

Crops which contain more than one biotechnology-derived traits 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 (i.e. functionally-related traits) 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 inadequate¹; 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. Absence of interaction between individual GM events must be demonstrated using data on mode of action of GM traits present in the stacked GMO;
2. Genetic stability of the recombinant genomic DNA must be demonstrated in the stacked GMO;
3. Information on the stability of GM traits introduced by individual GM event such as the presence of protein expression, in comparison to that in the single GM event; and
4. Compositional analysis.

¹ To qualify that the breeding stacked event does not harbor any genetic/molecular interactions between two (or more) GM traits (i.e. functionally-related 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 to undergo full review.

Scenario at which the breeding stacked event is exempted from assessment:

Prior endorsement of higher order combination stacked events covers respective lower order combinations. For single and stacked events derived from prior GMAC-endorsed higher order stacked events, a formal notification can be submitted to GMAC for exemption from assessment. This exemption applies to lower order combinations derived from both GMAC-endorsed higher order stacked events with functionally-related traits as well as those containing traits with no interaction.

The notification will include:

1. Name of single/stacked event(s) for exemption
2. Name of corresponding higher order combination stacked event (GMAC-endorsed)
3. Characteristic(s) present (Herbicide tolerance, insect resistance, etc.)

Concurrent application submission:

Related applications may be submitted together in a single email submission to GMAC:

When submitting the dossier for full assessment or bridging documentation (as applicable for the stacked event), applicants may also submit alongside a formal notification of corresponding lower order combinations for exemption from assessment, should they wish to do so. GMAC will review the stacked event, and upon its assessment and endorsement, exemption of lower order combinations as written in the notification will apply. Applicants will be concurrently notified of the assessment status for the stacked event and exemption status of the lower order combinations.

The flowchart for evaluating breeding stacked events is presented as follows.

Flowchart for Evaluating Breeding Stacked Events

