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**Risk assessment of information on the subcombination
Bt11 × 1507 × GA21, related to the application of
Syngenta (EFSA-GMO-DE-2011-99) for authorisation of
food and feed containing, consisting and produced
from genetically modified maize
Bt11 × 59122 × MIR604 × 1507 × GA21**

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Abstract

The GMO Panel has previously assessed the single events Bt11, 59122, MIR604, 1507 and GA21 as well as different stacked events corresponding to combinations of these events and no safety concerns were identified. In its assessment of the five-event maize stack Bt11 × 59122 × MIR604 × 1507 × GA21 (application EFSA-GMO-DE-2011-99), the GMO Panel also assessed all the subcombinations of these events not previously assessed, including some for which little or no experimental data were provided, including the three-event stack Bt11 × 1507 × GA21. In line with Article 5 of the decision for authorisation of application EFSA-GMO-DE-2011-99, the European Commission received from Syngenta information on the levels of the newly expressed proteins in subcombination Bt11 × 1507 × GA21 and tasked EFSA to analyse these data and to indicate whether they have an impact on the previously issued opinion on the five-event stack Bt11 × 59122 × MIR604 × 1507 × GA21 and its subcombinations. Analyses of the levels of the newly expressed proteins Cry1Ab, PAT, Cry1F and mEPSPS showed that there is no indication of an interaction between the events combined in maize Bt11 × 1507 × GA21 that would affect the levels of the newly expressed proteins. Thus, the GMO Panel is of the opinion that the new information for maize Bt11 × 1507 × GA21 does not alter the conclusions of the scientific opinion on application EFSA-GMO-DE-2011-99.

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1. Introduction

The EFSA Panel on Genetically Modified Organisms (GMO) has previously assessed the single events Bt11, 59122, MIR604, 1507 and GA21 as well as different stacked events corresponding to combinations of these events (Table 1). In the framework of the risk assessment of the five-event stack Bt11 × 59122 × MIR604 × 1507 × GA21, the GMO Panel also assessed all 20 subcombinations of this stacked event not previously assessed such as the three-event stack maize Bt11 × 1507 × GA21 and concluded that they are expected to be as safe as the five-event stack maize (application EFSA-GMO-DE-2011-99, EFSA GMO Panel, 2016). The three-event stack maize, Bt11 × 1507 × GA21, was obtained by conventional crossing and data on the levels of the newly expressed proteins were produced and provided by the applicant. The GMO Panel assessed this information to determine whether it has an impact on the opinion previously issued by the European Food Safety Authority (EFSA) on the five-event stack Bt11 × 59122 × MIR604 × 1507 × GA21 and its 20 subcombinations.

Table 1: GMO Panel scientific opinions on the single maize events Bt11, 1507, MIR604, 1507 and GA21 and stacks containing these single events

Event	Application	EFSA Scientific Opinions
Bt11	C/F/96/05.10 EFSA-GMO-RX-Bt11 EFSA-M-2012-0232	EFSA (2005a), EFSA GMO Panel (2012), EFSA (2009a), EFSA GMO Panel (2012)
59122	EFSA-GMO-NL-2005-23 EFSA-GMO-RX-003	EFSA GMO Panel (2013a,b), EFSA GMO Panel (2017a)
MIR604	EFSA-GMO-UK-2005-11	EFSA (2009b)
1507	C/NL/00/10 C/ES/01/01,2001/18/EC EFSA-GMO-NL-02 EFSA-GMO-RX-1507 EFSA-GMO-RX-001	EFSA (2004), EFSA (2005b), EFSA (2005c), EFSA (2009c), EFSA GMO Panel (2017b)
GA21	EFSA-GMO-UK-2005-19 EFSA-GMO-RX-GA21 EFSA-GMO-RX-005	EFSA (2007), EFSA GMO Panel (2017c)
Bt11 × GA21	EFSA-GMO-UK-2007-49 EFSA-GMO-DE-2009-66	EFSA GMO Panel (2009a), EFSA GMO Panel (2015)
MIR604 × GA21	EFSA-GMO-UK-2007-48 EFSA-GMO-DE-2009-66	EFSA GMO Panel (2010a), EFSA GMO Panel (2015)
59122 × 1507	EFSA-GMO-DE-2005-15 EFSA-GMO-CZ-2008-62 EFSA-GMO-BE-2013-118	EFSA GMO Panel (2009b), EFSA GMO Panel (2010b), EFSA GMO Panel (2017d)
Bt11 × MIR604	EFSA-GMO-UK-2007-50 EFSA-GMO-DE-2009-66	EFSA GMO Panel (2010c), EFSA GMO Panel (2015)
Bt11 × GA21 × MIR604	EFSA-GMO-UK-2008-56 EFSA-GMO-DE-2009-66	EFSA GMO Panel (2010d), EFSA GMO Panel (2015)
Bt11 × 59122 × MIR604 × 1507 × GA21 (and 20 subcombinations)	EFSA-GMO-DE-2011-99	EFSA GMO Panel (2016)

1.1. Background and Terms of Reference as provided by the requestor

The completion of the risk assessment of the five-event stack maize event Bt11 × 59122 × MIR604 × 1507 × GA21 and its subcombinations independently of their origin (application EFSA-GMO-DE-2011-99 of Syngenta), was followed by the decision of the European Commission authorising the food and feed containing, consisting and produced from GM maize Bt11 × 59122 × MIR604 × 1507 × GA21 and subcombinations under Regulation (EC) 1829/2003 (Commission implementing decision 2017/1209/EU). As laid down in Article 5 of this decision, the authorisation holder is requested to provide information on the expression levels of the newly expressed proteins for any subcombinations that were to be created by targeted breeding approaches and commercialised.

On 18 August 2017, Syngenta informed the European Commission that the subcombination Bt11 × 1507 × GA21 will be produced by targeted breeding for commercialisation and in line with the Commission implementing decision 2017/1209/EU, sent information on the levels of the newly expressed proteins for this subcombination to the European Commission. On 15 September 2017, the European Commission requested EFSA to assess this information and indicate whether it has an impact on the opinion for application EFSA-GMO-DE-2011-99 adopted by EFSA.

2. Data and methodologies

2.1. Data

The applicant provided a study which included data on the levels of the newly expressed proteins, Cry1Ab, phosphinothricin acetyltransferase (PAT), Cry1F and mutated 5-enolpyruvylshikimate-3-phosphate-synthase (mEPSPS) in the three-event stack and the corresponding singles Bt11, 1507 and GA21.¹ The study contains data derived from plants grown in three locations in one season and is therefore in line with the latest GMO Panel guidelines for the risk assessment of genetically modified (GM) plants (EFSA GMO Panel, 2011) and also with the requirements as laid down in Regulation (EU) No 503/2013². On 27 October 2017, the GMO Panel requested further information on the statistical methodology applied to analyse the data on the levels of the newly expressed proteins. The applicant provided the requested information on 22 November 2017.³

2.2. Methodologies

In delivering this statement, the GMO Panel took into account the information provided by the applicant and carried out its scientific risk assessment based on the appropriate principles described in its guidelines for the risk assessment of GM plants (EFSA GMO Panel, 2011) and Regulation (EU) No 503/2013.

2.2.1. New information for the subcombination maize Bt11 × 1507 × GA21 submitted as part of the current mandate

Plants were grown under field conditions in USA in 2014 (three locations, five replicate plots).¹ The levels of Cry1Ab, PAT, Cry1F and mEPSPS proteins in the three-event stack maize and the three single events were quantified by enzyme-linked immunosorbent assay (ELISA). Protein levels were determined in leaves (V6 and R1 stages), roots (V6 and R1 stages), whole plants (V6 and R1 stages), pollen (R1 stage) and in grain (R6 and senescence stages) (Annex A).

3. Assessment

The GMO Panel assessed the levels of the newly expressed proteins in the three-event stack and the respective singles. The levels of the newly expressed proteins Cry1Ab, PAT, Cry1F and mEPSPS were similar in the three-event stack Bt11 × 1507 × GA21 and the corresponding single events Bt11, 1507 and GA21, in all tissues, except for the expected differences for the PAT protein levels resulting from the combination of single events Bt11 and 1507 both producing PAT protein in the three-event stack maize. For mEPSPS, quantitative data were not available for all tested tissues because in some tissues the expression levels were below the limit of detection (LOD) and limit of quantification (LOQ) (Annex A). Based on the available data, there is no indication of an interaction between the events that would affect the levels of the newly expressed proteins in this three-event stack maize Bt11 × 1507 × GA21. This is consistent with the conclusions of the GMO Panel for application EFSA-GMO-DE-2011-99.

¹ Comparison of Transgenic Protein Concentrations in Bt11 × TC1507 × GA21, Event Bt11, Event TC1507, and Event GA21 Maize Tissues Report No: TK0212355.

² Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L157, 8.6.2013, p. 1–48.

³ Additional information: 22/11/17.

4. Conclusions

Based on the analysis of the data provided, the GMO Panel considers that the new information for maize Bt11 × 1507 × GA21 does not alter the conclusions of the scientific opinion on application EFSA-GMO-DE-2011-99 (EFSA GMO Panel, 2016).

Documentation provided to EFSA

- 1) Letter from the European Commission, received on 15 September 2017, concerning a request to analyse additional information related to the application for authorisation of food and feed containing, consisting and produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21 and genetically modified maize combining two or three of the events under Regulation 1829/2003 (Commission Decision 2017/1209/EU).

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Abbreviations

Cry	crystal protein
ELISA	enzyme-linked immunosorbent assay
GM	genetically modified
GMO	EFSA Panel on Genetically Modified Organisms
LOD	limit of detection
LOQ	limit of quantification
mEPSPS	mutated 5-enolpyruvylshikimate-3-phosphate-synthase
PAT	phosphinothricin acetyltransferase

Annex A – Means, standard deviations and ranges (n = 15) of protein levels in plant tissues from different developmental stages ($\mu\text{g/g}$ dry weight) from maize events Bt11 × 1507 × GA21, Bt11, 1507 and GA21. Plants were not treated with intended herbicides

	Bt11 × 1507 × GA21	Bt11	1507	GA21
Cry1Ab				
Leaf (V6)	133.0 ^(a) ± 57.5 ^(b) (81.9–207) ^(c)	118.0 ± 57.5 (75.0–205.0)		
Leaf (R1)	50.7 ± 47.4 (14.8–80.9)	41.5 ± 47.4 (18.3–92.0)		
Root(V6)	46.7 ± 14.6 (30.5–59.8)	46.1 ± 14.6 (35.6–59.5)		
Root(R1)	21.4 ± 13.6 (7.65–35.5)	19.7 ± 13.6 (10.4–26.3)		
Whole plant (V6)	109.0 ± 35.7 (0.702–183)	97.0 ± 35.7 (60.2–144)		
Whole plant (R1)	27.4 ± 27.4 (9.30–55.6)	23.0 ± 27.4 (9.3–55.6)		
Pollen (R1)	0.14 ± 0.051 (0.105–0.199)	0.125 ± 0.051 (0.0899–0.189)		
Grain (R6)	4.5 ± 0.54 (3.67–5.59)	3.95 ± 0.54 (3.23–4.84)		
Grain (senescence)	4.0 ± 1.571 (2.65–4.96)	3.68 ± 1.571 (2.52–4.81)		
PAT^(d)				
Leaf (V6)	5.59 ± 2.028 (2.02–7.92)	0.383 ± 0.1737 (0.0849–0.594)	5.86 ± 1.649 (1.91–8.78)	
Leaf (R1)	8.15 ± 2.434 (0.139–0.931)	0.506 ± 0.1792 (0.142–0.695)	7.98 ± 1.942 (4.82–11.2)	
Root(V6)	0.772 ± 0.3024 (0.310–1.36)	0.503 ± 0.2351 (0.230–0.933)	0.358 ± 0.1329 (0.149–0.545)	
Root(R1)	0.822 ± 0.459 (< LOD–1.50)	0.590 ± 0.3293 (< LOD–0.976)	0.367 ± 0.245 (< LOD–0.717)	
Whole plant (V6)	3.56 ± 0.786 (2.52–5.63)	0.577 ± 0.2466 (0.139–0.931)	3.46 ± 0.764 (1.34–4.38)	
Whole plant (R1)	3.41 ± 2.201 (0.851–8.14)	0.583 ± 0.2247 (0.336–1.06)	3.24 ± 1.456 (1.42–6.35)	
Pollen (R1)	< LOD	< LOD	< LOD	
Grain (R6)	ND (< LOD–0.129)	ND (< LOD–0.0612)	ND (< LOD–0.0572)	
Grain (senescence)	ND (< LOD–0.0532)	ND (< LOD–0.0423)	ND (< LOD–< LOQ)	
Cry1F				
Leaf (V6)	28.7 ± 10.7 (20.5–37.5)		29.3 ± 10.7 (18.6–40.0)	
Leaf (R1)	22.5 ± 5.3 (15.8–25.7)		22.1 ± 5.3 (14.9–27.7)	
Root(V6)	9.69 ± 5.1 (6.99–13.3)		8.96 ± 5.1 (3.21–12.5)	
Root(R1)	6.57 ± 7.54 (1.65–11.6)		6.85 ± 7.54 (2.76–11.7)	
Whole plant (V6)	19.1 ± 7.0 (11.5–23.4)		18.4 ± 7.0 (11.8–24.0)	

	Bt11 × 1507 × GA21	Bt11	1507	GA21
Whole plant (R1)	13.0 ± 3.1 (8.43–16.5)		15.4 ± 3.1 (11.8–22.8)	
Pollen (R1)	43.1 ± 11.5 (34.1–53.2)		43.4 ± 11.5 (36.4–51.1)	
Grain (R6)	7.52 ± 7.53 (4.91–14.6)		8.44 ± 7.53 (5.05–14.0)	
Grain (senescence)	8.34 ± 4.38 (6.16–12.1)		8.53 ± 4.38 (6.23–12.5)	
mEPSPS				
Leaf (V6)	22.3 ± 34.98 (< LOQ–56.5)			33.3 ± 34.98 (< LOQ–73.6)
Leaf (R1)	ND (< LOD–60.1)			ND (< LOQ–89.0)
Root(V6)	ND (< LOD–< LOQ)			ND (< LOD–< LOQ)
Root(R1)	ND (< LOD–< LOQ)			ND (< LOQ–21.9)
Whole plant (V6)	ND (< LOD–57.3)			ND (< LOQ–52.3)
Whole plant (R1)	31.1 ± 22.35 (< LOD–57.7)			50.6 ± 22.35 (22.7–73.9)
Pollen (R1)	146.0 ± 15.7 (110.0–177.0)			115.0 ± 15.7 (90.1–130.0)
Grain (R6)	ND (< LOD–< LOQ)			ND (< LOQ–8.49)
Grain (senescence)	ND (< LOD–< LOQ)			ND (< LOQ–6.25)

LOD: limit of detection; LOQ: limit of quantification; PAT: phosphinothricin acetyltransferase; mEPSPS: mutated 5-enolpyruvylshikimate-3-phosphate-synthase; ND: Not determined.

(a): Mean.

(b): Standard deviation.

(c): Range.

(d): The standard deviation (SD) values reported for PAT levels in Bt11, 1507 and Bt11 × 1507 × GA21 were determined with descriptive statistics. The SD values for Cry1Ab, Cry1F and mEPSPS levels were determined with analysis of variance.