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A Comparative Study of Environment Risk Assessment Guidelines of Developing and Developed Countries Including Bangladesh

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Abstract: Genetically engineered (GE) plants are the need of time for increased demand for food. A complete set of regulations need to be followed from the development of a GE plant to its release into the environment. The whole regulation system is categorized into separate stages for maintaining the proper biosafety. Environmental risk assessment (ERA) is one of such crucial stages in the whole process. ERA identifies potential risks and their impacts through science-based evaluation where it is done in a case-by-case study. All the countries which deal with GE plants follow specific guidelines to conduct a successful ERA. In this study, ERA guidelines of 4 developing and 4 developed countries, including Bangladesh, were compared. ERA guidelines of countries such as India, Canada, Australia, the European Union, Argentina, Brazil, and the US were considered as a model to conduct the comparison study with Bangladesh. Initially, ten parameters were detected to compare the required data and information among all the guidelines. Surprisingly, an adequate amount of data and information requirements (e.g., if the intended modification/new traits of interest has been achieved or not, the growth habit of GE plants, consequences of any potential gene flow upon the cultivation of GE plants to sexually compatible plant species, potential adverse effects on the human health, etc.) matched between all the countries. However, a few differences in data requirement (e.g., agronomic conventions of non-transformed plants, applicants should clearly describe experimental procedures followed, etc.) were also observed in the study. Moreover, it was found that only a few countries provide instructions on the quality of the data used for ERA. If these similarities are recognized in a more framed manner, then the approval pathway of GE plants can be shared.

Keywords: GE plants, ERA, harmonization, ERA guidelines, Information and data requirements

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