



EFSA GMO PANEL STATEMENT ON RISK ASSESSMENT OF STACK APPLICATIONS

EFSA NIF Unit

Ad hoc meeting with GMO Industry Representatives

25 March 2026



SELF-TASK MANDATE ON STACKS (EFSA-Q-2026-00110)

A scientific statement regarding the assessment of GM plants containing stacked transformation events obtained by conventional crossing of genetically modified plants with one or several transformation event(s).

Deadline: 30 June



STATEMENT

A Statement of the Scientific Committee or Scientific Panel is a scientific output in the form of a concise document that does not go into the same level of detail as an Opinion. It may be developed for instance in response to a request for a fast-track response in order to address an urgent matter, provide a provisional scientific view or address a previous risk assessment published by EFSA.



TERMS OF REFERENCE

1. Summary of experience gathered by the GMO Panel in the assessment of GM plants containing stacked events over the last 20 years, including more recent complex cases. **(ToR1)**
2. Building on earlier experience, propose improvements in the way data are presented, allowing streamlining of the risk assessment process, with a focus on potential interactions. **(ToR2)**
3. Building on earlier experience, revise the data requirements for the assessment of interactions between the events combined in stacked applications and propose criteria to define cases where field trial data used for agronomic, phenotypic and compositional analysis may not be required. **(ToR3)**



TOR1: SUMMARY OF EXPERIENCE WITH STACKS

In the last 20 years, the EFSA GMO Panel assessed approximately 130 applications, of which 61 were for stacks*.

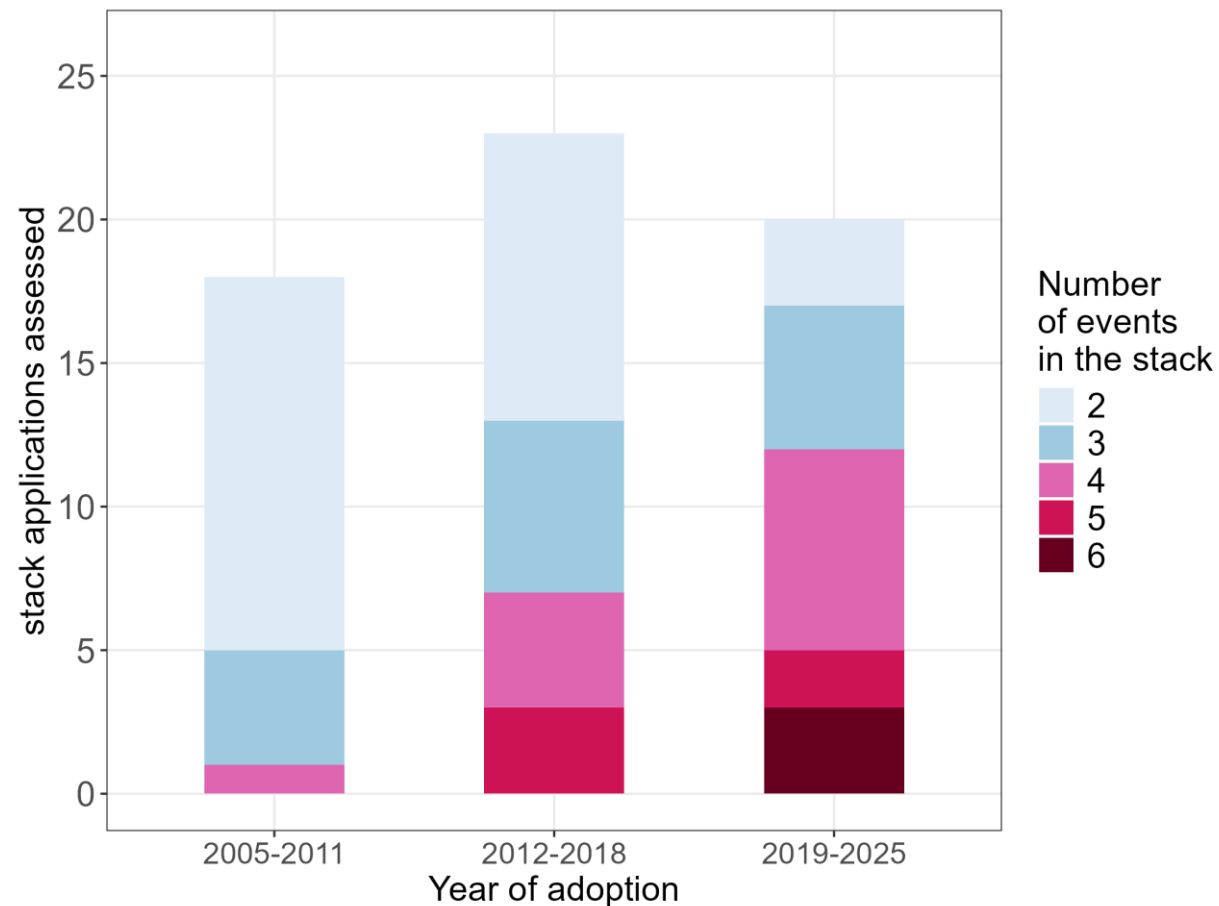
Crop	Number of stack applications
Maize	39
Soybean	11
Cotton	8
Oilseed rape	3
All crops	61

*updated to December 2025



TOR1: SUMMARY OF EXPERIENCE WITH STACKS

Since the publication of the current strategy (2011) the GMO Panel has assessed stack applications with increasing level of complexity (number of events – potential interactions).



TOR1: SUMMARY OF EXPERIENCE WITH STACKS

Single events with (a) specific traits obtained with (b) specific approaches have been assessed much more frequently than others in stacks.

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Cotton	8
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All crops	61



TOR1: SUMMARY OF EXPERIENCE WITH STACKS

Single events with (a) **specific traits** obtained with (b) specific approaches have been assessed much more frequently than others in stacks.

Crop	Number of stack applications	Number of stack applications containing at least one of the following traits					
		Herbicide tolerance	Insect resistance	Drought tolerance	PYE	Altered FA profile	MS / RF
Maize	39	38	35	2	1	-	-
Soybean	11	11	4	-	-	4	-
Cotton	8	8	7	-	-	-	-
Oilseed rape	3	3	-	-	-	-	3
All crops	61	60	36	2	-	-	3

PYE: potential yield enhancement; FA: fatty acid; MS /RF: male sterile / fertility restorer



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TOR1: SUMMARY OF EXPERIENCE WITH STACKS

Single events with (a) specific traits obtained with (b) **specific approaches** have been assessed much more frequently than others in stacks.

Crop	Number of stack applications	Number of stack applications where at least one of the traits was obtained with the following approach		
		NEP	RNAi	Altered expression of endogenous protein
Maize	39	39	3	1
Soybean	11	11	3	-
Cotton	8	8	-	-
Oilseed rape	3	3	-	-
All crops	61	61	6	1

NEP: newly expressed protein



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TOR2 AND TOR3

ToR2. The GMO Panel is drafting guidance on how to present data more effectively to facilitate the assessment of stacks (for example, how to summarise the comparative analysis of the single events to identify potential interactions).

ToR3. Based on the experience gained (ToR1), the GMO Panel is defining in which cases it would be justified to assess a stack without specific data sets, such as the field trial data used for agronomic, phenotypic and compositional analysis .



STATEMENT: TIMELINE TO ADOPTION



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