Position Paper

Regulatory Assessment of Plant Biotechnology-Derived Combined Event Products

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Scope

Combined event products (also known as "breeding stacks") are those products containing two or more individual biotechnology-derived events produced through conventional breeding by crossing plants carrying independent events to produce progeny containing the combination of events. This paper focuses on the regulatory safety assessment of combined event products obtained through conventional breeding.

Position

The member companies of CropLife International (CLI) believe that regulatory assessment of the safety of biotechnology-derived combined event products produced by conventional breeding is essentially not different from combining conventionally bred traits and therefore generally unnecessary. The safety assessment of the single events is fundamental to the safety assessment of combined events. Where individual biotechnology-derived single events have been determined to be as safe as their conventional counterparts, it is generally concluded, based on knowledge of conventional breeding, that the breeding combination of the single events is also as safe as the combination of non-biotech traits in conventional varieties (1).

However, CLI companies recognize that whereas some countries have chosen to not regulate combined event products (e.g. Canada), other do choose to regulate them. In countries where safety assessments may be required for combined events, these assessments should only be confirmatory and based on efficacy or composition/expression depending on the type of traits combined. If a safety concern has been identified or if there are plausible hypotheses of harm arising from interactions among the added traits, studies/additional risk assessment could be conducted that address the specific safety concern. In products with three or more single events combined, the safety assessment of the single events and the confirmatory assessment of the combination are sufficient to inform the safety of the sub-combinations of the combined event. Therefore, any regulatory assessments for combined event products should be based on the largest combination of events and cover all smaller combinations of those events.

Background

Conventional breeding has a history of safe use and should be recognized as the baseline for defining principles of risk assessment for combination of genetic information in plant variety production. The World Health Organization confirmed this position in 1995, stating that when two plants which are substantially equivalent to conventional varieties are crossed by conventional breeding techniques, the combined event product is expected to be substantially equivalent to the individual event products (2). Combined event products produced via conventional plant breeding of previously approved single events should be subject to the same regulatory oversight that is applied to conventionally-bred crops. For a crop that has a history of safe use, there is

no *a priori* scientific reason for undertaking additional safety assessments when biotechnology events are combined by normal breeding practices. In countries where safety assessments may be required for combined events, these assessments should only be confirmatory and based primarily on the single event assessments. In such cases, additional data to further confirm the assessment such as efficacy, composition or expression (depending on the type of traits combined) can demonstrate the single event assessments are still appropriate (3). Any assessments conducted on a combined event product containing three or more single events also apply to the smaller combinations of those events. Therefore any regulatory assessments for combined event products should be based on the largest combination of single events and include all smaller combinations.

In regulatory systems where a Combined Event Product has to be notified to the authorities, a thorough risk assessment regarding the nature of the traits and their potential combinatorial effects based on existing single events data is the appropriate basis for a regulatory decision (monograph).

Summary

- The safety assessment of the single events is fundamental to the safety assessment of combined events. Where individual biotechnology-derived single events have been determined to be as safe as their conventional counterparts, it is generally concluded, based on knowledge of conventional breeding, that the breeding combination of the single events is also as safe as the combination of non-biotech traits in conventional varieties (1) and further assessments are not necessary.
- In countries where safety assessments may be required for combined events, these assessments should only be confirmatory and based on efficacy or composition/expression depending on the type of traits combined.
- In products with three or more single events combined, the safety assessment of the single events and the confirmatory assessment of the combination are sufficient to inform the safety of the sub-combinations of the combined event. Therefore, any regulatory assessments for combined event products should be based on the largest combination of events and cover all smaller combinations of those events.

References

1. CLI. 2005. CropLife International. Regulation of plant biotechnology products containing two or more traits combined by conventional plant breeding http://www.croplife.org/files/documentspublished/1/en-us/PP/199_PP_2005_01_24_Position_Paper_-_Regulation_of_Plant_Biotechnology_Products_Containing_Two_or_More_Traits_Combined_By_Conventional_Plant_Breeding.pdf

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