

## Biosafety Permit for Direct Use as Food and Feed, or for Processing Number 21-083FFP

Stacked trait product **Cotton MON531 x MON1445** owned and licensed by Monsanto Philippines Inc., with office address at 2<sup>nd</sup> Flr. Bayer House, Canlubang Industrial Estate, Calamba, Laguna, has satisfactorily undergone biosafety assessment pursuant to the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1, Series of 2016.

The plant product with stacked traits conferred through conventional breeding has individual traits that have already been granted prior approval for direct use as food and feed, or for processing by the Bureau of Plant Industry (BPI), namely:

Cotton MON531, approved on October 29, 2019 Biosafety Permit No. 19-052 Cotton MON1445, approved on August 22, 2019 Biosafety Permit No. 19-039

No interactions were found among the stacked traits; hence this product was found to be as safe as conventional cotton and can substitute for its traditional counterpart for direct use as food and feed, or for processing. Monsanto Philippines is hereby notified that it may proceed with the activities for this stacked trait product. The importation of this stacked trait product is subject to the conditions stated in this permit.

Issued on **August <u>5</u>**, **2021** at the Bureau of Plant Industry, San Andres St., Malate, Manila subject to conditions stated at the back of this permit, and shall expire on **August <u>4</u>**, **2026**.

GEORGE Y. CULASTE, PhD

Bureau of Plant Industry

## **Biosafety Permit Conditions**

- The permittee shall duly inform the public of this approval by way of publishing in any one of the top three leading newspapers in the country. A copy of such publication shall be submitted to the Bureau of Plant Industry within ten days after publication;
- 2. The regulated article shall be imported solely and exclusively for direct use as food and feed, or for processing and not for field trial or commercial propagation;
- 3. Biosafety permit of the individual traits contained in this stack should be renewed at least 6 months before their respective expiration dates;
- 4. There shall be strict monitoring of the regulated article from port of entry to the traders/importers storage/warehouse as stated in Section 32 of JDC 1 s2016;
- 5. The importer shall ensure the proper and secure packaging of the regulated article for transport and the safety and durability of the transport vehicle, for prevention of any possible spillage or unintended release during transport/import. The Bureau of Plant Industry (BPI) shall conduct inspection of the shipment at the port of entry:
- 6. Control and mitigating measures as identified in the Environmental Management Plan (EMP) must be complied to prevent unwanted release of GM seeds into the environment:
- 7. In case of accidental release of cotton MON531 x MON1445, such as road spill during transport, it is the responsibility of the importers to inform the Bureau of Plant Industry (BPI) immediately. The BPI shall impose this condition on the Sanitary and Phytosanitary Import Clearance (SPSIC). Monsanto Philippines Inc. will assist the BPI to prevent unwanted germination of the GM seeds.
- 8. If new information on the regulated article and its effects on human health and the environment becomes available, and such information is relevant and significant, the risk assessment shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly; and
- 9. The permit holder shall comply with the conditions set by the BPI as stated in the Biosafety Permit for Direct Use (Article 7, Section 21.H of the JDC 1, s.2016).

Violation of any condition shall lead to revocation of this permit as provided in the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 Article VII, Section 21, J. In the event new information becomes available indicating that the regulated article could pose greater risks to biodiversity, human and animal health than its conventional counterpart, the applicant shall, on its own, immediately take measures necessary to protect human and animal health, and the environment.

I have read and understood the Terms and Conditions herein set forth and I enter in this agreement voluntarily and with my express consent, I have unto affix my signature with full knowledge of its legal effect.

Signature over printed name of the Technology Developer

Aug. 6, 2021