From: Madhu Soni
To: Dausch, Judith
Subject: RE: GRN 609 - Rice Protein -
Date: Friday, January 08, 2016 4:28:17 PM
Attachments: Genysis Lab report- including Arsenic total and inorganic.pdf
Eurofin lab report- inorganic arsenic.pdf

Dear Dr. Dausch,

Following our phone discussion yesterday, I checked the GRAS submission as well as the actual laboratory reports particularly on arsenic analysis. On page 11 of 33 in the GRAS (under section 2.7.3. Heavy Metals), we described arsenic concerns and Axiom policy to test each batch of rice for the arsenic levels. Axiom has also provided the batch data for ten lots (five each for 80 and 90% protein concentrate) in Table 6.

Additionally, we also described on page 11 of 33 that the inorganic arsenic was found to be below 0.015 ppm (below levels of detection). Please note that the inorganic arsenic analysis was performed at two independent laboratories, Eurofins and Genysis, from 10 lots using EPA and ICP-MS method, respectively. I am attaching these two reports (from Eurofin and Genysis labs) that show that inorganic arsenic measured with these two methods was not detectable at detection limits (0.012 ppm or 0.024 ppm). The Genysis report provides values for total arsenic on page 1 of 4 and inorganic arsenic on page on page 2 of 4 for all the lots tested. The total arsenic levels were also below 0.03 ppm.

As both the total arsenic (<0.03 ppm) and inorganic arsenic (<0.015 ppm) levels were very low, we did not further discuss this as these levels are commonly considered as safe. The inorganic arsenic levels as determined at two independent labs by two separate methods are much lower than the 2014 Codex proposed a maximum level for inorganic arsenic in polished rice of 0.200 mg/kg.

Given the low levels, we did not further discuss any arsenic concern or include the original lab reports for arsenic analysis. We are enclosing these reports (please see attached- Genysis lab report- 90% rice protein report is provided, the report for 80% is also available but not included as the file is large). We hope that this provides some insight on Axiom's efforts to make sure that the levels of arsenic in rice protein concentrate are safe. If you need the details of EPA and/or ICP-MS methods, please let me know and I will send it.

We look forward to discuss with you next week.

Best regards

Madhu

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Certificate Of Analysis

Axiom Foods
12049 Jefferson Blvd
Culver City, CA 90230

Certificate ID #: 31937
Report Date: 10-16-2015
Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31053

Analytical Testing Results

Customer Lot #: 20150716-4
Description: Oryzatein 90

Lab Sample ID: 402438

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Arsenic (As)	Rprt	0.019	ppm		0.013	0.033

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Cadmium (Cd)	Rprt	0.067	ppm		0.001	0.008

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Lead (Pb)	Rprt	0.031	ppm		0.005	0.013

Analysis Method: * DMA

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Mercury (Hg)	Rprt	0.014	ppm		0.001	0.010

Analysis Method: USP

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
pH	Rprt	5.70			N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Magnesium (Mg)	Rprt	0.007575	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Manganese (Mn)	Rprt	0.000312	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Phosphorus (P)	Rprt	0.21235	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Potassium (K)	Rprt	0.001082	%		N/A	N/A

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Customer Lot #: 20150716-4
Description: Oryzatein 90

Lab Sample ID: 402438

Analysis Method: RIDASCREEN Competitive

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Gluten	Rprt	<10.00	ppm		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Moisture	Rprt	0.4	%		N/A	N/A

Analysis Method: * AOAC 922.06 (mod)

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Fat	Rprt	0.4	%		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Ash	Rprt	0.7	%		N/A	N/A

Analysis Method: Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Carbohydrates	Rprt	7.13	%		N/A	N/A

Analysis Method: * AOAC 991.43

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Dietary Fiber	Rprt	5.3	%		N/A	N/A

Analysis Method: * Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Calories	Rprt	400	Cal/100g		N/A	N/A

Analysis Method: * ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Inorganic Arsenic	Rprt	ND	ppm		N/A	N/A

Analysis Method: Kjeldahl

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Protein	Rprt	91.37	%		N/A	N/A

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Previous Certificate ID#: 31053

Analytical Testing Results

Customer Lot #: 20150716-4
Description: Oryzatein 90

Lab Sample ID: 402438

Analysis Method: ^ AOAC 991.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Coliforms	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: ^ USP <2021>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Aerobic Plate Count	Rprt	600	cfu/g		N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
E.coli	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Staph aureus	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Salmonella	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ AOAC 997.02

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Yeasts & Molds	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

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Laboratory Comments:

Certificate ID#: 31937

Reviewed By: Les Reeves
Ben Stanfield

Approved By: _____
On Behalf of Genysis Labs

Date: 10-16-2015

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MRL = Method Reporting Limit, a verified value of method/media/instrument sensitivity

ND = Not Detected, testing result not detected above the MDL or MRL

^ = ISO 17025 certified method

* = Analysis performed at a subcontract location

*** = No result could be reported, see above comments

Supplement to Test Report
Additional Pages: N/A

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Certificate ID #: 31933
Report Date: 10-16-2015
Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31049

Analytical Testing Results

Customer Lot #: 20150716-1
Description: Oryzatein 90

Lab Sample ID: 402435

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Arsenic (As)	Rprt	0.025	ppm		0.013	0.033

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Cadmium (Cd)	Rprt	0.017	ppm		0.001	0.008

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Lead (Pb)	Rprt	0.054	ppm		0.005	0.013

Analysis Method: * DMA

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Mercury (Hg)	Rprt	0.014	ppm		0.001	0.010

Analysis Method: USP

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
pH	Rprt	5.74			N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Magnesium (Mg)	Rprt	0.00783	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Manganese (Mn)	Rprt	0.000383	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Phosphorus (P)	Rprt	0.1965	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Potassium (K)	Rprt	0.00130	%		N/A	N/A

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Analytical Testing Results

Customer Lot #: 20150716-1
Description: Oryzatein 90

Lab Sample ID: 402435

Analysis Method: RIDASCREEN Competitive

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Gluten	Rprt	<10.00	ppm		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Moisture	Rprt	0.3	%		N/A	N/A

Analysis Method: * AOAC 922.06 (mod)

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Fat	Rprt	0.2	%		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Ash	Rprt	0.9	%		N/A	N/A

Analysis Method: Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Carbohydrates	Rprt	8.07	%		N/A	N/A

Analysis Method: * AOAC 991.43

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Dietary Fiber	Rprt	7.5	%		N/A	N/A

Analysis Method: * Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Calories	Rprt	400	Cal/100g		N/A	N/A

Analysis Method: * ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Inorganic Arsenic	Rprt	ND	ppm		0.024	N/A

Analysis Method: Kjeldahl

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Protein	Rprt	90.53	%		N/A	N/A

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Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31049

Analytical Testing Results

Customer Lot #: 20150716-1
Description: Oryzatein 90

Lab Sample ID: 402435

Analysis Method: ^ AOAC 991.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Coliforms	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: ^ USP <2021>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Aerobic Plate Count	Rprt	1400	cfu/g		N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
E.coli	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Staph aureus	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Salmonella	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ AOAC 997.02

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Yeasts & Molds	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

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Laboratory Comments:

Certificate ID#: 31933

Reviewed By: Les Reeves
Ben Stanfield

Approved By: _____
On Behalf of Genysis Labs

Date: 10-16-2015

Laboratory Notes:

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Result Symbol Definitions:

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MRL = Method Reporting Limit, a verified value of method/media/instrument sensitivity

ND = Not Detected, testing result not detected above the MDL or MRL

^ = ISO 17025 certified method

* = Analysis performed at a subcontract location

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Supplement to Test Report
Additional Pages: N/A

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Certificate Of Analysis

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Culver City, CA 90230

Certificate ID #: 31934
Report Date: 10-16-2015
Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31050

Analytical Testing Results

Customer Lot #: 20150716-2
Description: Oryzatein 90

Lab Sample ID: 402436

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Arsenic (As)	Rprt	0.015	ppm		0.013	0.033

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Cadmium (Cd)	Rprt	0.010	ppm		0.001	0.008

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Lead (Pb)	Rprt	0.051	ppm		0.005	0.013

Analysis Method: * DMA

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Mercury (Hg)	Rprt	0.014	ppm		0.001	0.010

Analysis Method: USP

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
pH	Rprt	5.66			N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Magnesium (Mg)	Rprt	0.008217	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Manganese (Mn)	Rprt	0.000399	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Phosphorus (P)	Rprt	0.19410	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Potassium (K)	Rprt	0.00109	%		N/A	N/A

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Analytical Testing Results

Customer Lot #: 20150716-2
Description: Oryzatein 90

Lab Sample ID: 402436

Analysis Method: RIDASCREEN Competitive

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Gluten	Rprt	<10.00	ppm		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Moisture	Rprt	ND	%		N/A	N/A

Analysis Method: * AOAC 922.06 (mod)

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Fat	Rprt	0.2	%		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Ash	Rprt	0.8	%		N/A	N/A

Analysis Method: Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Carbohydrates	Rprt	8.05	%		N/A	N/A

Analysis Method: * AOAC 991.43

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Dietary Fiber	Rprt	6.6	%		N/A	N/A

Analysis Method: * Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Calories	Rprt	400	Cal/100g		N/A	N/A

Analysis Method: * ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Inorganic Arsenic	Rprt	ND	ppm		N/A	N/A

Analysis Method: Kjeldahl

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Protein	Rprt	90.95	%		N/A	N/A

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Analytical Testing Results

Customer Lot #: 20150716-2
Description: Oryzatein 90

Lab Sample ID: 402436

Analysis Method: ^ AOAC 991.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Coliforms	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: ^ USP <2021>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Aerobic Plate Count	Rprt	1100	cfu/g		N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
E.coli	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Staph aureus	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Salmonella	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ AOAC 997.02

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Yeasts & Molds	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

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Certificate ID #: 31936
Report Date: 10-16-2015
Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31935

Analytical Testing Results

Customer Lot #: 20150716-3
Description: Oryzatein 90

Lab Sample ID: 402437

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Arsenic (As)	Rprt	0.022	ppm		0.013	0.033

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Cadmium (Cd)	Rprt	0.014	ppm		0.001	0.008

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Lead (Pb)	Rprt	0.042	ppm		0.005	0.013

Analysis Method: * DMA

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Mercury (Hg)	Rprt	0.015	ppm		0.001	0.010

Analysis Method: USP

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
pH	Rprt	5.70			N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Magnesium (Mg)	Rprt	0.007765	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Manganese (Mn)	Rprt	0.000332	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Phosphorus (P)	Rprt	0.19214	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Potassium (K)	Rprt	0.001000	%		N/A	N/A

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Salt Lake City, Utah 84104
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Certificate Of Analysis

Axiom Foods
12049 Jefferson Blvd
Culver City, CA 90230

Certificate ID #: 31936
Report Date: 10-16-2015
Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31935

Analytical Testing Results

Customer Lot #: 20150716-3
Description: Oryzatein 90

Lab Sample ID: 402437

Analysis Method: RIDASCREEN Competitive

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Gluten	Rprt	<10.00	ppm		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Moisture	Rprt	0.4	%		N/A	N/A

Analysis Method: * AOAC 922.06 (mod)

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Fat	Rprt	0.4	%		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Ash	Rprt	0.7	%		N/A	N/A

Analysis Method: Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Carbohydrates	Rprt	7.35	%		N/A	N/A

Analysis Method: * AOAC 991.43

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Dietary Fiber	Rprt	5.3	%		N/A	N/A

Analysis Method: * Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Calories	Rprt	400	Cal/100g		N/A	N/A

Analysis Method: * ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Inorganic Arsenic	Rprt	ND	ppm		N/A	N/A

Analysis Method: Kjeldahl

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Protein	Rprt	91.15	%		N/A	N/A

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Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31935

Analytical Testing Results

Customer Lot #: 20150716-3
Description: Oryzatein 90

Lab Sample ID: 402437

Analysis Method: ^ AOAC 991.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Coliforms	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: ^ USP <2021>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Aerobic Plate Count	Rprt	1000	cfu/g		N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
E.coli	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Staph aureus	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Salmonella	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ AOAC 997.02

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Yeasts & Molds	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

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Laboratory Comments:

Certificate ID#: 31936

Reviewed By: Les Reeves
Ben Stanfield

Approved By: _____
On Behalf of Genysis Labs

Date: 10-16-2015

Laboratory Notes:

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Result Symbol Definitions:

MDL = Method Detection Limit, a statistical measurement of method/media/instrument sensitivity

MRL = Method Reporting Limit, a verified value of method/media/instrument sensitivity

ND = Not Detected, testing result not detected above the MDL or MRL

^ = ISO 17025 certified method

* = Analysis performed at a subcontract location

*** = No result could be reported, see above comments

Supplement to Test Report
Additional Pages: N/A

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Certificate Of Analysis

Axiom Foods
12049 Jefferson Blvd
Culver City, CA 90230

Certificate ID #: 31938
Report Date: 10-16-2015
Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31109

Analytical Testing Results

Customer Lot #: 20150716-5
Description: Oryzatein 90

Lab Sample ID: 402439

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Arsenic (As)	Rprt	0.029	ppm		0.013	0.033

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Cadmium (Cd)	Rprt	0.012	ppm		0.001	0.008

Analysis Method: AOAC 993.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Lead (Pb)	Rprt	0.040	ppm		0.005	0.013

Analysis Method: * DMA

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Mercury (Hg)	Rprt	0.013	ppm		0.001	0.010

Analysis Method: USP

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
pH	Rprt	5.65			N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Magnesium (Mg)	Rprt	0.007709	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Manganese (Mn)	Rprt	0.000293	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Phosphorus (P)	Rprt	0.20242	%		N/A	N/A

Analysis Method: ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Potassium (K)	Rprt	0.000972	%		N/A	N/A

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Customer PO #:
Receipt Date: 07-24-2015
Test Completion Date: 09-18-2015

Previous Certificate ID#: 31109

Analytical Testing Results

Customer Lot #: 20150716-5
Description: Oryzatein 90

Lab Sample ID: 402439

Analysis Method: RIDASCREEN Competitive

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Gluten	Rprt	<10.00	ppm		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Moisture	Rprt	0.4	%		N/A	N/A

Analysis Method: * AOAC 922.06 (mod)

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Fat	Rprt	0.6	%		N/A	N/A

Analysis Method: * AOAC

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Ash	Rprt	0.9	%		N/A	N/A

Analysis Method: Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Carbohydrates	Rprt	7.13	%		N/A	N/A

Analysis Method: * AOAC 991.43

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Dietary Fiber	Rprt	7.4	%		N/A	N/A

Analysis Method: * Calculation

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Calories	Rprt	400	Cal/100g		N/A	N/A

Analysis Method: * ICP-MS

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Inorganic Arsenic	Rprt	ND	ppm		N/A	N/A

Analysis Method: Kjeldahl

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Protein	Rprt	90.97	%		N/A	N/A

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Previous Certificate ID#: 31109

Analytical Testing Results

Customer Lot #: 20150716-5
Description: Oryzatein 90

Lab Sample ID: 402439

Analysis Method: ^ AOAC 991.14

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Coliforms	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: ^ USP <2021>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Aerobic Plate Count	Rprt	<100	cfu/g		N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
E.coli	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Staph aureus	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ USP <2022>

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Salmonella	Negative	Negative	/10g	Pass	N/A	N/A

Analysis Method: ^ AOAC 997.02

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
Yeasts & Molds	Rprt	<10	cfu/g		N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Analysis Method: N/A

Analyte	Specification	Results	U/M	Pass/Fail	MDL	MRL
N/A	N/A	N/A	N/A	N/A	N/A	N/A

391 S. Orange Street Ste. F
Salt Lake City, Utah 84104
Phone: 801.973.8824 -- Fax: 801.456.4287

Laboratory Comments:

Certificate ID#: 31938

Reviewed By: Les Reeves
Ben Stanfield

Approved By: _____
On Behalf of Genysis Labs

Date: 10-16-2015

Laboratory Notes:

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^ = ISO 17025 certified method

* = Analysis performed at a subcontract location

*** = No result could be reported, see above comments

Supplement to Test Report
Additional Pages: N/A

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11720 Northcreek Pkwy N, Suite 400
Bothell, WA 98011
425.686.1996 Phone
425.686.3096 Fax

Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402435 Oryzatein 90 20150716-1

1509310-01

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.012 ppm)	0.012	0.024	EPA 1632

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This report was revisied for the following reason: Results reported down to MDL

Amy Goodall, Project Manager

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425.686.1996 Phone
425.686.3096 Fax

Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402436 Oryzatein 90 20150716-2

1509310-02

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.015 ppm)	0.015	0.029	EPA 1632

Eurofins Frontier Global Sciences, Inc.

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This report was revisied for the following reason: Results reported down to MDL

Amy Goodall, Project Manager

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402437 Oryzatein 90 20150716-3

1509310-03

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.015 ppm)	0.015	0.029	EPA 1632

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402438 Oryzatein 90 20150716-4

1509310-04

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.015 ppm)	0.015	0.030	EPA 1632

Eurofins Frontier Global Sciences, Inc.

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This report was revisied for the following reason: Results reported down to MDL

Amy Goodall, Project Manager

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402439 Oryzatein 90 20150716-5

1509310-05

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.014 ppm)	0.014	0.029	EPA 1632

Eurofins Frontier Global Sciences, Inc.

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This report was revisied for the following reason: Results reported down to MDL

Amy Goodall, Project Manager

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402440 Oryzatein 80 20150715-1

1509310-06

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.015 ppm)	0.015	0.030	EPA 1632

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This report was revisied for the following reason: Results reported down to MDL

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402441 Oryzatein 80 20150715-2

1509310-07

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.014 ppm)	0.014	0.027	EPA 1632

Eurofins Frontier Global Sciences, Inc.

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This report was revisied for the following reason: Results reported down to MDL

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402442 Oryzatein 80 20150715-3

1509310-08

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.014 ppm)	0.014	0.027	EPA 1632

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Amy Goodall, Project Manager

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402443 Oryzatein 80 20150715-4

1509310-09

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.013 ppm)	0.013	0.026	EPA 1632

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Genysis Nutritional Labs	Project: Heavy Metals	
391 South Orange Street	Project Number: 6822	**Reported:**
Salt Lake City UT, 84104	Project Manager: Edgar Gregorian	22-Sep-15 14:09

402444 Oryzatein 80 20150715-5

1509310-10

Analysis	Result	MDL	MRL	Method
Inorganic Arsenic	Not Detected (< 0.015 ppm)	0.015	0.029	EPA 1632

Eurofins Frontier Global Sciences, Inc.

The results in this report only apply to the samples analyzed in accordance with the chain of custody document. This analytical report must be reproduced in its entirety.

This report was revisied for the following reason: Results reported down to MDL

Amy Goodall, Project Manager

Perrier, Judith

From: Madhu Soni <sonim@bellsouth.net>
Sent: Friday, February 19, 2016 5:10 PM
To: Dausch, Judith
Subject: RE: GRN 609 - Rice Protein Concentrate - Follow up
Attachments: Rice Protein Concentrate - GRN 609- FDA query response Final.pdf

Dear Dr. Dausch,

Please find attached responses to FDA queries on GRN 609 (Rice Protein Concentrate GRAS notification). Hope the information and clarifications, along with some discussion in the response addresses your queries. If you have any questions or need additional explanation, please let me know. Thank you for the opportunity to provide this explanation.

Best regards

Madhu

Madhu Soni, *PhD, FACN, FATS*
Soni & Associates Inc
749 46th Square
Vero Beach, FL 32968
Phone: 772-299-0746
Cell: 772-538-0104
www.soniassociates.net

Dear Dr. Dausch,

RE: GRN 609- Rice Protein Concentrate GRAS Notice

This responds to your email of February 4, 2016 regarding clarifications and additional information required for our GRAS Notification No. 000609 for Rice Protein Concentrate. We are providing a point-by-point response to your queries along with some relevant clarifications/discussion.

FDA Query 1: Arsenic Levels - Provide the arsenic data from non-consecutive lots based on the appropriate methodology for measuring arsenic levels in your product

Response: As per the teleconference discussion of January 12, 2016 and suggestions from the FDA, the notifier (Axiom Foods) commissioned additional testing of arsenic levels from ten non-consecutive lots (five for Rice Protein concentrate 80% and five for 90%; each lot analyzed in triplicate) using appropriate FDA approved analytic methods (suggested during the conference call). The methods employed for these analyses included AOAC 2013.06 for total arsenic (ICP-MS) and FDA EAM Section 4.11 (modified) for arsenic speciation (LC-ICP-MS). The arsenic speciation method was employed to analyze inorganic arsenic (total, Arsenic III and Arsenic V) and organic arsenic [dimethylarsinic acid (DMA) and monomethylarsenic acid (MMA)]. The limits of detection for the methods AOAC 2013.06 and FDA EAM were 0.02 ppm and 0.05 ppm, respectively.

The result of the additional analysis for total arsenic (AOAC 2013.06) showed (Table 1) arsenic levels for all 10 batches (tested in triplicate) to be well below the 0.2 ppm specification that has been established by Axiom Foods, with an average across all 10 batches of 0.037 ppm, 82% below the established specifications.

Table 1. Analytical results of total Arsenic from ten non-consecutive lots of rice protein concentrate (five for 80% and five for 90%)*

Date Manufactured	Product Description	Lot No.	Arsenic Concentration in Triplicate (ppm)			Average (ppm)	% Below Specification (0.2 ppm)
			REP 1	REP 2	REP 3		
5/5/2015	Organic Oryzatein Silk 80	20150505	0.05	0.05	0.05	0.05	75%
5/23/2015	Organic Oryzatein 80	20150523	0.04	0.04	0.04	0.04	80%
10/19/2015	Organic Oryzatein Silk 80	20151019	0.02	0.03	0.03	0.027	87%
12/3/2015	Organic Oryzatein Silk 80	20151203	0.03	0.03	0.03	0.03	85%
12/10/2015	Organic Oryzatein Silk 80	20151210	0.02	0.02	0.02	0.02	90%
3/17/2015	Organic Oryzatein Ultra 90	20150317	0.08	0.1	0.08	0.087	57%

7/16/2015	Oryzatein 90	20150716	0.03	0.02	0.02	0.023	89%
9/6/2015	Organic Oryzatein Silk 90	20150906	<0.02	0.02	0.02	<0.02	>90%
9/15/2015	Organic Oryzatein Silk 90	20150915	0.02	0.02	0.02	0.02	90%
11/26/2015	Organic Oryzatein Silk 90	20151126	0.05	0.05	0.05	0.05	75%
Total Averages			**0.036**	**0.038**	**0.036**	**0.037**	**82%**

The analytical results from 10 non-consecutive batches (analyzed in triplicate) for total arsenic using method AOAC 2013.06 method (ICP-MS) and for arsenic speciation using FDA EAM Section 4.11 (modified) method (LC-ICP-MS) from Eurofins Analytical Laboratories Inc., are provided in Appendix I.

The results of arsenic speciation analysis revealed that the inorganic arsenic (As III, As V and total) as well as organic arsenic (DMA and MMA) were non-detectable or below the level of quantification at 0.05 ppm for all 10 batches tested in triplicate (same batches as tested for total arsenic detailed in Table 1, with additional detail contained in Appendix I).

FDA Query 2: Toxicology Narrative – Provide a paragraph that summarizes one or two studies from the published literature that address the safety issues of arsenic in rice. Also, include a statement that there is no safety concern with the intended use of rice protein concentrate based on the arsenic data provided.

Response: The toxicity of arsenic has been comprehensively reviewed by regulatory and other agencies (ATSDR, 2007[1]; EFSA, 2009[2], 2014[3]; WHO, 2011[4]; IARC, 2012[5]). Arsenic is one of the World Health Organization's 10 chemicals of major public health concern. From a toxicological perspective, arsenic health concerns are derived primarily from the inorganic arsenic. In humans, chronic oral exposure to elevated levels of inorganic arsenic has resulted in gastrointestinal effects, anemia, peripheral neuropathy, skin lesions, hyperpigmentation, and liver or kidney damage. Chronic exposure to high levels of arsenic is associated with higher rates of skin, bladder, and lung cancers, as well as heart disease. The Agency for Toxic Substances and Disease Registry (ATSDR, 2007) has derived a Minimal Risk Level (MRL)[6] of 0.0003 mg/kg bw/day (0.3 µg/kg bw/day) for inorganic arsenic for chronic oral exposure. In 2009, the EFSA Panel assessed the risks to human health related to the presence of arsenic in food and established a benchmark dose lower confidence limit ($BMDL_{01}$) between 0.3 and 8 µg/kg bw/day for an increased risk of cancer of the lung, skin and bladder, as well as skin lesions.

[1] ATSDR, 2007. Toxicological profile of Arsenic. Available at: http://www.atsdr.cdc.gov/ToxProfiles/tp2.pdf
[2] EFSA, 2009. Scientific opinion on arsenic in food. EFSA Journal 7(10):1351, 199 pp.
[3] EFSA, 2014. Dietary exposure to inorganic arsenic in the European population. EFSA Journal 12(3):3597, 68 pp.
[4] WHO, 2011 Safety evaluation of certain contaminants in food. WHO Food Additives Series, No. 63/FAO JECFA Monographs 8.
[5] IARC, 2012. Arsenic and Arsenic Compounds. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 100C: 41–93.
[6] An MRL is defined as an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (noncarcinogenic) over a specified duration of exposure.

The available information suggests that arsenic in food may be present as inorganic arsenic or organic arsenic. Unfortunately, the most common analytical procedures look at total arsenic and do not speciate among its organic and inorganic forms. As a result, dietary arsenic exposure assessments using total arsenic findings may overestimate exposure to inorganic arsenic unless efforts are made to estimate the fraction of total arsenic existing as inorganic arsenic. Of the two forms, inorganic arsenic has been associated with both acute and chronic health effects. Among the inorganic arsenic compounds, arsenic III is considered more harmful than arsenic V. The inorganic arsenic intake from food and drinking water varies depending on the geographic arsenic background. The available information indicates that as compared to other grains, rice takes up arsenic from soil and water more readily.

On September 6, 2013, FDA released the analytical results of approximately 1,100 new samples of rice and rice products (FDA, 2013a)[7]. None of the 487 samples tested including basmati, instant, jasmine, parboiled, or white (long, medium, and short-grain) rice showed inorganic arsenic levels exceeding 200 ppb. Among the 99 samples of brown rice tested, 18 showed inorganic arsenic levels above 200 ppb, with a maximum of 249 ppb. The levels of inorganic arsenic in rice and rice products were considered to be well below the levels that would result in any immediate or short-term health risks. FDA is looking at the potential long-term health effects associated with the consumption of arsenic in rice and rice products. It should be noted that rice hull tends to concentrate arsenic. Hence, the arsenic levels in brown rice are expected to exceed those of white rice where the rice hulls are removed in the processing. For these reasons, the Joint FAO/WHO Food Standards Programme, Alimentarius Commission (Codex) has established inorganic arsenic standard of 200 ppb for polished rice, and not to brown rice (JECFA, 2014[8]).

Besides rice and rice products, since 1991, FDA has conducted routine surveillance for arsenic in apple juice. FDA monitoring data demonstrated that 90 of 94 apple juice samples tested showed levels of total arsenic below 10 ppb and the four samples where total arsenic exceeded 10 ppb. All samples had inorganic arsenic below 10 ppb (FDA, 2013b)[9]. The agency recently conducted a quantitative assessment of the risk for cancer associated with exposure to inorganic arsenic in apple juice and concluded that an action level of 10 µg/kg or 10 ppb is adequate to protect the public health based on its risk assessment. In addition to apple juice, FDA has also set a standard for arsenic in bottled water (70 Fed. Reg. 33694, June 9, 2005). The maximum level of arsenic allowed in bottled water is 10 ppb. The FDA evaluated and adopted EPA's standard of 10 ppb for arsenic in public drinking water as the standard for bottled water for the protection of public health. Based on the USDA data (Smiciklas-Wright et al., 2002[10]), the mean and 90th percentile total apple juice intake is 207 and 496 g/person/day. If the apple juice contains 10 ppb inorganic arsenic, the resulting mean and 90th percentile intake of inorganic arsenic from the consumption of apple juice will be 2.07 and 4.96 µg/person/day. Similarly, based on USDA data (Sebastian et al., 2011[11]) on the

[7] FDA, 2013a. Analytical results from inorganic arsenic in rice and rice products sampling. Available at: http://www.fda.gov/ downloads/Food/FoodborneIllnessContaminants/Metals/ UCM352467.pdf

[8] Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, 37th Session, Geneva, Switzerland, 14-18 July 2014.

[9] FDA, 2013b. Supporting Document for Action Level for Arsenic in Apple Juice. Docket No. FDA-2012-D-0322

[10] Smiciklas-Wright, H., Mitchell, D.C., Mickle, S.J., Cook, A.J., Goldman, J.D., 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, 252 pp.

[11] Sebastian RS, Wilkinson Enns C, Goldman JD. Drinking Water Intake in the U.S.: What We Eat In America, NHANES 2005-2008. Food Surveys Research Group Dietary Data Brief No. 7. September 2011.

average daily drinking water (tap and bottled water) intake of 3.9 cups (923 ml) and assuming that the drinking water contains 10 ppb arsenic, the resulting daily exposure to arsenic will be 9.23 µg/person/day. Inorganic arsenic compounds are the predominant forms in drinking water. Hence, it can be assumed that drinking water will primarily result in an intake of inorganic arsenic only. As described below, the intended use of rice protein concentrate results in maximum (90^{th} percentile) intake of <1.025 µg inorganic arsenic/person/day and as compared to the intake from apple juice or water this value is low and is considered safe.

As described in response to Query 1, the levels of inorganic arsenic in rice protein concentrate (the subject of the present GRAS assessment) was found to be <0.05 ppm (below detection limits). Based on this, the resulting intake of inorganic arsenic from the 90^{th} percentile intake of 20.5 g of rice protein concentrate will be <1.025 µg/person/day (<0.017 µg/kg bw/day for an individual weighing 60 kg). Compared to the ATSDR derived MRL of 0.3 µg/kg bw/day, the resulting intake of inorganic arsenic from the intended uses of rice protein concentrate is very small and is considered to be safe. Recently, Codex proposed a maximum level for inorganic arsenic in polished rice of 0.200 mg/kg (JECFA, 2014). The results of triplicate arsenic analyses for 10 non-consecutive lots (five each for 80% and 90% rice protein concentrate) analyzed by Axiom Foods showed that the total (mean of 0.037 mg/kg) as well as inorganic arsenic level (<0.05 mg/kg) are well below the level recommended by the Codex for inorganic arsenic of 200 ppb. It should be noted that the inorganic arsenic levels are not detectable in rice protein concentrate.

While FDA has not yet established an action level for arsenic in rice or rice products to date, based on published studies FDA has advised that cooking rice in excess water, and draining the excess water, can reduce from 40 to 60% of the inorganic arsenic content, depending on the type of rice (FDA, 2015[12]). FDA's own research in this area has shown that the amounts of inorganic and total arsenic is decreased significantly using this approach. We note that the process for the production of rice protein concentrate involves the use of water and this may further reduce any potential presence of arsenic.

FDA Query 3: Background and Dietary Exposure to Inorganic Arsenic from Rice and Other Sources: This issue may be addressed

Response: Exposure to arsenic primarily occurs from dietary intake and drinking water. The major food contributors to total arsenic exposure have been reported as fish, shellfish, rice, fruit juices and fruits, and meats, while the major food contributors to inorganic arsenic exposure have been vegetables, fruit juices and fruits, rice, beer and wine, and flour, corn, and wheat. Approximately 10% of total arsenic exposure from foods is in inorganic form. Among the different major food contributors to inorganic arsenic exposure, rice has been reported to contribute 17% of the total, while vegetables and fruit juices and fruit contributed 24% and 18%, respectively (Xue et al., 2010)[13]. Generally estimates of arsenic dietary intake are based on food consumption data coupled with total arsenic data from a market basket survey of a large variety of foods or composite diet samples.

[12] FDA, 2015. Questions & Answers: Arsenic in Rice and Rice Products. Available at: http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319948.htm

[13] Xue, J., Zartarian, V., Wang, S.W., Liu, S.V., Georgopoulos, P., 2010. Probabilistic modeling of dietary arsenic exposure and dose and evaluation with 2003-2004 NHANES Data. Environ. Health Perspect. 118(3):345-50.

Regulatory agencies, such as FDA and EFSA, have estimated the exposure to arsenic and found the data to be comparable. According to FDA's estimates, the range of the average intake of arsenic in the US is from 23.4 µg/person/day for 2-year olds to 92.1 µg/person/day for 60-65 year-old men (Tao and Bolger, 1999)[14]. The inorganic arsenic intake was reported to range from 1.34 µg/day in infants to 12.54 µg/day in 60- to 65-year-olds. In another study, Yost et al. (2004)[15] reported similar inorganic arsenic intake by U.S. children of 3.2 µg/day on average, with a range of 1.6-6.2 µg/day. The EFSA (2009)[16] estimates the inorganic arsenic exposure from food and water across 19 European countries to range from 0.13 to 0.56 µg/kg bw/day for average consumers and from 0.37 to 1.22 µg/kg bw/day for 95th percentile consumers. For a 70 kg person, these intakes correspond to 9.1-39.2 µg/person/day for average consumers and 25.9-85.4 µg/person/day for 95th percentile consumers.

In conclusion, Axiom arsenic levels are well below established specifications in the case of total arsenic, and below the detection limits for inorganic arsenic. Given that inorganic arsenic is widely accepted to be of the greatest health concern, and that the Axiom products (tested in triplicate in 10 non-consecutive batches) does not have a single observation above the detection limits, the data clearly supports the safety of the products related to arsenic. In addition, rice protein concentrate is not intended to be marketed for infant and toddler foods; thus, this population is unlikely to be exposed to even the very low levels of arsenic from the use of rice protein concentrate.

In addition to the above queries, we are also responding to FDA's earlier query from the Memorandum of Telephone Conversations (Date January 7 and 12, 2016):

FDA Query: The description of manufacturing process is not sufficiently detailed. In particular more information on the conditions of initial hydrolysis step and also for the subsequent washing of rice protein concentrate may help the manufacturer demonstrate whether the manufacturing process removes most of the arsenic that may be present in the rice…

Response: The process of hydrolyzing the rice involves creating a slurry of milled rice, heated water and approved GRAS or food additive enzymes. Once the hydrolysis is complete, the liquid is removed using a plate and frame filter press which removes approximately 80% of the liquid as syrup. The remaining product is a crude protein which is further processed into a higher grade protein involving an additional water rinse, again removing approximately 80% of the water, to increase the final product to 80 or 90% protein (dry basis). The protein is then dried and milled to the appropriate mesh. As indicated above (FDA Query 2- Response), the use of water in the extraction of protein may remove arsenic that may be present in the rice.

[14] Tao, S.S., Bolger, P.M., 1999. Dietary arsenic intakes in the United States. FDA Total Diet Study, September 1991 - December 1996. Food Addit. Contam. 16:465-472.
[15] Yost, I.J., Tao, S-H., Egan, S.K., Barraj, L.M., Smith, K.M., Tsuji, J.S., 2004. Estimation of dietary intake of inorganic arsenic in US children. Hum. Ecol. Risk Assess. 10:473-483.
[16] EFSA, 2009. Scientific opinion on arsenic in food. EFSA Journal 7(10):1351. [199 pp].

We hope the above information and clarification addresses your queries. If you have any questions or need additional explanation, please let me know.

Thank you for the opportunity to provide this explanation.

Best regards

Madhu Soni, PhD

Agent for Axiom Foods and SPRIM

Enclosures: Appendix I

Appendix I

Analytical results for Total Arsenic and Arsenic Speciation

from ten non-consecutive batches

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Reporting Date 01/22/2016

AR-16-QA-003126-01

REPORT OF ANALYSIS

Sample Code 468-2016-0115B211

Sample Description 20150505-1 ORYZATEIN SILK 80 REP 2
Client Sample Code EFGS LAB ID: 1601261-02
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.05 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/22/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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AR-16-QA-003127-01

REPORT OF ANALYSIS

Sample Code 468-2016-0115B212

Sample Description 20150505-1 ORYZATEIN SILK 80 REP 3
Client Sample Code EFGS LAB ID: 1601261-03
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.05 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/22/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003138-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003138-01.

Sample Code 468-2016-0115B213

Sample Description 20150523-2 ORYZATEIN SILK 80 REP 1
Client Sample Code EFGS LAB ID: 1601261-04
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.04 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003139-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003139-01.

Sample Code 468-2016-0115B214

Sample Description 20150523-2 ORYZATEIN SILK 80 REP 2
Client Sample Code EFGS LAB ID: 1601261-05
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.04 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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AR-16-QA-003140-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003140-01.

Sample Code 468-2016-0115B215

Sample Description 20150523-2 ORYZATEIN SILK 80 REP 3
Client Sample Code EFGS LAB ID: 1601261-06
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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AR-16-QA-003141-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003141-01.

Sample Code 468-2016-0115B216

Sample Description 20151019-3 ORYZATEIN SILK 80 REP 1
Client Sample Code EFGS LAB ID: 1601261-07
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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AR-16-QA-003143-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003143-01.

Sample Code 468-2016-0115B217

Sample Description 20151019-3 ORYZATEIN SILK 80 REP 2
Client Sample Code EFGS LAB ID: 1601261-08
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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AR-16-QA-003144-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003144-01.

Sample Code 468-2016-0115B218

Sample Description 20151019-3 ORYZATEIN SILK 80 REP 3
Client Sample Code EFGS LAB ID: 1601261-09
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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AR-16-QA-003145-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003145-01.

Sample Code 468-2016-0115B219

Sample Description 20151203-4 ORYZATEIN SILK 80 REP 1
Client Sample Code EFGS LAB ID: 1601261-10
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003146-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003146-01.

Sample Code 468-2016-0115B220

Sample Description 20151203-4 ORYZATEIN SILK 80 REP 2
Client Sample Code EFGS LAB ID: 1601261-11
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003147-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003147-01.

Sample Code 468-2016-0115B221

Sample Description 20151203-4 ORYZATEIN SILK 80 REP 3
Client Sample Code EFGS LAB ID: 1601261-12
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003148-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003148-01.

Sample Code 468-2016-0115B222

Sample Description 20151210-5 ORYZATEIN SILK 80 REP 1
Client Sample Code EFGS LAB ID: 1601261-13
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003149-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003149-01.

Sample Code 468-2016-0115B223

Sample Description 20151210-5 ORYZATEIN SILK 80 REP 2
Client Sample Code EFGS LAB ID: 1601261-14
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 01/27/2016

AR-16-QA-003150-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003150-01.

Sample Code 468-2016-0115B224

Sample Description 20151210-5 ORYZATEIN SILK 80 REP 3
Client Sample Code EFGS LAB ID: 1601261-15
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003151-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003151-02.

Sample Code 468-2016-0115B225

Sample Description 20150317-6 ORYZATEIN ULTRA 90 REP 1
Client Sample Code EFGS LAB ID: 1601261-16
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.08 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003152-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003152-02.

Sample Code 468-2016-0115B226

Sample Description 20150317-6 ORYZATEIN ULTRA 90 REP 2
Client Sample Code EFGS LAB ID: 1601261-17
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.10 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003153-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003153-02.

Sample Code 468-2016-0115B227

Sample Description 20150317-6 ORYZATEIN ULTRA 90 REP 3
Client Sample Code EFGS LAB ID: 1601261-18
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.08 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003154-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003154-02.

Sample Code 468-2016-0115B228

Sample Description 20150716-7 ORYZATEIN 90 REP 1
Client Sample Code EFGS LAB ID: 1601261-19
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.03 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003155-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003155-02.

Sample Code 468-2016-0115B229

Sample Description 20150716-7 ORYZATEIN 90 REP 2
Client Sample Code EFGS LAB ID: 1601261-20
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003156-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003156-02.

Sample Code 468-2016-0115B230

Sample Description 20150716-7 ORYZATEIN 90 REP 3
Client Sample Code EFGS LAB ID: 1601261-21
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003157-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003157-02.

Sample Code 468-2016-0115B231

Sample Description 20150906-8 ORYZATEIN SILK 90 REP 1
Client Sample Code EFGS LAB ID: 1601261-22
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	<0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003158-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003158-02.

Sample Code 468-2016-0115B232

Sample Description 20150906-8 ORYZATEIN SILK 90 REP 2
Client Sample Code EFGS LAB ID: 1601261-23
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003159-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003159-02.

Sample Code 468-2016-0115B233

Sample Description 20150906-8 ORYZATEIN SILK 90 REP 3
Client Sample Code EFGS LAB ID: 1601261-24
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003160-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003160-02.

Sample Code 468-2016-0115B234

Sample Description 20150915-9 ORYZATEIN SILK 90 REP 1
Client Sample Code EFGS LAB ID: 1601261-25
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003161-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003161-02.

Sample Code 468-2016-0115B235

Sample Description 20150915-9 ORYZATEIN SILK 90 REP 2
Client Sample Code EFGS LAB ID: 1601261-26
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003162-03

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003162-02.

Sample Code 468-2016-0115B236

Sample Description 20150915-9 ORYZATEIN SILK 90 REP 3
Client Sample Code EFGS LAB ID: 1601261-27
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.02 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/27/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003163-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003163-01.

Sample Code 468-2016-0115B237

Sample Description 20151126-10 ORYZATEIN SILK 90 REP 1
Client Sample Code EFGS LAB ID: 1601261-28
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.05 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/22/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003164-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003164-01.

Sample Code 468-2016-0115B238

Sample Description 20151126-10 ORYZATEIN SILK 90 REP 2
Client Sample Code EFGS LAB ID: 1601261-29
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.05 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/22/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Reporting Date 02/19/2016

AR-16-QA-003165-02

REPORT OF ANALYSIS

This analytical report supersedes AR-16-QA-003165-01.

Sample Code 468-2016-0115B239

Sample Description 20151126-10 ORYZATEIN SILK 90 REP 3
Client Sample Code EFGS LAB ID: 1601261-30
Sample Reference

Reception Date 01/15/2016
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 1601261

Test Results	Result
QA133 - Arsenic (ICP-MS)	
Completion Date: 01/22/2016 **Method:** AOAC 2013.06	
Arsenic (As)	0.05 mg/kg
QA12K - Arsenic Speciation (LC-ICP-MS)	
Completion Date: 01/22/2016 **Method:** FDA EAM Section 4.11 (modified)	
* Arsenic III (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic V (inorganic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* Arsenic, total inorganic	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* DMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	
* MMA (organic arsenic)	<0.05 mg/kg
Method not validated for the quantification of the analyte in this sample matrix.	

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Eurofins Sample Code: 468-2016-0115B238 **Client Sample Code: EFGS LAB ID: 1601261-29**

REPORT OF ANALYSIS

AR-16-QA-003164-01

Test Results **Result**

Respectfully Submitted,
Eurofins Central Analytical Laboratories

Cheryl D. Stephenson, Ph.D., Laboratory Director

Results shown in this report relate solely to the item submitted for analysis.
Uncertainty can be obtained upon request.

TESTING CERT #2993-01

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Perrier, Judith

From: Madhu Soni <sonim@bellsouth.net>
Sent: Friday, May 20, 2016 4:21 PM
To: Perrier, Judith
Subject: RE: GRN 609 - Rice Protein - FDA Questions

Dear Dr. Perrier,

As desired, please see below responses provided next to the queries:

1. Please state whether the slurry of milled rice that is hydrolyzed using amylase is in water. Yes, the slurry of milled rice is hydrolyzed using amylase in water.

2. Without divulging confidential information from the manufacturer, please provide some additional information that distinguishes how the 80% and 90% rice protein products are made. Initially, the whole grain brown rice received is tested to determine protein content. The higher protein gets tagged for the 90% product. In addition, the water process rinses out the carbohydrates and other residues. To reach the higher protein content, the factory cycles 2-3 times with water to remove more of the carbohydrates.

Hope the above responses addresses the agency queries. Please let me know, if you have any questions. Thank you for the opportunity to provide this clarification.

Best regards

Madhu

Madhu Soni, *PhD, FACN, FATS*
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