Commission Implementing Decision (EU) 2019/2087 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 8428) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/2087

of 28 November 2019

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 8428)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(1)], and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 16 December 2011, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application to the national competent authority of Germany for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 (‘the application’), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products containing or consisting of genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 for uses other than food and feed, with the exception of cultivation.

(2) In addition, the application covered the placing on the market of products containing, consisting of or produced from 56 sub-combinations of the single transformation events constituting maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21. 22 of those sub-combinations were already authorized as follows: Bt11 × MIR162 × MIR604

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× GA21, Bt11 × MIR162 × MIR604, Bt11 × MIR162 × GA21, Bt11 × MIR604 × GA21, MIR162 × MIR604 × GA21, Bt11 × MIR162, Bt11 × MIR604, Bt11 × GA21, MIR162 × MIR604, MIR162 × GA21 and MIR604 × GA21, authorised by Commission Implementing Decision (EU) 2016/1685[(2)]; Bt11 × MIR604 × 1507 × GA21, Bt11 × MIR604 × 1507, Bt11 × 1507 × GA21, MIR604 × 1507 × GA21, Bt11 × 1507, MIR604 × 1507 and 1507 × GA21, authorised by Commission Implementing Decision (EU) 2017/1209[(3)]; and Bt11 × MIR162 × 1507 × GA21, Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507, authorised by Commission Implementing Decision (EU) 2019/1305[(4)].

(3) This Decision covers the remaining 34 sub-combinations: six sub-combinations of five events (Bt11 × MIR162 × MIR604 × 1507 × 5307, Bt11 × MIR162 × MIR604 × 1507 × GA21, Bt11 × MIR162 × MIR604 × 5307 × GA21, Bt11 × MIR162 × 1507 × 5307 × GA21, Bt11 × MIR604 × 1507 × 5307 × GA21 and MIR162 × MIR604 × 1507 × 5307 × GA21); 12 sub-combinations of four events (Bt11 × MIR162 × MIR604 × 1507, Bt11 × MIR162 × MIR604 × 5307, Bt11 × MIR162 × 1507 × 5307, Bt11 × MIR162 × 5307 × GA21, Bt11 × MIR604 × 1507 × 5307, Bt11 × MIR604 × 5307 × GA21, Bt11 × 1507 × 5307 × GA21, MIR162 × MIR604 × 1507 × 5307, MIR162 × MIR604 × 1507 × GA21, MIR162 × MIR604 × 5307 × GA21, MIR162 × 1507 × 5307 × GA21 and MIR604 × 1507 × 5307 × GA21); 11 sub-combinations of three events (Bt11 × MIR162 × 5307, Bt11 × MIR604 × 5307, Bt11 × 1507 × 5307, Bt11 × 5307 × GA21, MIR162 × MIR604 × 1507, MIR162 × MIR604 × 5307, MIR162 × 1507 × 5307, MIR162 × 5307 × GA21, MIR604 × 1507 × 5307, MIR604 × 5307 × GA21 and 1507 × 5307 × GA21); and five sub-combinations of two events (Bt11 × 5307, MIR162 × 5307, MIR604 × 5307, 1507 × 5307 and 5307 × GA21).

(4) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council[(5)]. It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.

(5) On 5 April 2019, the European Food Safety Authority (‘the Authority’) issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[(6)]. The Authority concluded that genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and its sub-combinations, as described in the application, are as safe as its non-genetically modified comparator and the tested non-genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.

(6) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(7) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

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(8) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21, and of the 34 sub-combinations indicated in recital (3) and listed in the application, should be authorised for the uses listed in the application.

(9) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004[7].

(10) On the basis of the opinion of the Authority, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council[8], appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

(11) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environment effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC[9].

(12) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council[10].

(15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

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Article 1

Genetically modified organisms and unique identifiers

Genetically modified maize (*Zea mays* L.), as specified in point (b) of the Annex to this Decision, are assigned the following unique identifiers, in accordance with Regulation (EC) No 65/2004:

(a) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21;

(b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307;

(c) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × GA21;

(d) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × MIR604 × 5307 × GA21;

(e) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × 1507 × 5307 × GA21;

(f) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR604 × 1507 × 5307 × GA21;

(g) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × MIR604 × 1507 × 5307 × GA21;

(h) the unique identifier SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 for genetically modified maize Bt11 × MIR162 × MIR604 × 1507;

(i) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × MIR604 × 5307;

(j) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × 1507 × 5307;

(k) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR162 × 5307 × GA21;

(l) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR604 × 1507 × 5307;

(m) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × MIR604 × 5307 × GA21;

(n) the unique identifier SYN-BTØ11-1 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × 1507 × 5307 × GA21;

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(o) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × MIR604 × 1507 × 5307;

(p) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × MIR604 × 1507 × GA21;

(q) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × MIR604 × 5307 × GA21;

(r) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × 1507 × 5307 × GA21;

(s) the unique identifier SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR604 × 1507 × 5307 × GA21;

(t) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR162 × 5307;

(u) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × MIR604 × 5307;

(v) the unique identifier SYN-BTØ11-1 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × 1507 × 5307;

(w) the unique identifier SYN-BTØ11-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize Bt11 × 5307 × GA21;

(x) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize MIR162 × MIR604 × 1507;

(y) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × MIR604 × 5307;

(z) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × 1507 × 5307;

(aa) the unique identifier SYN-IR162-4 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR162 × 5307 × GA21;

(bb) the unique identifier SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize MIR604 × 1507 × 5307;

(cc) the unique identifier SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize MIR604 × 5307 × GA21;

(dd) the unique identifier DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9 for genetically modified maize 1507 × 5307 × GA21;

(ee) the unique identifier SYN-BTØ11-1 × SYN-Ø53Ø7-1 for genetically modified maize Bt11 × 5307;

(ff) the unique identifier SYN-IR162-4 × SYN-Ø53Ø7-1 for genetically modified maize MIR162 × 5307;

(gg) the unique identifier SYN-IR6Ø4-5 × SYN-Ø53Ø7-1 for genetically modified maize MIR604 × 5307;

(hh) the unique identifier DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 for genetically modified maize 1507 × 5307;