Data Transportability for Studies Performed to Support an Environmental Risk Assessment for Genetically Modified (GM) Crops

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Abstract

Laboratory and field data generated on genetically modified (GM) plants in one country can inform the environmental risk assessment and support regulatory decision-making for GM plants being cultivated in another country. Well-designed studies that test clear risk hypotheses and that follow well-established methods allow for conclusions to be made about potential environmental effects from cultivation of a GM plant relative to its conventional counterparts. Following the principle of data transportability, if no biologically relevant differences between a GM plant and its conventional counterparts are observed in one country or region, data from these studies can be used to inform the risk assessment in another country, regardless of agroclimatic zone. Similarly, if biologically relevant differences are observed in studies conducted in one country, these data can be used to assess potential environmental harm in another country. Gathering additional data for the ERA in a different country or in expanded regions may increase the weight of evidence of environmental safety, but additional field study data are only warranted if specific hypotheses of risk remain after assessing risk based on the existing data, and if they would affect the outcome of decision-making. This approach is similar to the standard practice of mutual acceptance of data that has broad acceptance within the chemical industry and is supported by international organizations such as the Organisation for Economic Cooperation and Development (OECD). Transportation of product data across regions has been successfully used by multiple countries to eliminate redundancy, create regulatory efficiencies, and enable timely realization of the benefits of GM plants.

Key words: data transportability, environmental risk assessment, genetically modified plant, agroclimate,