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GM Food & Feed - Community Register of GM Food and Feed

Event	MON863 x MON810
Notifier	Monsanto Services International S.A./N.V.
Notifier address	Monsanto Services International S.A./N.V. Avenue de Tervuren 270-272 B-1150 Brussels - BELGIUM
Scope of notification	Feed materials produced from MON-00863-5 x MON-00810-6 maize notified as existing feed falling within the scope of Article 20(1)(b) of Regulation (EC) No 1829/2003, namely as feed materials which are produced from a genetically modified organism (GMO).
Designation	<p>The maize hybrid MON 863 x MON 810 was produced by conventional breeding to combine the rootworm resistance trait in MON 863 with the lepidopteran insect resistance trait present in GM maize, MON 810.</p> <p>Inbred lines and hybrids derived from maize line MON 810 containing the cryIA (b) gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> under the control of the enhanced 35S promoter from cauliflower mosaic virus and an intron from the gene coding for the heat shock protein 70 from maize. The insect-protected maize line was generated by particle acceleration technology using two plasmids; PV-ZMBK07 and PV-ZMGT10. The transgenic maize line produced expresses the cry1A(b) gene (origin - <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>) which encodes a cry1A(b) insect control protein (Btk).</p> <p>The genetically modified maize MON 863 was generated by transformation of <i>Zea mays</i> cell culture line AT824 (initiated from immature embryos of an inbred maize line AT) with a <i>MluI</i> restriction fragment from plasmid PV-ZMIR13 using particle acceleration technology. The DNA fragment used for transformation carried two expression cassettes; a selectable marker gene <i>nptII</i> encoding neomycin phosphotransferase II and a trait gene encoding a variant <i>Bacillus thuringiensis</i> Cry3Bb1 insecticidal protein. The <i>nptII</i> gene was regulated by the 35S promoter and used the NOS 3' polyadenylation sequence as terminator. Regulation of the variant <i>cry3Bb1</i> gene involved: a CaMV 35S promoter containing four tandem copies of the AS-1 element; the untranslated 5'mRNA leader sequence of the wheat major chlorophyll a/b-binding protein; the rice actin intron (<i>ract1</i>); a 3' nontranslated region of the wheat heat shock protein 17.3 which terminates transcription and directs polyadenylation. The linear DNA fragment used for transformation was prepared by digestion of plasmid PV-ZMIR13 with restriction endonuclease <i>MluI</i>, separation of the fragments by agarose gel electrophoresis and isolation of the DNA fragment that encoded the <i>cry3Bb1</i> and <i>nptII</i> expression cassettes. Thus, the <i>MluI</i> fragment used for transformation was not expected to contain plasmid backbone DNA sequences.</p> <p>The variant Cry3Bb1 protein expressed in MON 863 maize has seven amino acid differences from wild type Cry3Bb1 and was designed to enhance its expression in plants and insecticidal activity against corn rootworm.</p>
Labelling	Article 25(1) of Regulation (EC) No 1829/2003
Method for detection	<p>See for the parental MON-00863-5 maize line:</p> <ul style="list-style-type: none"> • Event specific real-time quantitative PCR based method for genetically modified MON-00863-5 maize • Validated by the Joint Research Centre (JRC) of the European Commission, URL: http://gmo-crl.jrc.it/detectionmethods/MON863-WEB-Protocol-Validation.pdf <p>See for the parental MON-00810-6 maize line:</p> <ul style="list-style-type: none"> • Event specific Real-time PCR method for quantification of genetically modified MON-00810-6 maize

	<ul style="list-style-type: none"> This detection method was validated by BfR, AACC and the Joint Research Centre (JRC) of the European Commission , URL: http://gmo-crl.jrc.it/statusofdoss.htm
Reference material	<ul style="list-style-type: none"> Joint Research Centre (JRC) of the European Commission, URL: http://www.irmm.jrc.be(for the single events MON-00863-5 and MON-00810-6)
Unique identifier	MON-00863-5 x MON-00810-6
Annex II to the Cartagena Protocol	-
Conditions or restrictions on the placing on the market	Not applicable
Post-market monitoring requirements	Not appropriate
Date of entry into the register	18-04-2005
Date of placing on the market	01/01/2003
Legal base	Art. 20(1)(b) of the Regulation (EC) No 1829/2003
Further information on risk assessment	<p>European Food Safety Authority, <i>The EFSA Journal</i> (2004) 49, 1-25, URL: http://www.efsa.eu.int/science/gmo/gmo_opinions/381/opinion_gmo_06_en1.pdf (under Part C of Directive 2001/18/EC)</p> <p>European Food Safety Authority, <i>The EFSA Journal</i> (2004) 50, 1-25, URL: http://www.efsa.eu.int/science/gmo/gmo_opinions/383/opinion_gmo_07_en1.pdf(under Article 4 of the Novel Food Regulation (EC) No 258/97)</p>