Application for authorisation to place on the market MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-NL-2017-139/ EFSA-Q-2017-00115

Part IV

Labelling

Data protection.
This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

1. **A proposal for labelling in all official languages of the Union, where a proposal for specific labelling is required in accordance with Articles 5(3)(f) and 17(3)(f) of Regulation (EC) No 1829/2003**

The analytical data for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 have demonstrated that this maize has no meaningful differences to the conventional counterpart and to commercially available maize varieties, except for the herbicide tolerance, drought tolerance and insect protection traits conferred by the expression of the CP4 EPSPS, CspB, NptII[1], Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and the DvSnf7 dsRNA. The safety assessment of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 concluded that this product is as safe as conventional maize, and that food and feed products that contain, consist of, or are produced from MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 are as safe as their counterparts derived from conventional maize. Consequently, no labelling in accordance with Article 13(2) and (3) and Article 25(2)(c) and (3) is warranted or required.

2. **Either a reasoned statement that the food or feed does not give rise to ethical or religious concerns or a proposal for labelling in all official languages of the Union as required by Articles 5(3)(g) and 17(3)(g)**

Several scientific societies, peer-reviewed journals and comprehensive Internet websites dedicated to Bioethics report on the ethical debate over the use of genetically modified crops (*e.g.* Nuffield Council on Bioethics[2]; European Society for Agricultural and Food Ethics (EurSafe)[3]; Journal of Agricultural and Environmental Ethics[4]; Centre for Science, Technology and Ethics[5] and Food Ethics Council[6]). The Working Party of the Nuffield Council on Bioethics have published their conclusions, bringing together scientific, socio-economic, religious and ethical considerations on the potential of GM crops, as well as their possible risks (Nuffield Council on Bioethics, 1999 and 2003[7]).

As socio-cultural and personal values differ greatly between individuals, opinions on the use of modern plant biotechnology may be very diverse, which has led to public debate over the use of GM plants in many European countries. However, the conclusions of ethical debates throughout Europe have recognized the importance of the possible benefits which agricultural biotechnology can offer (Nuffield Council on Bioethics, 1999 and 2003[7]). At the same time, ethical considerations of the possible benefits and risks have also contributed to the development of the existing policies and the current stringent regulatory framework in the EU, which allows for the placing on the market of GM foods and feeds after satisfactory analysis of the safety aspects.

The origin of all the elements contained in the MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 inserts has been described in the Part II of this application. MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 does not contain human or animal genes, which is consistent with Monsanto's commitment not to use human or animal genes in any GM plants for food or feed uses. Moreover, as demonstrated in Part II of this application, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is not

[1] NptII acts as a selectable marker by enambling transformed plant cells to be resistant to kanamycin.
[2] http://www.nuffieldbioethics.org - in English – Accessed on 2 February 2017.
[3] http://www.eursafe.org/ - in English – Accessed on 2 February 2017.
[4] http://www.springerlink.com/content/102919/ in English – Accessed on 2 February 2017.
[5] http://www.kuleuven.be/cwte - in English – Accessed on 2 February 2017.
[6] http://www.foodethicscouncil.org – in English – Accessed on 2 February 2017.
[7] http://www.nuffieldbioethics.org/gm-crops-developing-countries and http://www.nuffieldbioethics.org/gm-crops – Accessed on 2 February 2017.

different from other maize, with the exception of its herbicide tolerance, drought tolerance and insect protection. With respect to composition, nutritional value, intended use of the foods and feeds, and health implications, it is reasonable to conclude that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is as safe as its conventional counterpart.

Therefore, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is not considered to have characteristics or properties that would give rise to ethical or religious concerns. Accordingly, specific labelling according to Articles 13(2)(b) or 25(2)(d) of Regulation (EC) No 1829/2003 is not required.

3. When appropriate a proposal for labelling complying with the requirements of point A(8) of Annex IV to Directive 2001/18/EC Articles 5(5)(a) and 17(5)(a): In the case of GMOs or food/feed containing or consisting of GMOs, […] the information required by Annex[es] … IV to Directive 2001/18/EC […],

Labelling threshold

In accordance with Articles 12(2) and 24(2) of the Regulation (EC) No 1829/2003 on genetically modified food and feed, Article 21(2) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Articles 7(2) of the Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and food and feed products produced from genetically modified organisms, it is proposed that a labelling threshold of 0.9% be applied for the placing on the market of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize[8] and derived products.

Unique identifier

In accordance with quidance from the Organization for Economic Co-operation and Development (OECD) Working Group on the Harmonization of Regulatory Oversight in Biotechnology, the unique identifiers[9] for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 are:

MON-87427-7 × MON-8746 Ø -4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON 87411-9 × DAS-59122-7

[8] Maize grain is the product of genetic segregation of the seed from which it is produced. Consequently MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain includes a mixture of the combined event product, any combination of these events and the single events.

[9] List of the Unique Identifiers for the GMO's contained in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, excluding the single events, for which EFSA overall opinions have already been issued and in case of MON 87411 for which EFSA's review is underway, and upon which the risk assessment of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and its sub-combinations is based.

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
MON-87427-7 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3
MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1
MON-87427-7 × MON-8746Ø-4 × MON 87411-9
MON-87427-7 × MON-8746Ø-4 × DAS-59122-7
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-87427-7 × MON-89Ø34-3 × MON 87411-9
MON-87427-7 × MON-89Ø34-3 × DAS-59122-7
MON-87427-7 × DAS-Ø15Ø7-1 × MON 87411-9
MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-87427-7 × MON 87411-9 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-8746Ø-4 × MON-89Ø34-3 × MON 87411-9
MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7
MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON 87411-9
MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-8746Ø-4 × MON 87411-9 × DAS-59122-7
MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON 87411-9
MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7
MON-89Ø34-3 × MON 87411-9 × DAS-59122-7
DAS-Ø15Ø7-1 × MON 87411-9 × DAS-59122-7
MON-87427-7 × MON-8746Ø-4
MON-87427-7 × MON-89Ø34-3
MON-87427-7 × DAS-Ø15Ø7-1
MON-87427-7 × MON 87411-9
MON-87427-7 × DAS-59122-7
MON-8746Ø-4 × MON-89Ø34-3
MON-8746Ø-4 × DAS-Ø15Ø7-1
MON-8746Ø-4 × MON 87411-9
MON-8746Ø-4 × DAS-59122-7
MON-89Ø34-3 × DAS-Ø15Ø7-1
MON-89Ø34-3 × MON 87411-9
MON-89Ø34-3 × DAS-59122-7
DAS-Ø15Ø7-1 × MON 87411-9
DAS-Ø15Ø7-1 × DAS-59122-7
MON 87411-9 × DAS-59122-7

The internationally accepted format quidance from OECD also formed the basis for Commission Regulation (EC) No 65/2004, establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

Labelling of foods and feeds consisting of or containing MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122

In accordance with Articles 12 to 14 and 24 to 26 of Regulation (EC) No 1829/2003, Article 13(2)(f) and Annex IV of Directive 2001/18/EC, and with Article 4 of Regulation (EC) No 1830/2003, operators shall be required to label products containing or consisting of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 with the words "genetically modified maize" or "contains genetically modified maize", and operators shall be required to declare the above mentioned unique identifiers in the list of GMOs that have been used to constitute the mixture that contains or consists of this GMO.

Labelling of foods and feeds produced from MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122

For food and feed products produced from MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 that are not exempted according to Article 5(4) of Regulation (EC) No 1830/2003, operators shall be required to label foods and feeds derived from MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 with the words "produced from genetically modified maize", in accordance with Articles 12 to 14 and 24 to 26 of Regulation (EC) No 1829/2003 and the requirements of Article 5 of Regulation (EC) No 1830/2003. In the case of products for which no list of ingredients exists, operators shall ensure that an indication that the food or feed product is "produced from genetically modified maize" is transmitted in writing to the operator receiving the product.

Additional measures taken by the applicant

Although Monsanto Europe S.A./N.V. is the applicant under Regulation (EC) No 1829/2003 for consent to place MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 on the market for import, processing and all uses as any other maize in the EU, Monsanto is not an operator handling or using the product in the EU.

Operators handling or using MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize and derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products. Given that explicit requirements for the traceability and labelling of GMOs and derived foods and feeds are laid down in Regulations (EC) No 1829/2003 and 1830/2003, and that authorised foods and feeds shall be entered in the Community Register, operators in the food/feed chain will be fully aware of the traceability and labeling requirements for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122. Therefore, no further specific measures are to be taken by the applicant.