Weight-of-Evidence Risk Assessment is Sufficient for Intractable Proteins

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Abstract

When introduced proteins in genetically modified plants are expressed at levels too low for purification, or are not amenable to heterologous expression, a weight-of-evidence safety assessment provides a comprehensive review to determine food and feed safety of the introduced protein. A weight-of-evidence safety assessment of a plant resistance protein (R-protein) introduced into potato demonstrates minimal hazard and negligible exposure and supports a conclusion of close to zero risk for consumption of the protein in the genetically modified crop. The protein hazard and exposure assessments are reviewed. This tiered, weight-of-evidence safety assessment approach is supported by CODEX guidelines, is sufficient to evaluate risk, and has been accepted by several regulatory agencies globally. This method is particularly important for intractable proteins when traditional protein safety and toxicity data are not available.

Key words: weight-of-evidence, food safety, risk assessment, intractable protein