DA AO No. 8, Series of 2002.

Consistent with the National Biosafety Framework (NBF) and the principles of the Cartagena Protocol on Biosafety (CPB), the 2016 JDC dictates that risk assessment is mandatory and central in making biosafety decisions for the importation and release into the environment of GE plants in all stages of development. It identifies and evaluates the perceived risks on the environment and human and animal health. The Circular also outlines the approval process and requirements for field testing to obtain bio-efficacy data, commercial propagation, and importation for direct use as food or feed or for processing of GE plant and products are through the issuance of biosafety permits.

Three years after its implementation, the Competent National Authorities (CNAs) from the five government departments recommended to review the 2016 JDC to address the challenges of its implementation and to take into consideration the coming into force of Republic Act No. 11032 or the Ease of Doing Business Law which prescribes specific timeframes for all government transactions, including the process of securing a biosafety permit under the said Circular. The revised version of the Circular came into force on March 23, 2022, fifteen (15) days after its publication in two newspapers of general circulation.

Problems in the Implementation of the 2016 JDC

The applicants for biosafety permits from the private sector and non-profit research organizations, sought a dialogue with DA on March 7, 2018 to present the problems they have encountered in securing a biosafety permit under the 2016 JDC. Their primary issue was the delay in the issuance of the permits which can be attributed to the conflicting interpretations of the Biosafety Committees (BCs) in some provisions of the Circular. Under the 2016 JDC, a biosafety permit must be issued within 85 working days. Prior to 2016, the DENR and DOH were not involved in the approval process for biosafety permits for field trials, commercial propagation, and direct use under DA AO No. 8, Series of 2002.

On March 9, 2018, the NCBP conducted a workshop among the officials of the CNAs to identify and address inter- and intra-agency issues arising from the implementation of the JDC. Most of the issues raised were the lack of common time among the BCs of CNAs and their members to undertake evaluation of the risk assessments submitted; the lack of clear understanding of some of the processes stipulated in the JDC; and the need for a review process to streamline and enable the agencies to comply with the specified time frame.

Review of the Joint Department Circular

Taking these issues into consideration, the CNAs unanimously proposed to revisit the Circular to make the regulatory system functional, predictable, facilitative on all stages of development, and pursuant to the Ease of Doing Business Law. Thus, in May 2019, the National Committee on Biosafety of the Philippines (NCBP) created an Ad Hoc Technical Working Group to revisit and review the 2016 JDC. This group was led by the National Academy of Science and Technology – Philippines President and NCBP Environmental Scientist Dr. Rhodora V. Azanza and then-DOST Biosafety Committee Physical Scientist Dr. Flerida A. Cariño.

Two years after, the Ad Hoc Technical Working Group submitted the proposed revised version of the JDC to the NCBP. It underwent a series of virtual public consultations and was finalized in October 2021. The DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2021 (2021 JDC) was virtually signed by the five Departments' Secretaries and deputies on November 8, 2021 and came into force on March 23, 2022 after its publication in two newspapers of general circulation and submission to the Office of the National Administrative Register.

Competent National Authorities' Role in the implementation of the JDC

Consistent with the NBF and other applicable laws the following government agencies were identified to implement the JDC. The first four departments have established Biosafety Committees composed of members with scientific and technological knowledge necessary for the evaluation of applications through the Joint Assessment Group (JAG).

- **Department of Agriculture** - mandated to lead in addressing biosafety issues related to agricultural productivity and food security as well as the evaluation and monitoring of regulated articles for field trial, commercial propagation, and direct use.

- **Department of Science and Technology** - ensures that biosafety policies, measures, guidelines, and decisions are science-based, of highest quality, multi-disciplinary, peer reviewed, and consistent with international standards as they evolve, as well as lead in the evaluation and monitoring of regulated articles intended for contained use.

- **Department of Environment and Natural Resources** - ensures that applicable environmental assessments are undertaken, and potential impacts of biosafety are identified and leads in the evaluation and monitoring of regulated articles intended for bioremediation, improvement of forest genetic resources, and wildlife genetic resources.

- **Department of Health** - leads the evaluation and monitoring of processed food derived from or containing GMOs, as well as reviews and evaluates results of an applicable health impact assessments related to modern biotechnology and its applications.

- **Department of the Interior and Local Government** - tasked to inform local government units of their role in the conduct of public consultations, hearings and the issuance of a resolution to conduct a field trial activity of a regulated article in the locale.

Salient Revisions of the Joint Department Circular

The following changes were the salient revisions introduced in the 2021 JDC to streamline the approval process for biosafety permits for Field Trial, Commercial Propagation, and Direct Use of GM Plant and Plant Products without compromising safety for the environment, human, and animal health.

- **Shortened approval process.** Securing a biosafety permit for field trial, commercial propagation, and direct use as food and feed or for processing starting from the receipt of complete application documents up to the issuance of biosafety permit will be covered within forty (40) working days pursuant to the Ease of Doing Business Law.

- **Creation of Joint Assessment Group (JAG).** A JAG will be established for every application to jointly evaluate applications while promoting a common understanding of assessing and managing risks relevant to the purpose of the regulated article. The JAG, composed of two qualified representatives from each biosafety committees makes recommendations to the Bureau of Plant Industry director on the approval of biosafety permit applications. This reform streamlines and shortens the risk assessment and approval process, as well as lessens dependence on external expert members of the Scientific and Technical Review Panel (STRP).

- **Policy on field trial of regulated articles.** Permit applications for regulated articles developed in other economies may be filed directly for a Biosafety Permit for Field Trial. If the Bureau of Plant Industry determines that the data set generated on the field trial conducted and/or commercial propagation experience in other regions are applicable to the local setting, the applicants may no longer be required to undergo contained or confined tests in the Philippines, following the principle of data transportability. If biologically relevant differences are observed in studies conducted in one region or country, these data can be used to assess potential environmental harm in another country.

- **Social, economic, ethical, and cultural considerations.** The revised JDC shifts the language of SEC inclusion from "shall take into account" into "may take into account" suggesting that SECs will now be optional and not mandatory. This aligns with the language provided in the CPB. Public consultations will be the avenue to account for SECs instead of the application process.

- **Validity of biosafety permits.** Biosafety approvals for direct use and commercial propagation will no longer require renewals after five years of safe use and will remain valid unless revoked. Routine review will still be conducted upon receipt of new and science-based information on the biotech crop.

- **No deregulation.** There will be no deregulation under the 2021 JDC, but greater emphasis is directed to revocation grounds so permits can be invalidated at any time as well as address the major point of delay in the process. BPI will monitor compliance to permit conditions.

- **GM plants and plant products with stacked events.** Plants with stacked traits produced through conventional breeding of approved genetically modified parental lines and their derived products are not considered novel, and therefore need not be assessed. The permit holder may request for the registration of the stacked and intermediate or sub-stacked events in the BPI Approval Registry for Propagation or for Direct Use, as the case may be.

- **Petition for reconsideration.** The aggrieved party for decisions made on applications for field trial, commercial propagation and direct use may file for a reconsideration to the Department of Agriculture Secretary within 15 working days from the announcement of the decision.

Conclusion

Modern biotechnology provides farmers and consumers with products that contribute sufficient and affordable nutrient enhanced food that considers environmental sustainability. A regulatory environment that allows these products to come to market and be accepted by the public is essential.

The revised 2021 JDC provides for a streamlined process in handing applications on GE crops, and clearly defined the roles and responsibilities of each concerned departments/agencies in the decision-making process. Essentially, the revised JDC shortens the timeline of approvals, which will also reduce compliance costs for commercializing GM crops. Transparency and public participation continue to be an essential component of the regulatory process following the government's policies on transparency, efficiency, and accountability. These decisions redound to the benefit of our most important stakeholders- the farmers and consumers who will enjoy the benefits of sustained availability of improved products in the market. It is also important to ensure that the regulations also provide clear access to timely recourse and remedies in the event of non-compliance or violations.

Finally, it is hoped that the changes made on the framework will hasten the safety assessment of GM crops and its products without the burden of unnecessary regulatory processes.

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