

Seeds Regulatory Affairs Manager
EAME

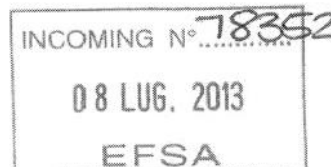
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Abteilung Gentechnik
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Germany



5 July 2013

Scope of applications EFSA-GMO-DE-2009-66 (Bt11 x MIR162 x MIR604 x GA21 maize) and EFSA-GMO-DE-2009-67 (Bt11 x MIR162 x GA21 maize)

Dear Sirs,

We refer to the correspondence from DG SANCO dated 28 June 2013 (Ref. SANCO/EI/JP/mn sanco.ddg2.e. 1(2013)2442772; see Annex 1 for ease of your reference), asking Syngenta to complete the initial scope of the above mentioned applications so that the scope includes all combinations of two or three single GM events constituting Bt11 x MIR162 x MIR604 x GA21 maize independently of their origin and asking Syngenta to consider that the two applications could be merged into one single application.

In accordance with that request, Syngenta hereby completes the scope of application EFSA-GMO-DE-2009-66 so as to include Bt11 x MIR162 x MIR604 x GA21 maize and all sub-combinations from Bt11 x MIR162 x MIR604 x GA21 maize independently of their origin. Namely:

- Bt11 x MIR162 x MIR604 x GA21 maize (SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5 x MON-00021-9),
- Bt11 x MIR162 x MIR604 maize (SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5),
- Bt11 x MIR162 x GA21 maize (SYN-BT011-1 x SYN-IR162-4 x MON-00021-9),
- Bt11 x MIR604 x GA21 maize (SYN-BT011-1 x SYN-IR604-5 x MON-00021-9),
- Bt11 x GA21 maize (SYN-BT011-1 x MON-00021-9),
- Bt11 x MIR162 maize (SYN-BT011-1 x SYN-IR162-4),
- Bt11 x MIR604 maize (SYN-BT011-1 x SYN-IR604-5),
- MIR162 x GA21 maize (SYN-IR162-4 x MON-00021-9),
- MIR162 x MIR604 maize (SYN-IR162-4 x SYN-IR604-5),
- MIR604 x GA21 maize (SYN-IR604-5 x MON-00021-9).

Syngenta has also agreed that the two applications EFSA-GMO-DE-2009-66 and EFSA-GMO-DE-2009-67 are merged into one single application (see Annex 2). Consequently, we withdraw application EFSA-GMO-DE-2009-67.

Please note that all the data provided with the above mentioned applications should be sufficient to allow the GMO Panel to positively conclude on the safety of Bt11 x MIR162 x MIR604 x GA21 maize and all its sub-combinations independently of their origin.

Yours sincerely,

Syngenta Crop Protection AG

Seeds Regulatory Affairs Manager EAME

Legal Counsel Seeds

Copy:

- Dr D. André (DG SANCO)
- Ms E. Waigmann (EFSA GMO Unit)
- Dr K. Lheureux (EFSA APDESK)

Annex 1

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5 July 2013

Scope of applications EFSA-GMO-DE-2009-66 (Bt11 x MIR162 x MIR604 x GA21 maize) and EFSA-GMO-DE-2009-67 (Bt11 x MIR162 x GA21 maize)

Dear Dr André,

Further to your letter dated 28 June 2013 (Ref. SANCO/EI/JB/nn sanco.ddg2.e.1(2013)2442772) requesting that Syngenta completes the initial scope of the above mentioned applications, we hereby confirm that Syngenta agrees:

1.- To complete the initial scope of application EFSA-GMO-DE-2009-66 (Bt11 x MIR162 x MIR604 x GA21 maize) so that it includes all combinations of two or three single GM events constituting Bt11 x MIR162 x MIR604 x GA21 maize independently of their origin and of whether they are currently authorised in the EU or not. Namely:

- Bt11 x MIR162 x MIR604 x GA21 maize (SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5 x MON-00021-9),
- Bt11 x MIR162 x MIR604 maize (SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5),
- Bt11 x MIR162 x GA21 maize (SYN-BT011-1 x SYN-IR162-4 x MON-00021-9),
- Bt11 x MIR604 x GA21 maize (SYN-BT011-1 x SYN-IR604-5 x MON-00021-9),
- Bt11 x GA21 maize (SYN-BT011-1 x MON-00021-9),
- Bt11 x MIR162 maize (SYN-BT011-1 x SYN-IR162-4),
- Bt11 x MIR604 maize (SYN-BT011-1 x SYN-IR604-5),
- MIR162 x GA21 maize (SYN-IR162-4 x MON-00021-9),
- MIR162 x MIR604 maize (SYN-IR162-4 x SYN-IR604-5),
- MIR604 x GA21 maize (SYN-IR604-5 x MON-00021-9).

2.- That the initial authorisation decisions for the combinations currently authorised in the EU are withdrawn when the GM stacks are authorised; and,

3.- That the two applications EFSA-GMO-DE-2009-66 and EFSA-GMO-DE-2009-67 are merged into one single application.

Accordingly, we are informing the Competent Authority of Germany by separate mail of your request and our agreement (please see Annex 1 attached).

Yours sincerely,

Syngenta Crop Protection AG

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Legal Counsel Seeds