Risk Assessment for Stacked Events   Annex

Crops which contain more than one biotechnology-derived trait are commonly known as events with "stacked" (or "combined") traits or stacked events (or crops). Conventional crossing of single GM events is the most common method to stack genes in GM events – Breeding stacked events. This will involve the cross-fertilisation of two or more individual GM events to produce a new plant line with traits of its parent lines. Other than conventional crossings, "stacked" crops can also be generated through introduction of more than one novel genes into a single plant line using gene technology.

The scope of this section addresses the risk assessment of breeding stacked events.

Scenarios at which the breeding stacked event are required to undergo full assessment:

a) Breeding stacked events with one or more traits that have not been endorsed by GMAC;
b) Presence of genetic and/or molecular interaction(s) of two (or more) GM traits[1] derived from the parental lines used in generating the final breeding stacked event;
c) Information verifying any non-interaction(s) (genetic and/or molecular) is inadequate[2]; and/or
d) When breeding stacked events are meant for purpose of cultivation.

For those derived from GMAC-endorsed parental GM events (in Singapore) with no interaction among the stacked traits, bridging documentation instead of a full dossier can be submitted for evaluation and endorsement. This documentation set will include:

1. Genetic stability of the recombinant genomic DNA must be demonstrated in the stacked GMO;
2. Information on the stability of GM traits introduced by individual GM event such as expression levels and protein stability, in comparison to that in the single GM event; and
3. Compositional analysis and agronomic variables.

The Flowchart for evaluating breeding stacked events is presented under **Appendix 4**.

Appendix 4: Flowchart for Evaluating Stacked Events

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1 Evidence must be shown that there are no potential genetic interactions and/or interactions between the expressed proteins of the individual traits found in the stacked GM product.

2 To qualify that the breeding stacked event does not harbor any genetic/molecular interactions between two (or more) GM traits derived from its parental lines, proponents need to produce adequate information for GMAC's verification. The GMAC reserves the right to subject the breeding stacked event undergo full review.

Intention to Register "Stacked" Events in Singapore

For Cultivation

For Use as Food or Feed or for Processing

Applicant to submit full dossier to GMAC for a complete risk assessment, in accordance with the provisions of the Singapore Guidelines on the Release of Agriculture-related GMOs

Yes ← Are the stacked traits functionally-related?

No

No ← Have the individual parental GM varieties been previously assessed and endorsed by GMAC?

Yes

Bridging Documentation

Release Subcommittee under GMAC assesses (May seek clarifications/additional Information, as necessary)

Recommendations by Release Subcommittee, Endorsement by GMAC, Approval by AVA.