

# The Characteristics of Japan's ERA of Genetically modified crops and proposal for streamlining data requirements

Satsuki Furubayashi<sup>1\*</sup>, Ryo Ohsawa & Mai Tsuda

<sup>1</sup>*University of Tsukuba, Ibaraki Pref., Japan*

\*Satsuki\_furubayas370@maff.go.jp

## Abstract

For the cultivation of genetically modified (GM) crops, most of countries require environmental risk assessment (ERA) before releasing them into environment. Many efforts for international harmonization of ERA have been made and recently it is proposed to streamline the data required for ERA. GMOs have been used in Japan for more than 30 years. Although there is almost no cultivation of GM crops in Japan, Japan has approximately one hundred and fifty risk assessment including applications based on cultivation. Based on those experience, some of the data and procedures required in ERA have been streamlined considering the concept of data transportability. However, the adaptations of such efficient procedure are limited to some crops and transgene combinations. In order to conduct even more efficient and appropriate assessment in the future, it is necessary to review the structure of the Japanese ERA itself. In doing so, it would be useful to compare the ERA framework and individual data/analysis on cultivation with those of the US and EU. One of the unique features of Japan's ERA is the way it captures the substance of "cultivation" and the need for the ERA to assume unintended domestic cultivation of GM when imports of crop products, mixed with GM and non-GM, are expected. Then it is required agronomic data from confined field trials within Japan. However, considering the importance of data of field trials conducted in multiple locations, agronomic data in other countries would be adopted in the ERA of Japan. Looking at ERA frameworks in different countries, the endpoints of ERA framework are roughly similar, but there are some differences. There are also some different types of data required. It is worthwhile to analyze why these differences occur and what kind of data should be communicated in conducting ERA in Japan.

**Key words:** genetically modified crop, environmental risk assessment, data transportability, cultivation, international harmonization