

CERTIFICATE OF ANALYSIS

ERM[®]-BF425c

SOYA SEED POWDER		
	Certified values	Uncertainty ³⁾
Soya 356043 mass fraction ¹⁾	10.0 g/kg ²⁾	1.1 g/kg
Soya 356043 DNA copy number ratio ⁴⁾	0.85 % ⁵⁾	0.11 %
1) Mass fraction of soya 356043 (unique identifier code DP-356Ø43-5) based on the masses of genetically modified 356043 soya seed powder and non-modified soya seed powder and their respective water content. 2) The certified value is traceable to the International System of Units (SI). 3) The certified uncertainty is the expanded uncertainty with a coverage factor $k = 2$, corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008. 4) The copy number ratio of soya 356043 (unique identifier code DP-356Ø43-5) is defined by the soya 356043 real-time Polymerase Chain Reaction quantification method validated by the European Union Reference Laboratory for GM Food & Feed (EURL-GMFF, available on http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm) and calibrated with the soya 356043 plasmid DNA Certified Reference Material ERM[®]-AD425. 5) The certified DNA copy number ratio is the unweighted mean of 15 accepted data sets. It is traceable to the International System of Units (SI).		

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 200 mg.

NOTE

European Reference Material ERM[®]-BF425c was produced and certified under the responsibility of the Institute for Reference Materials and Measurements of the European Commission's Joint Research Centre according to the principles laid down in the technical guidelines of the European Reference Materials[®] co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (<http://www.erm-crm.org>).

Accepted as an ERM[®], Geel, December 2007

Latest revision: June 2011

Signed: 
INFORMATION ONLY

DESCRIPTION OF THE MATERIAL

ERM-BF425c has been produced from whole kernels of a non-modified soya and the genetically modified soya 356043 both delivered by Pioneer Hi-Bred International Inc. (Johnston, IA, US). According to the information provided by Pioneer the genetically modified soya has been self pollinated for several generations in order to establish homozygosity of the transgene. In accordance with the European Commission regulation (EC) No 65/2004, the soya 356043 event, also referred to as DP-356043-5, received the unique identifier DP-356043-5.

The CRM is available in glass bottles containing approximately 1 g of maize powder closed under argon atmosphere. ERM-BF425c is part of a set of four soya powder CRMs containing different mass fractions (< 0.5, 1.0, 10.0 and 100 g/kg) of GM soya 356043. This set of soya powder CRMs was first certified for its GM soya 356043 mass fraction. In 2011, ERM-BF425c has been certified for its DNA copy number ratio.

ANALYTICAL METHODS USED FOR CERTIFICATION

The gravimetric preparation of ERM-BF425c was verified by real-time Polymerase Chain Reaction.

The certified DNA copy number ratio value has been established using the soya 356043 event-specific real-time Polymerase Chain Reaction targeting the 5' plant/insert junction and a single copy target of the *lectin* gene (*le1*) (Event-specific Method for the Quantification of Soybean Event DP-356043-5 using real-time PCR. Validated Method. EURL-GMFF, available via <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>). Measurements were calibrated with the plasmid DNA calibrant ERM-AD425.

PARTICIPANTS

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- Ente Nazionale Delle Sementi Elette ENSE, Tavazzano, IT
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- Lifepoint GmbH DNA Analysis, Illertissen, DE¹ (DAP, DAP-PL-3515.00)
- Livsmedelsverket - National Food Administration, Biology Division, Uppsala, SE¹ (SWEDAC, 1457)
- National Food Research Institute, Molecular Engineering Lab, Tsukuba, JP¹ (International Accreditation Japan, ASNITE 0018R)
- Nacionalni Inštitut za Biologijo - National Institute of Biology (NIB), Ljubljana, SI¹ (DAP, DAP-PL-3328.99)
- Nacionalinė Veterinarijos Laboratorija - National Veterinary Laboratory, Vilnius, LT¹
- NEOTRON, Modena, IT¹ (SINAL, 0026)

¹ Laboratory holds ISO/IEC17025 accreditation for DNA based GMO measurements. The accreditation body and registration number are mentioned between brackets.

- Ontario Plant Laboratories - Canadian Food Inspection Agency, Ontario, CA¹ (Standards Council of Canada, 316)
- RIKILT, Wageningen, NL¹ (RvA, L014)
- Ministère Agriculture et Pêche, Laboratoire National de la Protection des Végétaux, Fleury les Aubrais, FR
- Staatliches Gewerbeaufsichtsamt Hildesheim, Dez. 33 Gentechnik, Hildesheim, DE¹ (DACH, DAC-PL-0360-05-00)
- TNO quality of life - Food & Biotechnology Innovations - GMO foods, Zeist, NL¹ (RvA, L027)
- Tullilaboratorio - Finnish Customs Laboratory, Espoo, FI¹ (FINAS, T006)
- Umweltbundesamt, Wien, AT¹ (BMWA, 200)
- USDA, Grain Inspection, Technical Service Division, Kansas City, MO, US
- Vysoka Skola Chemicko-technologicka v Praze - Institute of Chemical Technology, Prague, CZ¹ (Czech accreditation institute, No. 111/2006)
- Výzkumný ústav rostlinné výroby/ Research Institute for Crop Production, Prague, CZ¹ (Czech accreditation institute, No. 8/2007)

SAFETY INFORMATION

The usual laboratory safety precautions apply. The CRM does not contain viable seeds.

INSTRUCTIONS FOR USE

The material ERM-BF425c, certified for its soya 356043 mass fraction, is intended to be used for calibration or quality control of methods for the detection of genetically modified food and feed containing GM soya 356043.

The material ERM-BF425c, certified for the DNA copy number ratio, is intended to be used for quality control of measurements of the soya 356043 DNA copy number ratio in genetically modified food and feed ingredients. Experiments should be performed exclusively in conjunction with the ERM-AD425 calibrant and the soya 356043 event-specific detection method

The minimum sample intake is 200 mg.

The dry CRM powder is hygroscopic. Users are therefore advised to close bottles immediately after taking a sample.

STORAGE

Bottles should be stored dry and in the dark at maximum temperature of 4 °C. However, the European Commission cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.

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NOTE

A detailed technical report is available on www.irmm.jrc.be. The first report (published in 2007) describes the processing and certification of ERM-BF425 for its soya 356043 mass fraction, the second report (published in 2011) describes the certification of ERM-BF425c for its soya 356043 DNA copy number ratio. A paper copy can be obtained from the Joint Research Centre, Institute for Reference Materials and Measurements on request.