Stacked Trait Products Are As Safe As Non-Genetically Modified (GM) Products Developed By Conventional Breeding Practices

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Abstract

Stacked trait products are increasingly used around the world because they provide robust and sustainable solutions; however, regulatory approaches to stacked trait products vary from country to country. Variations in regulatory approaches between countries results in asynchronous approvals, increasing the potential for trade flow disruptions, and adds to the regulatory burden for product developers. After more than 25 years of experience with genetically modified (GM) crops and over 20 years of experience with stacked trait products, it is clear that stacked trait products created via conventional breeding of approved single trait crops pose no additional risk and are as safe as the parental single events, unless there is a potential for the stacked traits to interact. For this reason, additional safety assessments of a stacked trait product produced by conventional breeding should not be required unless there is a plausible and testable hypothesis for interaction of the traits. The potential for trait interaction can be assessed based on the mode of action without the need for additional, experimental data in many cases. Many countries have recognized the safety and benefits of stacked trait products and either do not require additional safety assessments, if the single trait parents are approved, or have substantially simplified their requirements. Harmonized, science-based regulatory approaches are needed to support innovative GM products including stacked trait products. This presentation will discuss science-based regulatory approaches for stacked trait products and also survey the current regulatory climate for these products.

Key words: stacked trait product, breeding stack, genetically-modified plant, GM event.