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# Report on the Verification of the Performance of MON 87708 and MON 89788 Event-specific PCR-based Methods Applied to DNA Extracted from GM Stack MON 87708 x MON 89788 Soybean

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2014



Report EUR 26590 EN

Joint  
Research  
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JRC89453

EUR 26590 EN

ISBN 978-92-79-36884-4 (PDF)

ISSN 1831-9424 (online)

doi: 10.2788/47811

Luxembourg: Publications Office of the European Union, 2014

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Printed in Italy

# **Report on the Verification of the Performance of MON 87708 and MON 89788 Event-specific PCR-based Methods Applied to DNA Extracted from GM Stack MON 87708 x MON 89788 Soybean**

**14 March 2014**

**European Union Reference Laboratory for GM Food and Feed**

## **Executive Summary**

An application was submitted by Monsanto Company to request the authorisation of genetically modified stack (GM stack) MON 87708 × MON 89788 soybean (tolerant to dicamba and to glyphosate) and all sub-combinations of the individual events as present in the segregating progeny, for food and feed uses, and import and processing, in accordance with articles 5 and 17 of Regulation (EC) N° 1829/2003 GM Food and GM Feed. The unique identifier assigned to GM stack MON 87708 × MON 89788 soybean is MON-87708-9 x MON-89788-1.

The GM stack MON 87708 × MON 89788 soybean has been obtained by conventional crossing between two genetically modified soybean events: MON 87708 and MON 89788, without any new genetic modification.

The EU-RL GMFF has previously validated individually, and declared fit for purpose, the detection methods for the single events MON 87708 and MON 89788 (see <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>). In line with the approach defined by the ENGL ([http://gmo-crl.jrc.ec.europa.eu/doc/Min\\_Perf\\_Requirements\\_Analytical\\_methods.pdf](http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf)) the EU-RL GMFF has carried out only an *in-house* verification of the performance of each validated method when applied to genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean.

The results of the *in-house* verification led to the conclusion that the individual methods meet the ENGL performance criteria also when applied to genomic DNA extracted from the GM stack MON 87708 × MON 89788 soybean.

This report is published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>.

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## Quality assurance

The EU-RL GMFF is ISO 17025:2005 accredited [certificate number: ACCREDIA 1172 (Flexible Scope for DNA extraction and qualitative/quantitative PCR) - Accredited tests are available at [http://www.accredia.it/accredia\\_labsearch.jsp?ID\\_LINK=293&area=7](http://www.accredia.it/accredia_labsearch.jsp?ID_LINK=293&area=7)].

The original version of the document containing evidence of internal checks and authorisation for publication is archived within the EU-RL GMFF quality system.

The EU-RL GMFF is also ISO 17043:2010 accredited (proficiency test provider) and applies the corresponding procedures and processes for the management of ring trials during the method validation.

The EU-RL GMFF conducts its activities under the certification ISO 9001:2008 of the Institute for Health and Consumer Protection (IHCP) provided by CERMET.

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## 1. Introduction

The EU legislative system <sup>(1, 2)</sup> for genetically modified food and feed provides that any GMO for food and feed use shall undergo the authorisation process before it can be placed on the market. This holds true also for a GMO containing more than one single GM event obtained by conventional crossing, co-transformation or re-transformation (genetically modified stack).

Consequently, the application for authorisation of a GM stack shall be accompanied, among others, by an event-specific method for detection, identification and quantification for each GM event composing the stack, and by samples of the stack and food and feed derived from it. The EU-RL GMFF shall validate the event specific methods of detection proposed by the applicant with regard to their performance when applied to DNA extracted from the stack, and shall report to the European Food Safety Authority, who will include the EU-RL GMFF report in the overall opinion concerning the risk assessment and potential authorisation of the assessed stack. In line with the approach defined by the ENGL ([http://gmo-crl.jrc.ec.europa.eu/doc/Min\\_Perf\\_Requirements\\_Analytical\\_methods.pdf](http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf)) the EU-RL GMFF carries out an *in-house* verification of the performance of each event-specific methods if this method has previously been validated by the EU-RL GMFF for the parental single-line event and these events have been stacked by conventional crossing. These criteria are met for the GM stack MON 87708 × MON 89788 soybean.

Upon reception of methods, samples and related data (step 1), the EU-RL GMFF carried out the assessment of the documentation (step 2) and the *in-house* verification of the methods (step 3) according to the requirements of Regulation (EC) No 641/2004 (Annex I).

The results of the *in-house* verification study were evaluated with reference to ENGL method performance requirements and to the validation results on the individual events.

## 2. Step 1 (dossier reception and acceptance)

Monsanto Company submitted the detection methods, data demonstrating their adequate performance, and the corresponding control samples DNA extracted from GM stack soybean MON 87708 × MON 89788 and from non-GM soybean.

The dossier was found to be complete and thus was moved to step 2.

## 3. Step 2 (dossier scientific assessment)

The data provided by the applicant were assessed against the method acceptance criteria set out by the ENGL <sup>(3)</sup> and with regard to their documentation and reliability.

Table 1 shows values of trueness (expressed as bias %) and precision (expressed as RSD<sub>r</sub> %) calculated by the applicant for the two methods on the stack DNA. Means are the average of fifteen replicates obtained through one run performed with ABI 7500 real-time PCR equipment. Percentages are expressed as GM DNA / total DNA x 100.

Table 1. Trueness (expressed as bias %) and precision (expressed as relative repeatability standard deviation, RSD<sub>r</sub> %) for the MON 87708 and MON 89788 methods applied to GM stack MON 87708 x MON 89788 soybean.

<b>MON 87708</b>			
<b>Unknown sample GM%</b>	<b>Expected value (GMO %)</b>		
	<b>0.085</b>	<b>1.0</b>	<b>10</b>
<b>Mean</b>	0.090	1.0	10
RSD <sub>r</sub> (%)	12	6.2	4.7
Bias (%)	5.8	4.5	0.68
<b>MON 89788</b>			
<b>Unknown sample GM%</b>	<b>Expected value (GMO %)</b>		
	<b>0.085</b>	<b>1.0</b>	<b>10</b>
<b>Mean</b>	0.086	1.1	9.6
RSD <sub>r</sub> (%)	14	6.4	5.5
Bias (%)	0.75	6.4	-4.4

The EU-RL GMFF verified the data and concluded that they were reliable and seemed to confirm that the methods meet the ENGL performance criteria <sup>(3)</sup>.

Two requests of complementary information regarding control samples and DNA sequences were addressed to the applicant. The EU-RL GMFF verified the data and the complementary information received and accepted the received clarifications as satisfactory.

The dossier was therefore moved to step 3.

## **4. Step 3 (EU-RL GMFF experimental testing)**

In step 3 the EU-RL GMFF implemented the two methods in its own laboratory and performed a verification of their performance when applied to DNA extracted from GM stack MON 87708 x MON 89788 soybean.

### **4.1 Materials**

The following control samples were provided by the applicant:

- genomic DNA extracted from homogenised seeds of GM stack MON 87708 × MON 89788 soybean
- genomic DNA extracted from homogenized seeds of non GM soybean.

The EU-RL GMFF prepared test samples of different GMO concentrations by mixing genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean and genomic DNA extracted from non GM soybean in a constant amount of total soybean DNA. The same concentrations as in the validation of the methods for the single lines were achieved. Table 2 shows the five GM concentrations used in the verification of the MON 87708 and MON 89788 methods when applying them to genomic DNA extracted from the GM stack MON 87708 × MON 89788 soybean. These are the same concentrations used in the validation of these methods for the parental single line GMOs.

Table 2. Percentage of MON 87708 and MON 89788 in MON 87708 × MON 89788 in the verification samples.

<b>MON 87708 GM%</b> (GM DNA / Non-GM DNA x 100)	<b>MON 89788 GM%</b> (GM DNA / Non-GM DNA x 100)
0.10	0.10
0.45	0.40
0.90	0.90
4.0	4.0
8.0	8.0

The protocols (reagents, concentrations, primer/probe sequences) described by the applicant were implemented precisely in the EU-RL GMFF laboratory. The in-house verification followed the protocols already published as validated methods for the individual MON 87708 and MON 89788 events (available at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>).

## 4.2 DNA extraction

A method for DNA extraction from soybean seeds was previously evaluated by the EU-RL GMFF with regard to its performance characteristics and was considered valid, i.e. fit the purpose of providing soybean DNA of appropriate quality and amount for being used in subsequent PCR experiments. The protocol for the DNA extraction method is available at [http://gmo-crl.jrc.ec.europa.eu/summaries/MON89788\\_Soya\\_DNAExtrSampl\\_report.pdf](http://gmo-crl.jrc.ec.europa.eu/summaries/MON89788_Soya_DNAExtrSampl_report.pdf).

Consequently, the EU-RL GMFF did not verify the DNA extraction method proposed by the applicant.

## 4.3 Experimental design

Eight PCR runs for each method were carried out. In each run, samples were analysed in parallel with both the GM-specific system and the reference system *AdhC* (*alcohol dehydrogenase C gene*). Five GM levels were examined per run, for each GM level in



duplicate. PCR analysis was performed in triplicate for all samples. In total, for each method (GHB614 and LLCotton25), the quantification of the five GM levels was performed as an average of sixteen replicates per GM level (8 runs x 2 replicated levels per run). An Excel spreadsheet was used for determination of GM%.

#### **4.4 PCR methods**

During the verification study, the EU-RL GMFF carried out parallel tests on DNA extracted from GM stack MON 87708 × MON 89788 soybean using the single detection methods previously validated for the respective single GM events MON 87708 and MON 89788.

For detection of GM soybean events MON 87708 and MON 89788, DNA fragments of 91-bp and 139-bp respectively are amplified using specific primers. PCR products are measured during each cycle (real-time) by means of target-specific oligonucleotide probes labelled with two fluorescent dyes: FAM (6-carboxyfluorescein) as reporter dye at their 5'-end and TAMRA (6-carboxytetramethylrhodamine) as a quencher dye at their 3'-end.

For quantification of GM soybean events MON 87708 and MON 89788, a taxon-specific reference system amplifies a 74-bp fragment of *lectin (Le1)* a soybean endogenous gene (GenBank K00821), using two *Le1* gene-specific primers and a *Le1* gene-specific probe labelled with FAM and TAMRA.

For quantification of GM soybean events MON 87708 and MON 89788, standard curves are generated both for the MON 87708 and MON 89788, and for the *Le1* specific system by plotting Ct values of the calibration standards against the logarithm of the DNA copy numbers and by fitting a linear regression into these data. Thereafter, the normalised Ct values of the unknown samples are measured and, by means of the regression formula, the relative amount of MON 87708 and MON 89788 DNA is estimated.

For detailed information on the preparation of the respective standard curve calibration samples please refer to the protocols of the validated methods at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>.

#### **4.5 Deviations from the validated methods**

No deviations from the original validated methods were introduced.

#### **4.6 Results**

Tables 3 and 4 present the values of the slopes of the different standard curves generated by the EU-RL GMFF when using DNA extracted from the GM stack, from which the PCR efficiency is calculated using the formula  $[10^{(-1/\text{slope})} - 1] \times 100$ , and of the  $R^2$  (expressing the linearity of

the regression) reported for all PCR systems in the eight runs, for GM soybean events MON 87708 and MON 89788.

Table 3. Values of standard curve slope, PCR efficiency and linearity ( $R^2$ ) for the MON 87708 method on GM stack MON 87708 × MON 89788 soybean.

Run	MON 87708			<i>Le1</i>		
	Slope	PCR Efficiency (%)	Linearity ( $R^2$ )	Slope	PCR Efficiency (%)	Linearity ( $R^2$ )
1	-3.37	98	1.00	-3.36	98	1.00
2	-3.40	97	1.00	-3.37	98	1.00
3	-3.36	98	1.00	-3.38	98	1.00
4	-3.39	97	1.00	-3.39	97	1.00
5	-3.36	98	1.00	-3.41	96	1.00
6	-3.38	98	1.00	-3.36	99	1.00
7	-3.39	97	1.00	-3.37	98	1.00
8	-3.37	98	1.00	-3.38	98	1.00
<b>Mean</b>	<b>-3.38</b>	<b>98</b>	<b>1.00</b>	<b>-3.38</b>	<b>98</b>	<b>1.00</b>

Table 4. Values of standard curve slope, PCR efficiency and linearity ( $R^2$ ) for the MON 89788 method on GM stack MON 87708 × MON 89788 soybean.

Run	MON 89788			<i>Le1</i>		
	Slope	PCR Efficiency (%)	Linearity ( $R^2$ )	Slope	PCR Efficiency (%)	Linearity ( $R^2$ )
1	-3.32	100	1.00	-3.39	97	1.00
2	-3.28	102	1.00	-3.31	101	1.00
3	-3.31	100	1.00	-3.38	98	1.00
4	-3.31	101	1.00	-3.34	99	1.00
5	-3.38	98	1.00	-3.42	96	1.00
6	-3.43	96	1.00	-3.37	98	1.00
7	-3.41	96	1.00	-3.40	97	1.00
8	-3.41	96	1.00	-3.38	98	1.00
<b>Mean</b>	<b>-3.36</b>	<b>99</b>	<b>1.00</b>	<b>-3.37</b>	<b>98</b>	<b>1.00</b>

The mean PCR efficiencies of the GM and species-specific systems were above 90% (98% for the MON 87708 and the *Le1* systems, and 99% for MON 89788, respectively). The linearity of the methods ( $R^2$ ) was 1.00 for all systems in all cases. The data presented in Tables 3 and 4 confirm the appropriate performance characteristics of the two methods when tested on GM stack MON 87708 × MON 89788 soybean in terms of PCR efficiency and linearity.

The EU-RL GMFF also assessed the values of trueness (expressed as bias %) and precision (expressed as relative repeatability standard deviation, RSD<sub>r</sub> %) of the two methods applied to samples of DNA extracted from GM stack MON 87708 × MON 89788 soybean, see tables 5 and 6.

Table 5. Estimates of trueness (expressed as bias %) and relative repeatability standard deviation (RSD<sub>r</sub> %) of the MON 87708 method applied to genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean.

<b>MON 87708</b>					
<b>Unknown sample GM%</b>	<b>Expected value (GMO%)</b>				
	<b>0.10</b>	<b>0.45</b>	<b>0.90</b>	<b>4.0</b>	<b>8.0</b>
<b>Mean</b>	0.10	0.42	0.92	3.7	8.3
SD	0.01	0.04	0.03	0.35	0.40
RSD <sub>r</sub> (%)	7.5	10	3.6	9.3	4.8
Bias (%)	4.5	-6.2	1.8	-6.8	4.3

Table 6. Estimates of trueness (expressed as bias %) and relative repeatability standard deviation (RSD<sub>r</sub> %) of the MON 89788 method applied to genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean.

<b>MON 89788</b>					
<b>Unknown sample GM%</b>	<b>Expected value (GMO%)</b>				
	<b>0.10</b>	<b>0.40</b>	<b>0.90</b>	<b>4.0</b>	<b>8.0</b>
<b>Mean</b>	0.11	0.38	0.93	3.9	8.5
SD	0.01	0.03	0.05	0.41	0.29
RSD <sub>r</sub> (%)	9.7	9.0	5.3	11	3.4
Bias (%)	6.6	-4.1	3.0	-1.8	6.4

The trueness of the method is estimated using the measurements of the method bias for each GM level. According to the ENGL acceptance criteria and method performance requirements, the trueness of the method should be  $\pm 25\%$  across the entire dynamic range. As shown in Tables 5 and 6, the values range from -6.8% to 4.5% MON 87708 and from -4.1% to 6.6% for MON 89788. Therefore, the two methods satisfy the above mentioned requirement throughout their respective dynamic ranges, also when applied to DNA extracted from GM stack MON 87708 × MON 89788 soybean.

Tables 5 and 6 also show the relative repeatability standard deviation (RSD<sub>r</sub>) as estimated for each GM level. According to the ENGL acceptance criteria and method performance requirements, the EU-RL GMFF requires RSD<sub>r</sub> values to be below 25%. As the values range between 3.6% and 10% for MON 87708 and between 3.4% and 11% for MON 89788, the two methods satisfy this requirement throughout their respective dynamic ranges when applied to DNA extracted from GM stack MON 87708 × MON 89788 soybean.

## 5. Comparison of method performance on MON 87708 × MON 89788 and on the single events

An indicative comparison of the performance (bias, RSD<sub>r</sub> %) of the two methods applied to GM stack MON 87708 × MON 89788 soybean and on the single-line events is shown in Tables 7 and 8. The performance of the methods on the single lines was previously validated through international collaborative trials (<http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>).

*Note: the comparison of data generated in different testing conditions and different times is intended to be only of qualitative nature; differences in the figures reported are not necessarily statistically significant.*

Table 7. Qualitative comparison of the performance of the MON 87708 detection method applied to genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean and to genomic DNA extracted from the single line event MON 87708.

Trueness and repeatability of MON 87708 quantification on MON 87708 × MON 89788			Trueness and repeatability of MON 87708 quantification on single event MON 87708*		
GM%	Bias (%)	RSD <sub>r</sub> (%)	GM%	Bias (%)	RSD <sub>r</sub> (%)
0.10	4.5	7.5	0.10	3.4	17
0.45	-6.2	10	0.45	7.0	13
0.90	1,8	3.6	0.90	3.4	6.6
4.0	-6.8	9.3	4.0	15	13
8.0	4.3	4.8	8.0	-0.3	11

\*method validated in inter-laboratory study (<http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>)

Table 7. Qualitative comparison of the performance of the MON 89788 detection method applied to genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean and to genomic DNA extracted from the single line event MON 89788.

Trueness and repeatability of MON 89788 quantification on MON 87708 × MON 89788			Trueness and repeatability of MON 89788 quantification on single event MON 89788*		
GM%	Bias (%)	RSD <sub>r</sub> (%)	GM%	Bias (%)	RSD <sub>r</sub> (%)
0.10	6,6	9.7	0.10	-14	16
0.40	-4.1	9.0	0.40	-5.0	22
0.90	3.0	5.3	0.90	-0.9	15
4.0	-1.8	11	4.0	10	13
8.0	6.4	3.4	8.0	2.8	12

\*method validated in inter-laboratory study (<http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>)

## 6. Conclusions

The performance of the two event-specific methods for the detection and quantification of soybean events MON 87708 and MON 89788, when applied to genomic DNA extracted from GM stack MON 87708 × MON 89788 soybean, meets the ENGL performance requirements, as assessed on the control samples provided by the applicant.

The method verification has demonstrated that the PCR efficiency, linearity, trueness and repeatability of the methods were within the limits established by the ENGL.

In conclusion, the verification study confirmed that the two methods are capable to detect, identify and quantify each of the GM events when applied to genomic DNA of suitable quality, extracted from GM stack MON 87708 × MON 89788 soybean.

Therefore these methods, developed and validated to detect and quantify the single events, can be equally applied for the detection and quantification of the respective events combined in GM stack MON 87708 × MON 89788 soybean.

## 7. References

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Luxembourg: Publications Office of the European Union

2014 – 16 pp. – 21.0 x 29.7 cm

EUR – Scientific and Technical Research series –ISSN 1831-9424 (online)

ISBN 978-92-79-36884-4 (PDF)

doi: 10.2788/47811

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