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Stacked events not from conventional crossing

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3.4 Comparators for other approaches to gene, trait and event stacking.

Re-transformation, Co-transformation and multiple genes in cassettes

Non-GMO ➔ GMO techniques ➔ ➔ ➔ GMO(A+B).

A and B can be genes, inserted DNA or other directed changes in the genome.

Choice of comparator case by case based on:

- linkage of the genes in resulting GMO
- existing (assessed?) GMO-A or GMO-B
- variety used as host or for backcrossing
- the methods used is of no importance

If linkage the comparator could be the closest non GM e.g. the host for transformation or backcrossing variety

3.4.1 Re-transformation.

GMO-A →GMO-A+B

If GMO-A is approved it is safe and can be used as comparator in field trials.

Comparator can be GMO-A or non-GMO based on the closest genetic background e.g. variety used for backcrossing.

The assessment always involves the use of data from approval of the single GMO-A event.

If neither of the single events A or B have been assessed.

If linkage: Comparator as for single events .

If no linkage: Comparator as for single events **and** either the GMO-A or GMO-B

Exemption from this: case by case if scientifically justified e.g. due to knowledge that the two genes are or are not expected to interact.

Above suggestion is based on scientific experience such as no unexpected interactions have taken place e.g. between insect resistance and herbicide resistance.

3.4.2+3 Co-transformation and transformation by multiple genes in cassettes

In principle as re-transformation.

Normally **linkage** is expected ➔ comparator as single events

If **no linkage** ➔ comparator as described in re-transformation

General questions:

Is there any scientific justification for handling the transformation of an approved GMO different from the transformation of a non-GMO?