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Ms Dorothée André
Head of Unit
DG SANCO E1
European Commission
B-1049 Brussels

Subject: Your request for clarifications on two recently published scientific opinions on applications EFSA-GMO-CZ-2008-62 and EFSA-GMO-NL-2009-65

Dear Ms André,

In response to your letter (ref: SANCO/E1/SP/mb Ares (2010) 778843) received on 20 October 2010, please find below EFSA's clarifications on the two recently published scientific opinions related to GMOs for food and feed uses: application MON 89034 × 1507 × MON 88017 × 59122 maize and MON 89034 × 1507 × NK603 maize.

The applicants provided information on the scope of maize MON 89034 × 1507 × MON 88017 × 59122 and maize MON 89034 × 1507 × NK603 in their applications as well as in several letters to EFSA (16 June 2010, 19 July 2010, 30 July 2010).

EFSA would like to confirm that the EFSA overall opinions related to maize MON 89034 × 1507 × MON 88017 × 59122 and maize MON 89034 × 1507 × NK603 address the scope as requested by the applicants and interpreted by EFSA and the EFSA GMO Panel following various exchange of information (please see Annex). The EFSA overall opinions cover maize MON 89034 × 1507 × MON 88017 × 59122 and maize MON 89034 × 1507 × NK603 and all sub-combinations of the individual events as present in its segregating progeny and do not cover the sub-combinations as independent stacks.

In the case where DG SANCO would like the EFSA GMO Panel to conclude on the safety of all sub-combinations of the individual events of maize MON 89034 × 1507 × MON 88017 × 59122 and maize MON 89034 × 1507 × NK603 as independent stacks, EFSA will need further discussion with the experts of the EFSA GMO Panel and in relevant working groups. In such case, EFSA would be pleased to receive a mandate from DG SANCO to complement the EFSA overall opinions issued on 29 September 2010.

Yours sincerely,



Per Bergman
Head of GMO Unit

Annex:**Extracts from application (technical dossier) and letters related to the scope of applications EFSA-GMO-CZ-2008-62 and EFSA-GMO-NL-2009-65**

The scope of these applications as defined in the technical dossier, part I, is as follows: *“The scope of this application according to Articles 5 and 17 of Regulation (EC) No 1829/2003 on genetically modified food and feed includes all uses of MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) grain equivalent to the uses of any other maize grain”* with the following footnote text: *“Maize grain is the **product of genetic segregation** of the seed from which it is produced. Consequently MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) grain includes the combined event product and any combination of these events.”*

On 26 May 2010, following a letter from DG SANCO, the applicants *“confirmed that the scope includes import, processing and all uses of maize MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) grain equivalent to the uses of any other maize grain. Since maize grain is **the product of genetic segregation** and reunion of genetic components according to Mendelian law, F2 grain produced from MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) hybrid (F1) seeds, will include a mixture of MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) and all combinations with fewer of these **segregating events**. For the avoidance of doubt, all these combinations are included in the scope of our application for authorisation”*.

Furthermore, in a letter dated 29 July 2010, the applicants reconfirmed the scope as follows: *“With respect to your reference in your letter of July 26, 2010 to the “recent extension of scope”, we would like to confirm once more that we have at no point requested an extension to the scope of this application. Our initial application of October 2008 covered all uses of MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) according to Art 3(1) and Art 15(1) of Regulation (EC) N° 1829/2003. Section A.4 (p4) of our initial application includes a footnote to explain that MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) also includes any combination of the single events. This specification of scope was confirmed in our response of March 30, 2010 and in our letter of July 14, 2010”*

Thus, in the view of the EFSA GMO Panel, the applicants confirm the scope as initially defined in their applications as all food and feed uses of maize MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) and grain produced by MON 89034 × 1507 × MON 88017 × 59122 (and MON 89034 × 1507 × NK603) including all sub-combinations of the individual events **derived from genetic segregation**.