

**Application for authorization to place on the market
MON 87769 × MON 89788 soybean in the European
Union, according to Regulation (EC) No. 1829/2003
on genetically modified food and feed**

Part IV

Labelling and Unique Identifier

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 traditional 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 87769 × MON 89788 have demonstrated that this soybean is compositionally and nutritionally equivalent to its conventional counterpart and to commercially available soybean. The safety assessment of MON 87769 × MON 89788 concluded that this product is as safe as conventional soybean and that food and feed products that contain, consist of, or are produced from MON 87769 × MON 89788 are as safe as their counterparts derived from conventional soybean. Therefore, the placing on the market of foods and feeds produced from MON 87769 × MON 89788 does not have implications for certain sections of the population or specific groups of animals. Consequently, 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 Bioethics¹; European Society for Agricultural and Food Ethics (EurSafe)²; Journal of Agricultural and Environmental Ethics³; Center for Science, Technology and Ethics⁴; Food Ethics Council⁵, European Biotech Consultancy ()⁶). The Working Party of the Nuffield Council on Bioethics have recently 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)¹.

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). 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.

¹ <http://www.nuffieldbioethics.org/go/ourwork/gmcrops/introduction> – Accessed on November 2, 2010

² <http://www.eursafe.org/> – Accessed on November 2, 2010

³ <http://www.kluweronline.com/issn/1187-7863/contents> – Accessed on November 2, 2010

⁴ <http://www.kuleuven.be/cwte/> – Accessed on November 2, 2010

⁵ <http://www.foodethicscouncil.org> – Accessed on November 2, 2010

⁶ <http://www.bio-ned.info> - Accessed on November 2, 2010

The origin of all the elements of the insert in MON 87769 × MON 89788 has been described in Part I of this application. MON 87769 × MON 89788 does not contain human or animal genes, which is consistent with Monsanto's commitment not to use animal or human genes in any GM plants for food or feed uses. Moreover, as demonstrated in Part I of this application, MON 87769 × MON 89788 is substantially equivalent to other soybean, with the exception of the inherited SDA production trait and tolerance to glyphosate trait. With respect to composition, nutritional value, intended use of the food and feeds and health implications, it is reasonable to conclude that, with the expected increase in omega-3 fatty acid content, MON 87769 × MON 89788 is as safe as conventional soybean.

Therefore, MON 87769 × MON 89788 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 87769 × MON 89788 soybeans 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 87769 × MON 89788 is MON-87769-7 × MON-89788-1. 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 87769 × MON 89788

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 87769 × MON 89788 with the words “genetically modified soybean” or “contains genetically modified soybean”, and operators shall be required to declare the unique identifier

MON-87769-7 × MON-89788-1 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 87769 × MON 89788

For food and feed products produced from MON 87769 × MON 89788 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 87769 × MON 89788 with the words “produced from genetically modified soybean”, 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.

Additional measures taken by the applicant

Although Monsanto Europe S.A. is the applicant under Regulation (EC) No. 1829/2003 for consent to place MON 87769 × MON 89788 soybean on the market for import, processing, and food and feed use in the EU, Monsanto is not an operator handling or using the product in the EU.

Operators handling or using MON 87769 × MON 89788 soybeans 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 authorized 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 87769 × MON 89788. Therefore, no further specific measures are to be taken by the applicant.