SOPs / Handout

Adopted by the 25th Meeting of National Biosafety Committee (NBC) on the import of Genetically Modified Organisms (GMOs) and their products for direct use in Food, Feed, and/or Processing (FFP)

For the import of Genetically Modified Organisms (GMOs) and Living Modified Organisms (LMOs) or products thereof for direct use as Food or Feed or for Processing (FFP) following SOPs provide guidance to the importers and other relevant stakeholders.

i. Initially, importer will apply for licence to import GMOs for FPP only through a public sector IBC. IBC will process and evaluate application for import of GMOs for FFP purposes and submit its evaluation & recommendation to Pak-EPA for consideration of TAC. The evaluation of TAC will be placed before NBC for a final decision. After one year, the importers will be allowed to process their cases from any IBC notified by Pak-EPA.

ii. The Importer will be responsible in case of adverse impact resulting from improper transportation, spillage, improper use, during offloading and processing.

iii. The importer will be responsible for ensuring that same GMOs or product thereof are imported as permitted under the Licence. The importer will also ensure that release order by DPP is issued only after the consignment-specific permit is issued by Pak-EPA.

iv. Random sampling of GMOs and/or their products will be carried out on arrival of consignments. In case of violation or non-compliance of the terms of the Licence by an importer, strict legal action will be undertaken including fines and confiscation/destruction of the consignment. In addition, the license to import GMOs and their products will also be cancelled. The imported commodity, if required, will be returned to the country of origin at the cost of the importer.

v. Every importer will declare in their licence application the quantity of GMOs they intend to import. This declaration should be in line with the importers' capacity, like provision of the importers' previous year's import-data or feed utilization or financial statements.

vi. The licence will be for one GMO commodity including all of its Events.

vii. While processing an application for import of GMO product intended for FFP, IBC concerned will take into consideration toxicity, allergenicity, digestibility assessments and compositional analysis of the all the individual Events using secondary data. The importer shall be responsible for revision of his license if any new Event is developed and released in the country of origin.

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viii.The importer shall give all necessary data of the GMO intended for use in FPP to the IBC to prepare the case in effective manner. IBC will forward its recommendations to the TAC based on desk-based studies after obtaining secondary data from the applicant that is premised on international biosafety risk assessments by the developers as well as other countries that allow import of GMOs.

ix. After obtaining an import licence, the importer will have to obtain a consignment specific permit from Pak-EPA every time he imports a certain quantity of GMOs or products thereof, within his licenced annual limit, in order to enable Pak-EPA to report exact quantity imported on the Biosafety Clearing House. With reference to the Section 6, sub-section 2(d)(ii) and Section 7(c) of Pakistan Environmental Protection Act 1997 and the Rule 26 of Pakistan Biosafety Rules, 2005, a processing fee of Rs.300/ton will be paid by the importer to Pak-EPA at the time of getting permit for import of each consignment of GMO. The fee will be deposited in the Clean Environment Fund.

IBC may charge to Pak-EPA a processing fee of Rs. 10,000/- per gene-Event at the stage of providing its assessment of application for import of GMO/LMO to TAC.

Pak-EPA shall develop an electronic portal for grant of consignment specific permits. Pak -EPA may hire consultants for review of cases received for consideration and deliberation by TAC. The fees of such consultants may be charged to the Clean Environment Fund with the approval of its Board.

Disclaimer:

These SOPs have been developed through stakeholders' consultation. The same were considered by the TAC in its 30th meeting held on 14-03-2023, and further reviewed and adopted as SOPs in the 25th meeting of NBC held on 20-03-2023.An application format and amendments in Pakistan Biosafety Rules 2005 and National Biosafety Guidelines 2005 were finalized to accommodate application for import of GMOs/LMOs for direct use as FFP. The amendments will become effective after approval of the Federal Government.

The SOPs are for facilitation purposes only and are based on the National Biosafety Guidelines (Amended 2023). In cases where there is contradiction, the Pakistan Biosafety Rules (Amended 2023) and National Biosafety Guidelines (Amended 2023)will prevail.