

Plants with stacked genetically modified events: to assess or not to assess?

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The principles for the safety assessment of genetically modified (GM) organisms (GMOs) are harmonised worldwide to a large extent. There are, however, still differences between the European GMO regulations and the GMO regulations as they have been formulated in other parts of the world. One of these differences relates to the so-called ‘stacked GM events’, that is, GMOs, plants so far, where new traits are combined by conventional crossing of different GM plants. This paper advocates rethinking the current food/feed safety assessment of stacked GM events in Europe based on an analysis of different aspects that currently form the rationale for the safety assessment of stacked GM events.

Background on the policy for stacked GM events

Global harmonisation has been reached to a large extent on the principles for the safety assessment of GMOs, based on well-accepted advisory reports that have been published by, for instance, the Food and Agriculture Organization/World Health Organization (FAO/WHO) and the Organisation for Economic Cooperation and Development (OECD) [1–3], and incorporated into GMO regulation. Differences can, however, still be observed between the European GMO regulations and those in other parts of the world. One of these differences relates to the so-called stacked GM events, that is, plants where new traits are combined by conventional crossing of different (GM) plants.

In the EU, stacked GM events are assessed as new GMOs, although not all aspects of the safety assessment for single GM events are deemed to be as relevant for stacked GM events [4]. As stated in a report from the

European Commission Directorate General for Health and Consumers [5], ‘This procedure is not defined as such in Regulation (EC) No 1829/2003, which covers applications for putting “a GMO” on the market. It derives from the assumed rationale that a stack of two GMOs is simply another distinct GMO, a “new” entity requiring as such a full application, ...’ This rationale seems to some extent in contradiction with the definition of a GMO as defined in EU Directive 2001/18/EC: ‘...an organism... in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination’. All stacked GM events have so far been obtained by conventional crosses of plants with single GM events. In other parts of the world the Codex guideline is mostly used, which does not mention stacked GM events as new GM plant varieties [6].

As a result of this EU decision also to evaluate stacked GM events, applicants need to provide many of the same data for stacked GM events as for new single GM events. In the Commission Implementation Regulation (EU) No 503/2013, which came into force in June 2013 (EC, 2013), it is stated that stacked GM events need to be assessed in relation to: (i) stability of the inserts; (ii) expression of the introduced genes and their gene products; and (iii) potential synergistic or antagonistic effects. This also pertains to any subcombinations, in the case of a multiple stacked GM event, of the stacked GM event that has not yet been authorised separately.

The food/feed safety assessment of stacked GM events was introduced after the *de facto* moratorium on the authorisation of new GM varieties was lifted in 2004 and when the first stacked GM events moved towards the European market [7]. This assessment was then subsequently substantiated in the European Food Safety Authority (EFSA) guidance documents on the safety assessment of food and feed derived from GM plants [4,8]. The revision with respect to the stacked GM events in the guidance document as published in 2011 was based on another guidance document issued by EFSA [9], which specifically focused on the stacked

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Keywords: stacked GM event; safety assessment; genetically modified organism.

0167-7799/\$ – see front matter

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Table 1. Stacked events for which EFSA have issued their scientific opinion

Dossier reference	EFSA has issued its scientific opinion	Stacked event
EFSA-GMO-BE-2010-81	6-09-2012	MS8 × RF3 rapeseed
EFSA-GMO-NL-2009-73	26-01-2012	MON 87701 × MON 89788 soybean
EFSA-GMO-NL-2009-65	8-09-2010	1507 × MON 89034 × NK603 maize
EFSA-GMO-CZ-2008-62	8-09-2010	MON 89034 × 1507 × MON 88017 × 59122 maize
EFSA-GMO-UK-2008-56	29-04-2010	Bt11 × GA21 × MIR604 maize
EFSA-GMO-UK-2007-50	29-04-2010	Bt11 × MIR604 maize
EFSA-GMO-UK-2007-49	15-09-2009	Bt11 × GA21 maize
EFSA-GMO-UK-2007-48	29-04-2010	MIR604 × GA21 maize
EFSA-GMO-NL-2007-39	10-03-2010	MON 89034 × MON 88017 maize
EFSA-GMO-NL-2007-38	9-09-2009	MON 89034 × NK603 maize
EFSA-GMO-CZ-2006-33	2-07-2009	MON 88017 × MON 810 maize
EFSA-GMO-UK-2005-21	3-04-2009	59122 × 1507 × NK603 maize
EFSA-GMO-UK-2005-20	19-11-2008	59122 × NK603 maize
EFSA-GMO-NL-2005-16	26-05-2010	281-24-236 × 3006-210-23 cotton
EFSA-GMO-NL-2005-15	21-04-2009	1507 × 59122 maize
EFSA-GMO-UK-2005-09	8-03-2012	MON 1445 × MON 531 cotton
EFSA-GMO-BE-2004-07	6-07-2005	MON 810 × MON 863 × NK603 maize
EFSA-GMO-UK-2004-06	6-07-2005	MON 863 × NK603 maize
EFSA-GMO-UK-2004-05	28-03-2006	1507 × NK603 maize
EFSA/GMO/DE/2004/03	8-06-2005	MON 810 × MON 863 maize
EFSA-GMO-UK-2004-01	13-10-2005	NK603 × MON 810 maize
EFSA-GMO-RX- (renewal)	08-03-2012	MON 1445 × MON 531 cotton

GM events. EFSA did not deem it necessary to require similar comprehensive datasets for the stacked GM events compared to the single GM events.

At that time, arguments were also put forward as to why assessment of stacked GM events was not necessary from a scientific point of view (UK Advisory Committee on Releases to the Environment; ACRE) [10]. These arguments against assessing stacked GM events were not strongly expressed, perhaps because food/feed safety assessment of new single GM events was still in its infancy and a cautious approach was adopted. In the past decade EFSA has assessed more than 20 different stacked GM events (Table 1). In all cases the conclusion was that the crossing of the single GM events did not result in interactions that cause compositional, agronomic, or phenotypic changes that would raise safety concerns. Now, after over 20 years of experience with the safety assessment of GM events, it is time to rethink the current food/feed safety assessment of stacked GM events in Europe.

Safety assessment of stacked GM events

Safety assessment for plants with single GM events

Within the EU, EFSA performs science-based safety assessments of each single GM event for which an application is filed by the applicant for authorisation of introduction into the European market. This assessment includes a molecular characterisation of the genetic construct that was inserted in the GM plant variety, including the flanking sequences; a toxicological assessment of the new gene products (including potential allergenic properties); an agronomic, phenotypic, and compositional comparison of the GM plant variety with its comparator(s); and a nutritional assessment of the whole GMO-derived food/feed [4,5,8]. The comparative compositional analysis of the GM plant variety and its comparators includes relevant micro- and macronutrients, anti-nutrients, and natural

toxins. The OECD has issued consensus documents on all major crops providing overviews of these key nutrients, and key anti-nutrients per crop, as well as recommendations on which components should be included in the comparison [11,12]. On the basis of these basic data, it is evaluated whether additional toxicological or nutritional studies are required to form an opinion on the safety of the new GM plant variety. All member states have access to the full dossier and their views and comments are replied to by EFSA and, where relevant, incorporated in the final opinion of EFSA.

The EFSA assessments of single GM events provide insight into the effect of the genetic modification on the physiology of the respective plant variety. These assessments are deemed sufficient to allow subsequent crossing of the assessed GM plant variety with any conventional plant variety to obtain new cultivars without a need to assess each of these cultivars for their food or feed safety. Crosses allow for many new interactions of genes, gene products, and plant components. In the EFSA evaluation, foreseeable interactions between the newly introduced trait and traits as known from commercial varieties have been part of the assessment.

Safety aspects of plants with stacked GM events

When looking at the different aspects that, according to the Implementation Regulation (EU) No 503/2013, need special attention in cases of plants with stacked GM events, it is clear that singling out crosses of single GM events compared to crosses of GM plant varieties with conventional plant varieties is no longer justified.

Genetic stability. The first aspect is the stability of the insert. Including this aspect in the safety assessment of stacked GM events reflects the concern that stability of the insert would be at greater risk when crossing GM plant

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