

ANNEX A

Completion of scope of application EFSA-GMO-DE-2011-99 and scientific justification related to the risk assessment

Scope of the application

Upon request from DG SANCO, Syngenta has completed the scope of application EFSA-GMO-DE-2011-99. As a result, the scope of the application includes all sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21 maize independently of their origin apart from the 1507 x 59122 sub-combination approved by Dow Agro-Sciences which will remain under the existing approval² (see Table 1 below).

In addition, Syngenta has requested to extend the authorisation for import, food and feed use and processing for all potential uses as any other maize of the sub-combinations already approved in the EU apart from the 1507 x 59122 sub-combination approved by Dow Agro-Sciences which will remain under the existing approval (see Table 2).

The unique identifier assigned for Bt11 x 59122 x MIR604 x 1507 x GA21 maize in accordance with Commission Regulation (EC) 65/2004 is SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9.

The unique identifiers assigned to Bt11 x 59122 x MIR604 x 1507 x GA21 maize sub-combinations are the following:

**Table 1: Unique identifiers assigned to all of the sub-combinations of
Bt11 x 59122 x MIR604 x 1507 x GA21 maize**

Stack sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21	Unique identifiers
Bt11 x 59122:	SYN-BTØ11-1 x DAS-59122-7
Bt11 x MIR604:	SYN-BTØ11-1 x SYN-IR6Ø4-5
Bt11 x 1507:	SYN-BTØ11-1 x DAS-Ø15Ø7-1
Bt11 x GA21:	SYN-BTØ11-1 x MON-ØØØ21-9
59122 x MIR604:	DAS-59122-7 x SYN-IR6Ø4-5
59122 x GA21:	DAS-59122-7 x MON-ØØØ21-9
MIR604 x 1507:	SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
MIR604 x GA21:	SYN-IR6Ø4-5 x MON-ØØØ21-9
1507 x GA21:	DAS-Ø15Ø7-1 x MON-ØØØ21-9
Bt11 x 59122 x MIR604:	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5

² EC (2010a) Commission Decision of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 5131). *Official Journal of the European Union* L202: 11-15.

Stack sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21	Unique identifiers
Bt11 x 59122 x 1507:	SYN-BTØ11-1 x DAS-59122-7 x Ø15Ø7-1
Bt11 x 59122 x GA21:	SYN-BTØ11-1 x DAS-59122-7 x MON-ØØØ21-9
Bt11 x MIR604 x 1507:	SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
Bt11 x MIR604 x GA21:	SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9
Bt11 x 1507 x GA21:	SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
59122 x MIR604 x 1507:	DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
59122 x MIR604 x GA21:	DAS-59122-7 x SYN-IR6Ø4-5 x MON-ØØØ21-9
59122 x 1507 x GA21:	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
MIR604 x 1507 x GA21:	SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
Bt11 x 59122 x MIR604 x 1507:	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
Bt11 x MIR604 x 1507 x GA21:	SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
Bt11 x 59122 x MIR604 x GA21:	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4- x MON-ØØØ21-9
59122 x MIR604 x 1507 x GA21:	DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
59122 x 1507 x GA21 x Bt11:	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØØ21-9 x SYN-BTØ11-1

Table 2: List of the sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21 maize already approved in the EU

Product	Unique identifiers	Approval	Expiry
1507 x 59122	DAS-Ø15Ø7x DAS-59122-7	(EC, 2010a ³)	27 July 2020
Bt11 x GA21	SYN-BTØ11-1 x MON-ØØØ21-9	(EC, 2010b)	27 July 2020
Bt11 x MIR604	SYN-BTØ11-1 x SYN-IR6Ø4-5	(EC, 2011a)	21 Dec 2021
MIR604 x GA21	SYN-IR6Ø4-5 x MON-ØØØ21-9	(EC, 2011b)	21 Dec 2021
Bt11 x MIR604 x GA21	SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9	(EC, 2011c)	21 Dec 2021

³ Remains under the existing authorisation (EC (2010a) Commission Decision of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 5131). *Official Journal of the European Union* L202: 11-15.)

Scientific justification related to the risk assessment of the sub-combinations of Bt11 x 59122 x MIR604 x 1507 x GA21 maize independently of their origin

The combined maize trait product Bt11 x DAS-59122-7 x MIR604 x TC1507 x GA21 maize (hereafter referred to as 'Bt11 x 59122 x MIR604 x 1507 x GA21 maize') is a genetically modified maize (GM) that is produced by conventional breeding crosses of the following GM maize events: Bt11, DAS-59122-7 (hereafter referred to as 59122 maize), MIR604, TC1507 (hereafter referred to as 1507 maize) and GA21.

Syngenta has already provided in the above mentioned application a thorough risk assessment and data that should be sufficient to allow EFSA to positively conclude on the safety of Bt11 x 59122 x MIR604 x 1507 x GA21 maize and all of its sub-combinations independently of their origin.

In particular, the data and the conclusions of the risk assessment confirm the conclusions reached in previous safety assessments of the relevant single and stacked maize events previously authorised. Furthermore, some of the data presented in the application represents updated information of that previously provided in the applications for Bt11, 59122, MIR604, 1507 and GA21 maize, such as the bioinformatic searches, which also confirm the previous conclusions reached in the assessments conducted for such maize products.

Considering that:

- i) The risk assessment of GM plants containing stacked events focuses on issues related to stability of the inserts, expression of the introduced genes and their products and potential synergistic or antagonistic effects resulting from the combination of the events (EFSA, 2011);
- ii) The Bt11 x 59122 x MIR604 x 1507 x GA21 maize and all of its sub-combinations independently of their origin have been produced by conventional breeding crosses of the GM maize single events Bt11, 59122, MIR604, 1507 and GA21 maize;
- iii) There is no new genetic modification in Bt11 x 59122 x MIR604 x 1507 x GA21 maize or in any of its sub-combinations independently of their origin;
- iv) The novel proteins expressed in the GM maize events Bt11, 59122, MIR604, 1507 and GA21 maize have been thoroughly characterised and evaluated and considered to be safe for human and animal health and the environment;
- v) Bt11 x 59122 x MIR604 x 1507 x GA21 maize expresses the novel traits present in the single GM maize events through the production of the respective novel proteins;
- vi) Each sub-combination of Bt11 x 59122 x MIR604 x 1507 x GA21 maize will produce a subset of the corresponding proteins from the single events present in that particular sub-combination;
- vii) The molecular characterisation of Bt11 x 59122 x MIR604 x 1507 x GA21 maize has confirmed the expected DNA hybridization patterns from each individual event in the stacked maize demonstrating preservation of the integrity of the insert from each individual event to Bt11 x 59122 x MIR604 x 1507 x GA21 maize and therefore to all the sub-combinations of fewer of these events independently of their origin;
- viii) The molecular characterisation of Bt11 x 59122 x MIR604 x 1507 x GA21 maize has also confirmed the sub-cellular location of the insert from each

- individual event in Bt11 x 59122 x MIR604 x 1507 x GA21 maize and therefore in all the sub-combinations of fewer of these events independently of their origin;
- ix) The protein expression in Bt11 x 59122 x MIR604 x 1507 x GA21 maize is not substantially different from that of the Bt11, 59122, MIR604, 1507 or GA21 single maize events;
 - x) The analysis of the protein expression also confirms that the crossing of the single maize events Bt11, 59122, MIR604, 1507 and GA21 results in no interactions between them in Bt11 x 59122 x MIR604 x 1507 x GA21 maize or the sub-combinations of fewer of these events independently of their origin;
 - xi) The genetic and phenotypic stability of the single events Bt11, 59122, MIR604, 1507 and GA21 maize has been confirmed in Bt11 x 59122 x MIR604 x 1507 x GA21 maize and therefore there is no evidence for genetic or phenotypic interactions in Bt11 x 59122 x MIR604 x 1507 x GA21 maize or the sub-combinations of fewer of these events independently of their origin;
 - xii) The analysis of forage and grain from Bt11 x 59122 x MIR604 x 1507 x GA21 maize and from the respective single events confirms that they are compositionally equivalent to conventional maize varieties except for the presence of the intended traits;
 - xiii) That the results from the compositional analysis also confirm that there are no biologically significant changes in composition as an unintended result of the transformation process in the single events, the breeding process to produce Bt11 x 59122 x MIR604 x 1507 x GA21 maize; or, the expression of the transgenes in Bt11 x 59122 x MIR604 x 1507 x GA21 maize;
 - xiv) The comparative assessment of the agronomic traits between Bt11 x 59122 x MIR604 x 1507 x GA21 maize and its conventional counterpart confirms that Bt11 x 59122 x MIR604 x 1507 x GA21 maize is agronomically and phenotypically equivalent to conventional maize, apart from the introduced traits;
 - xv) The results obtained from the agronomic and phenotypic evaluation of Bt11 x 59122 x MIR604 x 1507 x GA21 maize also provide further evidence that there are no agronomic or phenotypic interactions in Bt11 x 59122 x MIR604 x 1507 x GA21 maize or the sub-combinations of fewer of these events independently of their origin;
 - xvi) Toxicological and allergenic assessments of the newly expressed proteins have already been performed as part of the risk assessments conducted to support the applications for the authorisation of the single maize events under Regulation (EC) No. 1829/2003; and, no further studies are required for the assessment of the stack.

As a result of the above considerations, we conclude:

1. The risk assessment of Bt11 x 59122 x MIR604 x 1507 x GA21 maize containing the events Bt11, 59122, MIR604, 1507 and GA21 maize has confirmed:
 - a. the stability of the inserts;
 - b. expression of the introduced genes and their products; and,
 - c. the absence of any indications of potential synergistic or antagonistic effects resulting from the combination of the events;
2. There are no indications of interactions of any safety concern between the combined events present in Bt11 x 59122 x MIR604 x 1507 x GA21 maize plants;

3. The results obtained from the comparative assessment provided in the application provide strong evidence for the absence of any safety concerns arising from Bt11 x 59122 x MIR604 x 1507 x GA21 maize or any of the sub-combinations from Bt11 x 59122 x MIR604 x 1507 x GA21 maize independently of their origin; and,
4. There is no need to perform any additional toxicity tests for the toxicological assessment of Bt11 x 59122 x MIR604 x 1507 x GA21 maize or any of the sub-combinations from Bt11 x 59122 x MIR604 x 1507 x GA21 maize independently of their origin.

Taking into account all the considerations and conclusions presented above and the data and risk assessment included in application EFSA-GMO-DE-2011-99, the information provided allows to conclude on the safety of Bt11 x 59122 x MIR604 x 1507 x GA21 maize and all of the sub-combinations independently of their origin and no additional experimental data is necessary.

REFERENCES:

EC (2010a) Commission Decision of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 5131). *Official Journal of the European Union* L202: 11-15.

EC (2010b) Commission Decision of 28 July 2010 renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11xGA21 (SYN-BTØ11-1xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 5135)). *Official Journal of the European Union*. L199: 36-39.

EC (2011a) Commission Decision of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604 (SYN-BTØ11-1xSYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2011) 9535)). *Official Journal of the European Union*. L344: 59-63.

EC (2011b) Commission Decision of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2011) 9535)). *Official Journal of the European Union*. L344: 55-58.

EC (2011c) Commission Decision of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2011) 9536)). *Official Journal of the European Union*. L344: 64-68.

EFSA (2011) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. *EFSA Journal* 2011; 9(5): 2150. [37 pp.] doi:10.2903/j.efsa.2011.2150. Available online: www.efsa.europa.eu/efsajournal.htm