

**Application for authorisation of MON 88017 × MON 810  
maize in the European Union, according to  
Regulation (EC) No 1829/2003 on  
genetically modified food and feed**

**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.

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1. **Articles 5(3)(f) and 17(3)(f): Either an analysis [...] showing that the characteristics of the food/feed are not different from those of its conventional counterpart [...], or a proposal for labelling the food/feed in accordance with Article 13(2)(a) and (3) / Article 25(2)(c) and (3).**

The analytical data for MON 88017 × MON 810 has demonstrated that this maize is compositionally and nutritionally not different from conventional counterpart and to commercially available maize varieties, except for the inherited traits. Moreover, the intended uses of MON 88017 × MON 810 are the same as for conventional maize; the placing on the market of these foods and feeds does not have implications for certain sections of the population or specific groups of animals; and the product has a conventional counterpart. Therefore, no labelling in accordance with Article 13(2)(a) and (3) and Article 25(2)(c) and (3) is warranted or required.

2. **Articles 5(3)(g) and 17(3)(g): Either a reasoned statement that the food/feed does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b) / Article 25(2)(d)**

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<sup>1</sup>; European Society for Agricultural and Food Ethics (EurSafe)<sup>2</sup>; Journal of Agricultural and Environmental Ethics<sup>3</sup>; Centre for Science, Technology and Ethics<sup>4</sup> and Food Ethics Council<sup>5</sup>). 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<sup>6</sup>).

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 recognised the importance of the possible benefits which agricultural biotechnology can offer (Nuffield Council on Bioethics, 1999 and 2003<sup>6</sup>). 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 of the inserts in MON 88017 × MON 810 have been described in the initial application. The inserts in MON 88017 × MON 810 do not contain human or animal genes, which is consistent with Bayer's commitment not to use animal or human genes in any GM plants for food or feed uses.

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<sup>1</sup> <http://www.nuffieldbioethics.org> - in English – Accessed on November 25, 2020

<sup>2</sup> <http://www.eursafe.org/> - in English – Accessed on November 25, 2020

<sup>3</sup> <http://www.springerlink.com/content/102919/> in English – Accessed on November 25, 2020

<sup>4</sup> <https://set.kuleuven.be/ethicsatarenberg/expertise-center-ethics-arenberg-1> - in English – Accessed on November 25, 2020

<sup>5</sup> <http://www.foodethicscouncil.org> – in English – Accessed on November 25, 2020

<sup>6</sup> <http://www.nuffieldbioethics.org/gm-crops-developing-countries> and <http://www.nuffieldbioethics.org/gm-crops> – Accessed on November 25, 2020

Moreover, as demonstrated in the initial application, MON 88017 × MON 810 is not different from other maize varieties, with the exception of the tolerance to glyphosate and the protection against target coleopteran and lepidopteran pests, which are traits of agronomic interest. With respect to composition, nutritional value, intended use of the foods and feeds, and health implications, this maize does not have any characteristics or properties which would render food or feed that contains, consists of, or was produced from this maize any different from its conventional counterpart.

Therefore, MON 88017 × MON 810 is not considered to have characteristics or properties that would give rise to ethical or religious concerns. Accordingly, we consider that specific labelling according to Articles 13(2)(b) or 25(2)(d) of Regulation (EC) No 1829/2003 is not required.

**3. 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 [...], or where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision; and Articles 12-24 and 24-26: Labelling – scope, requirements, implementing measures**

*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 Article 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, we propose that a labelling threshold of 0.9 % be applied for the placing on the market of MON 88017 × MON 810 grain and derived products.

*Unique identifier*

In accordance with guidance from the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology, the unique identifier for MON 88017 × MON 810 is MON-88Ø17-3 × MON-ØØ81Ø-6. The internationally accepted format guidance 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 88017 × MON 810*

In accordance with Articles 12-14 and 24-26 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 88017 × MON 810 with the words “genetically modified maize” or “contains genetically modified maize”, and operators shall be required to declare the unique identifier MON-88Ø17-3 × MON-ØØ81Ø-6 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 88017 × MON 810*

For food and feed products produced from MON 88017 × MON 810 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 88017 × MON 810 with the words “produced from genetically modified maize”, in accordance with Articles 12-14 and 24-26 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 GMOs is transmitted in writing to the operator receiving the product.

*Measures taken by the notifier*

Although Bayer CropScience LP is the applicant under Regulation (EC) No 1829/2003 for consent to place MON 88017 × MON 810 on the market for import, processing, and food and feed use in the E.U., Bayer is not an operator handling or using the product in the E.U.

Operators handling or using MON 88017 × MON 810 grain and derived foods and feeds in the E.U. 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 labelling requirements for MON 88017 × MON 810. Therefore, no further specific measures are to be taken by the notifier.