

Thousands of evaluations over 25 years have repeatedly proven GM crops to be as safe as their conventional counterparts. It's time to evaluate how food/feed safety assessments are conducted for GM crops, and focus data requirements to address plausible risk.

The learnings and experience over the past 25 years now suggest improvements in how we evaluate the compositional safety of GM crops.

When GM crops were first commercialized over 25 years ago, crop composition studies were recommended due to uncertainty of the potential for transgene insertion to have a greater effect on the safety and nutrition of food and feed compared to traditional breeding methods with a history of safe use.

Advances in molecular biology and genetics have revealed that the genetic changes responsible for compositional variation are mechanistically the same in traditionally bred crops and GM crops, but those in GM crops are generally less frequent and less substantial.

Empirical evidence from all studies to date shows that development of a GM crop induces less compositional variation than development of traditionally bred varieties, and that the background genetics of the variety and the environment in which it is grown have a much larger impact on the composition of the crop.

Compositional changes produced through the insertion of a GM trait are predictable and no unexpected unsafe compositional changes have manifested in GM crops or commercial breeding stacks of GM events.

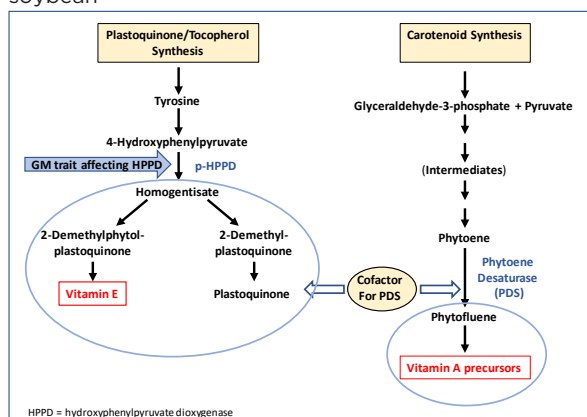
A greater understanding of both the genetics and mechanism for achieving a GM trait increase the ability to predict compositional changes in GM crops compared to traditional breeding. The mechanism of action for the transgene can be used to determine potential effects on metabolic pathways and the potential resulting effects on crop composition that could affect safety or nutrition.

Scientific advances in molecular biology and genetics allow for a more focused and streamlined approach to the evaluation of GM crop compositional safety.

Example Assessment:

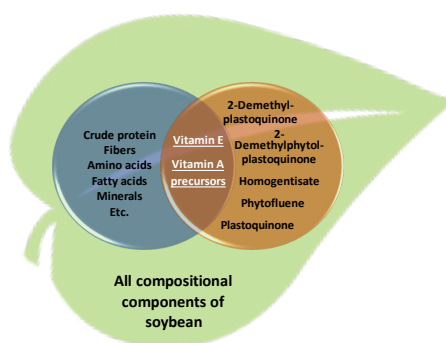
1) Determine what metabolites/components could be affected:

Trait affecting hydroxyphenylpyruvate dioxygenase (HPPD) in soybean



Inside blue circles: metabolites that are hypothesized to be affected by the GM trait

2) Determine what nutritional components should be quantified:



Blue circle: components considered to be important for nutrition or safety

Orange circle: components hypothesized to be affected by the GM trait(s) of interest

Circle overlap area: those components to be included in the nutritional assessment

3) Evaluate safety implications of any observed change

The learnings and experience over the past 25 years now suggest a hypothesis driven step-wise approach to evaluate the compositional safety of GM crops