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SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Final Report

TABLE OF CONTENTS

EXECUTIVE SUMMARY	2
BRIEF SUMMARY OF DELIVERABLES	2
§ C.3.2.1 and § C.3.2.2 <i>Templates and Performance Language</i>	2
§ C.3.2.3 <i>Consistent Nomenclature, Discounts & Micronutrient Minimums and Maximums</i>	4
§ C.3.3.1 <i>Commercial Contractual Practices</i>	6
§ C.3.3.2 <i>Vendor Compliance Verification</i>	6
§ C.3.3.3 <i>Sampling and Testing Regime</i>	8
§ C.3.3.4 <i>Lot Sizes</i>	8
§ C.3.3.5 <i>Analytical Methods</i>	9
§ C.3.3.6 <i>Internationally Accepted Practices</i>	9
§ C.3.3.7 <i>Analytical Costs</i>	9
§ C.3.3.8 <i>Selecting Qualified Analytical Testing Laboratories</i>	10
RECOMMENDATIONS	11
<i>Key Recommendations</i>	11
§ C.3.2.1 & C.3.2.2 <i>Templates and Performance Language</i>	11
§ C.3.2.3 <i>Consistent Nomenclature, Discounts & Micronutrient Minimums and Maximums</i>	11
§ C.3.3.1 <i>Commercial Contractual Practices</i>	14
§ C.3.3.2 <i>Vendor Compliance Verification</i>	15
§ C.3.3.3 <i>Sampling and Testing Regime</i>	15
§ C.3.3.4 <i>Lot Sizes</i>	16
§ C.3.3.5 <i>Analytical Methods</i>	16
§ C.3.3.7 <i>Analytical Costs</i>	16
§ C.3.3.8 <i>Selecting Qualified Analytical Testing Laboratories</i>	17
<i>Additional Recommendations</i>	18
<i>Product Specific Recommendations</i>	20
<i>New Products Recommendations</i>	21
CONSULTATIVE PROCESS	23
CHALLENGES	23
<i>Product Data Analyses</i>	24
APPENDICES	28

EXECUTIVE SUMMARY

SUSTAIN has successfully completed all requirements of contract AG-3151-C-07-0048, meeting all deliverables' deadlines. To set the stage for development of rigorous, uniform and clear commodity specifications (a critical element of quality control) the SUSTAIN team provided USDA with specification templates (one master template and individual templates for each product category), as well as product specific performance language. These materials can effectively guide the process of developing new product specifications for food aid products that meet the high quality standards of the U.S. commercial food industry. SUSTAIN has also submitted numerous recommendations for quality assurance in manufacturing and for sampling/testing protocols of sufficient rigor for USDA to independently verify product compliance to specification. Summarized here are the project's key deliverables, related recommendations for improving quality oversight of food aid, and additional recommendations for enhancing quality assurance systems not specifically addressed by USDA's RFP.

The importance of this project and of follow up (including the development of actual product specifications with the support of appropriate technical expertise) is illustrated by past problems with commodity quality and by historical data (from FGIS) showing significant percentages of product out of specification for some commodities and analytes. The extent to which lots out of specification were discounted or rejected is unknown. The fact that the FGIS data was based on composite rather than individual sample analysis has two important implications – first, estimates of percentages out of specification are understated; and second, such data cannot be used to develop scientifically valid sampling and testing plans for compliance verification.

The acceptance sampling plans requested by USDA in the original contract language should be based on accurate estimates of product/process variability, which cannot be made with composited samples – individual analyses of multiple samples over time are needed. Such plans must also rest on knowledge of analytical variability.

The limitations of the composite data USDA provided to SUSTAIN and the proprietary nature of information on process variation potentially available from industry presented a tremendous challenge. Ultimately the lack of data on process, product and analytical variability needed to develop scientifically valid sampling and testing plans led the agency to amend what was initially proposed in the RFP for some deliverables as detailed below.

BRIEF SUMMARY OF DELIVERABLES

§ C.3.2.1 and § C.3.2.2 Templates and Performance Language

Uniform template submitted January 8, 2008; Commercial Products template and performance language submitted February 29, 2008; Blended and Fortified Foods template and performance language submitted March 28, 2008; Whole or Partially Processed Grains template and performance language submitted April 18, 2008; and Vegetable Oils/Fats template and performance language submitted April 25, 2008.

As web addresses for Commercial Item Descriptions were updated during the course of this project, and considering that modifications/up-dates were also made to the current Commodity Requirements and supporting documents posted on USDA's website, as well as receipt of new information, SUSTAIN recognized the need to update the performance language documents that have been previously submitted. Where necessary, SUSTAIN has updated several performance language documents and included the revised documents as attachments to this report (see APPENDICES section).

Any number of criteria could have been used to segregate the products into categories. Product categories listed in § C.3.1 of the Request for Proposals (RFP), Solicitation Number AG-3151-S-07-0032 were reassigned (Table I) based on product similarities, the addition of micronutrients (if any) and/or the types of product (standard commodities, commercial products and lipid based products).

Table I. Revised Product Categories	
Blended and Fortified Foods Template	
a. All Purpose Wheat Flour/ Bread Flour	b. Bulgur / Soy Fortified Bulgur
c. Cornmeal	d. Corn-Soy Blend
e. Corn Soy Milk	f. Instant Corn Soy Milk
g. Instant Corn-Soya Masa Flour	h. Soy Fortified Cornmeal
i. Soy Fortified Sorghum Grits	j. Wheat Soy Blend
k. Wheat Soy Milk	
Whole or Partially Process Grains Template	
a. Barley	b. Bagged Whole Grains (Corn, sorghum, soybeans, wheat)
c. Buckwheat (Groats, Grits, Flour)	d. Dry Edible Beans (11 types of beans and Peas)
e. Milled Rice	f. Peas and Lentils (whole dry peas, split peas, lentils)
g. Bulk Soybean Meal (common product of commerce)	
Commercial Dry Products Template	
a. Canned Pink Salmon	b. Dehydrated Potato Products (several options)
c. Dehydrated Soup Mix (several options)	d. Non Fortified Nonfat Dry Milk
e. Value Added Soy Products (defatted flour, soy protein concentrate, soy protein isolate, soy milk replacer, textured soy protein)	
Vegetable Oil/Fats Template	
a. Bulk Oil (Crude, Degummed Soybean; Fully Refined Soybean	b. Corn Oil

Oil; Crude Corn Oil; Crude Sunflower Seed) and Tallow	
c. Refined Sunflower Seed Oil	d. Vegetable Oil (Soybean and vegetable)

SUSTAIN’s technical team thoroughly reviewed and evaluated the specification documents for commodities listed in § C.3.1 in light of contemporary food manufacturing practices, standards and requirements and relevant reference materials (e.g. Commercial Item Descriptions of USDA-AMS). The team reviewed each product group, identifying sections / information common to all products within a category to use as the basis for creating new templates. The review identified shortcomings of the existing commodity specifications documents and recommendations in the form of four templates and twenty-five (25) performance language documents.

Problems with inconsistent formatting across products, insufficient or excessive criteria to define the product and lack of defined sampling and testing requirements were corrected in the uniform templates provided for each product category and in the common structure for the individual performance language documents within each category. The standardized specification template SUSTAIN submitted to USDA in fulfillment of deliverable § C.3.2.1 contains optional sections for tailoring to specific commodities. The respective product category templates submitted in fulfillment of § C.3.2.2 are based on the standardized template and adapted to fulfill the specific needs of each category of products. The performance language documents are tailored to individual products in each category.

Templates for each of the four product categories in § C.3.1 contain appropriate sections for the chemical, macro- and micronutrient content, physical, microbiological attributes, quality systems, pertinent regulatory requirements, manufacturing controls, and other information as appropriate for that product category. Also included in the templates are sections for both generalized and commodity specific quality assurance requirements for manufacturers deemed necessary to ensure the quality, food safety, integrity, and traceability of commodities.

§ C.3.2.3 Consistent Nomenclature, Discounts & Micronutrient Minimums and Maximums

Consistent micronutrient terminology, standardized use of minimum and maximum micronutrient rates and recommendations for discount schedules, submitted June 20, 2008.

Consistent Nomenclature

As the Commodity Requirement documents have evolved since their inception through periodic updates, a number of different descriptors for ingredients have been incorporated. For example, the same document describes one of the optional sources of calcium and phosphorus in the fortified and blended foods as both ‘di-calcium phosphate’ and ‘dibasic calcium phosphate’, two ways of describing the same ingredient. Another example of multiple names for the same product is ‘tri-calcium phosphate’ which is identified in the Merck Index as ‘calcium phosphate, tribasic’ and is known colloquially as ‘tri-cal’ phosphate. SUSTAIN has provided recommendations for consistent nomenclature of micronutrients.

Also at issue is the lack of specificity regarding the form and amounts of micronutrients to be delivered. The Commodity Requirement documents for fortified and blended foods (e.g. CSB, CSM and others) specify the addition of ‘thiamine mononitrate’, a specific chemical compound,

whereas other milled products (e.g. wheat flour, cornmeal and others) specifies ‘thiamin’. Thiamin can exist in several different forms and each has a different amount of the ‘active’ component. (Thiamin mononitrate is ca 81.1 % thiamin and thiamin hydrochloride is ca 98 % thiamin). In cases where micronutrients exist in several forms, USDA should consult with USAID and verify the intended level of active component that should be added to the food aid products; the specifications should define the most appropriate micronutrient form.

In order to update and add uniformity to the nomenclature of the micronutrients added to food aid commodities in fulfillment of deliverable § C.3.2.3 SUSTAIN provided recommended nomenclature for the micronutrients. In some cases, these recommendations are consistent with and/or obtained from the Merck Index while other recommendations follow the latest nutritional recommendations of Institute of Medicine.

Discounts

Discount schedules are used in the milling industry as an incentive for purchasers to accept products that do not meet specifications. From a purchaser’s point of view, the amount of the discount should be sufficient so as not to reward the manufacturer for failure to meet specifications. For manufacturers, any discount value less than the amount required to rework the product (e.g. cost for the return, labor for breaking bags, and cost of repacking) is a benefit.

Specifications for blended and fortified foods (e.g. CSB) and fortified foods (wheat flour) are broad enough to have adequate margin and should pose no issues for manufacturers’ compliance. Thus the need for additional ‘cushion’ as defined by the discount schedule is probably not warranted. If the use of discounts is to be continued by the agency, the magnitude of the discount should be sufficient to minimize the product that does not meet specification.

The current discount schedules have been in place for a number of years, well before the recent increases in commodity prices. The June 3, 2004 Purchase Contract Award lists the price of CSB at \$341 / MT where as the June 4, 2008 CSB price was \$605 / MT. Thus the relative amount of the discount to the purchase price has decreased over the intervening years. Discount schedules should be updated and SUSTAIN recommends that USDA adopt discounts based on a fixed percentage of the contract price, similar to the discounts applied to vegetable oil and soybean meal under the trading rules of the National Oilseed Processors Association.

Micronutrient Minimums and Maximums

The terms ‘minimum’ and ‘maximum’ in specifications usually designate the lowest and highest acceptable levels of a defined component of a product. The term ‘target’ is indicative of a desired level of a component, but is not a contractual term; target levels are not subject to testing for compliance to specifications and target values, if provided should be informational only.

The specifications for the fortified and blended foods define the levels of each micronutrient that must be contained in the premix. Vitamin A and iron, the markers for the vitamin and mineral premixes, respectively, are the only components of the premixes that have upper and/or lower

specification limits¹, and the only components tested for specification compliance verification. The remaining components of the micronutrient premixes are added at levels that could be considered targets. In the case of the milled products, upper and lower limits are specified for all added micronutrients except vitamin A and folic acid; vitamin A is defined only by lower limits of addition. The case for folic acid addition is mixed; depending on the product, specifications state a minimum level only, upper and lower limit, or no folic acid requirement.

SUSTAIN offers several recommendations for better contractual definition of minimum and maximum levels of micronutrients in this project deliverable.

§ C.3.3.1 Commercial Contractual Practices

In fulfillment of the requirement for deliverable § C.3.3.1, SUSTAIN submitted a report summarizing current commercial practices of both the agricultural commodity and processed food industries on August 14, 2008. This report recapped discussions with quality systems experts and industrial quality control managers regarding industrial practices used to assure product quality. The SUSTAIN team provided a number of recommendations that USDA can use to improve food aid quality assurance that are reflective of common practice in the food industry. Recommendations include requirements for compliance to Good Manufacturing Practices and use of a verified Hazard Analysis and Critical Control Points (HACCP) program, including all of the relevant prerequisite programs. Commercial practice typically includes vendor prequalification as well as routine verifications, the frequency of which, in some cases, is based on the manufacturers' performance.

§ C.3.3.2 Vendor Compliance Verification

The original language in the RFP, "*Recommend a scientifically valid commodity sampling and testing regime to certify vendor compliance with commodity specifications*" was revised because the data needed to develop such plans² were unavailable for the following reasons:

1. It has been common practice in product verification testing by USDA to collect multiple samples from a lot and then commingle (composite) aliquots of those samples prior to conducting the analyses for product quality. This practice does not allow for the determination of variability of analytes within a lot.
2. One notable exception to the commingling of samples was an extensive testing activity conducted in response to the 'Green CSB' problem in which multiple individual samples were collected and assayed for the vitamin and mineral premix markers, vitamin A and iron, respectively. Review and critical analysis of these data by the SUSTAIN team revealed deficiencies with the data which precluded their use in the development of scientifically valid

¹ Upper and lower specification limits for both vitamin A and iron have been established for only CSB. Upper and lower limits for vitamin A have been defined as well as the lower limit for iron content in WSB. The remaining FBFs have only defined levels of addition for vitamin A and iron.

² Scientifically valid product specific sampling and testing plans require analytical data that describes the product and defines the variability of each analyte to be tested (or those analytes that will be routinely tested). Such data must reflect multiple individual observations for each lot so as to have a measure of the variability of that assay within each lot.

sampling and testing plans. Subsequent communications with FSA indicated that the USDA/AMS laboratory had acknowledged problems when conducting these analyses.

3. Vendors manufacturing food aid commodities monitor their respective processes by ongoing analyses as well as lot analyses. In an effort to try to secure the desired variability data, SUSTAIN prepared a letter for USDA to send to the trade (which was submitted to NAMA) to request the sharing of such data in a blinded format, through an independent entity. At USDA's request, SUSTAIN also verbally presented the background/rationale for this request at a NAMA industry meeting. However, NAMA noted that within lot individual test data was not available for either the export food aid products or any of their commercial products (memo to USDA & SUSTAIN dated February 14, 2008).
4. SUSTAIN also requested that USDA provide results of analyses of food aid products to determine the variability of important analytes within and between lots. USDA provided a data set on iron and vitamin A content of samples analyzed during the time period of November 2005 to June 2006. For reasons discussed below in more detail (see **CHALLENGES**) these data were also inadequate, largely due to problems with the accuracy and precision of the test results conducted by the USDA-AMS laboratory.

In compliance to the revised deliverable (Modification 0004, July 11, 2008), SUSTAIN delivered a summary of specific components and evaluation tools that are typical of commercial food manufacturing quality systems and processes on August 22, 2008. The preferred practice for quality systems is to design quality into the manufacturing process, starting with raw material specifications, process design and plant layout, appropriate standard operating procedures and controls, final product verification, sanitation and food safety practices and other systems designed for warehousing and transportation of quality products. Quality is best assured internally by integrating effective and efficient quality assurance procedures and systems across the manufacturing unit operations.

Certificates of Analysis (COA)

A second element of deliverable § C.3.3.2 was a request to describe current practices on Certificates of Analysis³, which SUSTAIN provided with this deliverable. USDA has provided sample COAs on their website⁴ for only nine (9) products. Two examples of technical errors contained in these documents are the titles (which are not consistent with the most recent version of the Commodity Requirement documents) and the lack of definition for some testing parameters. SUSTAIN recommended the COAs be updated concurrently with revisions to the Commodity Requirement documents.

In the case of food aid products, manufacturers conduct analyses for reporting lot information on Certificates of Analyses for only the analyses required by USDA and are based on composite samples extracted from that lot. Composite sample analyses for specification parameters only

³ A certificate of analysis is a description of chemical, physical functional and microbiological characteristics of a product lot. When provided, a COA guarantees the product characteristics are as stated in the specification and that when appropriately sampled and tested for verification, equivalent analytical results should be obtained within the range of normal statistical error.

⁴ <http://www.fsa.usda.gov/FSA/webapp?area=home&subject=coop&topic=pas-ex>

provide assurance of the product's averaged conformance to targets, not that within-lot variation is acceptable or that the entire product in a lot is within specification. Composite sampling should only be used when both the supplier and customer have sufficient data to ensure that, 1) within-lot variation is sufficiently small to assure full compliance with specifications, and 2) within-lot variation is stable from one lot to the next.

§ C.3.3.3 Sampling and Testing Regime

Exhaustive evaluation of each product lot is not possible and analysts must resort to sampling a portion of the product for lot disposition. Since all product is not tested, and due to the inherent variability within products, acceptable lots may sometimes be rejected, and unacceptable lots may sometimes be accepted. This deliverable provides guidance to developing practical sampling plans whose risks to both manufacturer and consumer are known. Due to the unavailability of data describing product variability (see section C.3.3.2 above), deliverable § C.3.3.3 was amended to provide a generalized sampling plans based on internationally accepted protocols and the sampling and testing regime was submitted on September 9, 2008. The sampling plans described in Deliverable § C.3.3.3 are philosophically and theoretically similar to those presented in the Codex Alimentarius Commission's document titled "CAC/GL 50-2004".⁵

The plans were simplified for ease of use and may not always be exact in terms of stated probabilities. Sample sizes are intentionally held low in order to minimize costs, and concessions were made to assure that manufacturers would not be pressed beyond their ability to deliver. Consequently, the protection against acceptance of out-of-specification commodities may not be as strong as one would wish. Inspectors should be encouraged to increase sample sizes within the guidelines offered whenever they suspect that conformance to specifications may be lacking.

§ C.3.3.4 Lot Sizes

Recommendations for lot sizes were submitted on June 27, 2008. In the context of food manufacturing, defining a large quantity of product as a single lot involves a balance between reward and risk. Defining a lot as a large quantity of product means reduced interruptions in manufacture (batch code and/or label changes) and reduced sampling and testing to comply with COA requirements. However, defining a large quantity of product as a single lot puts that large quantity at risk for recall if issues with quality or safety are found. The SUSTAIN technical team made a significant effort to obtain information on the typical lot size for food aid commodities based on current industry practices, which vary among product categories and the type of process system. The resources tapped include individuals working for companies producing food aid products and those in companies producing similar products, commodity groups representing various industry segments, USDA's own resources within GIPSA/FGIS, and the SUSTAIN technical team's personal knowledge and experience.

Current industry practices for defining lot size varies among product categories and the type of process system. In the processing of packaged foods, a lot may be defined as the quantity of product produced on a single process line during one eight (8) hour shift. Producers of highly processed foods (soy protein isolates) and foods dry blended from multiple ingredients to

⁵ http://www.codexalimentarius.net/web/index_en.jsp

achieve a high level of within batch uniformity may designate one blender load as a batch. Thermally processed foods (e.g. canned tuna) that use a static retort may designate a single retort load as a batch. However, when a continuous retort is used, a defined time interval may be the characterizing limit for a lot, usually the quantity produced during one shift on a single production line. In fulfilling this deliverable the SUSTAIN team provided recommendations that are consistent with current industrial practices.

§ C.3.3.5 Analytical Methods

In fulfillment of deliverable § C.3.3.5, SUSTAIN reviewed current testing indices and organoleptic performance elements. Where specific tests or assays are required of vendors to demonstrate compliance with contract specifications, SUSTAIN recommended test methods specific to the analyte and appropriate for the food matrix to be analyzed in the deliverable submitted on May 16, 2008. In general, these methods are those of the AOAC International, AACC International or referenced to other recognized and validated methods compendia. In some cases, references to product descriptions (milk grades, grain grades) defined by U.S. Government agencies were included by reference.

SUSTAIN recommends that the functional test methods of analysis contained in some of the Commodity Requirement documents (e.g. Consistency, Bostwick in CSB13 or Dough Handling, Bake and Flavor tests in MF10) be removed from the body of the document to improve readability and clarity. Functional test methods should be revised to provide step-by-step instructions that will improve analytical accuracy and precision of the test methods and eliminate potential for procedural modification by individual laboratories that may increase variation in the results. Test methods should be revised by experts familiar with analytical testing; the methods then reviewed by stakeholders and verified using an inter-laboratory collaborative study. The revised test methods should be made available through the USDA-FSA web site.

§ C.3.3.6 Internationally Accepted Practices

All deliverables under this contract are based on internationally accepted practices and standards.

§ C.3.3.7 Analytical Costs

Cost estimates for conducting product analyses were based on the average analytical costs posted on the websites of four commercial, for profit, analytical laboratories and were submitted on September 12, 2008. Some analyses listed in the COA (e.g., dispersibility of CSB in water) are not routinely conducted by commercial laboratories. Cost estimates for conducting these special tests were either provided by laboratories or based on costs for comparable analyses.

A section in the Commodity Template - *Special Requirements* – defines requirements that are already common practice in the food industry. Examples include pesticide residue screening, third party audits, validated HACCP plans and compliance to GMPs. All companies providing background information for deliverable §C.3.2.2 reported having such programs already in place that would meet the requirements of the recommendations. No additional costs are envisioned to meet the requirements of the Commodity Template.

§ C.3.3.8 Selecting Qualified Analytical Testing Laboratories

Recommendations for selecting a qualified analytical testing laboratory were submitted on June 13, 2008. Third-party laboratory compliance testing is critical to verification of test results reported by manufacturers. Results reported by USDA's laboratories of the "Green CSB" testing showed significant issues when assaying vitamin A and iron, the two markers for micronutrient premix addition. These issues could have been avoided with adequate internal laboratory quality control systems and periodic review of the results by laboratory management.

In an effort to identify sources of variation in the analysis of vitamin A, SUSTAIN conducted a round robin (a.k.a. ring test) involving sixteen (16) laboratories composed of commercial analytical, private sector and governmental laboratories. Results of the round robin showed a very high coefficient of variation (standard deviation / mean) of 36%. Only two laboratories, both commercial analytical laboratories, had consistent accuracy and precision for vitamin A analysis for all of the samples presented. Both of these laboratories have developed and implemented rigorous internal quality control procedures.

Consistent results of component analyses (moisture, protein, vitamins, etc) that define finished product characteristics, both within and between laboratories, are crucial to product quality and assurance. Measurements of the same analytes in the same matrix should be consistent between different laboratories and at different times. The methodologies / equipment used should be appropriate for the intended purpose

Depending upon the matrix and the intricacies/complexity of the analyses, a single laboratory may not be capable of adequately conducting all of the required analyses for a variety of reasons – lack of trained and experience analysts, lack of equipment, and/or it is not one of the assays the laboratory elects to conduct due to other limitations. Thus, multiple laboratories may be required to conduct all analyses required for a given sample.

There is a plethora of laboratory accreditation organizations ranging from useful and valid to unacceptable, thus, accreditation of a laboratory does not guarantee accurate and precise results. An International Standards Organization (ISO) certification is only valid for each test procedure for which an application was approved and does not confer accreditation to the entire laboratory (as is purported in some marketing literature). Even ISO certification does not guarantee accurate and precise results. To paraphrase an internationally respected analytical chemist "...it only guarantees that they will conduct the analysis the same way each time and if there is an error in the method, that error will be reproduced consistently."

For this deliverable SUSTAIN interviewed contract analytical services laboratories to determine how they select laboratories for sub-contracting analytical work. One overriding message from participants was that the laboratories should be pre-qualified before the need for their services arises. The emergence of a problem is not the right time to identify an appropriate analytical laboratory for contract services from among candidate facilities with no prequalification. Prequalification should consist of a thorough review of the laboratory's procedures and practices as well as their internal quality control programs. Participation in recognized proficiency programs, such as those managed by AOAC International or AOAC International high with proficiency ratings and internal monitoring programs is also a vital part of laboratory quality

control. As part of a pre-qualification process, a series of blind duplicate samples should be submitted to each and every candidate laboratory under consideration as a means of independently determining accuracy and precision. The submission of blinded samples to the testing laboratory should be continued on a periodic basis as part of an ongoing verification program.

RECOMENDATIONS

Key Recommendations

Below are abbreviated summaries of the key recommendations associated with each deliverable (for full details the reader should review the individual deliverable documents). SUSTAIN also summarizes here some additional recommendations on how USDA can improve quality assurance systems that are not specifically associated with or addressed by this contract's deliverables, but that represent standard industry practice for quality oversight.

§ C.3.2.1 & C.3.2.2 Templates and Performance Language

Many recommendations for injecting rigor, uniformity and clarity into commodity specifications are provided in the form of the specification templates and restructured performance language submitted as deliverables C.3.2.1 and C.3.2.2.

USDA, drawing on appropriate technical expertise, can now utilize the appropriate templates and product specific performance language to now create new specifications for each of each food aid commodities. This final step to enhancing a critical quality tool for food aid programs should proceed with the support of experts having in depth technical knowledge of individual products, quality assurance, manufacturing processes and analytical procedures.

§ C.3.2.3 Consistent Nomenclature, Discounts & Micronutrient Minimums and Maximums

With regard to Micronutrient Terminology SUSTAIN recommends:

1. 'Thiamin mononitrate' be the form of the micronutrient to be added to all applicable commodities and that this nomenclature be used in all relevant requirement documents. We recommend the target level of thiamin be identified by USDA. We recommend USDA follow the IOM DRI Reference Intake guides for folic acid. We recommend using $\mu\text{g RAE}/100\text{g}$ as a replacement of IU/lb in the specification for vitamin A. SUSTAIN recommends the specifications state the preferred, biologically active, form as "vitamin D₃ (cholecalciferol)." We recommend that amounts be specified as "mg α -tocopherol equivalents (mg α -TE)" to ensure that the correct amount of vitamin E is added based on vitamin E activity. The specification for ascorbic acid should clearly state the desired amount of ascorbic acid per unit of weight. The weight of coating material on the ascorbic acid should not be included in the target amount. SUSTAIN recommends the different formulations be adjusted to meet the desired levels of calcium and phosphorus in the finished products.
2. The current Commodity Requirement documents for fortified and blended foods specify an amount of "Zinc Sulfate, Monohydrate ($\text{ZnSO}_4 = \text{approx } 7\text{H}_2\text{O}$)." The description in

parentheses is not consistent with the nomenclature and should be deleted to maintain consistency with other specifications.

3. Some FBF specifications (CSB13 and others) state “Magnesium Oxide (MgO).” SUSTAIN recommends deleting the chemical formula in parenthesis to maintain consistency with other specifications.
4. SUSTAIN recommends that USDA, in consultation with USAID, define the form of mineral or vitamin to be added – not all forms deliver equal amounts of the biological active component. SUSTAIN also recommends that USDA consult with USAID to confirm that commodity specifications designate the preferred form of the vitamins and minerals.

With regard to micronutrient minimums and maximums, SUSTAIN recommends that:

1. Specifications documents consistently define both minimum and maximum levels for analytes that serve as markers for confirming addition of micronutrient premixes; results of analytical testing be reported on the product lot Certificate of Analysis for products in the following categories: Fortified and Blended Foods, Fortified Foods, and vegetable oil products. A copy of the Certificate of Analysis for the lot of premix used in the production of food aid products (including shelf life information) should accompany the manufacturers’ product COA and other required documentation submitted to USDA.
2. Minimum and maximum limits be established based on the process outlined in the WHO Guidelines document describing the requirements for establishing minimum and maximum levels of micronutrients.⁶ Parameters to consider include the food safety, manufacturers’ process variability and the ability to measure the parameter accurately and precisely.

USDA should seek recommendations from USAID on appropriate minimum (and/or maximum) levels of each micronutrient (the level of active nutrients desired in the final food product) added to the food aid products, and adjust/correct the micronutrient specifications accordingly.

3. Given the level of uncertainty around the analytical measurements, particularly vitamin A⁷ and the lack of availability on information on the process variability for food aid products, we recommend that USDA sponsor research to identify a more appropriate micronutrient marker analyte whose content can be measured accurately and precisely and then discontinue the use of vitamin A as the marker analyte. Additionally, USDA should consider combining the mineral and vitamin premixes (see ***Additional Recommendations*** below).

⁶ A procedure for estimating feasible levels for a mass fortification programme, Annex D in: Guidelines on food fortification with micronutrients, World Health Organization, 2006, Lindsay Allen, Bruno de Benoist, Omar Dary and Richard Hurrell, Editors, pages 294 – 312.

⁷ Results of an inter-laboratory study conducted by SUSTAIN determined the coefficient of variation for analysis of vitamin A in corn-soy blend was 36%.

4. Requirements should be added to commodity specifications to verify by assay the addition rate of micronutrients that are added to food aid products as separate ingredients and not as part of the micronutrient premix (e.g. a calcium source).
5. Since vitamin activity is known to decrease over time and fat rancidity develops under hot, humid conditions, we recommend that scientifically valid studies be conducted to determine the shelf-life stability of food aid products. Study storage parameters should replicate conditions food aid products under go during typical transit and storage.

Target Values

6. In the case of final product definition, inclusion of a target is a ‘nice to know’ item, but should not be construed as a product limitation.
7. Implementation of monetary discounts for analyte levels below (or above) a ‘target’ value, but within the defined specification limits, is not recommended.
8. Continued use of target values for the definition of vitamins and minerals in the micronutrient premix in the Commodity Requirements document is acceptable.

COAs

9. A copy of the Certificate of Analysis for the lot of premix used in the production of food aid products should accompany the manufacturer’ product COA and other required documentation submitted to USDA for payment. This requirement should be part of the requirements outlined in the Master Solicitation document.
10. Sample Certificates of Analysis should be provided for each commodity outlining the minimum acceptable testing requirements. Certificates of Analysis should be reviewed and updated concurrently with revisions to the Commodity Requirement documents, assuring specifications are the same and nomenclature is equivalent.

With regard to discount schedules, SUSTAIN recommends that:

1. Continuation of discounts for macronutrient deficiencies may be warranted as it is common practice in many industry segments such as flour milling, soybean meal and soybean oil. The schedule of discounts should be reviewed on a periodic basis to assure the impact for failing to meet quality remains constant during times of increasing commodity prices. A preferred alternative would be to create a discount schedule based on a percentage of the contract price rather than a fixed dollar amount that is currently used.
2. Where the use of discounts is to be continued by the agency, the magnitude of the discount should be sufficient to serve as a penalty – to discourage production of lots that do not meet specifications.
3. For those products that have a defined schedule of discounts for failure to meet the defined specifications, the application of discounts should be handled on a case-by-case basis.

4. Published discounts are not intended for use in defining key attributes of food aid products. They are intended as a means of penalizing manufacturers for failure to meet specifications. As such, they constitute a 'business function' of the contractual arrangement between USDA and the vendors and therefore should be removed from the document describing the quality attributes of the product. A statement in the Master Solicitation document should be included making potential bidders aware that product not meeting specifications may be rejected or subject to discount penalties, as appropriate.
5. Discounts should not be applicable to manufactured commercial products that fail to meet commercial product specifications.

§ C.3.3.1 Commercial Contractual Practices

With regard to aligning food aid procurement more closely to commercial contractual practices, SUSTAIN recommends that USDA:

1. Factor prior performance into contract awards. Whereas in the public sector, procurement rules at times mandate the least cost supplier as supplier of choice without any regard to previous history of performance and quality of product and service this practices carries inherent risks, and should be revised.
2. Review the specifications on an annual basis. More frequent reviews may be needed under certain circumstances (e.g. an ingredient is no longer available or crop conditions change).
3. Establish an Interagency Task Force to review food aid product specifications, qualified supplier lists, supplier performance and supplier product quality on a regular basis.
4. Review existing specifications for packaging to ensure the integrity of the processed food by the time it reaches the beneficiaries. It should be noted that shelf-life testing is a normal part of the commercial product development cycle.
5. For all processed food, implement the system used in commercial food industry contracts as specified in **§ C.3.3.1 Current Commercial Contracts in the Food Industry**.
6. Implement a product Traceability and Recall requirement for suppliers of all food aid products.
7. Institute a system of Supplier Qualification which includes evaluations of the quality system at each manufacturing location as well as normal commercial and financial components. Develop defined criteria for supplier qualification approval.
8. Institute a system of qualified Third Party Audits for qualified suppliers with the cost of Third Party audits borne by the supplier. Require the qualified supplier to meet a minimum standard or rating on the basis of the Third Party Audit.

9. Consider use of experienced third-party audit firms to conduct necessary audits and/or use of a qualified third party to review USDA auditor training programs and employee qualifications so that the audits can be developed and conducted more effectively.
10. Regularly monitor food aid products through an active verification program, which should include chemical, physical, microbiological and organoleptic (flavor/texture) parameters.

§ C.3.3.2 Vendor Compliance Verification

With respect to Vendor Compliance Verification SUSTAIN recommends that:

1. Food manufacturers be required to implement internal systems to ensure optimized laboratory quality control of technical performance and subscribe to a proficiency testing program from a recognized third-party professional organization.
2. Specifications for both raw materials and products be clear and concise and describe only those requirements necessary to define critical attributes of the ingredients or products.
3. Manufacturers be required to schedule regular objective third party audits with results made available to USDA upon request.
4. Continuous process improvement techniques be applied across the manufacturing system.
5. Acceptable quality programs have a complete set of Standard Operating Procedures that are reviewed and updated on an ongoing basis.
6. Manufacturers be required to have a verifiable HACCP plan along with the necessary pre-requisite programs and adhere to GMPs.
7. Process data and quality improvement tools be used in manufacturing to make data driven decisions for corrective and preventative actions to deliver continuous improvement.
8. Skip-lot testing be introduced when manufacturers have demonstrated continual compliance to specifications and adequate internal quality systems to assure future performance and compliance to specifications.
9. The COA provide reliable data demonstrating compliance to the specification for chemical, physical, functional and microbiological parameters.
10. Technical competency be maintained through regular employee training programs in state-of-the art for food safety and quality.

§ C.3.3.3 Sampling and Testing Regime

With regard to sampling and testing protocols, SUSTAIN recommends that:

1. Stratified sampling (e.g. selecting a sample on the basis of a predetermined time interval, as in hourly samples in a flour mill) is acceptable for the purposes addressed here.

2. If it is known that the assumption of lot homogeneity is not met, the manufacturer's lot should be divided into homogeneous sub-lots and disposition of each sub-lot be determined separately.
3. All sources of variability be monitored carefully in order to assure the best possible decision making with regard to lot disposition.
4. While composite sampling saves analytical costs and provides an estimate of the lot mean, it provides no information on the variation within the lot and should not be used for determining lot disposition except as explained in Deliverable § C.3.3.3.
5. USDA initiate collection of data, multiple observations for the analytes of interest (e.g. moisture, protein, fat, vitamin A, iron, etc.) to determine within lot variability and to develop the basis upon which construct scientifically valid sampling and testing plans.

§ C.3.3.4 Lot Sizes

Recommendations for lot size determination were provided in the submitted deliverable.

1. Generally, for milled or fortified and blended foods, a lot is defined as the quantity of 'one transportation unit' (truck load or rail car, not to exceed 81 MT).
2. For commodities such as CSB, WSB, wheat flour, cornmeal and similar products, a single lot should not exceed the quantity stated in Table II of Deliverable § C.3.3.4 and that quantity shall be produced on a single manufacturing process system (i.e. line) within twenty-four (24) consecutive hours.
3. Products such as dehydrated soup mixes, canned salmon and similar products shall be the quantity produced during a single "shift" (typically 8 hours) on one production line.
4. It is recommended that a lot shall be declared upon a significant interruption in the manufacturing process system. Breaks in processing to clear blockages or other minor mechanical repairs would not require designation of a new lot.
5. A complete certificate of analysis is recommended as a requirement for each lot.

§ C.3.3.5 Analytical Methods

SUSTAIN's deliverable provides a summary of recommended analytical methods from recognized methods compendia (AOAC International, AACC International, FDA, USDA grading standards etc.).

§ C.3.3.7 Analytical Costs

With respect to COAs, SUSTAIN recommends that:

1. Manufacturers be required to conduct assays and report findings for all components / attributes listed on the sample COAs that were included in the respective performance language documents submitted as deliverable § C.3.2.2.

2. Verification testing of randomly selected lots consists of all assays / attributes listed on the Certificate of Analysis. Alternatively, USDA may assay only those components / attributes for which there is a cause or need to conduct additional verification testing.

§ C.3.3.8 Selecting Qualified Analytical Testing Laboratories

With respect to Selecting Qualified Analytical Testing Laboratories SUSTAIN recommends that USDA:

1. Conduct a business analysis to make certain this is an acceptable company backed by sufficient financial resources to remain a viable entity during the expected term of service. If the laboratory or parent company is financially unstable, it may not be a viable business entity throughout the duration of the contract. This is also an opportunity to evaluate the business relationships and organizational make up of the laboratory and determine if it is part of a larger entity that could influence the outcome by engaging a broader range of technical resources.
2. Conduct a 'paper audit' to ascertain a laboratory's capabilities. This may be completed using a questionnaire to obtain the necessary background information on the laboratory's accreditations, standard operating procedures, internal quality control, proficiency testing, and other relevant topics. (A sample survey instrument is provided in Annex B of deliverable § C.3.3.8.) Responses from the paper survey must be evaluated by specialist(s) proficient in laboratory operation and quality systems to ascertain the completeness and appropriateness of their responses.

Arrange for ongoing determination of the laboratory's capability of producing accurate and precise results from performance testing by a recognized organization (e.g. AOAC, AACC and others). This should be done using check samples in matrices similar to the product of interest. Evaluation of laboratory performance results must be conducted by specialist(s) proficient in analytical methodology and statistical analysis, and must be ongoing to assure the laboratory remains capable and qualified. Recommendations from experts state that blinded (analyte levels are unknown to the recipient laboratories) qualifications / proficiency verification samples should be repeated on a regular quarterly basis. Minimum acceptable proficiency, as defined by z-score within ± 2 .

Alternatively, or if the laboratory does not have a sufficient length of performance history, the entity contracting for analytical services may want to submit its own qualification samples to laboratories for their own evaluation of accuracy and precision. A set of qualification samples would need to be created with a series of known levels of the analyte(s) of interest in a matrix representing the food product of interest. Preparing qualification samples to assure the analytical results are representative is challenging. The facility designated to prepare the samples must obtain representative materials and prepare a blend that has the ingredients uniformly distributed throughout, using mixing equipment which may not be available in all laboratories. In the case of a qualification set comparable to CSB, this would require obtaining the ingredients, preparing the blends, conducting sufficient analyses to assure the analytes of interest are evenly distributed through the test batch and that levels are equivalent to the respective targets.

The prepared blend to be used for qualification samples must be sampled and sufficient assays conducted to assure homogeneity and uniformity of key analytes throughout. Once the samples are prepared they must be stored and shipped in a way that prevents degradation of labile analytes (e.g., vitamin A).

3. Engage a specialist proficient in evaluating laboratory operations and quality systems to conduct a site visit to verify the accuracy and validity of the information reported in the questionnaire. This on-site visit must be conducted by someone proficient regarding laboratory equipment / instrumentation, standard operating procedures for laboratories, analytical methodologies, and good laboratory practices. Items to evaluate during a site visit include, but are not limited to:
 - a. Verify the laboratory actually exists (not a contractor submitting samples to a third party),
 - b. Laboratory has the necessary equipment,
 - c. Staff counts are consistent with the preliminary audit survey,
 - d. Stated accreditations are current,
 - e. Proficiency testing is current.

Additional Recommendations

In the course of this initiative the SUSTAIN team and expert consultants developed a number of recommendations that extend beyond the scope of the contract deliverables. We offer these for USDA's consideration.

1. Conduct Shelf Life Evaluation for Each Food Aid Product

A critical step in the development and introduction of new commercial food products is shelf-life testing to define the limits of product stability and acceptability. These tests, conducted prior to introduction, are typically conducted under conditions of elevated temperature and humidity. Only anecdotal information on the stability of blended and fortified products exists, with no statistically designed experiments to support the published Best Used by Date. There have been a number of instances of product arriving at its destination in an unacceptable condition. Studies should be conducted to determine actual shelf life of each of the food aid commodities.

 - a. Measure actual shipping and storage condition to verify the actual conditions to which food aid commodities are subjected in order to assure realistic testing parameters.
 - b. Conduct storage study to determine product stability and objectively determine shelf-life.
 - c. Shelf-Life studies should include parameters for both food quality (e.g. rancidity and nutrient stability) as well as food safety (e.g. water activity; too high supports microbial growth).
2. Combining Vitamin and Mineral Premixes
 - a. Separate vitamin and mineral premixes were originally specified for the blended and fortified food aid commodities (e.g. CSB and WSB) to avoid negative interactions between vitamins and minerals. SUSTAIN has conducted preliminary evaluations on combined vitamin and mineral premixes (which are

common in commercial practice) and the results are generally favorable for combining the premixes.

- b. Additional studies need to be conducted to confirm the preliminary results, quantify expected vitamin degradation over time, and compare combined premixes to the individual premixes.
 - c. The benefits of a combined premix are that manufacturers would need to purchase and inventory fewer ingredients, less opportunity exists for manufacturers to make errors in addition, and testing requirements are reduced (one premix “marker” instead of two).
3. **Alternate Markers (for vitamin Premix)**

Vitamin A is currently identified as the marker for the vitamin premix addition to fortified and blended foods. It is subject to losses of ca 1% per month and the analysis of vitamin A has a large coefficient of variation, both within a laboratory and between laboratories. Given the significant problems with the reliability of lab assays of vitamin A, it is absolutely critical that an alternative marker to vitamin A be identified and validated.
 4. **Periodic Review of Current Specifications**

Specifications and quality systems requirements should be reviewed by a panel of experts on a regular basis, annually or not less frequent than biennially, to assure compliance with current industry standards and practices.
 5. **New / Revised Specification Review Process**

USDA should develop a specification review process for new or revised Commodity Requirement documents (specifications) before release to eliminate the introduction of new errors (as has happened in the past). A current example may be found by examining Footnote 4 in the Commodity Requirement document SFSG13 which introduces an error in microbiological counts.
 6. **Trace and Recall System**

USDA should implement requirements for a Trace and Recall System, a common industry practice and a prerequisite program for HACCP.
 7. **Remove Test Methods from Specifications**

USDA should limit contents of specification documents to those requirements that are necessary to define the product and assure quality and remove functional test methods from product specification document. Methods should be web accessible. Functional test methods should be revised to provide complete and specific details for conducting the analyses to minimize analyst or laboratory induced variation in test results. The methods should be reviewed by a team of technical experts and procedures verified by collaborative studies between laboratories.
 8. **Minimum Criteria for Food Quality Systems**

If / when in-country acquisition of food aid products is initiated, USDA must have minimum criteria for food quality systems: product specifications, sampling and testing

guidelines, defined analytical methods, criteria for selecting analytical services, ingredient acceptance, release and storage, manufacturing, product testing, packaging, storage, third-party audit inspection and other criteria.

9. Antioxidants

CSB and other commodity requirement documents specify two different levels for the antioxidants BHA and BHT. These levels are contingent upon the source of the additions – either as a component of the vitamin/antioxidant premix or as a component of the vegetable oils.

- a. Adjust level specified in the vitamin/antioxidant premix to 22.7 g / 2,000 pounds blended product to maintain a common end product level of antioxidant.
- b. Through storage studies, determine if this level (25 ppm each antioxidant) is adequate and functional at this level. The level of 25 ppm each of BHA/BHT is the level for direct food additives in dry breakfast cereals intended for direct consumption. The level of 90 ppm BHA is allowed for “Dry mixes for beverages and desserts”⁸

10. Packaging Requirements

For some products, the current packaging requirements stipulate 50 pound bags (22.7 Kg), whereas 20 Kg (44.2 lb) bags are often more common in international commerce. For those companies that are tooled-up to pack products in 20 kg bags, retooling packaging lines to meet the 50-lb package may be prohibitively expensive. If field operations can accommodate either size pack, USDA should consider adjusting the specifications to allow either 50 lb (22.7 Kg) or 20 kg (44.2 lb) packaging units -- which may increase the pool of qualified bidders.

Product Specific Recommendations

1. Dehydrated Potatoes

Addition of vitamin A and iodine to dehydrated potato products is defined as a requirement in the invitation for bids and is not a requirement for all potato products. When the dehydrated potato products are fortified with vitamin A, iodine and other micronutrient, analytical testing and reporting requirements for those fortified micronutrients should be defined. Currently, CR DPP4 does not have any finished product analytical testing requirements for fortified potato products. Specific analytical testing requirements would have to be developed with inputs from the DPP industry. Sulfating agents in dehydrated potato products are known allergens and as such should be declared / labeled (21 CFR 101.100 and 182.3739).

2. Instant Corn-Soy Masa Flour

Recommend adding a color specification to masa flour using an objective measurement such as the Minolta CR301.

3. Instant Corn-Soy Milk

⁸ http://a257.g.akamaitech.net/7/257/2422/26mar20071500/edocket.access.gpo.gov/cfr_2007/aprqrtr/21cfr172.110.htm

The current specification has only a minimum consistency (viscosity) specification and no upper limit defined. Porridges made from fortified and blended foods that have too high a consistency and water must be added so it can be fed to infants and small children, thereby diluting the micronutrient content delivered. Without an upper consistency, ICSM could be delivered by a manufacturer that has a consistency that is too high and requires excessive dilution before feeding. An upper consistency (viscosity) level specification should be determined and implemented as part of the specifications.

4. Cornmeal

The current Commodity Requirement for cornmeal uses four (4) sieves to define the particle size. It is consensus of experts contacted for this review that fewer screens could adequately define the product. USDA should undertake an evaluation of the product to determine new defining screen size parameters.

New Products Recommendations

1. New Product Protocols

To foster innovation in food aid programming USDA and USAID should develop and publish protocols for accepting new products into the food aid program. For USAID, the protocols should include target population, minimum nutritional requirements for that targeted population(s), ingredients (primary and alternatives) and other relevant factors. USDA's protocol should include a required template for specifications for all ingredients, formulations and manufacturing requirements, and quality control requirements.

2. Fortified milled rice

Rice fortification offers an opportunity to enhance quality of life for individuals in countries receiving rice from the United States. Rice provides nearly 30% of the calories in low income countries.⁹ Nearly 50% of South Asia has inadequate energy intake.¹⁰ In countries where rice is the staple, deficiencies in Vitamin A, iron, iodine, zinc, thiamine and riboflavin are common.^{11,12,13} In the United States over 95% of the rice is enriched. In 1998 folic acid was included in the domestic rice enrichment. In Japan multi-nutrient enriched rice has been used since 1981. Currently the Philippines require iron fortification of rice.¹⁴ Fortification of export rice for donation can address several

⁹ Von Braun J, Bos MS (2005) The changing economics and politics of Rice: implications for global food security globalization and environmental sustainability. *Rice is Life Scientific Perspectives for the 21st Century: Scientific Perspectives for the 21st Century*. World Rice Research Conference, International Rice Research Institute, Published by International Rice Research Institute p7 – 20.

¹⁰ Food and Agriculture Organization (FAO) (2004) Rice is Life. Italy: FAO.
<http://www.fao.org/newsroom/en/focus/200436887/index.html>.

¹¹ Kusch GS (2001) Challenges for meeting the global food and nutrient needs in the new millennium. *Proceedings of the Nutrition Society*. 60: 15-26

¹² Wuehler SE, Peerson JM, Brown KH (2005) Use of national food balance data to estimate the adequacy of zinc in national food supplies: methodology and regional estimates. *Public Health Nutrition*. 8: 812-819

¹³ Dattai, K, Rai M, Parki V, Oliva N, Tan J, Datta SK (2006) Improved 'golden' indica rice and post-transgeneration enhancement of metabolic target products of carotenoids (*b*-carotene) in transgenic elite cultivars (IR64 and BR29). *Current Science*. 91 (7).

¹⁴ Alavi S, Bugusu B, Cramer G, Dary O, Lee T-C, Martin L, McEntire J, Wailes E (2008) Rice Fortification in Developing Countries: A critical Review of the Technical and Economic Feasibility. *Academy for Educational Development*, Washington DC.

micronutrient deficiencies improving the health and quality of life of recipients. While not a magic bullet, rice fortification would incrementally enhance the nutritional status for many world populations. The cost of fortification is more than compensated for by the reduction in cost of treatment and the human toll of iron deficiency or Vitamin A deficiency diseases

Four manufacturing processes are available:

1. *In hot extrusion* a dough including rice flour, a fortificant mix, and water are extruded through either a single or twin screw extruder and the extrudate are cut it into grain-like structures that resemble rice kernels. This process involves relatively high temperatures (70-110°C) resulting in fully or partially pre-cooked simulated rice kernels that have similar appearance (sheen and transparency) as regular rice kernels. There is risk with this method because some fortificants can be damaged by the high heat of extrusion. The advantage is that the fortified “kernels” are difficult to differentiate from polished rice.

2. *The Cold extrusion* process is similar to pasta production and also produces rice-shaped simulated kernels by passing a dough made of rice flour, a fortificant mix, and water through a simple pasta press. This technology does not utilize any additional thermal energy input other than the heat generated during the process itself, and is primarily a low temperature (below 70°C) forming process resulting in grains that are uncooked, opaque, and easier to differentiate from regular rice kernels. Because of the ability to easily differentiate the fortified kernels the product may not be well accepted.

3. *Coating technology* combines the fortificant mix with ingredients such as waxes and gums. The mixture is sprayed to the rice on the surface of grain kernels in several layers to form the rice-premix and then is blended with polished rice. The technology yields an enrichment blend that can be added at 1:200 with milled rice. When rinsed prior to use the retention of the fortificant is over 80% and the rice is not easily differentiated from the bulk rice.

4. *Dusting* involves dosing the polished rice grains with the powder form of the micronutrient premix. The fortificants stick to the grain surface because of electrostatic forces. This is the lowest cost approach, but since rice is frequently rinsed prior to use, it is not recommended as substantial portions of the fortificant will be lost.

3. Discrepancy in Spec’s/Description for Non-Fat Dry Milk (NFDM)

The commodity requirements specification for non-fat dry milk (NFDM) (as posted on USDA’s site) and the NRDM product composition description (as posted on USAID’s site) are NOT consistent with regard to requirements and statements on fortification.

The USDA Commodity Requirements document for non-fortified nonfat dry milk (NFDM) (DME2) does not require the addition of typical domestic fortificants vitamin A & D. Yet the CRG¹⁵ states that fortified NFDM contains 3,000 IU vitamin A and 600 IU vitamin D per 100 g. The CGR also states that NFDM “may be used in therapeutic

¹⁵ http://www.usaid.gov/our_work/humanitarian_assistance/ffp/crg/fsnfdrymilk.htm

feeding or as an ingredient in supplementary food. Distribution of NFDM must be in accordance with policy guidelines”.¹⁶ The discrepancy between USAID’s Commodity Reference Guide (CRG) and the USDA Commodity Requirement (CR) specifications is significant and can cause confusion.

The Commodity Requirement (DME2) - Non-fortified Nonfat Dry Milk is consistent with Codex Standard 207-1999 and the Standards of Identity 21 CFR 131.125 which do not require the fortification of NFDM. (*Note: A standard of identity of fortified NFDM does exist (21 CFR 131.127 Fortified NFDM) and does define a fortified NFDM - each quart of the reconstituted product shall contain 200 IU vitamin A and 400 IU vitamin D).*

We urge USDA and USAID to consult the U.S. Standards of Identify for powdered milk destined for reconstitution (regarding fortification with vitamins A & D) and for processing, and to bring consistency and accuracy to description and definition of NFDM on the USDA Commodity Requirements site and the USAID CRG site.

4. Substitution of Whey Protein Concentrate for Non-Fat Dry Milk

The nutritional profile of Whey Protein Concentrate (WPC34) is comparable to Non-Fat Dry Milk (NFDM) and in more normal commodity markets, it is less expensive. SUSTAIN suggests USDA and USAID consider WPC34 as an alternative ingredient to NFDM. If the use of WPC34 as a substitute for NFDM is approved, a new product specification for whey protein concentrate 34 must be developed.

CONSULTATIVE PROCESS

SUSTAIN identified and consulted with leading experts from government, academic and industry to obtain background information during the development these deliverables to facilitate the integration of state of the art knowledge and accepted commercial practices and standards into product specifications and quality assurance requirements. Expertise tapped included food scientists, cereal chemists, and specialists/personnel in statistics, nutrition, and commodities. Specialists in the full range of processed, semi-processed and coarse grains and legumes identified in section § C.3.1 of the RFP were consulted, including experts in lipid chemistry, cereal chemistry, small grains, coarse grains, legumes and manufactured foods (commercial products that included canned salmon, value added soy products).

Recommendations for quality assurance requirements were obtained from experts in quality systems, industries that share similarities with food aid processing, and commercial food companies.

CHALLENGES

There was a lack of cooperation by some company stakeholders. Some company representatives expressed reluctance to share information on company’s quality assurance systems. Some company representatives also expressed concern about uncertainties associated with any redesign

¹⁶ http://www.usaid.gov/our_work/humanitarian_assistance/ffp/supplementary.html

of food aid quality assurance systems (especially in light of the disbandment of TQSA), and a desire to be consulted and to provide feedback on any changes contemplated.

In addition, company representatives were, in some cases, unwilling to discuss even their current product specifications out of concern for divulging information to a potential customer (USDA) or their competition.

Product Data Analyses

For the purpose of developing scientifically valid sampling plans (as part of the original request for deliverable § C.3.3.3), SUSTAIN requested from USDA results of analyses of food aid products to determine the variability of important analytes within and between lots. USDA provided a data set comparing results of analysis for iron and vitamin A by a Government laboratory and a manufacturer identified as ‘Vendor 1’ for sixty-seven (67) samples during the time period of November 2005 to June 2006. A plot of these data showed a poor correlation between the values reported on the certificate of analysis for those lots and the results reported by the USDA/AMS laboratory with calculated R^2 values for iron and vitamin A of 0.162 and 0.021, respectively. Highly correlated results would have an R^2 value of 0.80, or higher. These results indicate problems with using this laboratory as a facility to verify the product delivered meets the specifications. An internal USDA review of these results should have raised a ‘red flag’ and triggered an investigation into the causes of the discrepancies.

A second data set provided by USDA is believed to represent sample analyses obtained from the investigation of the ‘Green CSB’ problem in 2005. It includes results of analyses for iron and vitamin A for 851 samples, of which 777 were individual observations from 39 product lots. Plots of the results were constructed based on the sample ID Number, in the belief they were sequential by date of analysis. Figure 1 clearly shows a trend of declining values followed by an increase. These results represent results of iron analyses in CSB for four different manufacturers during the time period and it is extremely unlikely that all four manufacturers would have the same problem with micronutrient addition at the same time. The conclusion is that there were problems with analyses within the reference laboratory.

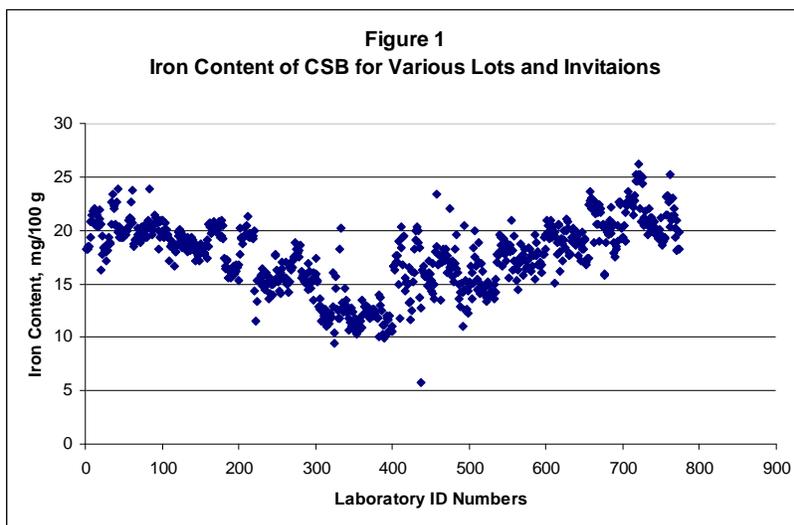
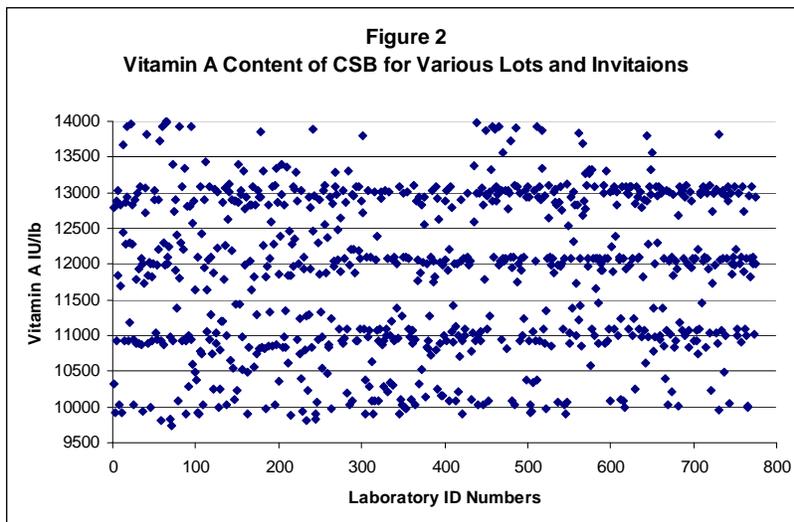


Figure 2 is a plot of vitamin A analysis from the same data set as used for the iron analyses. This plot clearly shows a distinct clustering around results evenly divisible by 1000. If these were true, unbiased results, a completely random distribution would be expected.



Given the obvious problems with analytical data provided, SUSTAIN inquired as to the availability of other data that USDA may have for use in developing scientifically valid sampling and testing plans. FGIS had provided results of analyses conducted during the monitoring program conducted in the 1990's. However, this pre-dated the quality assurance requirements instituted in 2000 which required manufacturer testing of vitamin and mineral "markers" (TQSA replaced the FGIS system for the monitoring of food aid quality in the late 1990's). Thus, no assay results for iron or vitamin A, the indicator markers for the addition of mineral and vitamin premixes, respectively, were available from this data set.

After reviewing the requirements for developing scientifically valid sampling and testing protocols with USDA during various teleconferences, it became apparent that there was a lack of data on product variability needed as a basis to create the type of sampling plan requested by USDA in the RFP. Deliverable § C.3.3.3 was thus amended to provide generalized sampling plans based on internationally accepted protocols. SUSTAIN noted that in order to create plans that would sufficiently detect when large quantities of product were out of specification, we would need to review a historic set of data representing major commodities and key analytes. The most recent data collected and stored by the USDA FGIS was from 1999. It contained over 15,000 records of test results listed by commodity, date tested, and analytes recorded.

In SUSTAIN's first analysis of the 1999 FGIS data we sought to develop an estimate of the number of observations that would be out of specification for four key analytes – moisture, ash, protein and crude fiber in all purpose flour, bread flour, CSB and WSB. These estimates are based on summary statistics of the actual 1999 FGIS data set, using the calculated mean and standard deviation, the specification limit and assuming a normal sample distribution. The data analysis results, summarized in Table II, indicate that about 2% of the all purpose flour, 12.3% of the bread flour and 17.1% of the CSB would not meet their respective moisture specification.

None of the bread flour lots were estimated to be non-compliant to the specification due to high ash content, but 38% of the bread flour was estimated to be below the minimum protein content of 11.3%. When the minimum acceptable protein content (subject to monetary discounts) of bread flour (10.8%) is used in the calculation, the estimated percent of assays not meeting specification is reduced to 7.2%. This same scenario applies to the other products and assays: the rate of rejection decreases substantially when the out-of-specification range defined by discounts schedule is taken into account. Thus, there may be a considerable amount of product that does not meet specifications but is still accepted and subject to discounts.

Table II. Estimated Number of Non-Compliant Analyses Based on the 1999 FGIS Monitoring Analytical Data

Assay		AP Flour	Bread	CSB	Wheat Soy
		APF-D	Flour BF-D	CSB-E	Blend WSB-E
Moisture	Mean	13.5	13.7	9.6	7.7
	Std Dev	0.24	0.25	0.37	0.12
	USL* %	14.0	14.0	10.0	11.0
	Est.% out of spec	2.01	12.34	17.07	0.00
	Number of samples	84	88	182	51
Ash	Mean	0.503	0.497		
	Std Dev	0.0472	0.0188		
	USL %	1.07	1.07		
	Est.% out of spec	0	0		
	Number of samples	862	205		
PROTEIN, 14% mb	Mean	10.3	11.4		
	Std Dev	0.64	0.43		
	LSL** %	9	11.3		
	Est.% out of spec	2.3	38.4		
	Number of samples	783	147		
Fiber	Mean			1.9	2.0
	Std Dev			0.21	0.18
	USL %			2	2.5
	Est.% out of spec			40.4	0.2
	Number of samples			140	47

*USL – Upper Specification Limit

**LSL – Lower Specification Limit

SUSTAIN scientists also reviewed this data set with a goal to estimate within lot variation, where possible. To this end, it was necessary to assume that for a given commodity and analyte combination, all results recorded on the same day represent replicate observations. While this assumption may not be strictly true, it is certainly likely that observations taken on a given day

are more alike than observations taken across days. Therefore this “nearest neighbor” approach to estimating within lot variation is as close to being fully valid as the data set will afford.

It is also recognized that the observations in the data set are composite means, not individual observations. This means that to generate a result, technicians accumulated multiple samples, composited them and then performed a single analysis on the composite.

Under this contract, USDA requested acceptance sampling plans, which typically requires that individual samples be taken in order to determine lot disposition. However, composite sampling has been the standard when USDA has collected data on product compliance in the recent past. Because composite means measure findings from multiple mixed samples, their variation is smaller than means based on individual samples. Therefore, estimates of percentages of product out of specification are understated in the 1999 FGIS data. The degree to which this happens is unknown because the number of individual samples going into each composite is unknown.

Estimates of percentages of product out of specification reported here, therefore, should be taken as lower bounds. The actual results are likely higher than what has been calculated.

Table III lists key results, showing the mean, standard deviation, specification limits and estimated percentages of product below the lower specification limit, above the upper specification limit and total, along with the degrees of freedom associated with the estimate of the standard deviation. Reliability of the estimate of the standard deviation increases with the degrees of freedom; for greatest reliability the degrees of freedom should exceed 30.

The table shows large percentages of product out of specification for some commodities and analytes. For example, when we look at moisture for bread flour (BF-D), 12.34 % of the product is out of specification. This does not necessarily mean that the product was rejected; just that it did not meet specification (product could have been accepted or discounted).

Under this contract, USDA requested and SUSTAIN provided recommendations for an acceptance sampling plan that would detect large quantities of product out of specification. After consultation with USDA representatives, USDA chose 2 alternative plans, one with a 2.5% AQL and the other with a 6.5% AQL. This means that if the manufacturer produces at the stated AQLs, approximately 95% of lots would be accepted. If we use moisture for bread flour as our example again, a Monte Carlo simulation shows that more than 22.5% of these lots would be rejected by a 6.5% AQL variables sampling plan with 10 samples per lot. However, considering the fact that the standard deviations are understated due to composite sampling, the estimate of 22.5% of lots rejected is conservatively low.

USDA reports a loss / rejection rate of food aid lots of less than 1% based on maritime claims for products that cannot be reclaimed or repackaged. It is unclear whether this information is based on lot shipping/tracking data or anecdotal information and requests to USDA for clarification have not been addressed to date. This stated level of loss / rejection is descriptive of product losses during transit but does not address the quantity of product that is not accepted for delivery by USDA.

Information describing the amount of product shipped to USDA that does not meet specification is not available. Given the use of discounts, there is a difference between quantity of products that do not meet specifications and product that is rejected for delivery. For most of the FBF products and the major analytes defining the product (protein, moisture, particle size ash, etc.), discount schedules provide for acceptance of products that are “only a little bit out of specification.” For example, in the case of the protein content of CSB, the minimum specified is 16.7%, however, product that is only 15.9% protein will not be rejected, but will be accepted subject to monetary discounts. Low rejection rates will also occur when the sampling frequency is small; a smaller number of samples will result in fewer numbers of lots found to be out of compliance to specifications.

SUSTAIN requested information on the frequency, for each commodity, in which one or more attributes were non-compliant over the past 12 months. More specifically, we asked for: 1) the total number of Certificates of Analysis received over the past 12 months and 2) the number of COAs having one or more attributes that are non-compliant to specifications. While this information was not received, we believe that it important data for USDA to track as it would provide insight into whether the large percentages of product out of spec are rejected or discounted.

APPENDICES

- CSM_Performance Language 9-26-08_revised
- ICSM_Performance Language 9-26-08_revised
- Performance Language_Bagged Grains 9-26-08_revised
- Performance Language_Bulk Oil and Tallow 9-26-08_revised
- Performance Language_Corn Oil 9-26-08_revised
- Performance Language_Dehydrated Potatoes 9-26-08_revised
- Performance Language_Dehydrated Soup Mix 9-26-08_revised
- Performance Language_Dry Edible Beans 9-26-08_revised
- Performance Language_NFDM 9-26-08_revised
- Performance Language_Refined Sunflower Seed Oil 9-26-08_revised
- Performance Language_Salmon 9-26-08_revised
- Performance Language_Soy Products 9-26-08_revised
- Performance Language_Vegetable Oil 9-26-08_revised
- WSM_Performance Language_9-26-08_revised

1 **Table III. FGIS 1999 Data Summary Statistics**

2

Assay		All Purpose Flour	All Purpose Flour	Bread Flour	Bread Flour	Cornmeal	Cornmeal	CSB	Soy-Fortified Bulgur	Soy-Fortified Cornmeal	Soy Fortified Sorghum Grits	Wheat Soy Blend
		APF-D	APF-E	BF-D	BF-E	CM-D	CM-E	CSB-E	SFB-E	SFCM-E	SFSG-E	WSB-E
Moisture	Mean	13.51	13.33	13.71	13.32		11.92	9.65	10.99	10.71	12.52	7.66
	Std Dev	0.24	0.37	0.25	0.55		0.51	0.37	0.17	0.64	0.48	0.12
	LSL											
	USL	14.0	14.0	14.0	14.0		13.0	10.0	11.5	13.0	13.5	11.0
	% Below LSL											
	% Above USL	2.01	3.52	12.34	10.76		1.80	17.07	0.18	0.02	2.03	0.00
	Total % out of spec	2.01	3.52	12.34	10.76		1.80	17.07	0.18	0.02	2.03	0.00
	df	84	262	88	53		7	182	104	106	32	51
Ash	Mean	0.50	0.79	0.50	0.79	0.56	0.90		2.57	1.64	1.91	
	Std Dev	0.05	1.04	0.02	0.04	0.05	0.19		0.15	0.16	0.25	
	LSL											
	USL	1.07	1.07	1.07	1.07	1.37	1.37		3.47	2.21	3.47	
	% Below LSL											
	% Above USL	0.00	39.19	0.00	0.00	0.00	0.63		0.00	0.02	0.00	
	Total % out of spec	0.00	39.19	0.00	0.00	0.00	0.63		0.00	0.02	0.00	
	df	862	3	205	68	15	296		102	104	31	
N_PRO	Mean	10.29	10.13	11.43	10.92							
	Std Dev	0.64	0.38	0.43	0.67							
	LSL	9.00	9.00	11.30	11.30							
	USL											
	% Below LSL	2.30	0.17	38.35	71.18							
	% Above USL											

Assay		All Purpose Flour	All Purpose Flour	Bread Flour	Bread Flour	Cornmeal	Cornmeal	CSB	Soy-Fortified Bulgur	Soy-Fortified Cornmeal	Soy Fortified Sorghum Grits	Wheat Soy Blend
		APF-D	APF-E	BF-D	BF-E	CM-D	CM-E	CSB-E	SFB-E	SFCM-E	SFSG-E	WSB-E
Assay	Total % out of spec	2.30	0.17	38.35	71.18							
	df	783	4983	147	23							
Fat	Mean						1.39	7.95	1.31	1.14	1.80	
	Std Dev						0.11	0.86	0.12	0.19	0.18	
	LSL							6.00			0.00	
	USL						1.50		2.60	1.50	2.00	
	% Below LSL						0.00	1.13				
	% Above USL						15.18		0.00	2.91	13.85	
	Total % out of spec						15.18	1.13	0.00	2.91	13.85	
	df						7	130	102	104	32	
Fiber	Mean							1.95	2.15	0.97	1.42	1.99
	Std Dev							0.21	0.16	0.13	0.23	0.18
	LSL											
	USL							2.00	2.60	2.00	2.10	2.50
	% Below LSL											
	% Above USL							40.44	0.18	0.00	0.17	0.17
	Total % out of spec							40.44	0.18	0.00	0.17	0.17
	df							140	103	104	31	47
BOSTU	Mean							10.33				
	Std Dev							3.41				
	LSL											
	USL							20.00				
	% Below LSL											

Assay		All Purpose Flour	All Purpose Flour	Bread Flour	Bread Flour	Cornmeal	Cornmeal	CSB	Soy-Fortified Bulgur	Soy-Fortified Cornmeal	Soy Fortified Sorghum Grits	Wheat Soy Blend
		APF-D	APF-E	BF-D	BF-E	CM-D	CM-E	CSB-E	SFB-E	SFCM-E	SFSG-E	WSB-E
	% Above USL							0.23				
	Total % out of specification							0.23				
								1369				
BOSTC	Mean							14.90				
	Std Dev							1.67				
	LSL							9.00				
	USL							21.00				
	% Below LSL							0.02				
	% Above USL							0.01				
	Total % out of specification							0.03				
								1367				
Sieve1	Mean					99.96	99.82	100.00	91.19	99.39	98.78	98.55
	Std Dev					0.13	0.25	0.01	1.64	0.48	1.11	0.40
	LSL					99.00	99.0	99.0	81.0	99.0	90.0	97.0
	USL					100.00	100.00	100.00	100.00	100.00	100	100.00
	% Below LSL					0.00	0.05	0.00	0.00	21.29	0.00	0.01
	% Above USL											
	Total % out of specification					0.00	0.05	0.00	0.00	21.29	0.00	0.01
						15	298	1367	102	116	31	49
Sieve2	Mean					98.60	97.26	60.32	17.39	97.47	25.88	
	Std Dev					0.42	0.89	7.08	2.40	0.82	7.42	
	LSL					90.00	90.00			91		
	USL					100	100	92.0	23.0	100.0	35.0	

Assay		All Purpose Flour	All Purpose Flour	Bread Flour	Bread Flour	Cornmeal	Cornmeal	CSB	Soy-Fortified Bulgur	Soy-Fortified Cornmeal	Soy Fortified Sorghum Grits	Wheat Soy Blend
		APF-D	APF-E	BF-D	BF-E	CM-D	CM-E	CSB-E	SFB-E	SFCM-E	SFSG-E	WSB-E
	% Below LSL					0.00	0.00	0.00	0.00	0.00	0.02	
	% Above USL					0.04	0.11	0.00	0.97	0.10	10.94	
	Total % out of spec					0.04	0.11	0.00	0.97	0.10	10.97	
	df					15	298	1367	102	116	31	
Sieve3	Mean					40.65	38.70	27.44	0.29	45.90	1.58	
	Std Dev					6.25	4.55	4.61	0.17	4.87	0.59	
	LSL					30.00	30.00	0.00	0.00	40.00	0.0	
	USL					100.0	100.0	57.0	1.2	100.0	5.0	
	% Below LSL					4.4	2.8	0.0	4.8	11.3	0.35	
	% Above USL					0.00	0.00	0.00	0.00	0.00	0.00	
	Total % out of spec					4.41	2.80	0.00	4.77	11.27	0.35	
	df					15	298	1367	102	116	31	
Sieve4	Mean					16.87	16.52			20.80		
	Std Dev					1.74	2.07			3.14		
	LSL					0.00	0.00			0.00		
	USL					20.00	20.00			32.00		
	% Below LSL					0.00	0.00			0.00		
	% Above USL					3.62	4.65			0.02		
	Total % out of spec					3.62	4.65			0.02		
	df					15	298			116		

3 * Ash values marked with an asterisk have specifications that are variable based on the amount of calcium added. Thus, the standard deviation of these
4 values is probably artificially large.

**DRAFT COMMODITY SPECIFICATION
TEMPLATE OUTLINE**

[Commodity Name]

[Commodity ID:]

[Date]

SUPERSEDING

[Former Commodity ID]

**[Former Commodity Effective
Date]**

Table of Contents

1	CHANGES FROM PREVIOUS VERSION	4
2	SCOPE	4
3	CLASSIFICATION	4
4	FINISHED PRODUCT CHARACTERISTICS	4
4.1	Finished Product Analytical Requirements	4
4.2	Chemical and Physical Properties	4
4.3	Grain Grading Requirements.....	5
4.4	Analytical Testing Methods	6
4.5	Test Result Precision	7
4.6	Reporting Results	7
4.6.1	Certificate of Analysis.....	8
4.6.2	Notification of Lots Failing to Meet Standards.....	9
4.7	Lot Size Definition	9
4.8	Sampling Procedures.....	9
4.8.1	Sample Collection	9
4.8.2	Composite Samples	10
4.8.3	(Intentionally Blank)	10
4.9	Uniform Product.....	10
4.10	Product Age.....	10
4.11	(Intentionally Blank)	10
5	MANUFACTURER'S REQUIREMENTS	10
5.1	General Requirements	10
5.2	Ingredients	11
5.3	Formulation	11
5.4	Ingredient Specifications.....	11
5.4.1	(Ingredient 1, Intentionally Blank).....	11
5.4.2	(Ingredient 2, Intentionally Blank).....	11
5.4.3	(Ingredient 3, Intentionally Blank).....	11
5.5	Fortification	11
5.5.1	Mineral Premix.....	11
5.5.2	Vitamin Premix	12
6	SPECIAL REQUIREMENTS	13
6.1	Pesticide Residues	13
6.2	Fumigation.....	13
6.3	Vomitoxin (Deoxynivalenol)	13
6.4	Aflatoxin.....	14
6.5	Official Grade Certificates	14
6.6	(Intentionally Blank)	14
7	MANUFACTURER'S QUALITY ASSURANCE	14
7.1	Conformance to Specification.....	14
7.2	Third Party Audits	14
7.3	Retained Samples	14
7.4	Records Retention	14
7.5	HACCP Requirement.....	15

7.8	Good Manufacturing Practices	15
7.9	FD&C Act Compliance	15
7.10	Currency of Specifications	15
7.11	(Intentionally Blank)	15
8	QUALITY DISCOUNTS	16
8.1	Discounts	16
8.2	Schedule of Discounts	16
8.3	(Intentionally Blank)	16
9	REFERENCES	16

1 CHANGES FROM PREVIOUS VERSION

This section contains a brief synopsis of changes from previous version. If new, then insert “New”.

2 SCOPE

This section should contain highlights of the product’s uses and a description of its major components.

3 CLASSIFICATION

Where foods are classified into categories based on their different varieties, flavors, sizes, appearances, etc. the purchaser must specify the categories and sub-categories that are desired. If this section is not applicable then insert “Not applicable”.

4 FINISHED PRODUCT CHARACTERISTICS

This section defines important attributes that affect the final quality of the product and may include items such as ingredient, defect level, shelf life, additives / preservatives, color, flavor, odor, and texture requirements.

4.1 Finished Product Analytical Requirements

This section summarizes analytical and microbiological requirements that are important in determining the final quality and safety of the food product to be purchased.

4.2 Chemical and Physical Properties

This table defines the characteristics, units of measure and minimum and maximum levels, as appropriate, for each parameter that is subject to testing and reporting.

Chemical	Units	Minimum	Maximum
Moisture	%	--	00.0
Protein (N x 6.25) ¹	%	00.0	--
Fat ¹	%	0.0	--
Crude Fiber ¹	%	--	0.0

¹ Moisture-Free Basis

Aflatoxin	ppb	--	20
Vomitoxin (Deoxynivalenol)	ppm	--	1.0
Micronutrients	Units	Minimum	Maximum
Thiamine	mg/100 g	--	--
Riboflavin	mg/100 g	--	--
Niacin or niacinamide	mg/100 g	--	--
Iron	mg/100 g	00.0	00.0
Vitamin A Palmitate	IU/100 g	0,000	00,000
Calcium	mg/100 g	000	000
Physical	Units	Minimum	Maximum
Particle Size Distribution			
Through US Std. No. __ sieve	%	00.0	--
Through US Std. No. __ sieve	%	--	00.0
Through US Std. No. __ sieve	%	--	0.0
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	CFU/g	--	50,000
<i>E. coli</i>	CFU/g	Negative to test	< 3
<i>Salmonella</i>	CFU/375 g	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase Positive	CFU/g	Negative to test	--
Yeast & Mold	CFU/g	--	300
Functional / Performance	Units	Minimum	Maximum
Consistency, uncooked	cm	--	00.0
Consistency, cooked (11.75% gruel)	cm	0.0	00.0
Dispersibility	Free of lumping when mixed with water		
Sensory	Description		
Odor	[PRODUCT NAME] must be essentially free from foreign material and will have good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		
Appearance	[PRODUCT NAME] appears equivalent to typical product.		

4.3 Grain Grading Requirements

Where applicable, include US Grain Grading Standards for the grade designated for the commodity. For example, wheat, corn, sorghum and soybeans are required to be grade No 2, or better. Include in this section the requirements from the Grain Grading Standards that define grade No. 2. If Grain Grading is not applicable, insert “Not applicable”.

4.4 Analytical Testing Methods

This summary of test methods is for example only as some methods listed below may not be appropriate for all food matrices. For example, the method for moisture measurement of cereal grain products is not the same procedure for measurement of moisture in non-fat dry milk. When completing this document, add analytical procedures that are needed to define the intended product and delete those test methods that are not needed.

Unless otherwise specified, analytical methods for the finished product and any ingredients shall be those identified in the Official Methods of the Association of Official Analytical Chemists (AOAC), the American Association of Cereal Chemists (AACC), the America Oil Chemists' Society (AOCS) and/or the FDA Bacteriological Analytical Manual (FDA-BAM), as applicable and in effect on the date of issuance of the Solicitation Document under which the contract involved was entered into, or in accordance with methods that yield equivalent results.

In the event the Government exercises its right, pursuant to FAR clause 52.246.2, Inspection of Supplies—Fixed Price, to perform its own testing, the following testing methods shall apply and will govern determinations as to whether or not the product meets the required specifications.

Additional test methods may be required for each specific product of interest and some of the tests defined in this sample table may not be appropriate to define the important characteristics for other products. Add or subtract methods as needed. These methods should be the same as above in Chemical and Physical Properties (Section 4.2) and also in the Certificate of Analysis (Section 4.6.1).

	Test	Method
Chemical	Moisture	AOAC 925.10
	Protein (N x 6.25)	AOAC 992.23
	Fat	AOAC 922.06
	Crude Fiber	AOAC 962.09E
	Aflatoxin	AOAC (TBD)
	Vomitoxin (Deoxynivalenol)	AOAC (TBD)
Micronutrients	Calcium	AOAC 985.01
	Iron	AOAC 999.11
	Sodium	AOAC 973.34
	Vitamin A Palmitate	AOAC 2001.13
Physical	Particle Size Distribution	Method Reference TBD
Microbiological	Aerobic Plate Count	FDA-BAM, 8th Ed., Chap 3
	<i>E. coli</i>	FDA-BAM, 8th Ed., Chap 4
	<i>Salmonella</i>	FDA-BAM, 8th Ed., Chap 5
	<i>Staphylococcus aureus</i> , Coagulase Positive	FDA-BAM, 8th Ed., Chap 12

	Yeast & Mold	FDA-BAM, 8th Ed., Chap 18
Functional / Performance	Consistency, uncooked	Method Reference TBD
	Consistency, cooked (11.75% gruel)	Method Reference TBD
	Dispersibility	Method Reference TBD
	Odor	Method Reference TBD
	Appearance	Method Reference TBD
	Vitamin A Stability	Method Reference TBD

4.5 Test Result Precision

Description of the precision which assay results should be reported. This paragraph is not all inclusive and other assays may be required and some assays may be deleted to appropriately define the product.

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat, crude fiber and particle size distribution values shall be reported to the nearest 0.1 percent. Bostwick consistency measurements shall be reported to the nearest 0.5 cm. Test results for iron shall be reported to the nearest 0.1 mg/100 g product. Calcium shall be reported to the nearest 1 mg/100 g product. Vitamin A shall be reported to the nearest 100 IU per 100 g product. Vomitoxin (deoxynivalenol) shall be reported to the nearest 1 ppm. Aflatoxin shall be reported to the nearest 1 ppb. Reporting of microbiological values varies with the type of organism and species being assayed. Aerobic plate count and Yeast & Mold should be reported to two (2) significant digits. *Staphylococcus aureus*, coagulase positive, *E. coli*, and *salmonella* should be reported as ‘negative’ (or ‘positive’) to test. Guidelines for reporting the precision of microbial assays found in the current issue of the FDA-BAM shall take precedence.

4.6 Reporting Results

This section should describe the process for reporting analytical results.

The contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results shall be evidenced by a Certificate of Analysis (COA). Copies of the original COA must be submitted as part of the invoice package. The COA shall provide the results of all tests specified. If quality discounts are provided in the contract, and the product to be delivered by the contractor falls within the quality discount table, those factors shall be identified on the COA.

All sample analysis may be performed by the supplier’s own in-house laboratory. The analytical results of each sample must be reported on the COA, refer to Section 4.6.1.

4.6.1 Certificate of Analysis

Insert a sample COA. The COA should contain ALL parameters that are required to define the product and assure quality and omit unnecessary items.

Sample Certificate of Analysis (For CSB)				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity (81 MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
		Units¹	Limit	Test Result
				Pass (Y/N)
Moisture		%	10.0 Max	
Protein (Nx6.25) ²		%	16.7 Min	
Fat ²		%	6.0 Min	
Crude Fiber ²		%	2.0 Max	
Iron		mg/100g	14.7 Min- 30.0 Max	
Vitamin A		IU/100 g	1,800 Min – 3,500 Max	
Particles through a US Standard No. 6 sieve		%	99 Min	
Particles through a US Standard No. 30 sieve		%	92 Min	
Particles through a US Standard No. 60 sieve		%	57 Min	
Consistency - Uncooked		cm	20.0 Max	
Consistency - Cooked 11.75 % Gruel		cm	21.0 Max	
Dispersibility	Essentially free from lumps or balling when mixed with water.		Pass/Fail	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail	
Odor	Good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		Pass/Fail	
Total Plate Count		CFU/g	50,000 Max	
<i>E. coli</i>		CFU/g	Negative to test	
<i>Salmonella</i>		CFU/375 g	Negative to test	
<i>Staphylococcus aureus</i> , Coagulase Positive		CFU/g	Negative to test	
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		

Sample Certificate of Analysis (For CSB)
¹ Percent weight basis. ² Moisture free basis

4.6.2 Notification of Lots Failing to Meet Standards

Contractors shall notify the Government immediately of lots that fail to meet contract requirements.

4.7 Lot Size Definition

Define appropriate lot size used in commercial practice for the commodity specified. A sample statement defining lot sized follows.

The Contractor may define a lot or batch as desired, to meet manufacturing process requirements. A single lot (or batch) shall not exceed the quantity produced in a 24 hour period and that quantity shall not exceed 180,000 pounds (81 metric tons).

4.8 Sampling Procedures

Define procedures and frequency for collecting representative samples from each lot to be used for assays representative of each lot.

As a minimum, Contractors shall use the following sampling frequency to obtain sub-samples for analysis based on lot size:

Lot Size (Pounds)	Lot Size (Kilograms)	Number of Bags Sampled Per Lot
45,000 or Less	20,250 or Less	12
45,001-180,000	20,251 - 81,000	20

4.8.1 Sample Collection

This section shall describe sample collection procedures where required. In the case of bagged product, the paragraph below may be representative. In the case of other products e.g. canned pink salmon, the collection of individual samples will be quite different and the test should reflect appropriate sampling procedures.

Bags shall be selected for sampling using a random number generator or a random number table. Samples shall be drawn from the selected filled and unclosed bag utilizing a stainless steel single-tube open-ended trier. The trier shall be inserted at one corner of the open end of the filled bag and moved diagonally through the center to the opposite corner of the bottom of the bag.

Collection of samples and assay procedures for *salmonella* differ based on the type of product being assayed. Category III² products, those that would normally be subjected to a process lethal to *salmonella* between the time of sampling and consumption include, but are not limited to blended and fortified foods, wheat flour and whole grains. Category II² products, foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption include, but is not limited to dehydrated potato products, dehydrated soup mixes, canned pink salmon,

4.8.2 Composite Samples

Samples drawn from each sampled bag shall be composited to represent the lot. The composite sample shall weigh approximately five pounds. This composite sample will be divided into two equal sub-samples; one will be for analysis and the other retained as a reserve by the supplier (see Section 7.3).

4.8.3 (Intentionally Blank)

4.9 Uniform Product

The contractor is responsible for ensuring that the commodity is uniform and substantially conforms to the specifications on a bag by bag basis.

4.10 Product Age

The product age requirement may vary with the product.

Unless otherwise specified in the solicitation, contract, or purchase order, the [PRODUCT NAME] shall be processed and/or packaged not more than 60 days prior to delivery to the purchaser.

4.11 (Intentionally Blank)

5 MANUFACTURER'S REQUIREMENTS

This section is targeted for the supplier of the food item. It lists the requirements that must be met if they are to manufacture the product for the purchaser.

5.1 General Requirements

Revise this general statement as appropriate for the product(s) of interest.

² Category III and Category II refers to FDA defined product classes and sampling requirements for *salmonella* testing based on the product being subjected to a process lethal to *salmonella* before consumption. See reference 'A'.

[PRODUCT NAME] shall be free from foreign material and will have good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors. The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or an extender to other foods.

5.2 Ingredients

[COMMODITY NAME] shall contain [LIST INGREDIENTS] at levels required to achieve the specified final product characteristics and consistent with good manufacturing practices.

5.3 Formulation

Formulation should be in a table format listing the percentage and the quantity (in pounds) per 2000 pound batch. Include footnotes as appropriate and/or required.

Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Ingredient 1	00.0	0,000
Ingredient 2	00.0	000
Ingredient 3	00.0	000
Mineral Premix	0.0	00
Vitamin Premix	0.0	00
Total	100.0	2,000

5.4 Ingredient Specifications

Each sub-section should describe the ingredients to be used in the product, including chemical, physical, functional, microbiological and other characterizing attributes of each ingredient. In the case of micronutrient premixes, the levels of the micronutrients must be included as well as antioxidants and carriers, if required.

5.4.1 (Ingredient 1, Intentionally Blank)

5.4.2 (Ingredient 2, Intentionally Blank)

5.4.3 (Ingredient 3, Intentionally Blank)

5.5 Fortification

5.5.1 Mineral Premix

The following statement must be included in the specification documents for all fortified and blended foods.

When the vendors elect to add calcium/phosphorus and/or salt independently from a mineral premix, verification of the correct addition level must be documented on the Certificate of Analysis.

Weight of Minerals per 2000 pounds of Finished Product³

	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
	lbs / Ton							
Calcium Phosphate, Tribasic	40.00			26.00	18.00	18.00		
Calcium Carbonate		36.00	36.00		12.00	12.00	10.00	10.00
Sodium Phosphate, Monobasic		32.00			16.00			
Calcium Phosphate, Dibasic				12.00				44.00
Potassium Phosphate, Monobasic			32.00			16.00		
Calcium Phosphate, Dibasic, Anhydrous							34.00	
Zinc Sulfate, Monohydrate ⁴	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Ferrous Fumarate, FCC Grade, Purified	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Magnesium Oxide (MgO)	2.75	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Iodized Salt (0.007% I ₂)	16.25	16.25	16.25	16.25	16.25	16.25	16.25	16.25
Mineral Premix, Total Weight	60.17	88.17	88.17	58.17	66.17	66.17	64.17	74.17

5.5.2 Vitamin Premix

Vitamin Premix Requirements

Vitamin Premix	g / 2000 lbs. of Final Product
Thiamin mononitrate	2.5
Riboflavin	3.5
Pyridoxine hydrochloride	1.5
Niacin	45.0
Calcium D-pantothenate	25.0
Folic Acid	1.8
Vitamin B ₁₂	0.012

³ Allowance of multiple formulas results in varying mineral premix weight.

⁴ Zinc sulfate heptahydrate ZnSO₄ • 7H₂O (0.4 lbs) may be used as an alternative to 0.25 lbs zinc monohydrate ZnSO₄ • H₂O.

Butylated hydroxy anisole ⁵	20.0
Butylated hydroxy toluene ⁵	20.0
Ascorbic Acid (Stabilized, ethyl cellulose coated) ⁶	364
	IU / 2000 lbs. Finished Product
Vitamin A-Palmitate (Stabilized)	21,000,000
Vitamin D (Stabilized)	1,800,000
Alpha tocopherol acetate	68,000
Carrier ⁷	As Required to reach total weight.
	lbs
Vitamin Premix, Total	2.0

6 SPECIAL REQUIREMENTS

If any item is not appropriate for the commodities processed, then state “None” or “Not applicable”.

6.1 Pesticide Residues

Manufacturers must be able to demonstrate compliance to pesticide residue levels as provided in 40 CFR 180 through documented analytical results of pesticide residue testing within the previous six (6) calendar months.

6.2 Fumigation

Fumigation is currently required for wheat flour and milled rice. If required, state minimum requirements of exposure time, temperature effects, and fumigant concentration. If not required, insert “Not applicable”.

6.3 Vomitoxin (Deoxynivalenol)

This section is applicable to wheat and wheat products. If not applicable, then insert “Not applicable”.

Wheat products used in the production of food aid commodities intended for human consumption must be compliant to the FDA’s advisory letter (Reference G) that the final product shall not contain more than 1 ppm vomitoxin.

⁵ If antioxidants (BHA and BHT) are added in the soy oil (Section 5.4), omit from this premix.

⁶ Ascorbic acid (stabilized), ethyl cellulose (coated). Ascorbic acid content shall be not less than 364 g.

⁷ Soy flour, defatted (toasted) or starch to reach total weight; (additional soy flour may be added as a carrier, if desired).

6.4 Aflatoxin

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity

6.5 Official Grade Certificates

Where required, the contractor shall be responsible for arranging and obtaining from FGIS, or any other organization designated by FGIS, official domestic and export weight and/or grade certificates. Procedures to follow and a schedule of fees for this service may be obtained at <http://151.121.3.117/aboutus/service/umap/usmap.htm>.

6.6 (Intentionally Blank)

7 MANUFACTURER'S QUALITY ASSURANCE

Need to identify manufacturing quality programs consistent with current commercial practices.

7.1 Conformance to Specification

The material shall conform to the quality parameters specified herein.

7.2 Third Party Audits

Manufacturers must have successfully completed sanitation and quality systems audits conducted by a qualified third-party within the preceding 12 months prior to the date of the awarding of the contract.

7.3 Retained Samples

Contractors shall retain a portion of each composited sample collected during manufacturing (Section 4.8.1) of approximately two and one-half (2.5) pounds for a period of _____ months. Retained samples shall be stored under conditions that will preserve the original condition of the sample, providing protection from insects, rodents, and avian pests as well as protection from excess heat or moisture damage.

7.4 Records Retention

Records of all ingredient, components, micronutrient premix certificates of analysis, and production batch records describing the process and any deviations from standard procedures shall be retained by the manufacturer for a period not less than twenty-four (24) months from the date of manufacture.

7.5 HACCP Requirement

Manufacturers must have developed and implemented a Hazard Analysis and Critical Control Points (HACCP) plan for the manufacturing process for delivering food aid commodities. The HACCP plan must be current, up to date, and reflect the actual manufacturing process used to produce the foods.

7.6 Continuing Guarantee

The seller shall warrant that the material shall comply with all applicable provisions of the Federal Food, Drug and Cosmetic Acts, all other applicable federal laws and regulations and State and Local codes as amended and that such material is neither adulterated nor misbranded. A letter of Continuing Guaranty shall be furnished by the Contractor annually.

7.7 Right to Inspection

The Government reserves the right to inspect supplier's facilities. Qualification as an approved supplier and/or retention of approved supplier status may be contingent upon inspection of pertinent areas of the supplier's manufacturing facilities.

7.8 Good Manufacturing Practices

[PRODUCT NAME] shall be produced, packaged and stored in accordance with good manufacturing practices as described in 21 CFR 110.

7.9 FD&C Act Compliance

[PRODUCT NAME] and all ingredients used therein, must conform in every respect to the provisions of the "Federal Food, Drug and Cosmetic Act," (21 CFR 9) as amended, and the regulations promulgated there under, including any Defect Action Level guidelines issued by the Food and Drug Administration (FDA) which may be applicable to this product. Shipments with counts in excess of the FDA Defect Action Level guidelines will be subject to rejection.

7.10 Currency of Specifications

Where the specifications refer to specific references (e.g. Standards of Identity, 21 CFR or Commercial Item Descriptions – AMS) and an updated specification has been issued by the responsible agency, it is the responsibility of the contractor to conform to the most current specifications available at the time the Invitation to Bid is issued.

7.11 (Intentionally Blank)

8 QUALITY DISCOUNTS

This section should contain a description of the discounts schedule and references to the applicable Quality Sections above. Discounts may not apply to all commodities and should state “None” or “Not applicable” and subsections should be deleted.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications listed in Section 4.2, Chemical and Physical Properties, of this Commodity Requirement but falls within the discounts listed in this table, the product may be delivered to CCC, but the purchase price will be reduced in accordance with the schedules of discounts in Section 8.2 for each 100 pounds (cwt.) of commodity delivered.

8.2 Schedule of Discounts

Discount schedules to be developed for each commodity, if appropriate. This is a sample table and may not contain all information for discounts for all applicable products.

Excess Moisture - Percent	\$/cwt.	Deficient Protein – Percent	\$/cwt.
Example 10.1 or 10.2		Example 16.6 through 16.4	
Example 10.3 or 10.4		Example 16.3 through 16.1	
Deficient Fat - Percent		Excess Crude Fiber - Percent	
Example 5.9 or 5.8		Example 2.1 through 2.2	
Example 5.7 or 5.6		Example 2.3 through 2.4	
Excess Iron, mg / 100 g			
Example 30.1 – 31.5			
Example 31.6 – 33.1			

8.3 (Intentionally Blank)

9 REFERENCES

This section lists USDA certification contacts, USDA analytical laboratory contacts, as well as sources of documents that may be referenced in the Commodity Requirement.

- A. *Salmonella* sampling requirements – [Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan:](http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html)
http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- B. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- C. Muncell Color Standards are available from **X-Rite Incorporated**
4300 44th Street SE, Grand Rapids, MI 49512, 800.248.9748 (*Not applicable to all products.*)

- D. Bostwick consistometer sources: Fisher Scientific, catalog number 15-347-50, or VWR, cat No. 23270-004 or equivalent". (*Not applicable to all products.*)

https://www.fishersci.com/wps/portal/SEARCHRESULTS?ru=http%3A%2F%2Fprodwcssserver%2Fwebapp%2Fwcs%2Fstores%2Fservlet%2FSearch&searchPref=no&position=search&preferProd=unchecked&searchType=Rapid&catalogCode=RE_SC&keyWord=15-347-50&catCode=ALL

OR

http://www.vwrsp.com/catalog/product/index.cgi?catalog_number=23270-004&inE=1&highlight=23270-004&from_search=1

- E. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/uscode_21_00000346---a000-.html
- F. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- G. FDA Guidance Letter - Deoxynivalenol (Vomitoxin)
<http://www.cfsan.fda.gov/~dms/graingui.html>
- H. (Intentionally Blank)

Performance Language

All Purpose Flour / Bread Flour

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers all purpose wheat flour and bread flour (WFBF) produced for the food assistance programs. All purpose wheat flour and bread flour are intended for use in all categories of food staples.

3 CLASSIFICATION

Purchaser must specify all purpose flour or bread flour.

4 FINISHED PRODUCT CHARACTERISTICS

All purpose flour and bread flour products are used in all categories of programs as a staple food.

4.1 Finished Product Analytical Requirements

All purpose flour and bread flour shall comply with the latest standards of identity for wheat flour, bleached [21 CFR 137.105, (a)] and enriched [21 CFR 137.165] available at: http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr137_07.html. The flour shall be passed through a centrifugal impact mill prior to packaging. In addition to these requirements, all purpose flour and bread flour shall meet the chemical and physical requirements defined in Section 4.2.1 and 4.2.2, respectively.

4.2 Chemical and Physical Properties

4.2.1 All Purpose Flour

All Purpose Flour Chemical, Physical and Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (N x 5.7) ²	%	9.0	--
Ash (prior to calcium addition) ²	%	--	0.53
Vomitoxin	ppm	--	1.0
Micronutrients			
	Units	Minimum	Maximum
Thiamine	mg/lb	2.9	--
Riboflavin	mg/lb	1.8	--
Niacin	mg/lb	24.0	--
Folic Acid	mg/lb	0.7	--
Iron (electrolytic iron, 325 mesh)	mg/lb	20.0	--
Calcium	mg/lb	500	750
Vitamin A Palmitate	mg/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Falling Number ²	sec	225	325

¹ Percent is on a weight/weight basis
² Reported on a 14% Moisture basis

4.2.2 Bread Flour

Bread Flour Chemical, Physical and Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (N x 5.7) ²	%	11.3	--
Ash (prior to calcium addition) ²	%	--	0.53
Vomitoxin	Ppm	--	1.0
Micronutrients			
Micronutrients	Units	Minimum	Maximum
Thiamine	mg/lb	2.9	--
Riboflavin	mg/lb	1.8	--
Niacin	mg/lb	24.0	--
Folic Acid	mg/lb	0.7	--
Iron	mg/lb	20.0	--
Calcium	mg/lb	500	750
Vitamin A Palmitate	mg/lb	8,400	16,000
Physical			
Physical	Units	Minimum	Maximum
Falling Number ²	sec	225	325
¹ Percent is on a weight/weight basis			
² Reported on a 14% Moisture basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture and protein (N x 5.7) shall be reported to the nearest 0.1 percent. Ash shall be reported to the nearest 0.01 percent. Falling number values shall be reported to the nearest second. Test results for iron shall be reported to the nearest 0.1 mg/lb of product. Vitamin A palmitate shall be to the whole number per pound of product. Calcium shall be reported to the nearest 1 mg/lb product.

4.6.1 Certificate of Analysis

4.6.1.1 Certificate of Analysis – All Purpose Wheat Flour

Sample Certificate of Analysis All Purpose Wheat Flour	
Invitation:	Pack Date:
Export Contract VEPE:	Mill Point:
Notice to Deliver VEPE:	Pack Size:
Car/Truck ID:	

Sample Certificate of Analysis All Purpose Wheat Flour				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	MT	LBS		Bags
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Protein (N x 5.7) ²	%	9.0 Min		
Ash ² (based on maximum calcium content, see Section 8.3)	%	variable		
Falling Number ²	sec	225 Min – 325 Max		
Calcium	mg/lb	500 Min – 750 Max		
Vitamin A Palmitate	mg/lb	8,400 Min - 16,000 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		
¹ Percent is on a weight/weight basis				
² Reported on a 14% Moisture basis				

4.6.1.2 Certificate of Analysis - Bread Flour

Sample Certificate of Analysis Bread Flour				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	MT	LBS		Bags
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Protein (N x 5.7) ²	%	11.3 Min		
Ash ² (based on maximum calcium content, see Section 8.3)	%	variable		
Falling Number ²	sec	225 Min – 325 Max		
Calcium	mg/lb	500 Min – 750 Max		

Sample Certificate of Analysis Bread Flour				
Vitamin A Palmitate	mg/lb	8,400 Min - 16,000 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent is on a weight/weight basis				
² Reported on a 14% Moisture basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Wheat shall be tested for vomitoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS) and any wheat testing higher than 2 ppm shall not be used in production of the commodity. The final product shall not contain more than 1 ppm of vomitoxin.

5.1.1 All Purpose Flour

All purpose flour shall be milled from the wheat classes: hard red spring, hard red winter, or soft red winter or hard white or soft white wheat, or any combination thereof, as defined in the "Official United States Standards for Grain" available at: <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>

5.1.2 Bread Flour

Bread flour shall be milled from the wheat classes of hard red spring, hard red winter, or hard white wheat as defined in the "Official United States Standards for Grain," which are available at: <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>.

5.2 Flour Enrichment

In addition to the enrichment requirements in the latest Standards of Identity for wheat flour (21 CFR 137.165), all purpose flour and bread flour shall contain vitamin A palmitate and calcium as described in Section 5.2.1 – 5.2.3. The requirements of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice are present.

5.2.1 Enrichment Ingredients

Enrichment Premix			
	Units	Min	Max

Thiamine mononitrate	mg/lb	2.0	--
Riboflavin	mg/lb	1.2	--
Niacin or niacinamide	mg/lb	16.0	--
Folic Acid	mg/lb	0.7	--
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	--
Vitamin A Palmitate	IU/lb	8,400	16,000
Calcium (in harmless and assimilable form)	mg/lb	500	750

5.2.2 Vitamin A

When used for fortifying wheat flour the vitamin A palmitate preparation shall contribute no off-flavoring or odor to the dry mix or to the cooked products prepared from the fortified flour.

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

5.2.3 Calcium

The calcium added must be in forms which are harmless and assimilable. Calcium amounts up to 1107 mg/lb are considered within the specifications limit so long as the ash/calcium ratio is met as shown in Table titled "Maximum Ash Allowable without Discount at Specified Calcium Levels" (Section 8.3).

If calcium is added independently from a micronutrient premix, verification of the correct addition level must be documented, by assay and reported on the Certificate of Analysis.

8.2 Schedule of Discounts

All Purpose Flour					
Deficient Protein	Units	\$/cwt.	Excess Moisture	Units	\$/cwt.
8.9 or 8.8	%	0.10	14.1 or 14.2	%	0.10
8.7 or 8.6	%	0.20	14.3 or 14.4	%	0.20
8.5	%	0.35	14.5	%	0.35
Excess Ash (above maximum)	Units	\$/cwt.	Deficient Falling Number	Units	\$/cwt.
.01 or .02	%	0.15	224 – 200	sec	0.20
.03 or .04	%	0.25			
.05	%	0.40			
Deficient Calcium	Units	\$/cwt.	Excess Calcium		
499-460	mg/lb	0.05	625-1107	mg/lb	0.00
459-440	mg/lb	0.10			
439-400	mg/lb	0.20			

Bread Flour					
Deficient Protein	Units	\$/cwt.	Excess Moisture	Units	\$/cwt.
11.2 or 11.1	%	0.10	14.1 or 14.2	%	0.10
11.0 or 10.9	%	0.20	14.3 or 14.4	%	0.20
10.8	%	0.35	14.5	%	0.35
Excess Ash (above maximum)	Units	\$/cwt.	Deficient Falling Number	Units	\$/cwt.
.01 or .02	%	0.15	224 – 200	sec	0.20
.03 or .04	%	0.25			
.05	%	0.40			
Deficient Calcium	Units	\$/cwt.	Excess Calcium		
499-460	mg/lb	0.05	750 - 1107	mg/lb	0.00
459-440	mg/lb	0.10			
439-400	mg/lb	0.20			

8.3 Maximum Ash Content without Discount

Maximum Ash Allowable Without Discount at Specified Calcium Levels					
Calcium Content Mg/Lb	Maximum Ash %	Calcium Content Mg/Lb	Maximum Ash %	Calcium Content Mg/Lb	Maximum Ash %
400-418	0.72	636-653	.85	872-889	.98
419-436	0.73	654-672	.86	890-907	.99
437-454	0.74	673-690	.87	908-926	1.00
455-472	0.75	691-708	.88	927-944	1.01
473-490	0.76	709-726	.89	945-962	1.02
491-508	0.77	727-744	.90	963-980	1.03
509-526	0.78	745-762	.91	981-998	1.04
527-545	0.79	763-780	.92	999-1016	1.05
546-563	0.80	781-799	.93	1017-1034	1.06
564-581	0.81	800-817	.94	1035-1053	1.07
582-599	0.82	818-835	.95	1054-1071	1.08
600-617	0.83	836-853	.96	1072-1089	1.09
618-635	0.84	854-871	.97	1090-1107	1.10

REVISED

Performance Language

Bagged Grains

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers bagged grains used in food assistance programs. Grains described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Solicitations for Bids for bagged grains shall specify one of the following whole grains:

1. Wheat
2. Corn
3. Sorghum
4. Soybeans

4 FINISHED PRODUCT CHARACTERISTICS

Grain purchased shall meet the requirements as defined in the "Official United States Standards" in effect at the time the applicable solicitation is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>

4.1 Finished Product Analytical Requirements

Whole grains shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.1 – 4.2.4.

4.2.1 Chemical and Physical Properties - Wheat

Wheat			
Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	13.5
Test weight – Hard red spring	lbs/Bu	57.0	
Test weight – Other classes	lbs/Bu	58.0	
Dockage	%		0.6

4.2.2 Chemical and Physical Properties – Corn

Corn			
Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	14.5
Broken kernels and foreign material	%		3.0
Damaged kernels	%		5.0
-Heat damaged kernels	%		0.2
Test weight	lbs/Bu	54.0	

4.2.3 Chemical and Physical Properties - Sorghum

Sorghum			
Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	14.5
Broken kernels and foreign material	%		7.0
-Foreign material	%		2.5
Damaged kernels	%		5.0
-Heat damaged kernels	%		0.5
Test weight	lbs/Bu	55.0	
Dockage	%		1.0

4.2.4 Chemical and Physical Properties - Soybeans

Soybean			
Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	14.0
Foreign material	%		2.0
Damaged kernels	%		3.0
-Heat damaged kernels	%		1.0
Test weight	lbs/Bu	54.0	
Splits	%		10.0

4.3 Grading Requirements

The contractor shall be responsible for arranging and obtaining from FGIS, or any other organization designated by FGIS, official domestic and export weight and grade certificates. Procedures to follow and a schedule of fees for this service may be obtained at <http://151.121.3.117/aboutus/service/USMAP.htm>. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

4.3.1 Grade Requirement - Wheat

Wheat shall be U.S. Grade No. 2 or better, 13.5 percent or less moisture, with a maximum of 0.6 percent dockage. Dockage shall be deductible. Wheat may be of any class: including hard red spring, hard red winter, hard white, soft red winter or soft white.

4.3.2 Grade Requirement - Corn

Whole corn shall be of the class yellow corn, U.S. Grade No. 2 or better, 14.5 percent or less moisture. With prior approval by the Government, U.S. Grade No. 3 yellow corn may be accepted, subject to discount, if the only grade determining factor is broken corn and foreign material.

4.3.3 Grade Requirement - Sorghum

Sorghum shall be of the class sorghum, U.S. Grade No. 2 or better, 14.0 percent or less moisture and a maximum of 1.0 percent dockage. Dockage is deductible.

4.3.4 Grade Requirement - Soybeans

Soybeans shall be of the class yellow soybeans, U.S. Grade No. 2 or better, 14.0 percent or less moisture.

4.3.5 Re-Inspection

If the product fails to meet contract specifications on one or more factors on the first inspection, the contractor may arrange with FGIS for subsequent inspections of the commodity. The inspections may be conducted at origin or a subsequent point of delivery if the provisions of Title 7 CFR 868.40 through 868.63 issued under the Agricultural Marketing Act of 1946, as amended, with respect to retest, appeal, and new inspections can be met. When subsequent inspections of the product are made, the results of the most recent inspection will be used as the basis for payment under the contract.

FGIS will perform a condition of container examination in accordance with the United States Standards for Condition of Food Containers (7 CFR Part 42) and the Agricultural Marketing Service Handbook for Inspection of the Condition of Food Containers.

4.4 Analytical Testing Methods

[Note: The following is a sample list of analytical testing methods references. A more complete list will be provided as deliverable C.3.3.8.] To be added?

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture shall be reported to the nearest 0.1 percent.

4.6.1.1 Certificate of Analysis - Wheat

Sample Certificate of Analysis				
Wheat				
Variety: _____				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units¹	Limit	Test Result	Pass (Y/N)
Moisture	%	13.5 Max		
Test weight – Hard red spring	lbs/Bu	57.0 Min		
Test weight – Other classes	lbs/Bu	58.0 Min		
Dockage	%	0.6 Max		
Comments:				

Sample Certificate of Analysis	
Wheat	
Variety: _____	
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Percent weight basis.	

4.6.1.2 Certificate of Analysis – Corn

Sample Certificate of Analysis					
Corn					
Variety: _____					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size		
Car/Truck ID:					
Lot Number:			Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags		
	Units¹	Limit	Test Result	Pass (Y/N)	
Moisture	%	14.5 Max			
Broken kernels and foreign material	%	3.0 Max			
Damaged kernels	%	5.0 Max			
-Heat damaged kernels	%	0.2 Max			
Test weight	lbs/Bu	54.0 Min			
Comments:					
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.					
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____		
¹ Percent weight basis.					

4.6.1.3 Certificate of Analysis - Sorghum

Sample Certificate of Analysis	
Sorghum	
Variety: _____	
Invitation:	Pack Date:

Sample Certificate of Analysis				
Sorghum				
Variety: _____				
Export Contract VEPE:			Mill Point:	
Notice to Deliver VEPE:			Pack Size	
Car/Truck ID:				
Lot Number:			Lot Quantity (TBD MT max)	
Contracted Quantity	MT	LBS	Bags	
	Units¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.5 Max		
Broken kernels and foreign material	%	7.0 Max		
-Foreign material	%	2.5 Max		
Damaged kernels	%	5.0 Max		
-Heat damaged kernels	%	0.5 Max		
Test weight	lbs/Bu	55.0 Min		
Dockage	%	1.0 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis.				

4.6.1.4 Certificate of Analysis - Soybeans

Sample Certificate of Analysis				
Soybean				
Variety: _____				
Invitation:			Pack Date:	
Export Contract VEPE:			Mill Point:	
Notice to Deliver VEPE:			Pack Size	
Car/Truck ID:				
Lot Number:			Lot Quantity (TBD MT max)	
Contracted Quantity	MT	LBS	Bags	
	Units¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Foreign material	%	2.0 Max		
Damaged kernels	%	3.0 Max		
-Heat damaged kernels	%	1.0 Max		
Splits	%	20.0 Max		
Test weight	lbs/Bu	54.0 Min		

Sample Certificate of Analysis	
Soybean	
Variety: _____	
Comments:	
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Percent weight basis.	

5.1 General Requirements

5.1.1 Wheat

Wheat shall be tested for vomitoxin by Federal Grain Inspection Service (FGIS). Any subplot containing in excess of two (2) ppm Vomitoxin shall be rejected to the contractor's account in accordance with FAR clause 52.246-2.

5.1.2 Corn

Corn shall be tested for aflatoxin in accordance with procedures approved by FGIS. If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the product shall be rejected pursuant to FAR clause 52.246-2.

Performance Language

Barley

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers barley produced for the food assistance programs.

3 CLASSIFICATION

Solicitations for Bids for Barley shall specify the Class from:

- a. Barley
- b. Hulless barley
- c. Dehulled barley

4 FINISHED PRODUCT CHARACTERISTICS

Hulled cut barley shall be milled from U.S. No. 1 food grade supplies. The barley shall be hulled and cut in accordance with good manufacturing practices. The bran layer shall remain intact for nutritional content.

The barley shall meet the specifications of the grade offered as defined in the “Official United States Standards for Barley,” in effect at the time the applicable solicitation for offers is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sqous>

except as the chemical and physical requirements listed in Section 4.2 shall take precedence.

4.1 Finished Product Analytical Requirements

The product shall be of particle size suitable for use in food products subjected to additional heat treatment and shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Barley			
Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (N x 6.25) ²	%	10.0	--
Vomitoxin	ppm	--	1
Physical	Units	Minimum	Maximum
Material through US Std. No 8 sieve	%	85.0	--
Material through US Std. No12 sieve	%	25.0	--
Material through US Std. No 16 sieve	%	25.0	--
Material through US Std. No 20 sieve	%	85.0	--
Material on US Std. No 20 sieve	%	95.0	--
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	100,000

Barley Chemical, Physical and Microbiological Properties			
Coliform	cfu/g	--	100
<i>E. coli</i>	cfu/g	--	Negative to test
Yeast & Mold	cfu/g	--	1000
<i>Salmonella</i>		--	Negative to test
¹ Percent is on a weight/weight basis ² Reported on 14% moisture basis			

4.3 Grading Requirements

The contractor shall be responsible for arranging and obtaining FGIS, or any other organization designated by FGIS, official domestic and export weight and grade certificates. Procedures to follow and a schedule of fees for this service may be obtained at <http://151.121.3.117/aboutus/service/emap/usmap.htm>. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), and screen sizes shall be reported to the nearest 0.1 percent. Aerobic plate count and yeast and molds shall be reported to two (2) significant digits. Coliform, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test'.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Barley				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Protein (Nx6.25) ²	%	10.0 Min		
Material through US Std. No 8 sieve	%	85.0 Min		
Material through US Std. No12 sieve	%	25.0 Min		
Material through US Std. No 16 sieve	%	25.0 Min		

Sample Certificate of Analysis				
Barley				
Material through US Std. No 20 sieve	%	85.0 Min		
Material on US Std. No 20 sieve	%	95.0 Min		
Vomitoxin	ppm	1 Max		
Aerobic plate count	cfu/g	100,000 Max		
Coliform	cfu/g	100 Max		
<i>E. coli</i>	cfu/g	Negative to test		
Yeast and Molds	cfu/g	1,000 Max		
<i>Salmonella</i>	Present / Absent	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis ² Reported on 12% moisture basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

5.2 Vomitoxin

All barley products shall be tested for vomitoxin by a method approved by the Federal Grain Inspection Service (FGIS). Any subplot in excess of one (1) ppm shall be rejected to the contractor's account in accordance with FAR clause 52.246-2.

Performance Language

Buckwheat

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers buckwheat produced for the food assistance programs.

3 CLASSIFICATION

Solicitations for Bids must specify the type of buckwheat product desired: buckwheat groats, buckwheat grits or buckwheat flour.

4 FINISHED PRODUCT CHARACTERISTICS

The buckwheat shall be cleaned using standard grain cleaning equipment to remove dockage, foreign matter, and stones in accordance with good manufacturing practices.

4.1 Finished Product Analytical Requirements

The product shall be of particle size suitable for use in food products.

4.2 Chemical and Physical Properties

The product shall meet the chemical, physical and microbiological requirements defined in Section 4.2.1 – 4.2.3.

4.2.1 Chemical and Physical Properties - Buckwheat Groats

Buckwheat Groats shall be prepared from the buckwheat fruit by separating buckwheat kernels from shells. The buckwheat groats shall have a pleasantly sweet taste, not sour or bitter, and no off odors. The finished product shall conform to the following analyses:

Buckwheat Groats			
Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (Nx6.25) ²	%	12.0	--
Ash ²	%	--	3.0
Crude Fiber ²	%	--	2.5
Physical	Units	Minimum	Maximum
Purity	%	99.2	
Whole Groats (Retained on US Std 7/64" round hole sieve)	%	95.0	--
Unhulled kernels	%	--	0.3
Whole groat	%	95.0	--
Foreign material	%	--	0.3
Mineral matter	%	--	0.05
Insect infestation (live insects)	Count	--	0
Insect infestation (dead insects)	Count	--	15
Color	Light green, with occasional red/tan pieces		
Aroma	Typical sweet grain aroma		

Buckwheat Groats			
Chemical, Physical and Microbiological Properties			
Flavor	Clean, sweet buckwheat taste		
Microbiological			
Aerobic Plate Count	cfu/g	--	500,000
Coliform	cfu/g	--	500
<i>E. coli</i>	cfu/g	--	10
<i>Salmonella</i>	Negative / Positive	Negative to test	--
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	Negative to test	
¹ Percent is on a weight/weight basis ² Reported on 14% moisture basis			

4.2.2 Chemical and Physical Properties - Buckwheat Grits

Buckwheat Grits shall be prepared from the buckwheat groats first by separating buckwheat kernels from shells, then by grinding to the desired texture. The buckwheat grits shall have a pleasantly sweet taste, not sour or bitter, and no off odors. The finished product shall conform to the following analyses:

Buckwheat Grits			
Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (Nx6.25) ²	%	12.0	--
Ash	%	--	3.0
Crude fiber	%	--	2.5
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 20 sieve	%	5	
Color	Light green, with occasional red/tan pieces		
Aroma	Typical sweet grain aroma		
Flavor	Clean, sweet buckwheat taste		
Microbiological			
	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	500,000
Coliform	cfu/g	--	500
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i>	Negative / Positive	Negative to test	--
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	Negative to test	

Buckwheat Grits Chemical, Physical and Microbiological Properties
¹ Percent is on a weight/weight basis
² Reported on 14% moisture basis

4.2.3 Chemical and Physical Properties - Buckwheat Flour

Buckwheat Flour shall be produced from the buckwheat fruit, in which a certain percent of hull is retained. The flour shall be of a medium fine ground texture free flowing and free of caked lump. Buckwheat flour should be white to gray color with black specks. The flour shall have a sweet flour aroma free of rancid or other off odors, a hearty and slightly acidic buckwheat taste. The finished product shall conform to the following analyses:

Buckwheat Flour Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (Nx6.25) ²	%	8.0	--
Ash ²	%	--	2.5
Crude Fiber ²	%	--	2.5
Physical	Units	Minimum	Maximum
Material through US Std. No. 80 sieve	%	95	--
Material through US Std. No. 200 sieve	%	50	--
Color	White to off white		
Aroma	Typical sweet grain flour aroma		
Flavor	Clean, sweet grain flour flavor		
Texture	Free flowing, free of caked lumps		
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	500,000
Coliform	cfu/g	--	500
<i>E. coli</i>	cfu/g	Negative to test	
<i>Salmonella</i>	Negative / Positive	Negative to test	
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	Negative to test	--
¹ Percent is on a weight/weight basis			
² Reported on 14% moisture basis			

4.3 Grading Requirements

Not applicable.

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), crude fiber, particle size, purity, whole grits, unhulled kernels, foreign material and ash shall be reported to the nearest 0.1 percent. Aflatoxin shall be reported to the nearest ppb and mineral matter shall be reported to the nearest 0.01 percent. Aerobic plate count and yeast and molds shall be reported to two (2) significant digits. Coliform, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test'.

4.6.1.1 Sample Certificates of Analysis – Buckwheat Groats

Sample Certificate of Analysis Buckwheat Groats						
Invitation:		Pack Date:				
Export Contract VEPE:		Mill Point:				
Notice to Deliver VEPE:		Pack Size:				
Car/Truck ID:						
Lot Number:		Lot Quantity (TBD MT max)				
Contracted Quantity	MT		LBS		Bags	
		Units ¹	Limit	Test Result	Pass (Y/N)	
Moisture		%	14.0 Max			
Protein (N x 6.25) ²		%	12.0 Min			
Ash ²		%	3.0 Max			
Crude Fiber ²		%	2.5 Max			
Purity		&	99.2 Min			
Whole Groats (Retained on US Std 7/64 in round hole sieve)		%	95.0 Min			
Unhulled kernels		%	0.3 Max			
Foreign material		%	0.3 Max			
Whole Groats		%	95.0 Min			
Color	Light green, with occasional red/tan pieces		Pass/Fail			
Aroma	Typical sweet grain aroma		Pass/Fail			
Flavor	Clean, sweet buckwheat taste		Pass/Fail			
Aerobic Plate Count		cfu/g	500,000			
Coliform		cfu/g	500			
<i>E. coli</i>		cfu/g	Negative to test			
<i>Salmonella</i>		Negative / Positive	Negative to test			
<i>Staphylococcus aureus</i> , coagulase positive		cfu/g	Negative to test			
Comments:						

Sample Certificate of Analysis Buckwheat Groats	
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Percent weight basis. ² Reported on 14% moisture basis	

4.6.1.2 Sample Certificate of Analysis – Buckwheat Grits

Sample Certificate of Analysis Buckwheat Grits				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Protein (Nx6.25) ²	%	10.0 Min		
Ash ²	%			
Crude fiber ²	%			
Material through US Std. No. 20 sieve	%	5		
Color	Light green, with occasional red/tan pieces		Pass/Fail	
Aroma	Typical sweet grain aroma		Pass/Fail	
Flavor	Clean, sweet buckwheat taste		Pass/Fail	
Aerobic Plate Count	%	25.0 Min		
Coliform	cfu/g	100 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Negative / Positive	Negative to test		
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		

Sample Certificate of Analysis Buckwheat Grits
¹ Percent weight basis. ² Reported on 14% moisture basis

4.6.1.3 Sample Certificate of Analysis – Buckwheat Flour

Sample Certificate of Analysis Buckwheat Flour				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Protein (Nx6.25) ²	%	10.0 Min		
Ash ²	%	2.5 Max		
Crude Fiber ²	%	2.5 Max		
Material through US Std. No. 80 sieve	%	95 Min		
Material through US Std. No. 200 sieve	%	50 Min		
Color	White to off white	Pass/Fail		
Aroma	Typical sweet grain flour aroma	Pass/Fail		
Color	Clean, sweet grain flour flavor	Pass/Fail		
Texture	Free flowing, free of caked lumps	Pass/Fail		
Aerobic Plate Count	%	500,000 Max		
Coliform	cfu/g	500 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Negative / Positive	Negative to test		
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		
¹ Percent weight basis. ² Reported on 14% moisture basis				

5.1 General Requirements

5.2 Aflatoxin

Buckwheat shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the buckwheat corn shall not be used in the production of the commodity. Manufacturers shall provide evidence of aflatoxin assays upon request.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
14.1 or 14.2	%	0.10	7.9 or 7.8	%	0.10
14.3 or 14.4	%	0.20	7.7 or 7.61	%	0.20
14.5 or 14.6	%	0.35	7.5 or 7.4	%	0.35

Performance Language

Bulgur / Soy-Fortified Bulgur

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers bulgur and soy-fortified bulgur (WBSF) produced for the food assistance programs.

3 CLASSIFICATION

Purchaser must specify bulgur or soy fortified bulgur.

4 FINISHED PRODUCT CHARACTERISTICS

Bulgur and soy-fortified bulgur are cracked, debranned, and partially cooked to reduce the final cooking time, reduce toughness, and lower the crude fiber content. Soy-fortified bulgur is composed of cracked bulgur and defatted soy grits. Both bulgur and soy-fortified bulgur contain added micronutrients for improved nutrition.

4.1 Finished Product Analytical Requirements

Bulgur and soy-fortified bulgur are used as a staple food for all categories of programs and shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.1 and 4.2.2.

4.2 Chemical and Physical Properties

4.2.1 Bulgur

Bulgur			
Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	11.5
Protein (N x 5.7) ²	%	9.3	--
Crude Fiber ²	%	--	2.3
Ash ² (prior to calcium enrichment)	%	--	2.00
Vomitoxin	ppm	--	1.0
Micronutrients			
	Units	Minimum	Maximum
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic acid	mg/lb	0.7	1.0
Calcium	mg/lb	500	750
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Foreign Material: other grains except wheat	%	--	0.1
Material except other grains ³	%	--	0.1
Scorched particles	%	--	0.2

Bulgur			
Chemical, Physical and Microbiological Properties			
Ungelatinized particles (whole or pieces of kernels)	%	--	1.0
Whole processed kernels retained on a US Std. No. 8 sieve	%	--	4.0
Material through US Std. No. 8 sieve	%	80.0	--
Material through US Std. No. 14 sieve	%	--	18.0
Material through US Std. No. 30 sieve	%	--	0.9
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
¹ Percent is on a weight/weight basis			
² Moisture free basis			
³ Including grain hulls either attached or detached. However, any hulls attached to product should be detached before inclusion in the hull fraction.			

4.2.2 Soy-Fortified Bulgur

Soy-Fortified Bulgur			
Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	11.5
Protein (N x 5.7) ²	%	17.3	--
Fat ²	%	--	2.6
Crude Fiber ²	%	--	2.6
Vomitoxin	ppm	--	1.0
Ash ² (Prior to calcium enrichment)	%	--	2.80
Micronutrients	Units	Minimum	Maximum
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Calcium	mg/lb	500	750
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical	Units ¹	Minimum	Maximum
Foreign Material: other grains except soy grits	%	--	0.1
Materials other than cereal grains or soy grits ³	%	--	0.1
Scorched particles (whole or pieces of kernels)	%	--	0.2

Soy-Fortified Bulgur Chemical, Physical and Microbiological Properties			
Ungelatinized particles (whole or pieces of kernels)	%	--	0.9
Whole processed kernels retained on a US Std. No. 8 sieve	%	--	3.5
Material through US Std. No. 8 sieve	%	81.0	--
Material through US Std. No. 14 sieve	%	--	23.0
Material through US Std. No. 30 sieve	%	--	1.2
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
¹ Percent is on a weight basis ² Moisture free basis ³ Including grain hulls either attached or detached. However, any hulls attached to product should be detached before inclusion in the hull fraction.			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 5.7), fat, crude fiber, particle size foreign material, scorched particles, ungelatinized particles shall be reported to the nearest 0.1 percent. Ash shall be reported to the nearest 0.01 percent. Test results for iron shall be reported to the nearest 0.1 mg/lb product. Vitamin A palmitate shall be to the whole number per pound of product. Vomitoxin results shall be reported to the nearest 0.5 ppm. Aerobic plate count shall be reported to two (2) significant digits. Calcium shall be reported to the nearest 1 mg/lb product.

4.6.1 Certificate of Analysis

4.6.1.1 Bulgur

Sample Certificate of Analysis Bulgur				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	11.5 Max		
Protein (N x 5.7) ²	%	9.3 Min		
Crude Fiber ²	%	2.3 Max		

Sample Certificate of Analysis				
Bulgur				
Ash ² (based on calcium content, see Section 8.3)	%	Variable		
Vomitoxin	ppm	1.0 Max		
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0 Min – 26.0 Max		
Calcium	mg/lb	500 Min – 750 Max		
Foreign Material: Other grains except wheat	%	0.10 Max		
Material, except other grains	%	0.1 Max		
Scorched particles	%	0.2 Max		
Ungelatinized articles (whole or pieces of kernels)	%	1.0 Max		
Material on US Std No. 8 Sieve	%	4.0 Max		
Material Through US Std No. 8 Sieve	%	80.0 Min		
Material Through US Std No. 14 Sieve	%	18.0 Max		
Material Through US Std No. 30 sieve	%	0.9 Max		
Aerobic Plate Count	cfu/g	50,000 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis				
² Moisture free basis				

4.6.1.2 Soy-Fortified Bulgur

Sample Certificate of Analysis					
Soy-Fortified Bulgur					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size:		
Car/Truck ID:					
Lot Number:			Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags		
	Units ¹	Limit	Test Result	Pass (Y/N)	
Moisture	%	11.5 Max			
Protein (N x 5.7) ²	%	17.3 Min			

Sample Certificate of Analysis Soy-Fortified Bulgur				
Crude Fat ²	%	2.6 Max		
Crude Fiber ²	%	2.6 Max		
Ash ² (based on calcium content, see Section 8.3)	%	variable		
Vomitoxin	ppm	1.0 Max		
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0 Min - 26.0 Max		
Calcium	mg/lb	500 Min – 750 Max		
Foreign Material: Other grains except soy grits	%	0.1 Max		
Material other than cereal grains or soy grits	%	0.1 Max		
Scorched particles	%	0.2 Max		
Ungelatinized articles (whole or pieces of kernels)	%	0.9 Max		
Material on US Std No. 8 Sieve	%	3.5 Max		
Material Through US Std No. 8 Sieve	%	81.0 Min		
Material Through US Std No. 14 Sieve	%	23.0 Max		
Material Through US Std No. 30 sieve	%	1.2 Max		
Aerobic Plate Count	cfu /g	50,000 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

The bulgur will be milled from wheat of any of the classes defined in the "Official United States Standards for Grain" except mixtures of wheat of contrasting classes. The wheat shall not contain more than 4.0 percent of damaged kernels. The grain standards are available at: <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sqous>

Wheat shall be tested for vomitoxin in accordance with procedures approved by the Federal Grain Inspection Service (FGIS) and any wheat testing higher than 2 ppm shall not be used in production of the commodity. The final product shall not contain more than 1 ppm of vomitoxin.

5.2 Formulation

5.2.1 Bulgur

Bulgur and vitamin premix.

5.2.2 Soy-Fortified Bulgur

Values in this formulation table are valid only for use with bulgur and defatted soy grits. Use of approved alternate ingredients (expeller soy grits) requires adjustments to the formula percentages. The final product shall meet all requirements defined in Section 4.2.2.

Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Bulgur, Cracked	85.0	1700
Soy grits, Defatted (toasted)	15.0	300
Vitamin Premix		As necessary to meet the requirements
Total	100.0	2,000

5.3 Ingredients

5.3.1 Bulgur

Bulgur shall be thoroughly and homogeneously mixed with the vitamin premix described in Section 5.3.4 to achieve the finished product requirements for bulgur defined in Section 4.2.1.

5.3.2 Soy-Fortified Bulgur

Ingredients listed in Sections 5.3.2.1 – 5.3.4.2 will be used in the preparation of bulgur and soy-fortified bulgur.

5.3.2.1 Bulgur, Cracked

Cracked bulgur flour shall conform to these requirements:

Bulgur, Cracked Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	11.5
Protein (N x 5.7) ²	%	10.5	--
Crude Fiber ²	%	--	2.0
Ash ²	%	--	1.8
Foreign material, total	%	--	0.2
Foreign Material: other than cereal grains.	%	--	0.05
Materials except other grains ³	%	--	0.1

Bulgur, Cracked			
Chemical, Physical and Microbiological Properties			
Scorched particles (whole or pieces of kernels)	%	--	0.2
Ungelatinized particles (whole or pieces of kernels)	%	--	1.0
Physical	Units	Minimum	Maximum
Whole processed kernels retained on a US Std. No. 8 sieve	%	--	4.0
Material through US Std. No. 8 sieve	%	80.0	
Material through US Std. No. 14 sieve	%		23.0
Material through US Std. No. 30 sieve	%		0.9
¹ Percent is on a weight/weight basis			
² Moisture free basis			
³ Including grain hulls either attached or detached. However, any hulls attached to product should be detached before inclusion in the hull fraction.			

5.3.2.2 Soy Grits, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling. The soy grits, defatted (toasted) shall conform to these requirements:

Soy Grits, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	12.0
Protein (N x 6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Ash ²	%	--	7.0
Material through a U.S. Std. No. 8 Sieve	%	90.0	--
Material through a U.S. Std. No. 14 Sieve	%	--	75.0
Material through a U.S. Std. No. 30 Sieve	%	--	5.0
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic Plate Count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2.3 Soy Grits, Expeller

Optional ingredient to defatted soy grits. Soy grits, expeller will be the screened, coarsely, ground product obtained from selected soybeans by cleaning, cracking, dehulling, heating, and expeller change to golden buff or tan, and cooling. The product shall conform to these requirements:

Soy Grits, Expeller			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	12.0
Protein (N x 6.25) ²	%	47.0	--
Fat ²	%	5.0	6.5
Ash ²	%	--	7.0
Material through a U.S. Std. No. 8 Sieve	%	90.0	--
Material through a U.S. Std. No. 14 Sieve	%	--	75.0
Material through a U.S. Std. No. 30 Sieve	%	--	5.0
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic Plate Count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.4 Enrichment Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added at a rate sufficient to achieve the following levels of micronutrients per pound of finished product.

Enrichment Ingredients			
	Units	Min	Max
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Calcium	mg/lb	500	750

5.3.4.1 Vitamin A

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

5.3.4.2 Calcium

The calcium added must be in forms which are harmless and assimilable. Calcium amounts up to 1247 mg/lb are considered within the specifications limit so long as the ash/calcium ratio is met as shown in Table titled “Maximum Ash Allowable without Discount at Specified Calcium Levels”, Section 8.3.

If calcium is added independently from a micronutrient premix, verification of the correct addition level must be documented, by assay and reported on the Certificate of Analysis.

8.2 Schedule of Discounts

8.2.1 Bulgur

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
11.6 - 11.7	%	0.10	9.2 or 9.1	%	0.10
11.8 - 11.9	%	0.20	9.0 or 8.9	%	0.20
12.0	%	0.35	8.8	%	0.35
Excess Ash Percentage Points Above Maximum			Deficient Calcium		
0.01 - 0.02	%	0.10	499 - 440	mg/lb	0.05
0.03 - 0.04	%	0.20	439 - 400	mg/lb	0.10
0.05	%	0.35	399 - 340	mg/lb	0.35
Excess Crude Fiber			Excess Calcium		
2.4 - 2.5	%	0.10	750 - 1247	mg/lb	0.00
2.6 - 2.7	%	0.20			
2.8	%	0.35			
Excess Ungelatinized Particles			Excess Scorched Particles		
1.1 - 1.4	%	0.10	0.21 - 0.30	%	0.25
1.5 - 1.8	%	0.20			
1.9 - 2.0	%	0.35			
Excess Whole Kernels on a No. 8 Sieve			Excess Material Other Than Cereal Grains		
4.1 - 4.4	%	0.10	0.11 - 0.20	%	0.25
4.5 - 4.8	%	0.20			
4.9 - 5.0	%	0.35			
Deficient Granulation Through a US Std. No. 8 Sieve			Excess Other Grains Except Wheat		
79.0 - 70.0	%	0.10	0.11 - 0.20	%g	0.25
Excess Granulation Through a No. 14 US Std Sieve			Deficient Granulation Through a US Std. No. 30 Sieve		

19.0 – 22.0	%	0.10	1.0 - 1.5	%	0.10
23.0 – 26.0	%	0.20	1.6 - 2.5	%	0.20
27.0 – 28.0	%	0.35	2.6 – 3.0	%	0.35

8.2.2 Soy Fortified Bulgur

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
11.6 - 11.7	%	0.10	17.2 - 17.1	%	0.10
11.8 - 11.9	%	0.20	17.0 - 16.9	%	0.20
12.0	%	0.35	16.8	%	0.35
Excess Ash Percentage Points Above Maximum			Deficient Calcium		
0.01 - 0.02	%	0.10	499 - 440	mg/lb	0.05
0.03 - 0.04	%	0.20	439 – 400	mg/lb	0.10
0.05	%	0.35			
Excess Crude Fiber			Excess Calcium		
2.7 - 2.8	%	0.10	750 - 1247	mg/lb	0.00
2.9 – 3.0	%	0.20			
3.1	%	0.35			
Excess Ungelatinized Particles			Excess Scorched Particles		
1.0 - 1.1	%	0.10	0.21 - 0.30	%	0.25
1.2 - 1.3	%	0.20			
1.4	%	0.35			
Excess Crude Fat			Excess Material Other Than Cereal Grains and Soy Grits		
2.7 - 2.8	%	0.10	0.11 - 0.20	%	0.25
2.9 - 3.0	%	0.20			
3.1	%	0.35			
Excess Whole Kernels on a No. 8 Sieve			Excess Other Grains Except Wheat and Soy Grits		
3.6 – 4.0	%	0.10	0.11 - 0.20	%	0.25
4.1 – 4.5	%	0.20			
4.6 – 5.0	%	0.35			
Deficient Granulation Through a US Std. No. 8 Sieve			Excess Granulation Through a No. 14 US Std Sieve		
80.0 - 79.0	%	0.10	24.0 - 26.0	%	0.10
78.0 - 77.0	%	0.20	27.0 - 29.0	%	0.20
76.0	%	0.35	30.0 - 32.0	%	0.35
Deficient Granulation Through a US Std. No. 30 Sieve					
1.3 - 1.8	%	0.10			
1.9 - 2.5	%	0.20			

8.3 Maximum Ash Content Based on Calcium Addition

8.3.1 Bulgur

Maximum Ash Allowable Without Discount at Specified Calcium Levels					
Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %
340 - 358	2.18	649 - 666	2.35	957 - 974	2.52
359 - 376	2.19	667 - 684	2.36	975 - 993	2.53
377 - 394	2.20	685 - 702	2.37	994 - 1011	2.54
395 - 412	2.21	703 - 720	2.38	1012 - 1029	2.55
413 - 430	2.22	721 - 739	2.39	1030 - 1047	2.56
431 - 448	2.23	740 - 757	2.40	1048 - 1065	2.57
449 - 466	2.24	758 - 775	2.41	1066 - 1083	2.58
467 - 485	2.25	776 - 793	2.42	1084 - 1101	2.59
486 - 503	2.26	794 - 811	2.43	1102 - 1120	2.60
504 - 521	2.27	812 - 829	2.44	1121 - 1138	2.61
522 - 539	2.28	830 - 847	2.45	1137 - 1156	2.62
540 - 557	2.29	848 - 866	2.46	1157 - 1174	2.63
558 - 575	2.30	867 - 884	2.47	1175 - 1192	2.64
576 - 593	2.31	885 - 902	2.48	1193 - 1210	2.65
594 - 612	2.32	903 - 920	2.49	1211 - 1228	2.66
613 - 630	2.33	921 - 938	2.50	1229 - 1247	2.67
631 - 648	2.34	939 - 956	2.51		

8.3.2 Soy-Fortified Bulgur

Maximum Ash Allowable Without Discount at Specified Calcium Levels					
Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %
340 - 358	2.98	649 - 666	3.15	957 - 974	3.32
359 - 376	2.99	667 - 684	3.16	975 - 993	3.33
377 - 394	3.00	685 - 702	3.17	994 - 1011	3.34
395 - 412	3.01	703 - 720	3.18	1012 - 1029	3.35
413 - 430	3.02	721 - 739	3.19	1030 - 1047	3.36
431 - 448	3.03	740 - 757	3.20	1048 - 1065	3.37
449 - 466	3.04	758 - 775	3.21	1066 - 1083	3.38
467 - 485	3.05	776 - 793	3.22	1084 - 1101	3.39
486 - 503	3.06	794 - 811	3.23	1102 - 1120	3.40
504 - 521	3.07	812 - 829	3.24	1121 - 1138	3.41
522 - 539	3.08	830 - 847	3.25	1137 - 1156	3.42
540 - 557	3.09	848 - 866	3.26	1157 - 1174	3.43

558 - 575	3.10	867 - 884	3.27	1175 - 1192	3.44
576 - 593	3.11	885 - 902	3.28	1193 - 1210	3.45
594 - 612	3.12	903 - 920	3.29	1211 - 1228	3.46
613 - 630	3.13	921 - 938	3.30	1229 - 1247	3.47
631 - 648	3.14	939 - 956	3.31		

REVISED

Performance Language

Bulk Oil and Tallow

This performance language document includes information that is intended to be inserted into the Vegetable Oils/Fats template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This commodity requirement covers bulk oils (crude, degummed soybean oil, fully refined soybean oil; crude corn oil; crude sunflower seed oils) and tallow.

3 CLASSIFICATION

Crude, degummed soybean oil, crude corn oil, crude sunflower seed oils and tallow are intermediates in production of fully refined, bleached and deodorized soybean oil, corn oil, sunflower seed oil and tallow.

4.1 Finished Product Analytical Requirements

The crude, degummed soybean oil, fully refined soybean oil, crude corn oil, crude sunflower see oil and tallow shall meet the chemical, physical and microbiological requirements defined in Section 4.2.1 – 4.2.5.

4.2 Chemical and Physical Properties

4.2.1 Chemical and Physical Properties – Crude, Degummed Soybean Oil

Crude, degummed soybean oil shall correspond to the specifications as described in Rule 103 of the National Oilseed Processors Association’s Yearbook and Trading Rules. It shall be from pure crude soybean oil produced from fair average quality soybean oil by removing the major portion of the naturally present gums by hydration and mechanical or physical separation. It shall be equal in quality to degummed soybean oil produced for domestic production of fully refined soybean oil.

Crude, Degummed Soybean Oil Chemical and Physical Properties			
Chemical	Units	Minimum	Maximum
Unsaponifiable matter	%	--	1.5
Free Fatty Acids, as Oleic	%	--	0.75
Moisture, Volatile matter and insoluble impurities	%	--	0.3
Flash Point	° F	250	--
Phosphorous	%	--	0.02

4.2.2 Chemical and Physical Properties – Fully Refined Soybean Oil

Fully refined soybean oil shall meet the specifications as described in Rule 103 of the National Oilseed Processors Association’s Yearbook and Trading Rules. Fully refined soybean oil sold for export shall be pure soybean oil. It shall be produced from fair average quality crude soybean oil by removing all the free fatty acids and non-oil substances chemical treatments and by mechanical or physical separation. The appearance shall be clear and brilliant at 70 °F – 85 °F. It shall be free from settlings or foreign matter of any kind and be bland and free from rancid, painty, musty, soapy, fishy, metallic, beany and other foreign or undesirable odors and flavors.

Fully Refined Soybean Oil Chemical and Physical Properties			
Chemical	Units¹	Minimum	Maximum
Color	Lovibond	--	20 Yellow 2.0 Red
Free Fatty Acids, as Oleic	%	--	0.05
Peroxide Value	meq/kg	--	2.0
Cold Test	Hours	--	5.5
Fat Stability (8 hours) – AOM	meg/kgm	35	--
Moisture + Volatile Matter	%	--	0.10

¹ Percent weight basis

4.2.3 Chemical and Physical Properties – Crude Corn Oil

Crude corn oil shall meet the specifications as described in Rule 6.14 of the National Institute of Oilseed Products Trading Rules http://www.oilseed.org/trading_rules.html. It shall be pure and produced only from corn of fair average quality.

Crude Corn Oil Chemical and Physical Properties			
Chemical	Units	Maximum	Basis
Free Fatty Acids, as Oleic	%	5.0	3.0
Moisture and Impurities	%	1.0	0.5

4.2.4 Chemical and Physical Properties – Crude Sunflower Seed Oil

Crude sunflower seed oil shall meet the specifications contained in the American Fats and Oils Association Inc. Rulebook for Vegetable Oils (Export Contract), Rule 14. It shall be pure and produced only from sunflower seeds of fair average quality by hydraulic, expeller or solvent extraction process.

Crude Sunflower Seed Oil Chemical and Physical Properties			
Chemical	Units	Minimum	Maximum
Flash Point	°F	250	--
Halphen Test		--	Negative
Saponification Value		188	194
Unsaponifiable	%	--	1.3
Free Fatty Acid, as Oleic	%	2.0	3.0
Moisture and Volatile Matter	%	--	0.5
Insoluble Impurities	%	--	0.3
Color (in 5 ¼ inch cell or tube) Bleached, after refining	Lovibond	--	2.5 Red
Linolenic Acid	%	--	1.0
Oleic Acid (as % of TFA)	%	55	75

(applicable for mid oleic acid sunflower seed oil only)			
---	--	--	--

4.2.5 Chemical and Physical Properties – Tallow

Tallow shall correspond to the specifications contained in Rule 7 of the Rules of the American Fats and Oils Association (AFOA) for animal tallow and grease (export contract), or any modifications thereof agreed to, that are in effect on the dates the contract is entered into. It shall contain only fluids and fatty acids natural to the product except for other such amounts as might occur unavoidably in accordance with industry practice.

4.4 Analytical Testing Methods

[Note: The following is a sample list of analytical testing methods references. A more complete list will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

The test results for free fatty acids and moisture and volatile matter shall be reported to the nearest 0.01 percent. The test results for peroxide value and linolenic acid shall be reported to the nearest 0.1 meg/kg and one percent, respectively. The test results for Lovibond color, fat stability, and iodine value shall be reported to the nearest whole number. The test results for insoluble impurities shall be “detected” or “not detected”. The test results for the AOCS cold test shall be “pass” or “fail”. Any result not conforming to the analytical requirements shall be cause for rejection of the lot.

[Note: Reporting test method precision will, by necessity, need to be included in deliverable C.3.3.5, standard analytical methods recommendations.]

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Bulk Oil and Tallow				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS	Bags	
Oil Source:				
	Units¹	Limit	Test Result	Pass (Y/N)
Flash point	°F	250 min		
Free Fatty Acids	%	3 max		
Moisture and volatiles	%	0.5 max		
Insoluble impurities	%	0.3 max		
Color	Lovibond	2.5 max		
Comments:				

Sample Certificate of Analysis Bulk Oil and Tallow	
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Percent weight basis	

4.7 Lot Size Definition

[Note: Recommendation for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.10 Product Age

Unless otherwise specified in the solicitation contract, or purchase order, the Bulk Oils shall be processed and/or packaged not more than sixty (60) days prior to delivery to the purchaser.

5.1 General Requirements

The bulk oils are intermediate products. Only fully refined soybean oil is suitable for direct consumption as a packaged product. Heavy metal scavengers, antifoaming agents, and antioxidants can be added provided levels of use are in accordance with appropriate Food and Drug Administration regulations. All bulk oils shall be free from foreign materials such as dirt, insect parts, hair, wood, glass or metals sludge and tank bottoms.

5.2 Weight

Determination of weight shall be by an independent surveyor, or by mutual agreement between the government and the contractor. The weight shall be determined at the time of loading onboard the vessel. Before such loading, each tank into which the bulk commodity is to be loaded shall be examined by such independent surveyor to determine that the tank(s) are clean and otherwise suitable for receipt and carriage of the bulk commodity.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications listed in Section 4.2, Chemical and Physical Properties, of this Commodity Requirement but falls within the discounts listed in the table in Section 8.2, the commodity may be delivered; but the purchase price shall be reduced in accordance with the schedules of discounts for each 100 pounds (net weight) of product delivered in Section 8.2.

8.2 Schedule of Discounts

8.2.1 Schedule of Discounts – Crude, Degummed Soybean Oil

	Units	Discount		Units	Discount
Phosphorous			Excess Free Fatty Acid		
0.021	%	0.2% of contract price	0.76-0.85	%	0.2% of contract price
0.022	%	0.4% of contract price	0.86-0.95	%	0.4% of contract price
0.023	%	0.6% of contract price	0.96-1.05	%	0.6% of contract price
0.024	%	0.9% of contract price	1.06-1.15	%	0.9% of contract price
0.025	%	1.2% of contract price	1.16-1.25	%	1.2% of contract price

8.2.2 Schedule of Discounts – Crude Corn Oil

The free fatty acids, as oleic, shall be discounted 0.5% of the contract value for each 1.0% in excess of 3%, fractions in proportion.

The moisture and impurities shall be discounted 0.1% of the contract value for each 0.1% in excess of 0.5%, fractions in proportion.

8.2.3 Schedule of Discounts – Crude Sunflower Seed Oil

Free Fatty Acid, as Oleic, shall be discounted 0.1% of the contract value for each 0.1% of free fatty acid in excess of 2.0%; fractions in proportion.

8.2.4 Schedule of Discounts – Tallow

All tolerances and discounts as provided for in AFOA rules 9, 10 and 11 shall apply.

9 REFERENCES

- A. FDA Regulation. Title 21. Chapter 9, Subchapter IV, § 346a Tolerances and Exemptions for Pesticide chemical residues.
- B. Good Manufacturing Practices
- C. Pesticide Residue 40 CFR 180

Performance Language

Bulk Soybean Meal

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers bulk soybean meal (SBM) produced for the food assistance programs.

3 CLASSIFICATION

Purchaser must specify if intended for human consumption.

4 FINISHED PRODUCT CHARACTERISTICS

Bulk soybean meal shall meet the requirements for high protein soybean meal (flakes) as described under Rule 2 - Quality, Section 3. b. of the National Oilseed Processors Association's "Trading Rules for the Purchase and Sale of Soybean Meal", adopted October 18, 1933 and all revisions thereto which may be found at http://www.nopa.org/content/trading/nopa_sbm_trading_rules_rev_feb_06_effective_10_1_06_v1007.pdf, except as the chemical and physical requirements listed in Section 4.2, Chemical and Physical Properties differ from the "Trading Rules, in which case, the requirements outlined in Section 4.2 shall take precedence.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use in food products subjected to additional heat treatment and shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Bulk Soybean Meal Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	12.0
Protein (N x 6.25) ²	%	48.0	--
Fat ²	%	--	1.5
Crude Fiber ²	%	--	3.5
Urease pH increase	pH units	0.02	0.3
Protein Dispersibility Index	%	10	30
Microbiological			
	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g		Negative to test
<i>Salmonella</i>			Negative to test

¹ Percent is on a weight/weight basis
² Reported on 12% moisture basis

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat and crude fiber shall be reported to the nearest 0.1 percent.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Bulk Soybean Meal				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	12.0 Max		
Protein (Nx6.25) ²	%	48.0 Min		
Fat ²	%	1.0 Max		
Crude Fiber	%	3.5 Max		
Urease pH increase	pH units	0.02 Min – 0.3 Max		
Protein Dispersibility Index	%	10 Min – 30 Max		
Aerobic plate count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Present / Absent	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____		Date: _____		
Title: _____				
Telephone: _____				
FAX: _____				
¹ Percent weight basis				
² Reported on 12% moisture basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Soybean Flakes and High Protein or Solvent Extracted Soybean Meal are produced by cracking, heating, and flaking dehulled soybeans and reducing the oil content of the

conditioned flakes by the use of hexane or homologous hydrocarbon solvents. The extracted flakes are cooled and marketed as such or ground into meal.

5.2 Soybean Meal Processing Guidelines

Soybeans used to produce soybean meal should be sound, clean, and free from other

In the case of soybean meal, the hull-free meats are coarsely ground, lightly steamed, flaked, and then solvent-extracted in conventional apparatus with hexane of a quality acceptable for food processing. The defatted flakes are steamed at atmospheric pressure to completely remove the solvent and are additionally steam-cooked ("toasted") to produce a palatable, cream-yellow product free from objectionable flavor and anti-biological factors.

Heat processing should be carefully controlled and sufficiently thorough to secure optimum flavor and palatability, as well as to inactivate objectionable anti-biological factors (e.g., anti-trypsin and hemagglutinins). It must not be so severe as to damage the protein, as evidenced by excessive loss of available lysine, or impairment of protein nutritional value. Once optimum improvement in these factors has been attained, the product, after final heat treatment, should be cooled quickly to ambient temperatures.

The fully processed flakes or granules should have a light yellow coloration that, in a more finely granulated form, assumes a creamy appearance. The flavor may be described as toasted and bland, completely free of the characteristic raw soybean flavor.

5.3 Conditioning Agents

Any of the above meal products (listed in Section 3 above) may contain a non nutritive inert, nontoxic conditioning agent to reduce caking and improve flowability, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 0.5% or 10 lbs. per ton by weight.

9 REFERENCES

- A. NOPA Soybean Meal Trading Rules
http://www.nopa.org/content/trading/nopa_sbm_trading_rules_rev_feb_06_effective_10_1_06_v1007.pdf
- B. WHO Guideline for production of edible, heat processed soy grits and flours
<http://www.unu.edu/unupress/food/8F021e/8F021E0c.htm>
- C. FAS Bulk Soybean Meal Fact Sheet -
<http://www.fas.usda.gov/excredits/FoodAid/commodities/soymeal.htm>

REVISED

Performance Language

Canned Pink Salmon

This performance language document includes information that is intended to be inserted into the commercial products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

Canned Salmon is the product prepared from headed and eviscerated fish of any of the species listed below from which the fins and tails have been removed, and to which salt, water, salmon oil and/or other edible oils may have been added.

Commercial Products described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Solicitations for Bids for canned pink salmon shall specify the Type, Species, Style and sodium level:

- a. Type A - Can
- b. Type B - Flexible retort pouch
- c. Species IV - *Oncorhynchus gorbuscha* - Pink
- d. Style - Regular - skin and bones included
- e. Sodium Level 1 - (Regular, (not more than 1.5% salt))

4 FINISHED PRODUCT CHARACTERISTICS

Performance language that is defined in specification(s), included herein by reference, will not be reproduced in this document.

4.1 Finished Product Analytical Requirements

Canned Pink Salmon should be in accordance with the chemical and physical properties, finished product analytical requirements and test result precision described and specified in Sections 5 & 6 of Commercial Item Description A-A-20158D at:

www.ams.usda.gov/fqa/aa20158d.htm

4.4 Analytical Testing Methods

Analytical testing method as described in Commercial Item Description A-A-20158D, Section 6, Analytical Requirements.

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis				
Canned Pink Salmon				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Can Size		
Car/Truck ID:				
Lot Number/Can Codes:		Lot Quantity		
Contracted Quantity	<u> </u> MT	<u> </u> LBS	<u> </u> Cans	
Analytical Test	Units¹	Limit	Test Result	Pass (Y/N)
Salt	%	Max 1.5		
Physical Appearance				
Color	Shall be pink to buff	Pass/Fail		
Texture	Shall be moderately firm to slightly soft	Pass/Fail		
Color of Oil	Shall be pink to light yellow	Pass/Fail		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____		Date: _____		
Title: _____				
Telephone: _____				
FAX: _____				

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.10 Product Age

Only current season, fresh or RSW (Refrigerated Sea Water) salmon shall be used for canned product.

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

The product shall be derived from raw material having characteristics that are indicative of good quality salmon, including, but not limited to, firmness of flesh, color typical of the species, and no off-odor of the gills and gut cavity. The washed salmon shall be free of objectionable material, including but not limited to, heads, viscera, and fins.

5.2 Quality Assurance

Quality assurance requirements are provided in Section 9 of Commercial Item Description for Salmon (A-A-20158D),

9 REFERENCES

- A. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- B. Canned Salmon Standards of Identity
http://a257.g.akamaitech.net/7/257/2422/26mar20071500/edocket.access.gpo.gov/cfr_2007/aprqr/21cfr161.170.htm
- C. *Salmonella* sampling requirements – Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan:
http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- D. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>

REVISED

Performance Language

Corn Oil

This performance language document includes information that is intended to be inserted into the Vegetable Oils/Fats template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement covers corn oil fortified with retinyl palmitate (vitamin A palmitate).

3 CLASSIFICATION

Corn oil

4.1 Finished Product Analytical Requirements

The corn oil delivered shall meet the requirements for Type I Vegetable oil, Section 6.1 of the latest revisions and amendments for Commercial Item Description (CID) A-A-20091D (May 7, 200) at:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006232>, except as these differ from the chemical and physical requirements listed in Section 4.2 'Chemical and Physical Properties', which will take precedence. In addition, corn oil shall be fortified with retinyl palmitate (vitamin A).

4.2 Chemical and Physical Properties

In addition to the chemical and physical requirements prescribed for Type I oil in Sections 5 and 6 of Commercial Item Description A-A-20091D, the following requirements apply:

Corn Oil Chemical and Physical Properties ¹			
	Units	Minimum	Maximum
Retinyl Palmitate	IU/g	60	75
Flavor	organoleptic	7.0	
OSI	hours	10	
Appearance	Visual	Clear to hazy	
Refractive Index (60 °C)	%	1.470	1.474
Saponification Value	mg KOH/g %	189	195
Unsaponifiable Matter	%		1.5
Antioxidants (<i>if added</i>) ²	ppm		200
Dimethylpolysiloxane (<i>if added</i>)	ppm	5	10
Specific Gravity (60 °C)	g/cc	0.922	0.928
Insoluble Impurities	%	0	0
Moisture and volatiles	%	0	0.10

¹ Determination shall be made within seven days after packaging. Samples submitted for testing shall be in a completely filled container.

² Maximum of 0.06 percent free fatty acid will be acceptable if propyl gallate is added as an antioxidant.

4.3 Grading Requirements

Not Applicable

4.4 Analytical Testing Methods

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

The test results for free fatty acids and moisture and volatile matter shall be reported to the nearest 0.01 percent. The test results for peroxide value and linolenic acid shall be reported to the nearest 0.1 meq/kg and one percent, respectively. The test results for Lovibond color, fat stability, and iodine value shall be reported to the nearest whole number. The test results for insoluble impurities shall be “detected” or “not detected”. The test results for the AOCS cold test shall be “pass” or “fail”. Any result not conforming to the analytical requirements shall be cause for rejection of the lot.

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis				
Corn Oil				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD, MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
Salad Oil Source:				
	Units	Limit	Test Result	Pass (Y/N)
Retinyl Palmitate	IU/g	60 min / 75 max		
Color ¹	Lovibond	3.0 Red		
Free Fatty Acid	(% as Oleic)	0.1		
Peroxide Value	meq/kg	1.0		
Iodine Value		118 Min/ 134 Max		
Moisture and volatiles	(%-KF)	0.10		
Flavor	organoleptic	7 min		
OSI	hours	10		
Cold Test	hours	5.5		
Appearance	Visual	Clear to hazy		
Antioxidants (if added)	ppm	200		
Dimethylpolysiloxane (if added)	ppm	5 - 10		
Insoluble Impurities	%	none		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				

Sample Certificate of Analysis	
Corn Oil	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Representative of source oil: Corn 3.5R	

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

5.1 General Requirements

Corn oil shall be clear and brilliant when held at 21.1 ° to 29.4 °C (70 ° to 85 °F). Heavy metal scavengers, antifoaming agents, and antioxidants can be added provided levels of use are in accordance with appropriate Food and Drug Administration regulations.

Corn oil shall have a light viscosity and shall not have a heavy oily mouth feel.

Corn oil shall have a clean, fresh flavor and shall be free from rancid, beany, painty, sour, or other objectionable flavors or odors.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications of CID A-A-20091D, dated May 7, 2002, the commodity may be delivered; but the purchase price shall be reduced in accordance with the schedules of discounts for each 100 pounds (net weight) of product delivered in Section 8.2.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Color - Red			Excess Free Fatty Acid		
3.6 or 3.7		0.05	0.06 or 0.07	%	0.10
3.8 or 3.9		0.10	0.08 or 0.09	%	0.20
4.0 or 4.1		0.15	0.10 or 0.11	%	0.30
Excess Peroxide Value					
2.1 – 2.3	Meq/kg	0.35			
2.4 – 2.5	Meq/kg	0.50			

9 REFERENCES

- A. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- B. Copies of the Official Methods of the American Oil Chemists' Society may be obtained from: American Oil Chemists' Society, P.O. Box 3489, Champaign, IL 61826-3489, telephone (217) 359-2344 or Fax (217) 351-8091.
<http://www.aocs.org/>
- C. (Intentionally Blank)

Performance Language

Corn-Soy Blend

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers corn-soy blend (CSB) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Corn-soy blend (CSB) is used as a supplemental food for emergency rations, displaced persons assistance, weaning food in Maternal Child Health Programs (MCH) and other programs. It is composed of cornmeal (pre-gelatinized), soy flour (toasted), soybean oil (refined, deodorized, bleached), a minerals premix and a vitamins and antioxidant premix.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or as an extender to other foods. The finished product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Corn-Soy Blend Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	10.0
Protein (N x 6.25) ²	%	16.7	--
Fat ²	%	6.0	--
Crude Fiber ²	%	--	2.0
Micronutrients			
	Units	Minimum	Maximum
Iron	mg/100 g	14.7	30.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 6 sieve	%	99.0	--
Material through US Std. No. 30 sieve	%	--	92.0
Material through US Std. No. 60 sieve	%	--	57.0
Functional / Performance			
	Units	Minimum	Maximum
Bostwick Consistency, cooked (11.75% gruel, w/w as is basis)	cm	9.0	21.0
Dispersibility	Essentially free of lumping or balling when mixed with water.		
Sensory			
Description			

Corn-Soy Blend Chemical, Physical and Microbiological Properties			
Appearance	Corn-soy blend appears equivalent to typical product.		
Odor	Corn-soy blend must be essentially free from foreign material and will have good characteristic taste and odor, and be free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i>	Present / Absent	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test	--
¹ Percent is on a weight/weight basis			
² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat, crude fiber and particle size shall be reported to the nearest 0.1 percent. Bostwick consistency measurements shall be reported to the nearest 0.5 cm. Test results for iron shall be reported to the nearest 0.1 mg/100 g product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits. *Staphylococcus aureus*, coagulase positive, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test'. Calcium and salt, if added as separate ingredients, shall be reported to the nearest 1 mg/100 g product.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Corn-Soy Blend				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (81 MT max)		
Contracted Quantity	MT	LBS	Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	10.0 Max		

Sample Certificate of Analysis Corn-Soy Blend				
Protein (Nx6.25) ²	%	16.7 Min		
Fat ²	%	6.0 Min		
Crude Fiber ²	%	2.0 Max		
Iron	mg/100g	14.7 Min- 30.0 Max		
Vitamin A Palmitate	IU/lb	8,400 Min – 16,000 Max		
Material through a US Standard No. 6 sieve	%	99.0 Min		
Material through a US Standard No. 30 sieve	%	92 Max		
Material through a US Standard No. 60 sieve	%	57 Max		
Bostwick Consistency (Cooked 11.75 % Gruel, w/w as is basis)	cm	9.0 Min – 21.0 Max		
Dispersibility	Essentially free from lumps or balling when mixed with water.		Pass/Fail	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail	
Odor	Good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		Pass/Fail	
Total Plate Count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Absent / Present	Negative to test		
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Corn-soy blend shall contain pregelatinized cornmeal, defatted, toasted soy flour, vegetable oil and vitamin mineral premixes at levels required to achieve the specified final product characteristics defined in Section 4.2 and shall be produced accordance with good manufacturing practices.

Corn-Soy blend may contain a corn germ fraction (Section 5.4.1.1) and/or full fat soy flour (Section 5.4.2.2).

5.2 Formulation

Values in this formulation table are valid only for use with defatted soy flour and not corn germ additive. Use of approved alternate ingredients (full-fat soy flour and/or corn-germ) alters the formula percentages of ingredients and changes to the percentages must be made. The final product shall meet all requirements defined in Section 4.2.

Formulation		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Cornmeal, pregelatinized	69.6	1,391
Soy Flour, Defatted, Toasted	21.9	437
Vegetable Oil	5.5	110
Mineral Premix	3.0	60
Vitamin Premix	0.1	2
Total	100.0	2,000

5.3 Ingredient Specifications

Ingredients listed in Sections 5.3.1 – 5.3.4 will be used in the preparation of corn-soy blend.

5.3.1 Cornmeal, Processed (Gelatinized)

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity. Manufacturers shall provide evidence of aflatoxin assays upon request.

The cornmeal processed (pre-gelatinized) shall be prepared from shelled yellow corn that has been dehulled and degermed. The corn used shall be clean, sound, and essentially free from other grains, weed seeds, and other foreign material. It shall be free of rancid, bitter, musty, sour, and other undesirable or foreign tastes and odors. The processed cornmeal shall be produced from yellow corn, as defined in the "Official United States Standards for Grain," found at

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>, in effect at the time the applicable solicitation for offers is issued.

The cornmeal shall be processed by adding moisture and partially cooking in continuous cookers or on heated flaking rolls, drying and cutting, or by any other process that yields a product meeting the requirements for the finished processed cornmeal, and for the corn-soy blend product.

A corn germ fraction in an amount not to exceed ten (10) percent of the total cornmeal fraction may be added before processing. The added amount of oil contained therein may be omitted from the soy oil added to the soy flour fraction or to the final mix, provided the blend contains a minimum of 21.8 percent of defatted soy flour. The weight of processed cornmeal plus soy oil specified shall include the weight of any corn germ fraction added thereto.

5.3.1.1 Analysis

The cornmeal, processed (gelatinized) shall conform to these requirements:

Pre-Gelatinized Cornmeal			
Assay	Units ¹	Requirements	
		Min.	Max.
Moisture	%	---	11.0
Ash ²	%	---	1.25
Material through a U.S. Std. No. 6 Sieve	%	99.0	---
Material through a U.S. Std No. 30 Sieve	%	---	85.0
Material Through a U.S. Std No. 60 Sieve	%	---	35.0
Consistency (Spread Test)	in	4.5	8.5
Aerobic Plate Count	cfu/g	---	50,000
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Soy Flour

5.3.2.1 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling.

5.4.2.1.1 Analysis

The soy flour, defatted (toasted) shall conform to these requirements:

Soy Flour, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0

Protein (Nx6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2.2 Soy Flour, Full Fat

Soy flour, full fat shall be the screened, finely-ground product obtained from selected soybeans by cleaning, cracking, (optional) dehulling, tempering, cooking (full cook with color change to light yellow or golden buff), and cooling.

5.4.2.2.1 Analysis

The soy flour, full fat shall conform to these requirements:

Soy Flour, Full Fat			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	44.0	--
Fat ²	%	22.0	--
Crude Fiber ²	%	--	3.0
Ash ²	%	--	6.0
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.3 Soybean Oil

Soy oil, refined, deodorized, and stabilized, shall contain 0.005 percent citric acid added on the cooling side of deodorization. The soy oil shall comply with the requirements of the latest revisions and amendments for Commercial Item Description A-A-20091D (May 7, 2002), <http://www.ams.usda.gov/fqa/aa20091d.htm>; type IV not winterized salad oil which is incorporated herein by reference.

Before addition to the product, the oil may be stabilized by the addition of butylated hydroxy anisole and butylated hydroxy toluene, each at a level of 2.5 mg. per 100 grams of formulated product. **Caution:** Antioxidant may be added to either the soy oil or to the vitamin antioxidant premix, but it shall not be added to both. [See Section 5.3.4.2]

5.3.4 Micronutrient Fortification

5.3.4.1 Mineral Premix

The minerals and vitamin premix shall not be combined and shall be added to the formulation separately.

The mineral premix shall contain the micronutrients listed in this Section, at the stated levels, and mineral premix identified as Option 1 shall be added to corn-soy blend at the rate of sixty (60) pounds per 2,000 pound batch of finished product. The weight of other mineral premix options vary and any deviation in weight from 60 pounds shall be added or subtracted, as appropriate, from the total final product batch weight.

Weight of Minerals per 60 pounds of Premix

	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
	lbs							
Calcium Phosphate, Tribasic	40.00			26.00	18.00	18.00		
Calcium Carbonate		36.00	36.00		12.00	12.00	10.00	10.00
Sodium Phosphate, Monobasic		32.00			16.00			
Calcium Phosphate, Dibasic				12.00				44.00
Potassium Phosphate, Monobasic			32.00			16.00		
Calcium Phosphate, Dibasic, Anhydrous							34.00	
Zinc Sulfate, Monohydrate ¹	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Ferrous Fumarate, FCC Grade, Purified	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Magnesium Oxide (MgO)	2.75	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Iodized Salt (0.007% I ₂)	16.25	16.25	16.25	16.25	16.25	16.25	16.25	16.25

Mineral Premix Total Weight, lbs	60.17	88.17	88.17	58.17	66.17	66.17	64.17	74.17
¹ Zinc sulfate heptahydrate (0.4 lbs) may be used as an alternative to 0.25 lbs zinc sulfate monohydrate.								

If calcium and phosphorus ingredients and/or salt are added independently from a mineral premix, verification of the correct addition level must be documented, by assay, on the Certificate of Analysis.

5.3.4.2 Vitamin Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added to corn-soy blend at the rate of two (2) pounds per 2,000 pound batch.

Weight of Vitamins per 2 Pounds of Premix

Vitamins	g
Thiamine mononitrate	2.5
Riboflavin	3.5
Niacin	45.0
Folic Acid	1.8
Pyridoxine hydrochloride	1.5
Calcium D-pantothenate	25.0
Vitamin B ₁₂	0.012
Butylated hydroxy anisole ¹	20.0
Butylated hydroxy toluene ¹	20.0
Ascorbic Acid (Stabilized, ethyl cellulose coated) ²	364
	IU
Vitamin A-Palmitate (Stabilized)	21,000,000
Vitamin D (Stabilized)	1,800,000
Alpha tocopherol acetate	68,000
Carrier ³	As Required to reach total weight of 2 lbs.
	Lbs
Vitamin Premix, Total	2.0
¹ If antioxidants (BHA and BHT) are added in the soy oil (Section 5.4), omit from this premix.	
² Ascorbic acid (stabilized), ethyl cellulose (coated). Ascorbic acid content shall be not less than 364 g.	
³ Soy flour, defatted (toasted) or starch to reach total weight.	

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		

10.1 or 10.2	%	0.10	16.6 - 16.4	%	0.10
10.3 or 10.4	%	0.20	16.3 - 16.1	%	0.20
10.5	%	0.35	16.0 or 15.9	%	0.35
Deficient Fat			Excess Crude Fiber		
5.9 or 5.8	%	0.10	2.1 – 2.2	%	0.10
5.7 or 5.6	%	0.20	2.3 – 2.4	%	0.20
5.5	%	0.35	2.5	%	0.35
Insufficient Material Through U.S Std. No. 6 Sieve			Excess Particles Through U.S Std. No. 30 Sieve		
98 or 97	%	0.10	93 or 94	%	0.10
96 or 95	%	0.20	95 or 96	%	0.20
Excess Material Through U.S Std. No. 60 Sieve			Excess Iron		
58 or 59	%	0.10	30.1 – 31.5	mg / 100 g	0.10
60 or 61	%	0.20	31.6 – 33.1	mg / 100 g	0.20
			33.2 – 35.0	mg / 100 g	0.35
Deficient Bostwick Consistency (Cooked, 11.75% Gruel)			Excess Bostwick Consistency (Cooked, 11.75% Gruel)		
8.0 or 8.5	cm	0.10	21.5 or 22.0	cm	0.10
7.0 or 7.5	cm	0.20	22.5 or 23.0	cm	0.20
6.0 or 6.5	cm	0.35	23.5 or 24.0	cm	0.35

9 REFERENCES

- A. Bostwick consistometer sources: Fisher Scientific, catalog number 15-347-50, or VWR, cat No. 23270-004 or equivalent”.

https://www.fishersci.com/wps/portal/SEARCHRESULTS?ru=http%3A%2F%2Fprodwcsserver%2Fwebapp%2Fwcs%2Fstores%2Fservlet%2FSearch&searchPref=no&position=search&preferProd=unchecked&searchType=Rapid&catalogCode=RE_SC&keyWord=15-347-50&catCode=ALL

OR

http://www.vwrsp.com/catalog/product/index.cgi?catalog_number=23270-004&inE=1&highlight=23270-004&from_search=1

- B. (Intentionally Blank)

REVISED

Performance Language

Corn-Soy Milk

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers corn-soy milk (CSM) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Corn-soy milk (CSM) is primarily used as a supplemental food for emergency rations, displaced persons assistance, weaning food in Maternal Child Health Programs (MCH) and other programs. It is composed of cornmeal (gelatinized), soy flour (toasted), nonfat dry milk, soybean oil (refined, deodorized, bleached), a minerals premix and a vitamin and antioxidant premix.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or as an extender to other foods. The finished product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical, Physical and Microbiological Properties

Corn-Soy Milk			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	9.5
Protein (N x 6.25) ²	%	19.0	--
Fat ²	%	6.0	--
Crude Fiber ²	%	--	2.0
Micronutrients			
	Units	Minimum	Maximum
Iron	mg/100 g	14.7	30.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Color, Munsell Color Std #13649	--	--	Identical to or lighter than
Material through US Std. No. 6 sieve	%	99.0	--
Material through US Std. No. 30 sieve	%	--	92.0
Material through US Std. No. 60 sieve	%	--	60.0
Functional / Performance			
	Units	Minimum	Maximum
Bostwick Consistency, cooked (11.75% gruel, w/w as is basis)	cm	10.0	22.0

Corn-Soy Milk			
Dispersibility	Essentially free of lumping or balling when mixed with water.		
Sensory		Description	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		
Odor	Corn-soy milk must be essentially free from foreign material and will have good characteristic taste and odor, and be free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i>	Present / Absent	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test	--
¹ Percent is on a weight/weight basis ² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat, crude fiber and particle size shall be reported to the nearest 0.1 percent. Bostwick consistency measurements shall be reported to the nearest 0.5 cm. Test results for iron shall be reported to the nearest 0.1 mg/100 g product. Vitamin A palmitate shall be to the whole number per pound of product. Muncell color disc comparison shall be reported as Pass/Fail. Aerobic plate count shall be reported to two (2) significant digits. *Staphylococcus aureus*, coagulase positive, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test. Calcium and salt, if added as separate ingredients, shall be reported to the nearest 1 mg/100 g product.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Corn-Soy Milk	
Invitation:	Pack Date:
Export Contract VEPE:	Mill Point:
Notice to Deliver VEPE:	Pack Size
Car/Truck ID:	

**Sample Certificate of Analysis
Corn-Soy Milk**

Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	MT	LBS	Bags	
	Units¹	Limit	Test Result	Pass (Y/N)
Moisture	%	9.5 Max		
Protein (N x 6.25) ²	%	19.0 Min		
Fat ²	%	6.0 Min		
Crude Fiber ²	%	2.0 Max		
Iron	mg/100g	14.7 Min- 30.0 Max		
Vitamin A palmitate	IU/lb	8,400 Min – 16,000 Max		
Color, Munsell Color Std #13649	--	Identical to or lighter than		
Material through a US Std No. 6 sieve	%	99.0 Min		
Material through a US Std No. 30 sieve	%	92.0 Max		
Material through a US Std No. 60 sieve	%	60.0 Max		
Bostwick Consistency (Cooked 11.75 % Gruel, w/w/ as is basis)	cm	10.0 Min – 21.0 Max		
Dispersibility	Essentially free from lumps or balling when mixed with water.		Pass/Fail	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail	
Odor	Good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		Pass/Fail	
Aerobic plate Count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Absent / Present	Negative to test		
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				

Sample Certificate of Analysis Corn-Soy Milk	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Percent weight basis. ² Moisture free basis	

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Corn-soy milk shall contain pregelatinized cornmeal, defatted, toasted soy flour, non-fat dry milk, vegetable oil and vitamin mineral premixes at levels required to achieve the specified final product characteristics and consistent with good manufacturing practices.

5.2 Formulation

Values in this formulation table are valid only for use with defatted soy flour and not corn germ additive. Use of approved alternate ingredients (full-fat soy flour and/or corn germ) alters the formula percentages of ingredients and adjustments to the formulation must be made. Irrespective of the use of approved alternate ingredients, the final product shall meet all requirements defined in Section 4.2.

Formulation		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Cornmeal, pregelatinized	58.9	1,178
Soy Flour, Defatted, Toasted	17.5	350
Nonfat Dry Milk	15.0	300
Vegetable Oil	5.5	110
Mineral Premix	3.0	60
Vitamin Premix	0.1	2
Total	100.0	2,000

5.3 Ingredient Specifications

Ingredients listed in Sections 5.3.1 – 5.3.5 will be used in the preparation of corn-soy milk.

5.3.1 Cornmeal, Processed (Gelatinized)

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity. Manufacturers shall provide evidence of aflatoxin assays upon request.

The cornmeal processed (pre-gelatinized) shall be prepared from shelled yellow corn that has been dehulled and degermed. The corn used shall be clean, sound, and essentially free from other grains, weed seeds, and other foreign material. It shall be free of rancid, bitter, musty, sour, and other undesirable or foreign tastes and odors. The processed cornmeal shall be produced from yellow corn, as defined in the "Official United States Standards for Grain," found at <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>, in effect at the time the applicable solicitation for offers is issued.

The cornmeal shall be processed by adding moisture and partially cooking in continuous cookers or on heated flaking rolls, drying and cutting, or by any other process that yields a product meeting the requirements for the finished processed cornmeal, and for the corn-soy milk product.

A corn germ fraction in an amount not to exceed ten (10) percent of the total cornmeal fraction may be added before processing. The added amount of oil contained there in may be omitted from the soy oil added to the soy flour fraction or to the final mix, provided the blend contains a minimum of 17.5 percent of defatted soy flour. The weight of processed cornmeal plus soy oil specified shall include the weight of any corn germ fraction added thereto.

5.3.1.1 Analysis

The cornmeal, processed (gelatinized) shall conform to these requirements:

Pre-Gelatinized Cornmeal			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	--	11.0
Ash ²	%	--	1.25
Material through a U.S. Std. No. 6 Sieve	%	99.0	--
Material through a U.S. Std No. 30 Sieve	%	--	85.0
Material through a U.S. Std No. 60 Sieve	%	--	35.0
Consistency [Spread Test]	in	4.5	8.5
Aerobic plate count	cfu/g	--	50,000
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Soy Flour

5.3.2.1 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling.

5.3.2.1.2 Analysis

The soy flour, defatted (toasted) shall conform to these requirements:

Soy Flour, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen solubility index	%	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic plate count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2.2 Soy Flour, Full Fat

Soy flour, full fat shall be the screened, finely-ground product obtained from selected soybeans by cleaning, cracking, (optional) dehulling, tempering, cooking (full cook with color change to light yellow or golden buff), and cooling.

5.3.2.2.1 Analysis

The soy flour, full fat shall conform to these requirements:

Soy Flour, Full Fat			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	44.0	--
Fat ²	%	22.0	--
Fiber ²	%	--	3.0
Ash ²	%	--	6.0
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen solubility index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic plate count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	

Texture	--	A homogeneous flour
¹ Percent on a weight/weight basis		
² Moisture-free basis		

5.3.3 Nonfat Dry Milk

Nonfat dry milk (spray process) is to be furnished by the Government or contractor (as specified in the solicitation) and shall be U.S. Standard Grade or better as defined in Section 58.2528 of U.S. Standard for grades of nonfat dry milk (spray process), which is included herein by reference, found at http://www.ams.usda.gov/standards/NDM_02-02-01.pdf and in addition, shall meet the further requirements of this Section, and where they are different the requirements defined in this Section shall take president. Grading certificates shall be dated not more than 180 days prior to the date of manufacture of the corn-soy-milk.

Non-Fortified Nonfat Dry Milk			
Requirements Different than Grading Standards			
Chemical	Units ¹	Minimum	Maximum
Protein (N x 6.38) ²	%	30.0	--
Antibiotics		Negative to test	--
Whey Protein Nitrogen Classification, High Heat	mg/g Undenatured whey protein	--	1.50
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase positive	cfu/g	Negative to test	--
¹ Percent weight basis			
² Moisture Free Basis			

5.3.4 Soybean Oil

Soy oil, refined, deodorized, and stabilized, shall contain 0.005 percent citric acid added on the cooling side of deodorization. The soy oil shall comply with the requirements of the latest revisions and amendments for Commercial Item Description A-A-20091D (May 7, 2002), <http://www.ams.usda.gov/fqa/aa20091d.htm>; type IV not winterized salad oil which is incorporated herein by reference.

Before addition to the product, the oil may be stabilized by the addition of butylated hydroxy anisole and butylated hydroxy toluene, each at a level of 2.5 mg per 100 grams of formulated product. **Caution:** Antioxidant may be added to either the soy oil or to the vitamin antioxidant premix, but it shall not be added to both. (See Section 5.3.5.2)

5.3.5 Micronutrient Fortification

5.3.5.1 Mineral Premix

The minerals and vitamin premix shall not be combined and shall be added to the formulation separately.

The mineral premix shall contain the micronutrients listed in this Section, at the stated levels, and mineral premix identified as Option 1 shall be added to corn-soy milk at the rate of sixty (60) pounds per 2,000 pound batch of finished product. The weight of other mineral premix options vary and any deviation in weight from 60 pounds shall be added or subtracted, as appropriate, from the total final product batch weight.

Weight of Minerals per 60 pounds of Premix

	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
	lbs							
Calcium Phosphate, Tribasic	40.00			26.00	18.00	18.00		
Calcium Carbonate		36.00	36.00		12.00	12.00	10.00	10.00
Sodium Phosphate, Monobasic		32.00			16.00			
Calcium Phosphate, Dibasic				12.00				44.00
Potassium Phosphate, Monobasic			32.00			16.00		
Calcium Phosphate, Dibasic, Anhydrous							34.00	
Zinc Sulfate, Monohydrate ¹	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Ferrous Fumarate, FCC Grade, Purified	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Magnesium Oxide (MgO)	2.75	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Iodized Salt (0.007% I ₂)	16.25	16.25	16.25	16.25	16.25	16.25	16.25	16.25
Mineral Premix Total Weight, lbs	60.17	88.17	88.17	58.17	66.17	66.17	64.17	74.17
¹ Zinc sulfate heptahydrate (0.4 lbs) may be used as an alternative to 0.25 lbs zinc sulfate monohydrate.								

If calcium and phosphorus ingredients and/or salt are added independently from a mineral premix, verification of the correct addition level must be documented, by assay, on the Certificate of Analysis.

5.3.5.2 Vitamin Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added to corn-soy milk at the rate of two (2) pounds per 2,000 pound batch.

Weight of Vitamins per 2 Pounds of Premix

Vitamins	g
Thiamine mononitrate	2.5
Riboflavin	3.5
Niacin	45.0
Folic Acid	1.8
Pyridoxine hydrochloride	1.5
Calcium D-pantothenate	25.0
Vitamin B ₁₂	0.012
Butylated hydroxy anisole ¹	20.0
Butylated hydroxy toluene ¹	20.0
Ascorbic Acid (Stabilized, ethyl cellulose coated) ²	364
	IU
Vitamin A-Palmitate (Stabilized)	21,000,000
Vitamin D (Stabilized)	1,800,000
Alpha tocopherol acetate	68,000
Carrier ³	As Required to reach total weight of 2 lbs.
	Lbs
Vitamin Premix, Total	2.0
¹ If antioxidants (BHA and BHT) are added in the soy oil (Section 5.4), omit from this premix.	
² Ascorbic acid (stabilized), ethyl cellulose (coated). Ascorbic acid content shall be not less than 364 g.	
³ Soy flour, defatted (toasted) or starch to reach total weight.	

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
9.6 or 9.7	%	0.10	18.9 - 18.6	%	0.10
9.8 or 9.9	%	0.20	18.5 - 18.3	%	0.20
10.0	%	0.35	18.2 or 18.1	%	0.35
Deficient Fat			Excess Crude Fiber		
5.9 or 5.8	%	0.10	2.1 - 2.2	%	0.10
5.7 or 5.6	%	0.20	2.3 - 2.4	%	0.20
5.5	%	0.35	2.5	%	0.35
Insufficient Material Through U.S Std.			Excess Particles Through U.S Std. No.		

No. 6 Sieve			30 Sieve		
98 or 97	%	0.10	93 or 94	%	0.10
96 or 95	%	0.20	95 or 96	%	0.20
Excess Material Through U.S Std. No. 60 Sieve			Excess Iron		
61 – 62	cm	0.10	30.1 – 31.5	mg / 100 g	0.10
63 - 64	cm	0.20	31.6 – 33.1	mg / 100 g	0.20
			33.2 – 35.0	mg / 100 g	0.35
Deficient Consistency (Cooked) 11.75% Gruel) Bostwick Units			Excess Consistency (Cooked) 11.75% Gruel - Bostwick Units		
9.5 or 9.0	cm	0.10	22.5 or 23.0	cm	0.10
8.5	cm	0.20	23.5	cm	0.20
8.0	cm	0.35	24.0	cm	0.35

9 REFERENCES

- A. Muncell Color Standards are available from **X-Rite Incorporated**
4300 44th Street SE, Grand Rapids, MI 49512, 800.248.9748
- B. Bostwick consistometer sources: Fisher Scientific, catalog number 15-347-50, or VWR, cat No. 23270-004 or equivalent.
https://www.fishersci.com/wps/portal/SEARCHRESULTS?ru=http%3A%2F%2Fprodwcssserver%2Fwebapp%2Fwcs%2Fstores%2Fservlet%2FSearch&searchPref=no&position=search&preferProd=unchecked&searchType=Rapid&catalogCode=RE_SC&keyWord=15-347-50&catCode=ALL
OR
http://www.vwrsp.com/catalog/product/index.cgi?catalog_number=23270-004&inE=1&highlight=23270-004&from_search=1
- C. Nonfat Dry Milk Standards
http://www.ams.usda.gov/standards/NDM_02-02-01.pdf
- D. (Intentionally Blank)

Performance Language

Cornmeal

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers cornmeal (CM) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Cornmeal is a processed commodity that is generally used as a staple food in all categories of food assistance programs. It is composed of cornmeal and a vitamin premix.

4.1 Finished Product Analytical Requirements

The cornmeal delivered shall be degermed and meet the requirements of the latest revisions and amendments for Commercial Item Description A-A-20066A (August 14, 2002) at <http://www.ams.usda.gov/fqa/aa20066A.htm>, for Type III, Class B, Granulation c, Color 2, except chemical and physical requirements listed in Section 4.2 which will take precedence where they are different from those contained in the Commercial Item Description.

4.2 Chemical and Physical Properties

Cornmeal Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	13.0
Fat ²	%		1.5
Crude Fiber ²	%	--	1.2
Ash ² (prior to calcium enrichment)	%		0.7
Ash ² (based on maximum calcium content, see Section 8.3)	%	--	Variable
Micronutrients			
	Units	Minimum	Maximum
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Calcium	mg/lb	500	750
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 20 sieve	%	99	--
Material through US Std. No. 25 sieve	%	90	--
Material through US Std. No. 45 sieve	%	30	--
Material through US Std. No. 80 sieve	%	--	20
Appearance	Cornmeal appears equivalent to typical product.		

Cornmeal Chemical, Physical and Microbiological Properties			
Microbiological	Units	Minimum	Maximum
Aerobic plate count	cfu/g	--	50,000
¹ Percent is on a weight/weight basis			
² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight/weight basis. Results for moisture, fat, crude fiber, ash and particle size shall be reported to the nearest 0.1 percent. Test results for calcium shall be reported to the nearest 0.1 mg/lb of product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Cornmeal				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	13.0 Max		
Fat ²	%	1.5 Max		
Crude Fiber ²	%	1.2 Max		
Ash ² (based on maximum calcium content, see Section 8.3)	%	variable		
Crude Fiber ²	%	1.2 Max		
Calcium	mg/lb	500 Min – 750 Max		
Vitamin A Palmitate	IU/lb	8,400 Min – 16,000 Max		
Material through a US Std No. 20 sieve	%	99 Min		
Material through a US Std No. 25 sieve	%	90 Min		
Material through a US Std No. 45 sieve	%	30 Min		

Sample Certificate of Analysis Cornmeal					
Material through a US Std No. 80 sieve		%	20 Max		
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail		
Total Plate Count		cfu/g	50,000 Max		
Comments:					
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.					
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____		
¹ Percent weight basis ² Moisture free basis					

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity. Manufacturers shall provide evidence of aflatoxin assays upon request.

Cornmeal shall be blended with the enrichment premix (Section 5.3.1) calcium and vitamin A to achieve the specified final product characteristics defined in Section 4.2.

5.2 Formulation

Not applicable

5.3 Ingredients

5.3.1 Vitamin Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added at a rate sufficient to achieve the following levels of micronutrients per pound of finished product.

Enrichment Premix			
	Units	Min	Max
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8

Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A palmitate	IU/lb	8,400	16,000
Calcium	mg/lb	500	750

5.3.1.1 Vitamin A

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

5.3.1.2 Calcium

The calcium added must be in forms which are harmless and assimilable. Calcium amounts up to 1247 mg/lb are considered within the specifications limit so long as the ash/calcium ratio is met as shown in Table titled “Maximum Ash Allowable without Discount at Specified Calcium Levels”, Section 8.3.

If calcium is added independently from a micronutrient premix, verification of the correct addition level must be documented, by assay and reported on the Certificate of Analysis.

6.4 Defect Action Levels

The corn meal shall not exceed the specified U.S. Food and Drug Administration (FDA) tolerance for “Defect Action Levels” (21 CFR Part 110.110).

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Excess Fat		
13.1 or 13.2	%	0.10	1.6 – 1.7	%	0.10
13.3 or 13.4	%	0.20	1.8 – 1.9	%	0.20
13.5	%	0.35	2.0	%	0.35
Deficient Material Through US Std No 20 Sieve			Deficient Material Through US Std No 25 Sieve		
98.0	%	0.10	89.0	%	0.10
97.0	%	0.20	88.0	%	0.20
96.0	%	0.35	87.0	%	0.35
Excess Material Through US Std No 45 Sieve			Excess Material Through US Std No 80 Sieve		
29.0 – 26.0	%	0.10	21.0 – 24.9	%	0.10
25.9 – 23.0	%	0.20	25.0 – 27.9	%	0.20
22.9 – 20.0	%	0.35	28.0 – 30.0	%	0.35
Excess Ash above Max (see Section 8.3)			Deficient Calcium		
0.01 - 0.02	%	0.10	499 - 440	mg / lb	0.05
0.03 - 0.04	%	0.20	439 - 400	mg / lb	0.10
0.05	%	0.35	399 - 340	mg / lb	0.20

Excess Calcium)			
751 - 1247	mg / lb	0.00	

8.3 Maximum Ash Allowed Without Discount

Maximum Ash Allowable Without Discount at Specified Calcium Levels					
Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %
340 - 358	.88	649 - 666	1.05	957 - 974	1.22
359 - 376	.89	667 - 684	1.06	975 - 993	1.23
377 - 394	.90	685 - 702	1.07	994 - 1011	1.24
395 - 412	.91	703 - 720	1.08	1012 - 1029	1.25
413 - 430	.92	721 - 739	1.09	1030 - 1047	1.26
431 - 448	.93	740 - 757	1.10	1048 - 1065	1.27
449 - 466	.94	758 - 775	1.11	1066 - 1083	1.28
467 - 485	.95	776 - 793	1.12	1084 - 1101	1.29
486 - 503	.96	794 - 811	1.13	1102 - 1120	1.30
504 - 521	.97	812 - 829	1.14	1121 - 1138	1.31
522 - 539	.98	830 - 847	1.15	1137 - 1156	1.32
540 - 557	.99	848 - 866	1.16	1157 - 1174	1.33
558 - 575	1.00	867 - 884	1.17	1175 - 1192	1.34
576 - 593	1.01	885 - 902	1.18	1193 - 1210	1.35
594 - 612	1.02	903 - 920	1.19	1211 - 1228	1.36
613 - 630	1.03	921 - 938	1.20	1229 - 1247	1.37
631 - 648	1.04	939 - 956	1.21		

REVISED

Performance Language

Dehydrated Potatoes

This performance language document includes information that is intended to be inserted into the commercial products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirements document covers dehydrated white potatoes, packed in commercially acceptable containers, for use by USDA in export programs. Dehydrated potato products shall be prepared from properly matured, wholesome, clean vegetables. The product shall be free from objectionable or foreign flavor or odor. Dehydrated potatoes come in several forms including powdered, flaked, and diced.

3 CLASSIFICATION

Solicitations for Bids for Dehydrated Potatoes shall specify the type, style and sizes of dehydrated potatoes in as defined in Commercial Item Description (CID) A-A-20032 F for potatoes white dehydrated:

Type II – Mashed (precooked, rapid rehydrating)

- 1) Styles A, B, C, and E,
- b. Type VI.

4 FINISHED PRODUCT CHARACTERISTICS

Performance language that is defined in specification(s), included herein by reference, will not be reproduced in this document.

4.1 Finished Product Analytical Requirements

Dehydrated potato products shall meet the requirements as specified in Section 6 of Commercial Item Description (CID) for potatoes, white, dehydrated, A-A-20032F, dated December 20, 2002, which is available at:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006936> the types and styles defined in Section 3.

4.2 Chemical and Physical Properties

In addition to the chemical and physical requirements prescribed in Sections 5 and 6 of Commercial Item Description identified above (Section 4.1), the following microbiological requirements apply:

Microbiological Specifications		
Aerobic Plate Count	cfu/g	50,000
<i>Salmonella</i> (Category II)	Absent / Present	Negative to test
Yeast	cfu/g	10
Mold	cfu/g	10
Coliform	cfu/g	10
<i>E. coli</i>	cfu/g	Negative to test
<i>Staph. aureus</i> , Coagulase Positive	cfu/g	Negative to test

4.3 Grading Requirements

4.3.1 Official Grade Certificates

Where required, the contractor shall be responsible for arranging and obtaining from AMS, FGIS, or their designated representative, official grading certificates and domestic and export weight and/or grade certificates.

4.3.1.1 Dehydrated Potato Products Inspection Procedures

Inspection shall be performed by an Agricultural Marketing Service (AMS) agent (hereinafter referred to as “USDA Grader”) as described in Section 9.3, USDA Certification, of CID A-A-20032F.

4.3.1.2 Lot Codes for inspection

Prior to sampling, the contractor shall furnish the USDA Grader with a list of codes and the approximate quantity per code. Inspection of products shall be performed not more than 90 days prior to shipment.

4.3.1.3 Contractor to Provide Equipment

Contractor shall provide scales suitable for random selection weighing.

4.3.1.4 Grade Certificates

The quality, weight, and packaging of the product shall be evidenced by certificates issued by the USDA Grader.

4.3.1.5 Acceptable Quality Level Requirement

Contractor shall not ship the product unless informed by the USDA Grader that the containers and markings meet the Acceptable Quality Level (AQL) of the United States Standards for Condition of Food Containers.

4.3.1.6 Re-Test

If the product fails to meet contract specifications on one or more factors on the first inspection, the Contractor may arrange with the USDA Grader for subsequent inspections. The inspections may be conducted at origin or a subsequent point of delivery if the provisions of Title 7 CFR 68.44 through 68.63 issued under the Agricultural Marketing Act of 1946, as amended, with respect to retest, appeal, and new inspections can be met. When subsequent inspections of the product are made, the results of the most recent inspection will be used as the basis for payment under the contract.

4.4 Analytical Testing Methods

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis Dehydrated Potatoes Type II A & B -Mashed Granules				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity		
Contracted Quantity	MT	LBS		Bags /Cans
		Units	Limit	Test Result
Moisture		%	Shall not exceed 9.0	Pass (Y/N)
Reducing sugars ¹		%	Shall not exceed 4.0	
Sulfite content ²		ppm	Non-sulfited potatoes shall not exceed 10	
Sulfur Dioxide (sulfited products)		ppm	200 - 500	
Type II Mashed, Style A Granules (Average of specks on the surface of the product in 100 mm circle)			65	
Type II Mashed, Flakes (Average discolorations and peel [Style B] per 100 grams. Defects are counted specs measuring over 1/16inch in any dimension.)			15	
Vitamin A			As specified in invitation to Bid	
Iodine			As specified in invitation to Bid	
(When specified in the Invitation to Bid, dehydrated potato products shall meet the minimum levels of Vitamin A and iodine and shall be reported herein.)				
Microbiological Specifications				
Aerobic Plate Count		cfu/g	50,000	
<i>Salmonella</i> (Category II)		Presence / Absence	Negative to test	
Yeast		cfu/g	10	
Mold		cfu/g	10	
Coliform		cfu/g	10	
<i>E. coli</i>		cfu/g	Negative to test	
<i>Staph. aureus</i> , Coagulase Positive		cfu/g	Negative to test	
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				

Sample Certificate of Analysis Dehydrated Potatoes Type II A & B -Mashed Granules	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
1 Calculated as percent invert sugar, dry weight basis. 2 Calculated as sulfur dioxide	

4.7 Lot Size Definition

The maximum number of packages in a lot is defined by the maximum number of cans, bags or other commercially acceptable containers manufactured during an 8-hour production shift from a single packaging line.

4.8 Sampling Procedures

Sampling procedures as described in Commercial Item Description A–A–20032F, Section 6.3.1.

4.10 Product Age

The vegetables used in the preparation of this product shall be prepared from the latest season’s pack or crop year

5 MANUFACTURER’S REQUIREMENTS

5.1 General Requirements

The specified type of Dehydrated Potato Product shall be made from sound peeled and trimmed potatoes. It shall be free from foreign material and have good characteristic taste and odor, and be free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.

8 QUALITY DISCOUNTS

8.2 Schedule of Discounts

Type of Deficiency	Test Results	Discounted Contract Price
Type II Mashed, Style A Granules (Average of specks on the surface of the product in 100 mm circle)	66 thru 70	\$0.01/lb.
	71 thru 80	\$0.02/lb.
	81 or more	Unacceptable
Type II Mashed, Flakes (Average discolorations and peel [Style B] per 100 grams. Defects are counted specs measuring over 1/16inch in any dimension.)	16 thru 20	\$0.01/lb.
	21 thru 25	\$0.02/lb.
	26 or greater	Unacceptable
Sulfur Dioxide	501 ppm or more	Fails/rejected
	100 – 199 ppm	\$0.01 per pound
	50 – 99 ppm	\$0.02 per pound
	0 – 49 ppm	Fails/rejected

9 REFERENCES

- A. United States for Grades of Potatoes for Processing, Effective April 14, 1983
<http://www.ams.usda.gov/standards/vppot.pdf>
- B. Commercial Item Description A-A-20032F- Potatoes, White, Dehydrated
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006936>
- C. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- D. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- E. *Salmonella* sampling requirements – Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan:
http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- F. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/usc_sec_21_00000346---a000-.html
- G. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html

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REVISED

Performance Language

Dehydrated Soup Mixes

This performance language document includes information that is intended to be inserted into the commercial products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement covers quick-cooking, instant and slow cooking dehydrated soup mixes, packed in commercially acceptable containers suitable for use by USDA export programs. The dehydrated vegetables used in the soup mix shall be prepared from properly matured, wholesome, clean vegetables. The vegetables used in the preparation of this product shall be prepared from the latest season's crops.

Commercial Products described herein shall be the same products offered for sale in the commercial marketplace as described in Commercial Item Description A_-A-20329A – Soup Mixes, dehydrated: .

3 CLASSIFICATION

Solicitations for Bids for Dehydrated Soup Mixes shall specify the Type, Style and Flavor:

- a. Type I, Type II or Type III,
 - 1) Style B
- b. Flavor 1, Flavor Profile a; Plain (no flavoring)
- c. Note: If a flavor such as spicy, chicken, beef, etc., is being purchased the flavor profile will be stated in the solicitation. Flavor shall meet the flavor profile characteristics as specified in Commercial Item Description A-A-20329A, dated August 24, 2000.

4 FINISHED PRODUCT CHARACTERISTICS

4.1 Finished Product Analytical Requirements

The dehydrated soup mix shall meet the salient characteristics in Commercial Item Description (CID) for dehydrated soup mixes, A-A-20329A, dated August 24, 2000, for the types, styles, flavor and flavor profile defined in Section 5, above, which is available at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006110>

4.3 Grading Requirements

Not Applicable

4.4 Analytical Testing Methods

Analytical testing methods as described in Commercial Item Description (CID) A–A–20329A, Section 6.4.

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis Dehydrated Soup Mixes				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity		
Contracted Quantity	MT	LBS		Bags /Cans
		Units	Limit	Test Result
Moisture		%	Shall not exceed 9.0	Pass (Y/N)
Microbiological Specifications				
Aerobic Plate Count		cfu/g	50,000	
<i>E. coli</i>		MPN / g	< 3	
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____		Date: _____		
Title: _____				
Telephone: _____				
FAX: _____				

4.7 Lot Size Definition

The maximum number of packages in a lot is defined by the maximum number of cans, bags or other commercially acceptable containers manufactured during an 8-hour production shift from a single packaging line.

4.8 Sampling Procedures

Sampling procedures as described in Commercial Item Description A-A-2032A, Section 6.3.1.

4.10 Product Age

The dehydrated soup mix shall be prepared in accordance with good manufacturing practices and shall be processed and packaged within the 12 months prior to purchase.

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

The product shall be prepared from properly matured, wholesome, clean vegetables. The vegetables used in the preparation of this product shall be prepared from the latest

season's crops. General requirements for ingredients, flavoring ingredients, color, and defects are described in Section 5.5 of Commercial Item Description A-A-20329A.

9 REFERENCES

- A. Good Manufacturing Practices http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- B. Commercial Item Description (CID) A-A-20329A -Soup Mixes, Dehydrated <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006110>
- C. *Salmonella* sampling requirements – Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan: http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- D. Microbiological Assay Methods, FDA-BAM <http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- E. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues. http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/usc_sec_21_00000346---a000-.html
- F. Pesticide Residue 40 CFR 180 http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- G. (Intentionally Blank)

REVISED

Performance Language

Dry Edible Beans

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

Dry edible beans come in a wide variety of market classes, including, black, black-eye, cranberry, dark red kidney, great northern, large red kidney, navy, pink, pinto, small red and miscellaneous beans.

Dry edible beans described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Solicitations for Bids for dry edible beans shall specify the type from as one of the following:

- a. Black
- b. Blackeye
- c. Cranberry
- d. Dark Red Kidney
- e. Great Northern
- f. Large Red Kidney
- g. Pea Beans (Navy)
- h. Pink
- i. Pinto
- j. Small Red Beans
- k. Miscellaneous: Adzuki, yellow eye, white kidney (cannellini), white marrow, and anasazi beans.

4 FINISHED PRODUCT CHARACTERISTICS

Dry edible beans shall meet the specifications as defined in the "Official United States Standards for Beans" in effect at the time the applicable solicitation is issued except as the chemical and physical requirements listed in Section 4.2, Chemical and Physical Properties differ from the Grading Requirements, in which case, the requirements outlined in Section 4.2 shall take precedence. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>

4.1 Finished Product Analytical Requirements

The product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Dry Edible Beans			
Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum

Dry Edible Beans			
Chemical, Physical and Microbiological Properties			
Moisture	%	--	14.0

4.3 Grading Requirements

The contractor shall be responsible for arranging and obtaining from FGIS, or any other organization designated by FGIS, official domestic and export weight and grade certificates. Procedures to follow and a schedule of fees for this service may be obtained at <http://151.121.3.117/aboutus/service/umap/usmap.htm>. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

4.3.1 Grade Requirement

Dry edible beans shall meet the specifications as defined in the "Official United States Standards for Beans" in effect at the time the applicable solicitation is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>.

Dry edible beans shall be grade U.S. No. 2 or better, except that marrow, great northern, flat small white, small white, white kidney, light red kidney, dark red kidney, small red, pink, black, and miscellaneous beans may include up to 5 percent total defects due to surface dirt which is readily removed during processing.

Pea beans (Navy) shall be grade U.S. No. 2 or better but may include up to 5 percent of beans with surface dirt and grime and total defects.

The grade certificate issued by GIPSA for all beans except pea beans, containing between 4 and 5 percent total defects due to surface dirt shall show the grade U.S. No. 3, and shall include the following statement:

“This lot meets the requirements applicable for U.S. No. 2 or better (class of beans) except for defects due to dirt and grime.”

The grade certificate issued by FGIS for pea beans shall include the following statement:

“This lot contains (percent) of beans with surface dirt and grime and total defects. Beans with surface dirt and grime are not considered damage in pea beans and are not included in the “Total Defects” results.”

4.3.2 Re-Inspection

If the product fails to meet contract specifications on one or more factors on the first inspection, the contractor may arrange with FGIS for subsequent inspections of the commodity. The inspections may be conducted at origin or a subsequent point of delivery if the provisions of Title 7 CFR 868.40 through 868.63 issued under the Agricultural Marketing Act of 1946, as amended, with respect to retest, appeal, and

new inspections can be met. When subsequent inspections of the product are made, the results of the most recent inspection will be used as the basis for payment under the contract.

FGIS will perform a condition of container examination in accordance with the United States Standards for Condition of Food Containers (7 CFR Part 42) and the Agricultural Marketing Service Handbook for Inspection of the Condition of Food Containers.

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture shall be reported to the nearest 0.1 percent.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Dry Edible Beans Variety: _____				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	13.0 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____		Date:		
Title: _____				
Telephone: _____				
FAX: _____				
¹ Percent weight basis.				

Performance Language

Instant Corn-Soy Masa Flour

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers instant corn-soy masa flour (MF) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

The product is designed for use in the preparation of tortillas and similar products to be consumed by both children and adults. It is composed of masa flour, soy flour, defatted (toasted) and is fortified with vitamins and minerals.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use in making tortillas and shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Instant Corn-Soy Masa Flour Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	11.5
Protein (N x 6.25) ²	%	11.0	--
Fat ²	%	3.0	--
Ash ²	%	--	2.5
pH		6.7	8.0
Micronutrients			
	Units	Minimum	Maximum
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Calcium	mg/lb	500	1000
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 30 sieve	%	99.0	--
Material through US Std. No. 50 sieve	%	85.0	--
Material through US Std. No. 100 sieve	%	52.0	--
Functional / Performance		Description	
Dough Handling	Typical, Cohesive, Pliable		
Baked Tortilla	Typical, no cracks		
Flavor	Typical lime-corn		

Instant Corn-Soy Masa Flour Chemical, Physical and Microbiological Properties			
Odor	Instant corn-soy masa must be essentially free from foreign material and will have good characteristic taste and odor, and be free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
¹ Percent is on a weight/weight basis			
² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat and particle size shall be reported to the nearest 0.1 percent. Ash shall be reported to the nearest 0.01 percent. The pH shall be reported to the nearest 0.1 unit. Results of iron assay shall be reported to the nearest 1 mg/lb. Aerobic plate count shall be reported to two (2) significant digits. Calcium, if added as a separate ingredient, shall be assayed and reported to the nearest 1 mg/lb product. Dough handling, baked tortilla and flavor shall be reported as Pass/Fail.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Instant Corn-Soy Masa Flour				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	MT	LBS	Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	11.5 Max		
Protein (Nx6.25) ²	%	11.0 Min		
Fat ²	%	3.0 Min		
Ash ² (based on maximum calcium content, see Section 8.3)	%	Variable		
pH	--	6.7 – 8.0		
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0 Min– 26.0 Max		
Material through a US Standard No. 30 sieve	%	100.0 Min		

Sample Certificate of Analysis Instant Corn-Soy Masa Flour				
Material through a US Standard No. 50 sieve	%	85.0 Min		
Material through a US Standard No. 100 sieve	%	52.0 Min		
Dough handling	Typical, cohesive, pliable		Pass/Fail	
Tortillas making	Typical, no cracks		Pass/Fail	
Flavor	Typical lime-corn		Pass/Fail	
Aerobic plate count	cfu/g	50,000 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis. ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Instant corn-soy masa flour shall contain instant corn masa flour, soy flour, defatted (toasted) and a vitamin premix at levels required to achieve the specified final product characteristics defined in Section 4.2.

5.2 Formulation

The final product shall meet all requirements defined in Section 4.2.

Formulation		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Instant corn masa flour	95.0	1900
Soy flour, defatted (toasted)	5.0	100
Vitamin Premix		As required to meet specifications (Section 4.2)
Total	100.0	2,000

5.3 Ingredients

Ingredients listed in Sections 5.3.1 – 5.3.3 shall be used in the preparation of instant corn-soy masa flour.

5.3.1 Instant Corn Masa Flour

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the qualitative aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity

The instant corn masa flour shall be produced from white or yellow corn which is clean, sound, essentially free from other grains, weed seeds, and other foreign material, as defined in the “Official United States Standards for Grain,” available at: <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>. The corn shall be processed into instant corn masa flour by steeping corn in lime water (calcium hydroxide, P.C.C. grade, plus water) rinsing, grinding, and drying.

5.3.1.1 Analysis

The instant corn masa flour shall conform to these requirements:

Instant Corn Masa Flour			
Assay	Units ¹	Requirements	
		Min.	Max.
Moisture	%	---	12.0
Fat ²	%	3.0	
pH	--	6.7	8.2
Material through a U.S. Std. No. 50 Sieve	%	85.0	---
Material through a U.S. Std No. 100 Sieve	%	52	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling. The defatted soy flour (toasted) shall meet the following requirements.

5.3.2.1 Analysis

The soy flour, defatted (toasted) shall conform to these requirements:

Soy Flour, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--

Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.3 Enrichment Premix

The vitamin shall be added as a premix and shall contain the micronutrients listed in this section. The premix shall be added at a level to achieve the following levels of these micronutrients, per pound, in the finished product.

Enrichment Ingredients			
	Units	Min	Max
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Calcium	mg/lb	500	1,000
Butylated hydroxy anisole (BHA) and Butylated hydroxy toluene (BHT) shall be added as part of the enrichment premix at a rate to achieve a final product concentration of 25 ppm each of BHA and BHT.			

5.3.3.1 Vitamin A

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

5.3.3.2 Calcium

The calcium added must be in forms which are harmless and assimilable. If calcium is added independently from the vitamin premix, verification of the correct addition level must be documented, by assay and reported on the Certificate of Analysis.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
11.6 or 11.7	%	0.10	10.9 or 10.8	%	0.10

11.8 or 11.9	%	0.20	10.7 or 10.6	%	0.20
12.0	%	0.35	10.5	%	0.35
Excess Ash			Excess or Deficient pH		
2.6 or 2.7	%	0.10	± 0.1 pH Units	--	0.05
2.8 or 2.9	%	0.20	± 0.2 pH Units	--	0.1
3	%	0.35	± 0.3 pH Units	--	0.2
Deficient Fat			Deficient Calcium		
2.9 or 2.8	%	0.10	499 - 490	mg/lb	0.10
2.7 or 2.6	%	0.20	489 - 480	mg/lb	0.20
2.5	%	0.35	479 - 470	mg/lb	0.35
Excess Calcium			Deficient Granulation through No 30 Sieve		
1001 - 1010	mg/lb	0.10	99.0	%	0.10
1011 - 1020	mg/lb	0.20	98.0 - 98.9	%	0.20
1021 - 1030	mg/lb	0.35	97.0 - 97.9	%	0.35
Deficient Granulation through No 50 Sieve			Deficient Granulation through No 100 Sieve		
84.0 - 81.0	%	0.10	51.0 - 48.0	%	0.10
80.9 - 78.0	%	0.20	47.9 - 44.0	%	0.20
77.9 - 75.0	%	0.35	43.9 - 40.0	%	0.35

REVISED

Performance Language

Instant Corn-Soy Milk

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers instant corn-soy milk (ICSM) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Instant corn-soy milk (ICSM) is primarily used as a supplemental food for emergency rations, displaced persons assistance, weaning food in Maternal Child Health Programs (MCH) and other programs. It is composed of cornmeal (gelatinized), soy flour (toasted), nonfat dry milk, soybean oil (refined, deodorized, bleached), a minerals premix and a vitamins and antioxidant premix; and is processed to have a low viscosity.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or as an extender to other foods. The finished product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical, Physical and Microbiological Properties

Instant Corn-Soy Milk			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	9.5
Protein (N x 6.25) ²	%	19.0	--
Fat ²	%	6.0	--
Crude Fiber ²	%	--	2.0
Micronutrients			
	Units	Minimum	Maximum
Iron	mg/100 g	14.7	30.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Color, Munsell Color Std #13649	--	--	Identical to or lighter than
Material through US Std. No. 40 sieve	%	97.0	--
Material through US Std. No. 100 sieve	%	--	46.0
Functional / Performance			
	Units	Minimum	Maximum
Bostwick Consistency, cooked (20.8% gruel)	cm	9.0	<i>Need to establish upper limit</i>
Dispersibility (12.5% gruel)	Essentially free of lumping or balling when mixed with water.		

Instant Corn-Soy Milk			
Sensory		Description	
Appearance		Instant corn-soy milk appears equivalent to typical product.	
Odor		Instant corn-soy milk must be essentially free from foreign material and will have good characteristic taste and odor, and be free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.	
Microbiological		Units	Minimum
Aerobic plate count		cfu/g	--
<i>E. coli</i>		cfu/g	Negative to test
<i>Salmonella</i> (Category II)		Present / Absent	Negative to test
<i>Staphylococcus aureus</i> , Coagulase Positive		cfu/g	Negative to test
¹ Percent is on a weight/weight basis ² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat, crude fiber and particle size shall be reported to the nearest 0.1 percent. Bostwick consistency measurements shall be reported to the nearest 0.5 cm. Test results for iron shall be reported to the nearest 0.1 mg/100 g product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits. *Staphylococcus aureus*, coagulase positive, *E. coli*, and *salmonella* should be reported as ‘negative’ (or ‘positive’) to test. Guidelines for reporting the precision of microbial assays found in the current issue of the FDA-BAM and shall take precedence where different. Calcium, phosphorus and salt, if added as separate ingredients, shall be reported to the nearest 1 mg/100 g product.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis			
Instant Corn-Soy Milk			
Invitation:		Pack Date:	
Export Contract VEPE:		Mill Point:	
Notice to Deliver VEPE:		Pack Size	
Car/Truck ID:			
Lot Number:		Lot Quantity (TBD MT max)	
Contracted Quantity	_____ MT	_____ LBS	_____ Bags

**Sample Certificate of Analysis
Instant Corn-Soy Milk**

	Units¹	Limit	Test Result	Pass (Y/N)
Moisture	%	9.5 Max		
Protein (N x 6.25) ²	%	19.0 Min		
Fat ²	%	6.0 Min		
Crude Fiber ²	%	2.0 Max		
Iron	mg/100g	14.7 Min- 30.0 Max		
Vitamin A palmitate	IU/lb	8,400 Min – 16,000 Max		
Color, Munsell Color Std #13649	--	Identical to or lighter than		
Material through a US Std No. 40 sieve	%	97.0 Min		
Material through a US Std No. 100 sieve	%	46.0 Max		
Bostwick Consistency (Uncooked (20.8% gruel, w/w as is basis)	cm	9.0 Min		
Dispersibility (12.5% gruel)	Essentially free from lumps or balling when mixed with water.		Pass/Fail	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail	
Odor	Good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		Pass/Fail	
Total Plate Count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i> (Category II)	Absent / Present	Negative to test		
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis. ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Instant corn-soy milk shall contain pregelatinized corn meal, defatted, toasted soy flour, non-fat dry milk, vegetable oil and vitamin mineral premixes at levels required to achieve the specified final product characteristics and consistent with good manufacturing practices.

Instant corn-soy milk may contain a corn germ fraction (Section 5.4.1.1) and/or full fat soy flour (Section 5.4.2.2).

5.2 Formulation

Values in this formulation table are valid only for use with defatted soy flour and not corn germ additive. Use of approved alternate ingredients (full-fat soy flour and/or corn germ) alters the formula percentages of ingredients and adjustments to the formulation must be made. Irrespective of the use of approved alternate ingredients, the final product shall meet all requirements defined in Section 4.2.

Formulation		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Cornmeal, pregelatinized	58.9	1,178
Soy Flour, Defatted, Toasted	17.5	350
Nonfat Dry Milk	15.0	300
Vegetable Oil	5.5	110
Mineral Premix	3.0	60
Vitamin Premix	0.1	2
Total	100.0	2,000

5.3 Ingredient

Ingredients listed in Sections 5.3.1 – 5.3.5 will be used in the preparation of instant corn-soy milk.

5.3.1 Cornmeal, Processed (Gelatinized)

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity. Manufacturers shall provide evidence of aflatoxin assays upon request.

The cornmeal processed (low viscosity, completely gelatinized) shall be prepared from shelled yellow corn that has been dehulled and degermed. The corn used shall be clean, sound, and essentially free from other grains, weed seeds, and other foreign material. It shall be free of rancid, bitter, musty, sour, and other undesirable or foreign tastes and odors. The processed cornmeal shall be produced from yellow corn, as defined in the "Official United States Standards for Grain," found at

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>, in effect at the time the applicable solicitation for offers is issued.

The cornmeal shall be processed by completely gelatinizing the starch in continuous extrusion cookers under conditions which produce high water solubility and minimum viscosity, drying and grinding, or by any other process that yields a product meeting the requirements for the processed cornmeal and for instant corn-soy milk.

A corn germ fraction in an amount not to exceed ten (10) percent of the total cornmeal fraction may be added before processing. The added amount of oil contained there in may be omitted from the soy oil added to the soy flour fraction or to the final mix, provided the blend contains a minimum of 17.5 percent of defatted soy flour. The weight of processed cornmeal plus soy oil specified shall include the weight of any corn germ fraction added thereto.

5.3.1.1 Analysis

The cornmeal, processed (low viscosity) shall conform to these requirements:

Pre-Gelatinized Cornmeal			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	--	10.0
Protein ²	%	7.0	--
Ash ²	%	--	0.8
Crude Fiber ²	%	--	0.8
Material through a U.S. Std. No. 20 Sieve	%	95.0	--
Material through a U.S. Std No. 40 Sieve	%	70.0	--
Material Through a U.S. Std No. 60 Sieve	%	--	40.0
Material Through a U.S. Std No. 100 Sieve	%	--	15.0
Bostwick Consistency uncooked, 10.0% gruel	cm	15.0	--
Water Solubility Index	%	25.0	--
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Soy Flour

5.3.2.1 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling.

5.3.2.1.1 Analysis

The soy flour, defatted (toasted) shall conform to these requirements:

Soy Flour, Defatted (Toasted)

Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count, per gram	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2.2 Soy Flour, Full Fat

Soy flour, full fat shall be the screened, finely-ground product obtained from selected soybeans by cleaning, cracking, (optional) dehulling, tempering, cooking (full cook with color change to light yellow or golden buff), and cooling.

5.3.2.2.1 Analysis

The soy flour, full fat shall conform to these requirements:

Soy Flour, Full Fat			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	44.0	--
Fat ²	%	22.0	--
Crude Fiber ²	%	--	3.0
Ash ²	%	--	6.0
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			

² Moisture-free basis

5.3.3 Nonfat Dry Milk

Nonfat dry milk (spray process) is to be furnished by the Government or contractor (as specified in the solicitation) and shall be U.S. Standard Grade or better as defined in Section 58.2528 of U.S. Standard for grades of nonfat dry milk (spray process), which is included herein by reference, found at http://www.ams.usda.gov/standards/NDM_02-02-01.pdf and in addition, shall meet the further requirements of this Section, and where they are different the requirements defined in this Section shall take president. Grading certificates shall be dated not more than 180 days prior to the date of manufacture of the corn-soy-milk.

Non-Fortified Nonfat Dry Milk Requirements Different than Grading Standards			
Assay	Units ¹	Minimum	Maximum
Protein (N x 6.38) ²	%	30.0	--
Antibiotics		Negative to test	--
Whey Protein Nitrogen Classification, High Heat	mg/g Undenatured whey protein	--	1.50
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase positive	cfu/g	Negative to test	--

¹ Percent weight basis
² Moisture Free Basis

5.3.4 Soybean Oil

Soy oil, refined, deodorized, and stabilized, shall contain 0.005 percent citric acid added on the cooling side of deodorization. The soy oil shall comply with the requirements of the latest revisions and amendments for Commercial Item Description A-A-20091D (May 7, 2002), <http://www.ams.usda.gov/fqa/aa20091d.htm>; type IV not winterized salad oil which is incorporated herein by reference.

Before addition to the product, the oil may be stabilized by the addition of butylated hydroxy anisole and butylated hydroxy toluene, each at a level of 2.5 mg. per 100 grams of formulated product. **Caution:** Antioxidant may be added to either the soy oil or to the vitamin antioxidant premix, but it shall not be added to both. [See Section 5.3.5.2]

5.3.5 Micronutrient Fortification

5.3.5.1 Mineral Premix

The minerals and vitamin premix shall not be combined and shall be added to the formulation separately.

The mineral premix shall contain the micronutrients listed in this Section, at the stated levels, and mineral premix identified as Option 1 shall be added to instant corn soy milk at the rate of sixty (60) pounds per 2,000 pound batch of finished product. The weight of other mineral premix options vary and any deviation in weight from 60 pounds shall be added or subtracted, as appropriate, from the total final product batch weight.

Weight of Minerals per 60 pounds of Premix

	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
	lbs							
Calcium Phosphate, Tribasic	40.00			26.00	18.00	18.00		
Calcium Carbonate		36.00	36.00		12.00	12.00	10.00	10.00
Sodium Phosphate, Monobasic		32.00			16.00			
Calcium Phosphate, Dibasic				12.00				44.00
Potassium Phosphate, Monobasic			32.00			16.00		
Calcium Phosphate, Dibasic, Anhydrous							34.00	
Zinc Sulfate, Monohydrate ¹	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Ferrous Fumarate, FCC Grade, Purified	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Magnesium Oxide (MgO)	2.75	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Iodized Salt (0.007% I ₂)	16.25	16.25	16.25	16.25	16.25	16.25	16.25	16.25
Mineral Premix Total Weight, lbs	60.17	88.17	88.17	58.17	66.17	66.17	64.17	74.17
¹ Zinc sulfate heptahydrate (0.4 lbs) may be used as an alternative to 0.25 lbs zinc sulfate monohydrate.								

If calcium and phosphorus ingredients and/or salt are added independently from a mineral premix, verification of the correct addition level must be documented, by assay, on the Certificate of Analysis.

5.3.5.2 Vitamin Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added to corn-soy milk at the rate of two (2) pounds per 2,000 pound batch.

Weight of Vitamins per 2 Pounds of Premix

Vitamins	g
Thiamine mononitrate	2.5
Riboflavin	3.5
Niacin	45.0
Folic Acid	1.8
Pyridoxine hydrochloride	1.5
Calcium D-pantothenate	25.0
Vitamin B ₁₂	0.012
Butylated hydroxy anisole ¹	20.0
Butylated hydroxy toluene ¹	20.0
Ascorbic Acid (Stabilized, ethyl cellulose coated) ²	364
	IU
Vitamin A-Palmitate (Stabilized)	21,000,000
Vitamin D (Stabilized)	1,800,000
Alpha tocopherol acetate	68,000
Carrier ³	As Required to reach total weight of 2 lbs.
	lbs
Vitamin Premix, Total	2.0

¹ If antioxidants (BHA and BHT) are added in the soy oil (Section 5.4), omit from this premix.
² Ascorbic acid (stabilized), ethyl cellulose (coated). Ascorbic acid content shall be not less than 364 g.
³ Soy flour, defatted (toasted) or starch to reach total weight.

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
9.6 or 9.7	%	0.10	18.9 - 18.6	%	0.10
9.8 or 9.9	%	0.20	18.5 - 18.3	%	0.20
10.0	%	0.35	18.2 or 18.1	%	0.35
Deficient Fat			Excess Crude Fiber		
5.9 or 5.8	%	0.10	2.1 - 2.2	%	0.10
5.7 or 5.6	%	0.20	2.3 - 2.4	%	0.20
5.5	%	0.35	2.5	%	0.35
Insufficient Material Through U.S Std. No. 40 Sieve			Excess Material Through U.S Std. No. 100 Sieve		
96 or 95	%	0.10	47 or 48	%	0.10
94 or 93	%	0.20	49 or 50	%	0.20
Deficient Consistency (Uncooked) 20.8%			Excess Iron		

Gruel, w/w as is basis)					
8.5 or 8.0	cm	0.10	30.1 – 31.5	mg / 100 g	0.10
7.5 or 7.0	cm	0.20	31.6 – 33.1	mg / 100 g	0.20
6.5 or 6.0	cm	0.35	33.2 – 35.0	mg / 100 g	0.35

9 REFERENCES

- A. Muncell Color Standards are available from **X-Rite Incorporated**
4300 44th Street SE, Grand Rapids, MI 49512, 800.248.9748
- B. Bostwick consistometer sources: Fisher Scientific, catalog number 15-347-50, or VWR, cat No. 23270-004 or equivalent. (*Not applicable to all products.*)
https://www.fishersci.com/wps/portal/SEARCHRESULTS?ru=http%3A%2F%2Fprodwcssserver%2Fwebapp%2Fwcs%2Fstores%2Fservlet%2FSearch&searchPref=no&position=search&preferProd=unchecked&searchType=Rapid&catalogCode=RE_SC&keyWord=15-347-50&catCode=ALL
OR
http://www.vwrsp.com/catalog/product/index.cgi?catalog_number=23270-004&inE=1&highlight=23270-004&from_search=1
- C. Nonfat Dry Milk Standards
http://www.ams.usda.gov/standards/NDM_02-02-01.pdf
- D. (Intentionally Blank)

Performance Language

Milled Rice

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers milled rice and parboiled rice produced for the food assistance programs.

3 CLASSIFICATION

Unless otherwise specified in the applicable invitation for offers, milled rice of the special grades “parboiled light” or “parboiled” which meet class and grade specifications will be acceptable. No specialty rice, including but not limited to aromatic rice, will be acceptable unless specified in the solicitation.

4 FINISHED PRODUCT CHARACTERISTICS

The Government will accept offers for long, medium, or short grain milled rice grading U.S. No. 5 or better, except the rice shall be well milled and not contain more than 20 percent broken kernels.

Milled rice shall meet the specifications of the class and grade offered as defined in the “Official United States Standards for Rice,” in effect at the time the applicable solicitation for offers is issued, except as the chemical and physical requirements listed in Section 4.2 differ and shall take precedence. The standards are available at:

http://archive.gipsa.usda.gov/reference-library/standards/ricestandards-milled_rice.pdf

4.1 Finished Product Analytical Requirements

The product shall meet the chemical and physical, requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Milled Rice Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	14.0
Protein (N x 6.25) ²	%	6.0	--
Heat damaged and/or paddy kernels combined	Per 500g	--	30
Physical	Units	Minimum	Maximum
Chalky kernels ³	%	10.0 Max	20.0
Removed by #5 Plate	%	0.7 Max	--
Removed by #6 Plate	%	3.0 Max	--
Through #6 Sieve	%	1.0 Max	
Other Types whole kernels	%	10.0 Max	
¹ Percent is on a weight/weight basis			
² Reported on 14% moisture basis			
³ For Parboiled rice cf 868.315c			

4.3 Grading Requirements

The contractor shall be responsible for arranging and obtaining FGIS, or any other organization designated by FGIS, official domestic and export weight and grade certificates. Procedures to follow and a schedule of fees for this service may be obtained at <http://151.121.3.117/aboutus/servicemap/usmap.htm>. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

The Government will accept delivery of rice grading better than the specified contract grade, but:

- (1) No adjustment in contract price will be made for rice grading better than the contract grade.
- (2) No substitution of one class of rice for another class of rice will be allowed after a contract has been awarded.

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), and screen sizes shall be reported to the nearest 0.1 percent. Aerobic plate count and yeast and molds shall be reported to two (2) significant digits. Coliform, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test'.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis				
Milled Rice				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Protein (Nx6.25) ²	%	6.0 Min		
Heat damaged and/or paddy kernels combined	Per 500g	30 Max		
Chalky kernels ³	%	10.0 Max		
Removed by #5 Plate	%	0.7 Max		
Removed by #6 Plate	%	3.0 Max		
Through #6 Sieve	%	1.0 Max		
Other Types whole kernels	%	10.0 Max		

Sample Certificate of Analysis				
Milled Rice				
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis. ² Reported on 12% moisture basis ³ For Parboiled rice cf 868.315c				

5.1 General Requirements

The rice must meet the specifications of the class and grade offered as defined in the "United States Standards for Milled Rice," in effect at the time the contract is made. See ["USDA: Grade Requirements, and Grade Designations"](#) for more information.

Unless otherwise specified, milled rice of the special grades "parboiled light" or "parboiled" which meet class and grade specifications shall be acceptable. No specialty rice, including but not limited to aromatic rice, shall be acceptable unless specified in the applicable invitation for offers.

5.2 Fumigation

Not more than ten (10) days prior to packaging, the milled rice shall be fumigated with methyl bromide or aluminum phosphide in a quantity and manner which will affect a kill in all stages of weevil or other insect infestation.

The Contractor shall submit with his invoice for payment a statement certifying that the rice was fumigated in accordance with this requirement.

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

REVISED

Performance Language

Non-Fortified Nonfat Dry Milk

This performance language document includes information that is intended to be inserted into the commercial products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

Non-Fortified Nonfat Dry Milk (NFDM) is the product resulting from removal of fat and water from milk and contains the lactose, milk proteins and milk minerals in the same relative proportions as in the fresh milk from which it was made.

Commercial Products described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Solicitations for Bids for Non-Fortified Nonfat Dry Milk shall specify the Type and Class from:

- a. Type I - Nonfat dry milk
 - 1) Class A - Low heat
 - 2) Class B - Medium heat
 - 3) Class C - High heat

4 FINISHED PRODUCT CHARACTERISTICS

Non-fortified nonfat dry milk shall meet requirements for nonfat dry milk of 21 CFR 131.125.

4.1 Finished Product Analytical Requirements

The non-fortified nonfat dry milk delivered shall meet the requirements of the latest revisions and amendments for Commercial Item Description A-A-20085C (February 13, 2001) at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006747> and the United States Standards for Grades of Nonfat Dry Milk (Spray Process), effective February 2, 2001 at http://www.ams.usda.gov/standards/NDM_02-02-01.pdf, except as chemical and physical requirements listed in Section 4.2 'Chemical and Physical Properties' differ from those in the Commercial Item Description or the "Grading Standards", in which case(s) Section 4.2 requirements will take precedence.

4.2 Chemical and Physical Properties

In addition to the chemical and physical requirements prescribed in Sections 5 and 6 of Commercial Item Description A-A-20085C, and Sections § 58.2525 – 58.2528 of the US Grading Standards, the following requirements apply:

Non-Fortified Nonfat Dry Milk			
Requirements Different than Grading Standards			
Chemical	Units ¹	Minimum	Maximum
Protein (N x 6.38) ²	%	34.0	--
Antibiotic		Negative to test	--
Whey Protein Nitrogen Classification			
Low Heat	mg/g undenatured whey protein	6.0	--
Medium Heat	mg/g undenatured whey protein	1.51	5.99
High Heat	mg/g undenatured whey protein	--	1.50
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--
Coliform	MPN	--	10
<i>Staphylococcus aureus</i> , Coagulase positive	cfu/g	Negative to test	
¹ Percent weight basis. ² Moisture Free Basis			

4.3 Grading Requirements

4.3.1 Official Grade Certificates

Where required, the contractor shall be responsible for arranging and obtaining from AMS, FGIS, or their designated representative, official grading certificates and domestic and export weight and/or grade certificates.

4.3.2 Grade Requirement

Non-fortified nonfat dry milk shall be in compliance with the requirements US Extra Grade as defined in the U.S. Standards for Grades of Nonfat Dry Milk (Spray Process), effective February 2, 2001.

4.4 Analytical Testing Methods

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis				
Non-Fortified Nonfat Dry Milk				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity		
Contracted Quantity	MT	LBS	Bags /Cans	
		Units	Limit	Test Result
				Pass (Y/N)
Moisture		%	Max 4.0	
Protein		%	Min 30.0	
Milk Fat		%	Max 1.5	
Scorched Particles		mg	Max 15.0	
Solubility Index		ml	1.2	
If high heat not greater than 2.0		ml	2.0	
Titrateable Acidity (lactic acid)		%	Max 0.15	
Microbiological Specifications				
Aerobic Plate Count		cfu/g	Max 10,000	
<i>Salmonella</i> (Category II)		Presence / Absence	Negative to test	
Coliform		MPN	Max 10	
<i>Staphylococcus aureus</i> , Coagulase positive,		cfu/g	Negative to test	
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____		Date: _____		
Title: _____				
Telephone: _____				
FAX: _____				
¹ Calculated as percent invert sugar, dry weight basis.				
² Calculated as sulfur dioxide				

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.10 Product Age

Non-fortified non-fat dry milk must meet the age requirements defined in Section 5.4 of Commercial Item Description A-A-20085C, and shall meet all product specifications for flavor and physical properties defined in the U.S. Standards for Grades of Nonfat Dry milk, Section 58.2525 – 58.2528.

5 MANUFACTURER’S REQUIREMENTS

5.1 General Requirements

5.1.1 US Origin

The product delivered to the Government shall have been processed in the United States from fluid milk which was produced in the United States, and shall not have been owned by the Government.

5.1.2 Dairy Processing Plant Inspection

The plants in which the product is to be processed shall be inspected and approved by the Dairy Grading Branch, Dairy Division, Agricultural Marketing Service (AMS).

5.1.3 Dairy Processing

As specified in the Invitation for Bid, the nonfat dry milk may be made from Grade A milk, which is received, processed, and dried in plants that comply with all applicable requirements of the current version of the “Grade A Pasteurized Milk Ordinance.” Additionally, the milk processing plants shall have a compliance rating of 90 or more at the time of contract award and while the product is made for delivery under the contract. The United States Public Health Service Publication, “Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers,” shows compliance ratings at the time of quarterly issuance.

5.1.4 Product Warranty

The product shall have a shelf life of at least one year from date of delivery to the Government. Product shall not be manufactured more than 60 days prior to delivery.

6 SPECIAL REQUIREMENTS

6.1 Grade Certificate Required

The quality, weight, and packaging of the nonfat dry milk will be evidenced by grading certificates issued by AMS. However, this does not relieve the contractor of its responsibility to deliver nonfat dry milk which complies with all contractual and specification requirements. Procedures and a schedule of fees for these services may be obtained by contacting AMS.

6.2 Processing Facilities

Nonfat dry milk produced in a plant found during inspection to be using unsatisfactory manufacturing practices, equipment, facilities, or to be operating under unsanitary conditions shall not be offered.

6.3 Acceptable Quality Level

The contractor shall not ship the commodity unless the contractor is informed by AMS that the containers, labels, and markings meet the Acceptable Quality Level (AQL) of the United States Standard for Condition of Food Containers. Notice by AMS that a lot scheduled for shipment does not meet the AQL standard shall constitute rejection.

6.4 Re-Inspection

If the nonfat dry milk fails to meet contract specifications on one or more factors on the first inspection, the contractor may arrange with AMS for subsequent inspections of the nonfat dry milk. The inspections may be conducted at origin or a subsequent point of delivery if the provisions of 7 CFR 58.22 through 58.32 issued under the Agricultural Marketing Act of 1946, as amended, with respect to retest, appeal, and new inspections can be met. At the option of the contractor, rejected lots may be reworked including correcting packaging deficiencies and removing unsatisfactory containers, and such reworked lots may be resubmitted for AMS inspection. When subsequent inspections of the nonfat dry milk are made, the results of the most recent inspection will be used as the basis of payment under the contract.

9 REFERENCES

- A. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- B. Nonfat Dry Milk Standards
http://www.ams.usda.gov/standards/NDM_02-02-01.pdf
- C. American Public Health Association
<http://www.apha.org/about/news/pressreleases/2004/04revised.htm>
- D. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- E. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/usc_sec_21_00000346---a000-.html
- F. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html

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Performance Language

Peas and Lentils

This performance language document includes information that is intended to be inserted into the Whole or Partially Processed Grains template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers peas and lentils used in food assistance programs. Peas and lentils described herein shall be the same products offered for sale in the commercial marketplace

3 CLASSIFICATION

Solicitations for Bids for Whole and Split peas shall specify the class from:

- a. Whole Yellow
- b. Split Yellow
- c. Whole Green
- d. Split Green

No classification is required for whole lentils.

4 FINISHED PRODUCT CHARACTERISTICS

Whole dry peas and split peas shall meet the specifications as defined in the "Official United States Standards" in effect at the time the applicable solicitation is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>

Whole lentils shall meet the specifications as defined in the "Official United States Standards" in effect at the time the applicable solicitation is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>

4.1 Finished Product Analytical Requirements

The product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Whole Dry Peas and Split Peas Chemical, Physical and Microbiological Properties			
Chemical	Units	Minimum	Maximum
Moisture	%	--	15.0

Whole Lentils Chemical, Physical and Microbiological Properties			
Chemical	Units	Minimum	Maximum
Moisture	%	--	14.0

4.3 Grading Requirements

The contractor shall be responsible for arranging and obtaining FGIS, or any other organization designated by FGIS, official domestic and export weight and grade certificates. Procedures to follow and a schedule of fees for this service may be obtained

at <http://151.121.3.117/aboutus/servicemap/usmap.htm>. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

4.3.2 Grade Requirement

Whole dry peas and split peas shall meet the specifications as defined in the "Official United States Standards" in effect at the time the applicable solicitation is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>.

Whole dry peas shall grade U.S. No. 2 or better, except U.S. No. 3 or better because of cracked seed coats. Split peas shall grade U.S. No. 2 or better.

Whole lentils shall meet the specifications as defined in the "Official United States Standards" for US No. 3, or better, in effect at the time the applicable solicitation is issued. The standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>.

4.3.3 Re-Inspection

If the product fails to meet contract specifications on one or more factors on the first inspection, the contractor may arrange with FGIS for subsequent inspections of the commodity. The inspections may be conducted at origin or a subsequent point of delivery if the provisions of Title 7 CFR 868.40 through 868.63 issued under the Agricultural Marketing Act of 1946, as amended, with respect to retest, appeal, and new inspections can be met. When subsequent inspections of the product are made, the results of the last inspection will be used as the basis for payment under the contract.

FGIS will perform a condition of container examination in accordance with the United States Standards for Condition of Food Containers (7 CFR Part 42) and the Agricultural Marketing Service Handbook for Inspection of the Condition of Food Containers.

4.4 Analytical Testing Methods

[Note: The following is a sample list of analytical testing methods references. A more complete list will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture shall be reported to the nearest 0.1 percent.

4.6.1.1 Certificate of Analysis – Whole Dry Peas and Split Peas

Sample Certificate of Analysis Whole Dry Peas and Split Peas Variety: _____
--

Sample Certificate of Analysis Whole Dry Peas and Split Peas Variety: _____				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	15.0 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		
¹ Percent weight basis				

4.6.1.2 Certificate of Analysis – Whole Lentils

Sample Certificate of Analysis Whole Lentils				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	14.0 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		
¹ Percent weight basis				

REVISED

Performance Language

Refined Sunflower Seed Oil

This performance language document includes information that is intended to be inserted into the Vegetable Oils/Fats template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement covers refined sunflower seed oil fortified with retinyl palmitate (vitamin A palmitate).

3 CLASSIFICATION

Mid-Oleic Sunflower Oil, the major type of sunflower seed oil produced, shall be fully refined, bleached, deodorized, and pure. It shall be produced from fair average quality crude mid-oleic sunflower seed oil from which essentially all of the free fatty acids and non-oil substances have been removed by chemical treatments and by mechanical or physical separation.

4.1 Finished Product Analytical Requirements

The Sunflower seed oil delivered shall meet the requirements for Type I Vegetable oil, Section 6.1 of the latest revisions and amendments for Commercial Item Description (CID) A-A-20091D (May7, 200) at:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006232>, except as these differ from the chemical and physical requirements listed in Section 4.2 'Chemical and Physical Properties' which will take precedence. In addition, sunflower seed oil shall be fortified with retinyl palmitate (Vitamin A).

4.2 Chemical and Physical Properties

In addition to the chemical and physical requirements prescribed for Type I oil in Sections 5 and 6 of Commercial Item Description A-A-20091D, the following requirements apply:

Refined Sunflower Seed Oil Chemical and Physical Properties ¹			
	Units	Minimum	Maximum
Retinyl Palmitate (Vitamin A)	IU/g	60	75
Flavor	organoleptic	7	
OSI	hours	5	
Appearance	Visual	Clear to brilliant	
Antioxidants ²	ppm		200
Dimethylpolysiloxane (<i>if added</i>)	ppm	5	10
Specific Gravity (20 °C)	g/cc	0.917	0.924
Insoluble Impurities	%	0	0
Oleic Acid ³		55	75
Free Fatty Acid	%		0.05

¹ Determination shall be made within seven days after packaging. Samples submitted for testing shall be in a completely filled container.
² Maximum of 0.06 percent free fatty acid will be acceptable if propyl gallate is added as an antioxidant.
³ Determined by gas chromatography of methyl esters of fatty acids.

4.3 Grading Requirements

Not Applicable

4.4 Analytical Testing Methods

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

The test results for free fatty acids and moisture and volatile matter shall be reported to the nearest 0.01 percent. The test results for peroxide value and linolenic acid shall be reported to the nearest 0.1 meq/kg and one percent, respectively. The test results for Lovibond color, fat stability, and iodine value shall be reported to the nearest whole number. The test results for insoluble impurities shall be “detected” or “not detected”. The test results for the AOCS cold test shall be “pass” or “fail”. Any result not conforming to the analytical requirements shall be cause for rejection of the lot.

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis Refined Sunflower Seed Oil				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS	Bags	
Salad Oil Source:				
	Units	Limit	Test Result	Pass (Y/N)
Retinyl Palmitate (Vitamin A)	IU/g	60 min / 75 max		
Color	Lovibond	2.5 Red		
Free Fatty Acid	(% as Oleic)	0.05		
Peroxide Value	meq/kg	2.0		
Iodine Value		88 Min/ 115 Max		
Oleic Acid (applicable to mid oleic sunflower seed oil)	% of TFA	55.0 Min / 75 Max		
Moisture	(%-KF)	0.1		
Flavor	organoleptic	7		
OSI	hours	5		
Cold Test	hours	5.5		
Appearance	Visual	Clear to brilliant		
Saponification Value	Mg KOH/g %	186-194		
Dimethylpolysiloxane (if added)	ppm	5-10 ppm		
Insoluble Impurities	%	0		
Comments:				

**Sample Certificate of Analysis
Refined Sunflower Seed Oil**

I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.

Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
--	-------------

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

5.1 General Requirements

Sunflower seed oil shall be clear and brilliant when held at 21.1 ° to 29.4 °C (70 ° to 85 °F). Heavy metal scavengers, antifoaming agents, and antioxidants can be added provided levels of use are in accordance with appropriate Food and Drug Administration regulations.

Sunflower seed oil shall have a light viscosity and shall not have a heavy oily mouth feel. It shall have a clean, fresh flavor and shall be free from rancid, beany, painty, sour, or other objectionable flavors or odors.

All ingredients shall be clean, sound, wholesome, and free from evidence of rodent or insect infestation. Sunflower seed oil shall be free from foreign material, such as, but not limited to, dirt, insect parts, hair, wood, glass, or metal.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications of CID A-A-20091D, dated May 7, 2002, the commodity may be delivered; but the purchase price shall be reduced in accordance with the schedules of discounts for each 100 pounds (net weight) of product delivered in Section 8.2.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Peroxide Value			Excess Free Fatty Acid		
2.1 – 2.3	Meq/kg	0.35	0.06 or 0.07	%	0.10
2.4 – 2.5	Meq/kg	0.50	0.08 or 0.09	%	0.20
			0.10 or 0.11	%	0.30

9 REFERENCES

A. Copies of the Official Methods of the American Oil Chemists' Society may be obtained from: American Oil Chemists' Society, P.O. Box 3489, Champaign, IL 61826-3489, telephone (217) 359-2344 or Fax (217) 351-8091.

<http://www.aocs.org/>

B. (Intentionally Blank)

Performance Language

Soy-Fortified Cornmeal

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers soy-fortified cornmeal (SFCM) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Soy fortified cornmeal will be a product of small particle size that is usable as a dietary supplement or as an extender to other foods. This processed commodity is most used in emergency programs and to a lesser extent in other categories.

4.1 Finished Product Analytical Requirements

The finished product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Soy-Fortified Cornmeal Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	13.0
Protein ²	%	13.0	--
Fat ²	%		1.5
Crude Fiber ²	%	--	2.0
Ash ² (prior to calcium enrichment)	%		1.60
Micronutrients			
	Units	Minimum	Maximum
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Calcium	mg/lb	500	750
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 20 sieve	%	99.0	--
Material through US Std. No. 25 sieve	%	90.0	--
Material through US Std. No. 45 sieve	%	40.0	--
Material through US Std. No. 80 sieve	%	--	32.0
Appearance	Cornmeal appears equivalent to typical product.		
Microbiological			
	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000

Soy-Fortified Cornmeal
Chemical, Physical and Microbiological Properties

¹ Percent is on a weight/weight basis

² Moisture free basis

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein, fat, crude fiber, ash and particle size shall be reported to the nearest 0.1 percent. Test results for calcium shall be reported to the nearest 0.1 mg/lb of product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Soy-Fortified Cornmeal						
Invitation:		Pack Date:				
Export Contract VEPE:		Mill Point:				
Notice to Deliver VEPE:		Pack Size:				
Car/Truck ID:						
Lot Number:		Lot Quantity (TBD MT max)				
Contracted Quantity	MT		LBS		Bags	
		Units ¹	Limit	Test Result	Pass (Y/N)	
Moisture		%	13.0 Max			
Protein ²		%	13.0 Min			
Fat ²		%	1.5 Max			
Ash ² (based on maximum calcium content, see Section 8.3)		%	variable			
Crude Fiber ²		%	2.0 Max			
Calcium		mg/lb	500 Min – 750 Max			
Iron (electrolytic iron, 325 mesh)		Mg/lb	13.0 Min – 26.0 Max			
Material through a US Std No. 20 sieve		%	99 Min			
Material through a US Std No. 25 sieve		%	91 Min			
Material through a US Std No. 45 sieve		%	40 Min			
Material through a US Std No. 80 sieve		%	20 Max			

Sample Certificate of Analysis Soy-Fortified Cornmeal				
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.	Pass/Fail		
Total Plate Count	cfu/g	50,000 Max		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		
¹ Percent weight basis. ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Corn shall be tested for aflatoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS). If the aflatoxin test proves positive, a quantitative test shall be performed. If the result of the quantitative test exceeds 20 ppb, the corn shall not be used in the production of the commodity. Manufacturers shall provide evidence of aflatoxin assays upon request.

Soy-fortified cornmeal shall contain cornmeal, defatted soy flour (toasted) and a vitamin premix and calcium in a harmless and assimilable form at levels required to achieve the specified final product characteristics defined in Section 4.2.

5.2 Formulation Soy-Fortified Cornmeal

The final product shall meet all requirements defined in Section 4.2.

Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Cornmeal	85.0	1700
Soy flour, defatted (toasted)	15.0	300
Vitamin Premix		As required to meet the requirements
Total	100.0	2,000

5.3 Ingredients

Ingredients listed in Sections 5.3.1 – 5.3.3 will be used in the preparation of corn-soy blend.

5.3.1 Cornmeal

The cornmeal delivered shall be degermed and meet the requirements of the latest revisions and amendments for Commercial Item Description AA-20066A (August 14, 2002) at <http://www.ams.usda.gov/fqa/aa20066A.htm>, except chemical and physical requirements listed in Section 4.2 which shall take precedence where they are different from those contained in the Commercial Item Description.

The degermed cornmeal shall be Type III, Class B, Granulation c, Color 2. In addition to the enrichment ingredients contained in the Commercial Item Description, calcium and Vitamin A Palmitate shall be added as shown in the previous table.

5.3.2 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling.

5.3.2.1 Analysis

The soy flour, defatted (toasted) shall conform to these requirements:

Soy Flour, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic plate count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.3 Vitamin Premix

Enrichment Premix			
	Units	Min	Max
Thiamine mononitrate	mg/lb	2.0	3.0

Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Calcium	mg/lb	500	750

5.3.3.1 Vitamin A

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

5.3.3.2 Calcium

The calcium added must be in forms which are harmless and assimilable. Calcium amounts up to 1247 mg/lb are considered within the specifications limit so long as the ash/calcium ratio is met as shown in Table titled “Maximum Ash Allowable without Discount at Specified Calcium Levels”, Section 8.3.

If calcium is added independently from a micronutrient premix, verification of the correct addition level must be documented, by assay and reported on the Certificate of Analysis.

6.4 Defect Action Levels

Cornmeal used in the preparation of this commodity shall not exceed the specified U.S. Food and Drug Administration (FDA) tolerance for “Defect Action Levels” (21 CFR Part 110.110).

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Excess Fat		
13.1 or 13.2	%	0.10	1.6 – 1.7	%	0.10
13.3 or 13.4	%	0.20	1.8 – 1.9	%	0.20
13.5	%	0.35	2.0	%	0.35
Excess Crude Fiber			Deficient Protein		
2.1 – 2.2	%	0.10	12.9 – 12.8	%	0.10
2.3 – 2.4	%	0.20	12.7 – 12.6	%	0.20
2.5	%	0.35	12.5	%	0.35
Deficient Material Through US Std No 20 Sieve			Deficient Material Through US Std No 25 Sieve		
98.0 – 97.0	%	0.10	90.0 - 89.0	%	0.10
96.9 – 95.0	%	0.20	88.9 – 87.0	%	0.20
94.9 – 93.0	%	0.35	86.9 – 85.0	%	0.35
Deficient Material Through US Std No 45 Sieve			Excess Material Through US Std No 80 Sieve		

39.0 – 38.0	%	0.10	33.0 – 34.9	%	0.10
37.9– 36.0	%	0.20	35.0 – 36.9	%	0.20
35.9 – 34.0	%	0.35	37.0 – 38.0	%	0.35
Excess Ash above Max (see Section 8.3)			Deficient Calcium		
0.01 - 0.02	%	0.10	499 - 440	mg / lb	0.05
0.03 - 0.04	%	0.20	439 - 400	mg / lb	0.10
0.05	%	0.35	399 - 340	mg / lb	0.20
Excess Calcium)					
751 - 1247	mg / lb	0.10			

8.3 Maximum Ash Allowed Without Discount

Maximum Ash Allowable Without Discount at Specified Calcium Levels					
Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %
340 - 358	1.78	649 - 666	1.95	957 - 974	2.12
359 - 376	1.79	667 - 684	1.96	975 - 993	2.13
377 - 394	1.80	685 - 702	1.97	994 - 1011	2.14
395 - 412	1.81	703 - 720	1.98	1012 - 1029	2.15
413 - 430	1.82	721 - 739	1.99	1030 - 1047	2.16
431 - 448	1.83	740 - 757	2.00	1048 - 1065	2.17
449 - 466	1.84	758 - 775	2.01	1066 - 1083	2.18
467 - 485	1.85	776 - 793	2.02	1084 - 1101	2.19
486 - 503	1.86	794 - 811	2.03	1102 - 1120	2.20
504 - 521	1.87	812 - 829	2.04	1121 - 1138	2.21
522 - 539	1.88	830 - 847	2.05	1137 - 1156	2.22
540 - 557	1.89	848 - 866	2.06	1157 - 1174	2.23
558 - 575	1.90	867 - 884	2.07	1175 - 1192	2.24
576 - 593	1.91	885 - 902	2.08	1193 - 1210	2.25
594 - 612	1.92	903 - 920	2.09	1211 - 1228	2.26
613 - 630	1.93	921 - 938	2.10	1229 - 1247	2.27
631 - 648	1.94	939 - 956	2.11		

Performance Language

Soy-Fortified Sorghum Grits

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers soy-fortified sorghum grits (SFSG) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

The soy fortified sorghum grits, when cooked by mixing one part by volume of the product with two parts by volume water, bringing the mixture to a boil, and boiling gently for 15-20 minutes, will be distinctly particulate (individual particles which adhere together to some extent after cooking but shall not disintegrate or otherwise lose their identity) but tender and palatable. They shall not be ropy or gluey.

4.1 Finished Product Analytical Requirements

The product shall have a good characteristic taste and be odor free from rancid, bitter, musty, sour, and other undesirable or foreign tastes and odors. In conformance with the chemical and physical requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Soy-Fortified Sorghum Grits Chemical, Physical and Microbiological Properties			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	13.5
Protein ²	%	15.0	--
Fat ²	%	--	2.0
Crude Fiber ²	%	--	2.1
Ash ² (prior to calcium enrichment)	%	--	2.60
Micronutrients			
	Units	Minimum	Maximum
Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Calcium	mg/lb	500	750
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 8 sieve	%	90.0	--
Material through US Std. No. 14 sieve	%	--	35.0
Material through US Std. No. 30 sieve	%	--	5.0
Appearance	Soy-fortified sorghum grits appears equivalent to typical product.		

**Soy-Fortified Sorghum Grits
Chemical, Physical and Microbiological Properties**

Microbiological	Units	Minimum	Maximum
Aerobic plate count ³	cfu/g	--	50,000
¹ Percent is on a weight/weight basis ² Moisture free basis ³ Bacterial plate counts in excess of 50,000 per gram will constitute rejection. However, at contractor's request only, the following additional requirements will apply: If the bacterial plate count is higher than 50,000 per gram but not more than 500,000 per gram, product will be rejected, unless coliform count does not exceed 100 organisms per gram of product. If the bacterial plate count is higher than 500,000 per gram but not more than 1,000,000 per gram, product will be rejected, unless the product provided contains: (1) No more than 100 coliform per gram; (2) No more than 10 <i>Staph. aureus</i> , coagulase positive per gram; or (3) No salmonella in 20 grams of product. Bacterial plate counts higher than 1,000,000 organisms per gram of product will be rejected. Cost of additional testing required for acceptance of product having plate counts in excess of 50,000 per gram will be for contractor's account.			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein, fat, crude fiber and particle size shall be reported to the nearest 0.1 percent. Assay results of ash shall be reported to the nearest 0.01 percent. Test results for calcium shall be reported to the nearest 0.1 mg/lb of product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Soy-Fortified Sorghum Grits				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	MT	LBS		Bags
		Units ¹	Limit	Test Result
				Pass (Y/N)
Moisture		%	13.5 Max	
Protein ²		%	15.0 Min	
Fat ²		%	2.0 Max	
Crude Fiber ²		%	2.1 Max	
Ash ² (based on maximum calcium content, see Section 8.3)		%	variable	

Sample Certificate of Analysis Soy-Fortified Sorghum Grits				
Calcium		mg/lb	500 Min – 750 Max	
Iron (electrolytic iron, 325 mesh)		mg/lb	13.0 Min – 26.0 Max	
Material through a US Std No. 8 sieve		%	90.0 Min	
Material through a US Std No. 14 sieve		%	35.0 Max	
Material through a US Std No. 30 sieve		%	5.0 Max	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail	
Total Plate Count		cfu/g	50,000 Max	
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis. ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Soy-fortified sorghum grits shall contain sorghum grits, defatted soy flour (toasted) and a vitamin premix and calcium in a harmless and assimilable form at levels required to achieve the specified final product characteristics defined in Section 4.2. At the manufacturer's option expeller soy grits may be substituted for defatted soy grits.

5.2 Formulation

Values in this formulation table are valid only for use with bulgur and defatted soy grits. Use of approved alternate ingredients (expeller soy grits) requires adjustments to the formula percentages. The final product shall meet all requirements defined in Section 4.2.

Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Sorghum grits	85.0	1700
Soy grits, defatted (toasted)	15.0	300
Vitamin Premix		As required to meet the requirements
Total	100.0	2,000

5.3 Ingredients

Ingredients listed in Sections 5.3.1 – 5.3.4 will be used in the preparation of soy blend.

5.3.1 Sorghum Grits

Sorghum grits will be milled from grain sorghum meeting the following requirements:

- a. Class: Yellow or white grain sorghum as defined by “Official United States Standards for Grain,” except that the grain shall contain no more than two percent of kernels having brown subcoats. The standards are available at: <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>
- b. Grade: U.S. No. 1, U.S. No. 2, or U.S. No. 3, if downgraded because of moisture only.
- c. The grain shall be thoroughly cleaned to remove stones, sticks, trash, weed seeds, and shriveled kernels; dehulled; degermed; and reduced to grits.
- d. The sorghum shall be milled to remove seed coat so that the product color and general appearance will be that of typical sorghum grits which are reasonably well milled.

5.3.1.1 Analytical Requirements

The sorghum grits shall conform to these requirements:

Sorghum Grits			
Assay	Units ¹	Min	Max
Moisture	%	---	13.5
Protein (N x 6.25) ²	%	9.0	--
Crude Fiber ²	%	--	1.8
Ash ²	%	--	1.8
Material through a U.S. Std. No. 8 Sieve	%	90.0	--
Material through a U.S. Std. No. 14 Sieve	%	--	26.0
Material through a U.S. Std. No. 30 Sieve	%	--	5.0
Material other than sorghum grits	%	--	0.05
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Soy Grits, Defatted (Toasted)

Soy grits, defatted (toasted) shall be the screened, coarsely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling. The soy grits, defatted (toasted) shall conform to these requirements:

Soy Grits, Defatted (Toasted)			
Assay	Units ¹	Min	Max
Moisture	%	---	12.0
Protein (N x 6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Ash ²	%	--	7.0
Crude Fiber	%	--	3.5

Material through a U.S. Std. No. 8 Sieve	%	90.0	--
Material through a U.S. Std. No. 14 Sieve	%	--	75.0
Material through a U.S. Std. No. 30 Sieve	%	--	5.0
Nitrogen Solubility Index	%	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic Plate Count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.3 Soy Grits, Expeller

Soy grits (expeller), may be used as a replacement for soy grits, defatted (toasted). Soy Grits (expeller) will be the screened, coarsely, ground product obtained from selected soybeans by cleaning, cracking, dehulling, heating, and lowering the fat content by an expeller process resulting in a change to golden buff or tan, and cooling. The product shall conform to these requirements:

Soy Grits, Expeller			
Assay	Units ¹	Min	Max
Moisture	%	---	12.0
Protein (N x 6.25) ²	%	47.0	--
Fat ²	%	5.0	6.5
Ash ²	%	--	7.0
Material through a U.S. Std. No. 8 Sieve	%	90.0	--
Material through a U.S. Std. No. 14 Sieve	%	--	75.0
Material through a U.S. Std. No. 30 Sieve	%	--	5.0
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Aerobic Plate Count	cfu/g	--	50,000
Color	--	Golden to tan	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A reasonably uniform grit	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.4 Vitamin Premix

Enrichment Premix			
	Units	Min	Max

Thiamine mononitrate	mg/lb	2.0	3.0
Riboflavin	mg/lb	1.2	1.8
Niacin or niacinamide	mg/lb	16.0	24.0
Folic Acid	mg/lb	0.7	1.0
Iron (electrolytic iron, 325 mesh)	mg/lb	13.0	26.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Calcium (in harmless and assimilable form)	mg/lb	500	750

5.3.4.1 Vitamin A

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

5.3.4.2 Calcium

The calcium added must be in forms which are harmless and assimilable. Calcium amounts up to 1247 mg/lb are considered within the specifications limit so long as the ash/calcium ratio is met as shown in Table titled “Maximum Ash Allowable without Discount at Specified Calcium Levels”, Section 8.3.

If calcium is added independently from a micronutrient premix, verification of the correct addition level must be documented, by assay and reported on the Certificate of Analysis.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
13.6 or 13.7	%	0.10	14.9 – 14.8	%	0.10
13.8 or 13.9	%	0.20	14.7 – 14.6	%	0.20
14.0	%	0.35	14.5	%	0.35
Excess Fat			Excess Ash above Max (see Section 8.3)		
2.1 – 2.2	%	0.10	0.01 - 0.02	%	0.10
2.3 – 2.4	%	0.20	0.03 - 0.04	%	0.20
2.5	%	0.35	0.05	%	0.35
Excess Crude Fiber			Deficient Material Through US Std No 8 Sieve		
2.2 – 2.3	%	0.10	89 – 88	%	0.10
2.4 – 2.5	%	0.20	87 – 86	%	0.20
2.6	%	0.35	85	%	0.35
Excess Material Through US Std No.14 Sieve			Excess Material Through US Std No 30 Sieve		
35 – 37	%	0.10	5.1 – 5.4	%	0.10
38 – 39	%	0.20	5.5 – 5.8	%	0.20
40 - 41	%	0.35			
Deficient Calcium			Excess Calcium)		

499 - 440	mg / lb	0.05	751 - 1247	mg / lb	0.00
439 - 400	mg / lb	0.10			
399 - 340	mg / lb	0.20			

8.3 Maximum Ash Allowed Without Discount

Maximum Ash Allowable Without Discount at Specified Calcium Levels					
Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %	Calcium Content mg/lb	Maximum Ash %
340 - 358	2.78	649 - 666	2.95	957 - 974	3.12
359 - 376	2.79	667 - 684	2.96	975 - 993	3.13
377 - 394	2.80	685 - 702	2.97	994 - 1011	3.14
395 - 412	2.81	703 - 720	2.98	1012 - 1029	3.15
413 - 430	2.82	721 - 739	2.99	1030 - 1047	3.16
431 - 448	2.83	740 - 757	3.00	1048 - 1065	3.17
449 - 466	2.84	758 - 775	3.01	1066 - 1083	3.18
467 - 485	2.85	776 - 793	3.02	1084 - 1101	3.19
486 - 503	2.86	794 - 811	3.03	1102 - 1120	3.20
504 - 521	2.87	812 - 829	3.04	1121 - 1138	3.21
522 - 539	2.88	830 - 847	3.05	1137 - 1156	3.22
540 - 557	2.89	848 - 866	3.06	1157 - 1174	3.23
558 - 575	2.90	867 - 884	3.07	1175 - 1192	3.24
576 - 593	2.91	885 - 902	3.08	1193 - 1210	3.25
594 - 612	2.92	903 - 920	3.09	1211 - 1228	3.26
613 - 630	2.93	921 - 938	3.10	1229 - 1247	3.47
631 - 648	2.94	939 - 956	3.11		

**DRAFT COMMODITY SPECIFICATION
TEMPLATE OUTLINE**

[Commodity Name]

**[Commodity ID:]
[Date]
SUPERSEDING
[Former Commodity ID]
[Former Commodity Effective
Date]**

This template is constructed for use in developing specifications for the products in the category “Blended and Fortified Foods” here divided into in two groups based on number of micronutrients added:

- a. 7 micronutrients-- [All Purpose Flour / Bread Flour (WFBF6) , Bulgur / Soy-Fortified Bulgur (WBSF13), Cornmeal (CM4), Instant Corn-Soya Masa Flour (MF10), Soy-Fortified Corn Meal (SFCM3), Soy-Fortified Sorghum Grits (SFSG13)]
- b. 18 micronutrients-- [Corn-Soy Blend (CSB13), Corn-Soy Milk (CSM3), Instant Corn-Soy Milk (ICSM3), Wheat-Soy Blend (WSB15), and Wheat-Soy Milk (WSM10)].

Table of Contents

1	CHANGES FROM PREVIOUS VERSION	4
2	SCOPE	4
3	CLASSIFICATION	4
4	FINISHED PRODUCT CHARACTERISTICS	4
4.1	Finished Product Analytical Requirements	4
4.2	Chemical and Physical Properties	4
4.3	Finished Product Grading Requirements	5
4.4	Analytical Testing Methods 4.3	6
4.5	Test Result Precision	7
4.6	Reporting Results	7
4.6.1	Certificate of Analysis.....	7
4.6.2	Notification of Lots Failing to Meet Standards.....	8
4.7	Lot Size Definition	8
4.8	Sampling Procedures	9
4.8.1	Sample Collection	9
4.9	Uniform Product.....	9
4.10	Product Age.....	9
4.11	(Intentionally Blank)	9
5	MANUFACTURER’S REQUIREMENTS	9
5.1	General Requirements	9
5.2	Formulation	10
5.3	Ingredient.....	10
5.3.1	(Ingredient 1, Intentionally Blank).....	10
5.3.2	(Ingredient 2, Intentionally Blank).....	10
5.3.3	(Ingredient 3, Intentionally Blank).....	10
5.3.4	Micronutrients	10
5.3.4.1	Mineral Premix.....	10
5.3.4.2	Vitamin Premix	10
6	SPECIAL REQUIREMENTS	10
6.1	Pesticide Residues	11
6.2	Official Grade Certificates	11
6.3	(Intentionally Blank)	11
7	MANUFACTURER’S QUALITY ASSURANCE	11
7.1	Conformance to Specification	11
7.2	Certificate of Warranty.....	11
7.3	Third Party Audits	11
7.4	Retained Samples	12
7.5	Records Retention	12
7.6	HACCP Requirement.....	12
7.7	Continuing Guarantee.....	12
7.8	Right to Inspection	12
7.9	Good Manufacturing Practices.....	12

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

7.10	FD&C Act Compliance	13
7.11	Currency of Specifications	13
7.12	(Intentionally Blank)	13
8	QUALITY DISCOUNTS	13
8.1	Discounts	13
8.2	Schedule of Discounts	13
8.3	(Intentionally Blank)	14
9	REFERENCES	14

1 CHANGES FROM PREVIOUS VERSION

Instructions: This section contains a brief synopsis of changes from the previous version. If new, then insert "New".

2 SCOPE

Instructions: This section should briefly introduce the product and its major components. This is a template. Actual descriptive language is product dependent.

3 CLASSIFICATION

Instructions: Where foods are classified into categories based on their different varieties, flavors, sizes, appearances, etc. the purchaser must specify the categories and sub-categories that are desired. If this section is not applicable then insert "Not applicable".

4 FINISHED PRODUCT CHARACTERISTICS

Instructions: Section 4 shall define important attributes that affect the final quality of the product and may include items such as ingredients, defect level, shelf life, additives / preservatives, color, flavor, odor, and texture requirements.

4.1 Finished Product Analytical Requirements

All sample analysis may be performed by the supplier's own in-house laboratory. The analytical results of each sample must be reported on the COA, refer to Section 4.6.1.

4.2 Chemical and Physical Properties

Instructions: This sample table may be used to define the characteristics, units of measure and minimum and maximum levels, as appropriate, for each parameter that is subject to testing and reporting. Performance criteria should be added or deleted, as appropriate for the food commodity.

Sample Table			
Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	00.0
Protein (N x 6.25) ²	%	00.0	--
Fat ²	%	0.0	--
Crude Fiber ²	%	--	0.0
Aflatoxin	Ppb	--	20

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

Micronutrients	Units	Minimum	Maximum
Thiamine	mg/100 g	--	--
Riboflavin	mg/100 g	--	--
Niacin or niacinamide	mg/100 g	--	--
Iron	mg/100 g	00.0	00.0
Vitamin A Palmitate	IU/100 g	0,000	00,000
Calcium	mg/100 g	000	000
Physical	Units	Minimum	Maximum
Product through US Std. No. __ sieve	%	00.0	--
Product through US Std. No. __ sieve	%	--	00.0
Product through US Std. No. __ sieve	%	--	0.0
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	--
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella (Class III)</i>	Absent / Present	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test	--
Yeast & Mold	cfu/g	--	--
Functional / Performance	Units	Minimum	Maximum
Consistency, cooked (11.75% gruel)	cm	0.0	00.0
Dispersibility	Free of lumping when mixed with water		
Sensory	Description		
Odor	[PRODUCT NAME] must be essentially free from foreign material and will have good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		
Appearance	[PRODUCT NAME] appears equivalent to typical product.		
¹ Percent is on a weight/weight basis			
² Moisture free basis			

4.3 Finished Product Grading Requirements

Instructions: If final product grading is not applicable, then input "Not Applicable".

4.4 Analytical Testing Methods 4.3

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.4.1 Product Verification

Instructions: As noted above, additional test methods to those defined in this template may be required for specific products. These methods should be appropriate to the food matrix for the assay designated in Chemical and Physical Properties (Section 4.2) and also in the Certificate of Analysis (Section 4.6.1).

In the event the Government exercises its right, pursuant to FAR clause 52.246.2, Inspection of Supplies—Fixed Price, to perform its own testing, the testing methods identified in this Section shall apply and will govern determinations as to whether or not the product meets the required specifications.

Sample Table		
Analytical Methods		
[Note: This table must be modified to fit each product and should contain the same performance criteria as defined in Section 4.2, Chemical & Physical Properties and Section 4.6.1, Certificate of Analyses.]		
	Test	Method
Chemical	Moisture	AOAC 925.10
	Protein (N x 6.25)	AOAC 992.23
	Fat	AOAC 922.06
	Crude Fiber	AOAC 962.09E
	Aflatoxin	AOAC (TBD)
	Vomitoxin (Deoxynivalenol)	AOAC (TBD)
Micronutrients	Calcium	AOAC 985.01
	Iron	AOAC 999.11
	Vitamin A Palmitate	AOAC 2001.13
Physical	Particle Size Distribution	Method Reference TBD
Microbiological	Aerobic Plate Count	FDA-BAM, 8th Ed., Chap 3
	<i>E. coli</i>	FDA-BAM, 8th Ed., Chap 4
	<i>Salmonella</i>	FDA-BAM, 8th Ed., Chap 5
	<i>Staphylococcus aureus</i> , Coagulase Positive	FDA-BAM, 8th Ed., Chap 12
	Yeast & Mold	FDA-BAM, 8th Ed., Chap 18
Functional / Performance	Consistency, uncooked	Method Reference TBD

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

	Consistency, cooked (11.75% gruel)	Method Reference TBD
	Dispersibility	Method Reference TBD
	Odor	Method Reference TBD
	Appearance	Method Reference TBD

4.5 Test Result Precision

Instructions: This section is a description of the precision required when reporting assay results and is specific to each product.

[Note: Reporting test method precision will, by necessity, need to be included in deliverable C.3.3.5, standard analytical methods recommendations.]

4.6 Reporting Results

Instructions: This section should describe the procedure for reporting analytical results.

The contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results shall be evidenced by a Certificate of Analysis (COA). Copies of the original COA must be submitted as part of the invoice package. The COA shall provide the results of all tests specified. If quality discounts are provided in the contract, and the product to be delivered by the contractor falls within the quality discount table, those factors shall be identified on the COA.

4.6.1 Certificate of Analysis

Instructions: The COA should contain ALL parameters that are required to define the product and assure quality and omit unnecessary items.

Sample Table					
Certificate of Analysis					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size:		
Car/Truck ID:					
Lot Number:			Lot Quantity (81 MT max)		
Contracted Quantity	MT	LBS		Bags	
		Units ¹	Limit	Test Result	Pass (Y/N)
Moisture		%	0.0 Max		
Protein (Nx6.25) ²		%	0.0 Min		
Fat ²		%	0.0 Min		
Crude Fiber ²		%	0.0 Max		
Iron		mg/100g	0.0 Min- 0.0 Max		

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

Sample Table				
Certificate of Analysis				
Vitamin A	IU/lb	Min – Max		
Product through a US Standard No. 6 sieve	%	00 Min		
Product through a US Standard No. 30 sieve	%	00 Min		
Product through a US Standard No. 60 sieve	%	00 Min		
Consistency – Uncooked	cm	0.0 Max		
Consistency - Cooked 11.75 % Gruel	cm	0.0 Max		
Dispersibility	Essentially free from lumps or balling when mixed with water.		Pass/Fail	
Appearance	Essentially free from foreign material and will have characteristics equivalent to typical product.		Pass/Fail	
Odor	Good characteristic taste and odor, free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors.		Pass/Fail	
Total Plate Count	cfu/g	Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i> (Category III)	Absent / Present	Negative to test		
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis ² Moisture free basis				

4.6.2 Notification of Lots Failing to Meet Standards

Contractors shall notify the Government immediately of lots that fail to meet contract requirements.

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

Instructions: Define procedures and frequency for collecting representative samples from each lot to be used for assays. Alternatively, sampling plans may be included by reference to recognized sources.

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.8.1 Sample Collection

Instructions: This section shall describe sample collection procedures where required. Sampling procedures may be defined in this section or included by reference to standard procedures described elsewhere.

4.9 Uniform Product

The contractor is responsible for ensuring that the commodity is uniform throughout the lot and substantially conforms to the specifications.

4.10 Product Age

Instructions: This section shall describe the maximum time interval between processing/packaging and delivery to purchaser.

Product age requirement may vary with the product. Sample language: Unless otherwise specified in the solicitation, contract, or purchase order, the [PRODUCT NAME] shall be processed and packaged not more than 60 days prior to delivery to the purchaser.

4.11 (Intentionally Blank)

5 MANUFACTURER'S REQUIREMENTS

Instructions: This section is targeted for the supplier of the food item. It lists the requirements that must be met for product to be acceptable to the purchaser.

5.1 General Requirements

Instructions: Revise this general statement as appropriate for the product(s) of interest.

Sample language: [PRODUCT NAME] shall be free from foreign material and will have good characteristic taste and odor, and be free from rancid, bitter, musty, sour and other undesirable or foreign tastes and odors. The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or an extender to other foods.

5.2 Formulation

Instructions: Formulation should be in a table format listing the percentage and the quantity (in pounds) per 2000 pound batch. Include footnotes as appropriate and/or required.

Sample Formulation Table		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Ingredient 1	00.0	0,000
Ingredient 2	00.0	000
Ingredient 3	00.0	000
Mineral Premix	0.0	00
Vitamin Premix	0.0	00
Total	100.0	2,000

5.3 Ingredient

Instructions: Each sub-section should describe the ingredients to be used in the product, including chemical, physical, functional, microbiological and other characterizing attributes of each ingredient. In the case of micronutrient premixes, the levels of the micronutrients must be included as well as antioxidants and carriers, if required. These subheadings may not be appropriate for all products, but are listed as an example.

5.3.1 (Ingredient 1, Intentionally Blank)

5.3.2 (Ingredient 2, Intentionally Blank)

5.3.3 (Ingredient 3, Intentionally Blank)

5.3.4 Micronutrients

Instructions: Input the required micronutrient premix(es) as required for each specific product.

5.3.4.1 Mineral Premix

Instructions: Include table of the mineral premix formula, as appropriate to the product.

5.3.4.2 Vitamin Premix

Instructions: Include table of the vitamin premix formula, as appropriate to the product.

6 SPECIAL REQUIREMENTS

Instructions: If any item is not applicable for the commodities processed, then state "Not applicable".

6.1 Pesticide Residues

Manufacturers must be able to demonstrate compliance to pesticide residue levels as provided in 40 CFR 180 through documented analytical results of pesticide residue testing within the previous six (6) calendar months.

6.2 Official Grade Certificates

Instructions: Where applicable, include US Grain Grading Standards for the grade designated for the commodity. For example, wheat, corn, sorghum and soybeans are required to be grade No 2, or better. Include in this section the requirements from the Grain Grading Standards that define grade No. 2. If Grain Grading is not applicable, input "Not applicable".

Where required, the contractor shall be responsible for arranging and obtaining from AMS, FGIS, or their designated representative, official grading certificates and domestic and export weight and/or grade certificates.

Where required, the contractor shall be responsible for arranging and obtaining from FGIS, or any other organization designated by FGIS, official domestic and export weight and/or grade certificates. Procedures to follow and a schedule of fees for this service may be obtained at <http://151.121.3.117/aboutus/servicemap/usmap.htm>.

6.3 (Intentionally Blank)

7 MANUFACTURER'S QUALITY ASSURANCE

Instructions: This section shall identify manufacturer's quality programs which should be consistent with current commercial practices

7.1 Conformance to Specification

The material shall conform to the quality parameters specified herein. For characteristics not required to be reported on the Certificate of Analysis (or Warranty), a signed statement from the Contractor attesting to compliance shall be provided.

7.2 Certificate of Warranty

A Certificate of Warranty shall provide warranty that the product complies with all specifications.

7.3 Third Party Audits

Manufacturers must have successfully completed sanitation and quality systems audits conducted by a qualified third-party within the preceding 12 months prior to the date of the awarding of the contract.

7.4 Retained Samples

Contractors shall retain approximately two and one-half (2.5) pounds of each composited sample collected during manufacturing (Section 4.8.1) for a period of TBD months. Retained samples shall be stored under conditions that will preserve the original condition of the sample, providing protection from insects, rodents, and avian pests as well as excess heat or moisture damage.

7.5 Records Retention

Records of all ingredients, components, micronutrient premix certificates of analysis, and production batch records describing the process and any deviations from standard procedures shall be retained by the manufacturer for a period not less than twenty-four (24) months from the date of manufacture.

7.6 HACCP Requirement

Manufacturers must have developed and implemented a Hazard Analysis and Critical Control Points (HACCP) plan for the manufacturing process for delivering food aid commodities. The HACCP plan must be current, up to date, and reflect the actual manufacturing process used to produce the foods.

7.7 Continuing Guarantee

The seller shall warrant that the material shall comply with all applicable provisions of the Federal Food, Drug and Cosmetic Acts, all other applicable federal laws and regulations and State and Local codes as amended and that such material is neither adulterated nor misbranded. A letter of Continuing Guaranty shall be furnished by the Contractor annually.

7.8 Right to Inspection

The Government reserves the right to inspect supplier's facilities. Qualification as an approved supplier and/or retention of approved supplier status may be contingent upon inspection of pertinent areas of the supplier's manufacturing facilities.

7.9 Good Manufacturing Practices

[PRODUCT NAME] shall be produced, packaged and stored in accordance with good manufacturing practices as described in 21 CFR 110 – Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food. Such evidence shall consist at a minimum of:

- a. A copy of the Contractor's Continuing Guarantee,
- b. A statement from the Contractor(s) that they are in compliance with the Bioterrorism Act of 2002,
- c. A statement from the contractor that they follow cGMPs,
- d. A summary of the Contractor's HACCP Plan,
- e. A summary of the Contractor's allergen management plan,
- f. A copy of the Table of Contents of the contractor's Quality Manual,

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

- g. Access to the Contractor’s most recent GMP/HACCP audit report,
- h. Verified Trace & Recall Program.

7.10 FD&C Act Compliance

[PRODUCT NAME] and all ingredients used therein, must conform in every respect to the provisions of the “Federal Food, Drug and Cosmetic Act,” (21 CFR 9) as amended, and the regulations promulgated there under, including any Defect Action Level guidelines issued by the Food and Drug Administration (FDA) which may be applicable to this product. Shipments with counts in excess of the FDA Defect Action Level guidelines will be subject to rejection.

7.11 Currency of Specifications

Where the specifications refer to specific references (e.g. Standards of Identity, 21 CFR or Commercial Item Descriptions – AMS) and an updated specification has been issued by the responsible agency, it is the responsibility of the contractor to conform to the most current specifications available at the time the Invitation to Bid is issued.

7.12 (Intentionally Blank)

8 QUALITY DISCOUNTS

Instructions: This section should contain a description of the discounts schedule and references to the applicable Quality Sections above. Discounts may not apply to all commodities. If discounts do not apply, this section should state “None” or “Not applicable” and subsections should be deleted.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications listed in Section 4.2, Chemical and Physical Properties, of this Commodity Requirement but falls within the discounts listed in the table in Section 8.2, the product may be delivered to Commodity Credit Corporation, but the purchase price will be reduced in accordance with the schedules of discounts in Section 8.2 for each 100 pounds (cwt.) of commodity delivered.

8.2 Schedule of Discounts

Instructions: Insert table of discount schedules specific to only those products to which discounts apply.

Sample Table of Discounts					
	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
10.1 or 10.2	%	0.10	16.6 through 16.4	%	0.10
10.3 or 10.4	%	0.20	16.3 through 16.1	%	0.20

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

10.5	%	0.35	16.0 or 15.9	%	0.35
Deficient Fat			Excess Crude Fiber		
5.9 or 5.8	%	0.10	2.1 through 2.2	%	0.10
5.7 or 5.6	%	0.20	2.3 through 2.4	%	0.20
5.5	%	0.35	2.5	%	0.35
Insufficient Product Through U.S Std. No. 6 Sieve			Excess Product Through U.S Std. No. 30 Sieve		
98 or 97	%	0.10	93 or 94	%	0.10
96 or 95	%	0.20	95 or 96	%	0.20
Excess Product Through U.S Std. No. 60 Sieve			Excess Iron		
58 or 59	cm	0.10	30.1 – 31.5	mg / 100 g	0.10
60 - 61	cm	0.20	31.6 – 33.1	mg / 100 g	0.20
			33.2 – 35.0	mg / 100 g	0.35
Deficient Consistency (Cooked) 11.75% Gruel) Bostwick Units			Excess Consistency (Cooked) 11.75% Gruel - Bostwick Units		
8.5 or 8.0	cm	0.10	21.5 or 22.0	cm	0.10
7.5 or 7.0	cm	0.20	22.5 or 23.0	cm	0.20
6.5 or 6.0	cm	0.35	23.5 or 24.0	cm	0.35

8.3 (Intentionally Blank)

9 REFERENCES

Instructions: This section lists USDA certification contacts, USDA analytical laboratory contacts, as well as sources of documents that may be referenced in the Commodity Requirement.

- A. *Salmonella* sampling requirements – Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan
http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- B. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- C. Muncell Color Standards are available from **X-Rite Incorporated**
4300 44th Street SE, Grand Rapids, MI 49512, 800.248.9748 (Not applicable to all products.)
- D. Bostwick consistometer sources: Fisher Scientific, catalog number 15-347-50, or VWR, cat No. 23270-004 or equivalent”. (Not applicable to all products.)

Contract AG-3151-C-07-0048
Deliverable C.3.2.2

https://www.fishersci.com/wps/portal/SEARCHRESULTS?ru=http%3A%2F%2Fprodwcssserver%2Fwebapp%2Fwcs%2Fstores%2Fservlet%2FSearch&searchPref=no&position=search&preferProd=unchecked&searchType=Rapid&catalogCode=RE_SC&keyWord=15-347-50&catCode=ALL

OR

http://www.vwrsp.com/catalog/product/index.cgi?catalog_number=23270-004&inE=1&highlight=23270-004&from_search=1

- E. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/usc_sec_21_00000346---a000-.html
- F. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- G. FDA Guidance Letter - Deoxynivalenol (Vomitoxin)
<http://www.cfsan.fda.gov/~dms/graingui.html>
- H. American Public Health Association
<http://www.apha.org/>
- I. Nonfat Dry Milk Standards
http://www.ams.usda.gov/standards/NDM_02-02-01.pdf
- J. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- K. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/usc_sec_21_00000346---a000-.html
- L. CODEX Wheat Flour Standard 152
<http://www.codexalimentarius.net/search/advancedsearch.do>
- M. (Intentionally Blank)

COMMERCIAL PRODUCTS TEMPLATE

[Commodity Name]

[Commodity ID:]
[Date]
SUPERSEDING
[Former Commodity ID]
[Former Commodity Effective
Date]

This template is constructed for use in developing specifications for the products in the category “Commercial Products” which includes Dehydrated Potatoes (DPP4), Dehydrated Soup Mixes (DSM2), Non-Fortified Nonfat Dry Milk (DME2), Canned Pink Salmon, and Value Added Soy Products (VASP4)

Table of Contents

1 CHANGES FROM PREVIOUS VERSION 3

2 SCOPE 3

3 CLASSIFICATION 3

4 FINISHED PRODUCT CHARACTERISTICS 3

 4.1 Finished Product Analytical Requirements 3

 4.2 Chemical and Physical Properties 3

 4.3 Grading Requirements..... 3

 4.3.1 Official Grade Certificates 4

 4.4 Analytical Testing Methods 4

 4.4.1 Product Verification 4

 4.5 Test Result Precision 5

 4.6 Reporting Results 5

 4.6.1 Certificate of Analysis..... 5

 4.6.2 Notification of Lots Failing to Meet Standards..... 5

 4.7 Lot Size Definition 5

 4.8 Sampling Procedures..... 5

 4.8.1 Sample Collection 6

 4.8.2 (Intentionally Blank) 6

 4.9 Uniform Product..... 6

 4.10 Product Age..... 6

 4.11 (Intentionally Blank) 6

5 MANUFACTURER’S REQUIREMENTS 6

 5.1 General Requirements 6

6 SPECIAL REQUIREMENTS 6

 6.1 Pesticide Residues 6

 6.2 (Intentionally Blank) 6

7 MANUFACTURER’S QUALITY ASSURANCE 6

 7.1 Conformance to Specification 6

 7.2 Certificate of Warranty..... 7

 7.3 Third Party Audits 7

 7.4 Retained Samples 7

 7.5 Records Retention 7

 7.6 HACCP Requirement 7

 7.7 Continuing Guarantee..... 7

 7.8 Right to Inspection 7

 7.9 Good Manufacturing Practices..... 7

 7.10 FD&C Act Compliance 8

 7.11 Currency of Specifications 8

 7.12 (Intentionally Blank) 8

8 QUALITY DISCOUNTS 8

 8.1 Discounts 8

 8.2 Schedule of Discounts 8

 8.3 (Intentionally Blank) 8

9 REFERENCES 9

1 CHANGES FROM PREVIOUS VERSION

Instructions: When reissuing Commodity Requirement Document documents this section should contain a synopsis of changes from previous version. If this is a specification for a new product, then insert “New” here.

2 SCOPE

Instructions: This section should briefly introduce the product and its major components. This is a template. Actual specification performance language will be product dependent.

Note: Commercial Products described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Instructions: Where foods are classified into categories based on their different varieties, flavors, sizes, appearances, etc. the purchaser must specify the categories and sub-categories that are desired. If this section is not applicable then insert “Not applicable”.

4 FINISHED PRODUCT CHARACTERISTICS

Instructions: Section 4 shall define important attributes that affect the final quality of the product and may include items such as ingredient, defect level, shelf life, additives / preservatives, color, flavor, odor, and texture requirements.

Performance language defined in the referenced specification(s), included herein by reference, will not be reproduced in this Commodity Requirement document.

4.1 Finished Product Analytical Requirements

Instructions: This section summarizes analytical and microbiological requirements that are important in determining the final quality and safety of the food product to be purchased.

4.2 Chemical and Physical Properties

Instructions: This table defines the characteristics, units of measure and minimum and maximum levels, as appropriate, for each parameter that is subject to testing and reporting, where they are different from the standards included by reference.

4.3 Grading Requirements

Instructions: Where applicable, include US Grading Standards for the grade designated for the commodity. If Grading is not applicable, insert “Not applicable”.

4.3.1 Official Grade Certificates

Where required, the contractor shall be responsible for arranging and obtaining from AMS, FGIS, or their designated representative, official grading certificates and domestic and export weight and/or grade certificates.

4.4 Analytical Testing Methods

Instructions: This section summarizes the source and specific analytical methods appropriate for the food matrix and analyte to be assayed.

[Note: The following is a sample list of analytical testing methods references. A more complete list will be provided as deliverable C.3.3.8.]

Unless otherwise specified, analytical methods for the finished product and any ingredients shall be those identified in the Official Methods of the Association of Official Analytical Chemists (AOAC), the American Association of Cereal Chemists (AACC), the America Oil Chemists' Society (AOCS), Standards Methods for the Examination of Dairy Products available from the American Public Health Association and/or the FDA Bacteriological Analytical Manual (FDA-BAM), as applicable and in effect on the date of issuance of the Solicitation Document under which the purchase contract was entered into, or in accordance with methods that yield equivalent results.

4.4.1 Product Verification

Instructions: As noted above, additional test methods to those defined in this template may be required for specific products. These methods should be appropriate to the food matrix for the assay designated in Chemical and Physical Properties (Section 4.2) and also in the Certificate of Analysis (Section 4.6.1).

In the event the Government exercises its right, pursuant to FAR clause 52.246.2, Inspection of Supplies—Fixed Price, to perform its own testing, the following testing methods shall apply and will govern determinations as to whether or not the product meets the required specifications.

<u>Sample Table of Analytical Methods</u>		
[Note: This table must be modified to fit each product.]		
	<u>Test</u>	<u>Method</u>
Chemical	Moisture	AOAC 925.10
	Protein (N x 6.25)	AOAC 992.23
	Fat	AOAC 922.06
Physical	Particle Size Distribution	Method Reference TBD
Microbiological	Aerobic Plate Count	FDA-BAM, 8th Ed., Chap 3
	<i>E. coli</i>	FDA-BAM, 8th Ed., Chap 4
	<i>Salmonella</i>	FDA-BAM, 8th Ed., Chap 5

4.5 Test Result Precision

Instructions: Description of the precision which assay results should be reported. This paragraph is not all inclusive; other assays may be required and some assays may be deleted on a product by product basis to appropriately define that product.

[Note: Reporting test method precision will, by necessity, need to be included in deliverable C.3.3.5, standard analytical methods recommendations.]

4.6 Reporting Results

Instructions: This section should describe the process for reporting analytical results.

The contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results shall be evidenced by a Certificate of Analysis (COA). Copies of the original COA must be submitted as part of the invoice package. The COA shall provide the results of all tests specified. If quality discounts are provided in the contract, and the product to be delivered by the contractor falls within the quality discount table, those factors shall be identified on the COA.

All sample analysis may be performed by the supplier's own in-house laboratory. The analytical results of each sample must be reported on the COA, refer to Section 4.6.1.

4.6.1 Certificate of Analysis

Instructions: The COA should contain ALL parameters that are required to define the product and assure quality. Insert Certificate of Analysis table here.

4.6.2 Notification of Lots Failing to Meet Standards

Contractors shall notify the Government immediately of lots that fail to meet contract requirements.

4.7 Lot Size Definition

Instructions: Define appropriate lot size used in commercial practice for the commodity specified. A sample statement defining lot sized follows.

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

Instructions: Define procedures and frequency for collecting representative samples from each lot to be used for assays representative of each lot. Alternatively, sampling plans may be included by reference to recognized sources.

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.8.1 Sample Collection

Instructions: This section shall describe sample collection procedures where required. Sampling procedures may be defined in this section or included by reference to standard procedures described elsewhere.

4.8.2 (Intentionally Blank)

4.9 Uniform Product

The contractor is responsible for ensuring that the commodity is uniform within a lot and between lots and substantially conforms to the required specifications.

4.10 Product Age

Instructions: The product age requirement may vary with the product.

4.11 (Intentionally Blank)

5 MANUFACTURER'S REQUIREMENTS

Instructions: This section is targeted for the supplier of the food item. It lists the requirements that must be met if they are to manufacture the product acceptable to the purchaser.

5.1 General Requirements

Instructions: Insert list of general requirements for manufacturers.

6 SPECIAL REQUIREMENTS

Instructions: If any item is not appropriate for the commodities processed, then state "None" or "Not applicable".

6.1 Pesticide Residues

Manufacturers must be able to demonstrate compliance to pesticide residue levels as provided in 40 CFR 180 through documented analytical results of pesticide residue testing within the previous six (6) calendar months.

6.2 (Intentionally Blank)

7 MANUFACTURER'S QUALITY ASSURANCE

Instructions: This section identifies manufacturer's quality programs and should consistent with current commercial practices.

7.1 Conformance to Specification

The material shall conform to the quality parameters specified herein. For characteristics not required to be reported on the Certificate of Analysis (or Warranty), a signed statement from the Contractor attesting to compliance shall be provided

7.2 Certificate of Warranty

A Certificate of Warranty shall provide warranty that the product complies with all specifications.

7.3 Third Party Audits

Manufacturers must have successfully completed sanitation and quality systems audits conducted by a qualified third-party within the preceding twelve (12) months prior to the date of the awarding of the contract.

7.4 Retained Samples

Contractors shall retain a portion of each composited sample collected during manufacturing (Section 4.9.2) of approximately two and one-half (2.5) pounds for a period of [TBD] months. Retained samples shall be stored under conditions that will preserve the original condition of the sample, providing protection from insects, rodents, and avian pests as well as protection from excess heat or moisture damage.

7.5 Records Retention

Records of all ingredient, components, micronutrient premix certificates of analysis, and production batch records describing the process and any deviations from standard procedures shall be retained by the manufacturer for a period not less than twenty-four (24) months from the date of manufacture.

7.6 HACCP Requirement

Manufacturers must have developed and implemented a Hazard Analysis and Critical Control Points (HACCP) plan for the manufacturing process for delivering food aid commodities. The HACCP plan must be current, up to date, and reflect the actual manufacturing process used to produce the foods. Evidence of implementation and continuation of a HACCP plan must be provided by the manufacturer upon request.

7.7 Continuing Guarantees

The seller shall warrant that the material shall comply with all applicable provisions of the Federal Food, Drug and Cosmetic Acts, all other applicable federal laws and regulations and State and Local codes as amended and that such material is neither adulterated nor misbranded. A letter of Continuing Guaranty shall be furnished by the Contractor annually.

7.8 Right to Inspection

The Government reserves the right to inspect supplier's facilities. Qualification as an approved supplier and/or retention of approved supplier status may be contingent upon inspection of pertinent areas of the supplier's manufacturing facilities.

7.9 Good Manufacturing Practices

[PRODUCT NAME] shall be produced, packaged and stored in accordance with good manufacturing practices as described in 21 CFR 110 – Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food. Such evidence shall consist at a minimum of:

1. A copy of the Contractors Continuing Guarantee,
2. A statement from the Contractor(s) that they are in compliance with the Bioterrorism Act of 2002,
3. A statement from the contractor that they follow cGMPs,
4. A summary of the Contractors HACCP Plan,
5. A summary of the Contractors allergen management plan,
6. A copy of the Table of Contents of the contractor's Quality Manual,
7. Access to the Contractors most recent GMP/HACCP audit report,
8. Verified Trace & Recall Program.

7.10 FD&C Act Compliance

[PRODUCT NAME] and all ingredients used therein, must conform in every respect to the provisions of the "Federal Food, Drug and Cosmetic Act," (21 CFR 9) as amended, and the regulations promulgated there under, including any Defect Action Level guidelines issued by the Food and Drug Administration (FDA) which may be applicable to this product. Shipments with counts in excess of the FDA Defect Action Level guidelines will be subject to rejection.

7.11 Currency of Specifications

Where the specifications refer to specific references (e.g. Standards of Identity, 21 CFR or Commercial Item Descriptions – AMS) and an updated specification has been issued by the responsible agency, it is the responsibility of the contractor to conform to the most current specifications available at the time the Invitation to Bid is issued.

7.12 (Intentionally Blank)

8 QUALITY DISCOUNTS

Instructions: This section should contain a description of the discounts schedule and references to the applicable Quality Sections above. Discounts may not apply to all commodities and should state "None" or "Not applicable" and subsections should be deleted.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications listed in Section 4.2, Chemical and Physical Properties, of this Commodity Requirement but falls within the discounts listed in the table in Section 8.2, the product may be delivered to CCC, but the purchase price will be reduced in accordance with the schedules of discounts in Section 8.2 for each 100 pounds (cwt.) of commodity delivered.

8.2 Schedule of Discounts

Instructions: Insert table of discount schedules specific to only those products to which discounts apply.

8.3 (Intentionally Blank)

9 REFERENCES

Instructions: This section lists USDA certification contacts, USDA analytical laboratory contacts, as well as sources of documents that may be referenced in the Commodity Requirement. Below are samples of references that may be included.

- A. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- B. *Salmonella* sampling requirements – Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan:
http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- C. Muncell Color Standards are available from **X-Rite Incorporated**
4300 44th Street SE, Grand Rapids, MI 49512, 800.248.9748 (*Not applicable to all products.*)
- D. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscodes/html/uscode21/usc_sec_21_00000346---a000-.html
- E. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- F. American Public Health Association
<http://www.apha.org/>
- G. Nonfat Dry Milk Standards
http://www.ams.usda.gov/standards/NDM_02-02-01.pdf
- H. Canned Salmon Standards of Identity
http://a257.g.akamaitech.net/7/257/2422/26mar20071500/edocket.access.gpo.gov/cfr_2007/aprqtr/21cfr161.170.htm
- I. Soy Products CODEX STAN 175-1989
www.codexalimentarius.net/download/standards/325/CXS_175e.pdf
- J. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- K. (Intentionally Blank)

VEGETABLE OILS/FATS TEMPLATE

[Commodity Name]

[Commodity ID:]
[Date]
SUPERSEDING
[Former Commodity ID]
[Former Commodity Effective
Date]

This template is constructed for use in developing specifications for the products in the category “Vegetable Oils/Fats” which includes Vegetable Oil (Soybean and Vegetable) (VO), Bulk Oil (Crude, Degummed Soybean; Fully Refined Soybean Oil, Crude Corn Oil; Crude Sunflower Seed) and Tallow (BOT), Corn Oil (CO) and Refined Sunflower Seed Oil (SFSO).

Table of Contents

- 1 CHANGES FROM PREVIOUS VERSION 3
- 2 SCOPE 3
- 3 CLASSIFICATION 3
- 4 FINISHED PRODUCT CHARACTERISTICS 3
 - 4.1 Finished Product Analytical Requirements 3
 - 4.2 Chemical and Physical Properties 3
 - 4.3 Grading Requirements..... 3
 - 4.3.1 Official Grade Certificates 4
 - 4.4 Analytical Testing Methods 4
 - 4.4.1 Product Verification 4
 - 4.5 Test Result Precision 5
 - 4.6 Reporting Results 5
 - 4.6.1 Certificate of Analysis..... 5
 - 4.6.2 Notification of Lots Failing to Meet Standards..... 5
 - 4.7 Lot Size Definition 5
 - 4.8 Sampling Procedures..... 5
 - 4.8.1 Sample Collection 6
 - 4.8.2 (Intentionally Blank) 6
 - 4.9 Uniform Product..... 6
 - 4.10 Product Age..... 6
 - 4.11 (Intentionally Blank) 6
- 5 MANUFACTURER’S REQUIREMENTS 6
 - 5.1 General Requirements 6
- 6 SPECIAL REQUIREMENTS 6
 - 6.1 Pesticide Residues 6
 - 6.2 (Intentionally Blank) 6
- 7 MANUFACTURER’S QUALITY ASSURANCE 6
 - 7.1 Conformance to Specification 6
 - 7.2 Certificate of Warranty..... 7
 - 7.3 Third Party Audits 7
 - 7.4 Retained Samples 7
 - 7.5 Records Retention 7
 - 7.6 HACCP Requirement 7
 - 7.7 Continuing Guarantee..... 7
 - 7.8 Right to Inspection 7
 - 7.9 Good Manufacturing Practices..... 7
 - 7.10 FD&C Act Compliance 8
 - 7.11 Currency of Specifications 8
 - 7.12 (Intentionally Blank) 8
- 8 QUALITY DISCOUNTS 8
 - 8.1 Discounts 8
 - 8.2 Schedule of Discounts 8
 - 8.3 (Intentionally Blank) 9
- 9 REFERENCES 9

1 CHANGES FROM PREVIOUS VERSION

Instructions: When reissuing Commodity Requirement Document documents this section should contain a synopsis of changes from previous version. If this is a specification for a new product, then insert “New” here.

2 SCOPE

Instructions: This section should briefly introduce the product and its major components. This is a template. Actual specification performance language will be product dependent.

Note: Commercial Products described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Instructions: Where foods are classified into categories based on their different varieties, flavors, sizes, appearances, etc. the purchaser must specify the categories and sub-categories that are desired. If this section is not applicable then insert “Not applicable”.

Solicitations for Bids for vegetable oils shall specify the origin of the oil to be delivered.

4 FINISHED PRODUCT CHARACTERISTICS

Instructions: Section 4 shall define important attributes that affect the final quality of the product and may include items such as ingredient, defect level, shelf life, additives / preservatives, color, flavor, odor, and texture requirements.

Performance language defined in the referenced specification(s), included herein by reference, will not be reproduced in this Commodity Requirement document.

4.1 Finished Product Analytical Requirements

Instructions: This section summarizes analytical and microbiological requirements that are important in determining the final quality and safety of the food product to be purchased.

4.2 Chemical and Physical Properties

Instructions: This table defines the characteristics, units of measure and minimum and maximum levels, as appropriate, for each parameter that is subject to testing and reporting, where they are different from the standards included by reference.

4.3 Grading Requirements

Instructions: Where applicable, include US Grading Standards for the grade designated for the commodity. If Grading is not applicable, insert “Not applicable”.

4.3.1 Official Grade Certificates

Where required, the contractor shall be responsible for arranging and obtaining from AMS, FGIS, or their designated representative, official grading certificates and domestic and export weight and/or grade certificates.

4.4 Analytical Testing Methods

Instructions: This section summarizes the source and specific analytical methods appropriate for the food matrix and analyte to be assayed.

[Note: The following is a sample list of analytical testing methods references. A more complete list will be provided as deliverable C.3.3.8.]

Unless otherwise specified, analytical methods for the finished product and any ingredients shall be those identified in the Official Methods of the Association of Official Analytical Chemists (AOAC), the American Association of Cereal Chemists (AACC), the America Oil Chemists' Society (AOCS), Standards Methods for the Examination of Dairy Products available from the American Public Health Association and/or the FDA Bacteriological Analytical Manual (FDA-BAM), as applicable and in effect on the date of issuance of the Solicitation Document under which the purchase contract was entered into, or in accordance with methods that yield equivalent results.

4.4.1 Product Verification

Instructions: As noted above, additional test methods to those defined in this template may be required for specific products. These methods should be appropriate to the food matrix for the assay designated in Chemical and Physical Properties (Section 4.2) and also in the Certificate of Analysis (Section 4.6.1).

In the event the Government exercises its right, pursuant to FAR clause 52.246.2, Inspection of Supplies—Fixed Price, to perform its own testing, the following testing methods shall apply and will govern determinations as to whether or not the product meets the required specifications.

<u>Sample Table of Analytical Methods</u>		
[Note: This table must be modified to fit each product.]		
	<u>Test</u>	<u>Method</u>
Chemical	Moisture	AOAC 925.10
	Protein (N x 6.25)	AOAC 992.23
	Fat	AOAC 922.06
Physical	Particle Size Distribution	Method Reference TBD
Microbiological	Aerobic Plate Count	FDA-BAM, 8th Ed., Chap 3
	<i>E. coli</i>	FDA-BAM, 8th Ed., Chap 4
	<i>Salmonella</i>	FDA-BAM, 8th Ed., Chap 5

4.5 Test Result Precision

Instructions: Description of the precision which assay results should be reported. This paragraph is not all inclusive; other assays may be required and some assays may be deleted on a product by product basis to appropriately define that product.

[Note: Reporting test method precision will, by necessity, need to be included in deliverable C.3.3.5, standard analytical methods recommendations.]

4.6 Reporting Results

Instructions: This section should describe the process for reporting analytical results.

The contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results shall be evidenced by a Certificate of Analysis (COA). Copies of the original COA must be submitted as part of the invoice package. The COA shall provide the results of all tests specified. If quality discounts are provided in the contract, and the product to be delivered by the contractor falls within the quality discount table, those factors shall be identified on the COA.

All sample analysis may be performed by the supplier's own in-house laboratory. The analytical results of each sample must be reported on the COA, refer to Section 4.6.1.

4.6.1 Certificate of Analysis

Instructions: The COA should contain ALL parameters that are required to define the product and assure quality. Insert Certificate of Analysis table here.

4.6.2 Notification of Lots Failing to Meet Standards

Contractors shall notify the Government immediately of lots that fail to meet contract requirements.

4.7 Lot Size Definition

Instructions: Define appropriate lot size used in commercial practice for the commodity specified. A sample statement defining lot sized follows.

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

Instructions: Define procedures and frequency for collecting representative samples from each lot to be used for assays representative of each lot. Alternatively, sampling plans may be included by reference to recognized sources.

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.8.1 Sample Collection

Instructions: This section shall describe sample collection procedures where required. Sampling procedures may be defined in this section or included by reference to standard procedures described elsewhere.

4.8.2 (Intentionally Blank)

4.9 Uniform Product

The contractor is responsible for ensuring that the commodity is uniform within a lot and between lots and substantially conforms to the required specifications.

4.10 Product Age

Instructions: The product age requirement may vary with the product.

4.11 (Intentionally Blank)

5 MANUFACTURER'S REQUIREMENTS

Instructions: This section is targeted for the supplier of the food item. It lists the requirements that must be met if they are to manufacture the product acceptable to the purchaser.

5.1 General Requirements

Instructions: Insert list of general requirements for manufacturers here.

6 SPECIAL REQUIREMENTS

Instructions: If any item is not appropriate for the commodities processed, then state "None" or "Not applicable".

6.1 Pesticide Residues

Manufacturers must be able to demonstrate compliance to pesticide residue levels as provided in 40 CFR 180 through documented analytical results of pesticide residue testing within the previous six (6) calendar months.

6.2 (Intentionally Blank)

7 MANUFACTURER'S QUALITY ASSURANCE

Instructions: This section identifies manufacturer's quality programs and should consistent with current commercial practices.

7.1 Conformance to Specification

The material shall conform to the quality parameters specified herein. For characteristics not required to be reported on the Certificate of Analysis (or Warranty), a signed statement from the Contractor attesting to compliance shall be provided.

7.2 Certificate of Warranty

A Certificate of Warranty shall provide warranty that the product complies with all specifications.

7.3 Third Party Audits

Manufacturers must have successfully completed sanitation and quality systems audits conducted by a qualified third-party within the preceding twelve (12) months prior to the date of the awarding of the contract.

7.4 Retained Samples

Contractors shall retain a portion of each composited sample collected during manufacturing (Section 4.9.2) of approximately two and one-half (2.5) pounds for a period of [TBD] months. Retained samples shall be stored under conditions that will preserve the original condition of the sample, providing protection from insects, rodents, and avian pests as well as protection from excess heat or moisture damage.

7.5 Records Retention

Records of all ingredient, components, micronutrient premix certificates of analysis, and production batch records describing the process and any deviations from standard procedures shall be retained by the manufacturer for a period not less than twenty-four (24) months from the date of manufacture.

7.6 HACCP Requirement

Manufacturers must have developed and implemented a Hazard Analysis and Critical Control Points (HACCP) plan for the manufacturing process for delivering food aid commodities. The HACCP plan must be current, up to date, and reflect the actual manufacturing process used to produce the foods. Evidence of implementation and continuation of a HACCP plan must be provided by the manufacturer upon request.

7.7 Continuing Guarantee

The seller shall warrant that the material shall comply with all applicable provisions of the Federal Food, Drug and Cosmetic Acts, all other applicable federal laws and regulations and State and Local codes as amended and that such material is neither adulterated nor misbranded. A letter of Continuing Guaranty shall be furnished by the Contractor annually.

7.8 Right to Inspection

The Government reserves the right to inspect supplier's facilities. Qualification as an approved supplier and/or retention of approved supplier status may be contingent upon inspection of pertinent areas of the supplier's manufacturing facilities.

7.9 Good Manufacturing Practices

[PRODUCT NAME] shall be produced, packaged and stored in accordance with good manufacturing practices as described in 21 CFR 110 – Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food. Such evidence shall consist at a minimum of:

1. A copy of the Contractors Continuing Guarantee,
2. A statement from the Contractor(s) that they are in compliance with the Bioterrorism Act of 2002,
3. A statement from the contractor that they follow cGMPs,
4. A summary of the Contractors HACCP Plan,
5. A summary of the Contractors allergen management plan,
6. A copy of the Table of Contents of the contractor's Quality Manual,
7. Access to the Contractors most recent GMP/HACCP audit report,
8. Verified Trace & Recall Program.

7.10 FD&C Act Compliance

[PRODUCT NAME] and all ingredients used therein, must conform in every respect to the provisions of the "Federal Food, Drug and Cosmetic Act," (21 CFR 9) as amended, and the regulations promulgated there under, including any Defect Action Level guidelines issued by the Food and Drug Administration (FDA) which may be applicable to this product. Shipments with counts in excess of the FDA Defect Action Level guidelines will be subject to rejection.

7.11 Currency of Specifications

Where the specifications refer to specific references (e.g. Standards of Identity, 21 CFR or Commercial Item Descriptions – AMS) and an updated specification has been issued by the responsible agency, it is the responsibility of the contractor to conform to the most current specifications available at the time the Invitation to Bid is issued.

7.12 (Intentionally Blank)

8 QUALITY DISCOUNTS

Instructions: This section should contain a description of the discounts schedule and references to the applicable Quality Sections above. Discounts may not apply to all commodities and should state "None" or "Not applicable" and subsections should be deleted.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications listed in Section 4.2, Chemical and Physical Properties, of this Commodity Requirement but falls within the discounts listed in the table in Section 8.2, the product may be delivered to Commodity Credit Corporation, but the purchase price will be reduced in accordance with the schedules of discounts in Section 8.2 for each 100 pounds (cwt.) of commodity delivered.

8.2 Schedule of Discounts

Instructions: Insert table of discount schedules specific to only those products to which discounts apply.

8.3 (Intentionally Blank)

9 REFERENCES

Instructions: This section lists USDA certification contacts, USDA analytical laboratory contacts, as well as sources of documents that may be referenced in the Commodity Requirement. Below are samples of references that may be included.

- A. Muncell Color Standards are available from **X-Rite Incorporated**
4300 44th Street SE, Grand Rapids, MI 49512, 800.248.9748 (*Not applicable to all products.*)
- B. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscde/html/uscode21/usc_sec_21_00000346---a000-.html
- C. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- D. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- E. (Intentionally Blank)

WHOLE or PARTIALLY PROCESSED GRAINS TEMPLATE

[Commodity Name]

[Commodity ID:]
[Date]
SUPERSEDING
[Former Commodity ID]
[Former Commodity Effective
Date]

This template is constructed for use in developing specifications for the products in the category “Whole or Partially Processed Grains” which includes Barley (BAR), Bagged Whole Grains (KCBG), Buckwheat - Groats, Grits, Flour (BWP), Bulk Soybean Meal (no abbreviation), Dry Edible Beans (DEB), Milled Rice (MR), and Peas and Lentils (PL).

Table of Contents

1 CHANGES FROM PREVIOUS VERSION 3

2 SCOPE 3

3 CLASSIFICATION 3

4 FINISHED PRODUCT CHARACTERISTICS 3

 4.1 Finished Product Analytical Requirements 3

 4.2 Chemical and Physical Properties 3

 4.3 Grading Requirements..... 3

 4.3.1 Official Grade Certificates 4

 4.4 Analytical Testing Methods 4

 4.4.1 Product Verification 4

 4.5 Test Result Precision 5

 4.6 Reporting Results 5

 4.6.1 Certificate of Analysis..... 5

 4.6.2 Notification of Lots Failing to Meet Standards 5

 4.6.3 Official Grade Certificates 5

 4.7 Lot Size Definition 5

 4.8 Sampling Procedures..... 5

 4.8.1 Sample Collection 6

 4.8.2 (Intentionally Blank) 6

 4.9 Uniform Product..... 6

 4.10 Product Age..... 6

 4.11 (Intentionally Blank) 6

5 MANUFACTURER’S REQUIREMENTS 6

 5.1 General Requirements 6

6 SPECIAL REQUIREMENTS 6

 6.1 Pesticide Residues 6

 6.2 (Intentionally Blank) 6

7 MANUFACTURER’S QUALITY ASSURANCE 6

 7.1 Conformance to Specification 7

 7.2 Certificate of Warranty..... 7

 7.3 Third Party Audits 7

 7.4 Retained Samples 7

 7.5 Records Retention 7

 7.6 HACCP Requirement 7

 7.7 Continuing Guarantee..... 7

 7.8 Right to Inspection 7

 7.9 Good Manufacturing Practices 8

 7.10 FD&C Act Compliance 8

 7.11 Currency of Specifications 8

 7.12 (Intentionally Blank) 8

8 QUALITY DISCOUNTS 8

 8.1 Discounts 8

 8.2 Schedule of Discounts 9

 8.3 (Intentionally Blank) 9

9 REFERENCES 9

1 CHANGES FROM PREVIOUS VERSION

Instructions: When reissuing Commodity Requirement Document documents this section should contain a synopsis of changes from previous version. If this is a specification for a new product, then insert “New” here.

2 SCOPE

Instructions: This section should briefly introduce the product and its major components. This is a template. Actual specification performance language will be product dependent.

Note: Commercial Products described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Instructions: Where foods are classified into categories based on their different varieties, flavors, sizes, appearances, etc. the purchaser must specify the categories and sub-categories that are desired. If this section is not applicable then insert “Not applicable”.

4 FINISHED PRODUCT CHARACTERISTICS

Instructions: Section 4 shall define important attributes that affect the final quality of the product and may include items such as ingredient, defect level, shelf life, additives / preservatives, color, flavor, odor, and texture requirements.

Performance language defined in the referenced specification(s), included herein by reference, will not be reproduced in this Commodity Requirement document.

4.1 Finished Product Analytical Requirements

Instructions: This section summarizes analytical and microbiological requirements that are important in determining the final quality and safety of the food product to be purchased.

4.2 Chemical and Physical Properties

Instructions: This table defines the characteristics, units of measure and minimum and maximum levels, as appropriate, for each parameter that is subject to testing and reporting, where they are different from the standards included by reference.

4.3 Grading Requirements

Instructions: Where applicable, include US Grading Standards for the grade designated for the commodity. If Grading is not applicable, insert “Not applicable”.

4.3.1 Official Grade Certificates

Where required, the contractor shall be responsible for arranging and obtaining from AMS, FGIS, or their designated representative, official grading certificates and domestic and export weight and/or grade certificates.

4.4 Analytical Testing Methods

Instructions: This section summarizes the source and specific analytical methods appropriate for the food matrix and analyte to be assayed.

[Note: The following is a sample list of analytical testing methods references. A more complete list will be provided as deliverable C.3.3.8.]

Unless otherwise specified, analytical methods for the finished product and any ingredients shall be those identified in the Official Methods of the Association of Official Analytical Chemists (AOAC), the American Association of Cereal Chemists (AACC), the America Oil Chemists' Society (AOCS), Standards Methods for the Examination of Dairy Products available from the American Public Health Association and/or the FDA Bacteriological Analytical Manual (FDA-BAM), as applicable and in effect on the date of issuance of the Solicitation Document under which the purchase contract was entered into, or in accordance with methods that yield equivalent results.

4.4.1 Product Verification

Instructions: As noted above, additional test methods to those defined in this template may be required for specific products. These methods should be appropriate to the food matrix for the assay designated in Chemical and Physical Properties (Section 4.2) and also in the Certificate of Analysis (Section 4.6.1).

In the event the Government exercises its right, pursuant to FAR clause 52.246.2, Inspection of Supplies—Fixed Price, to perform its own testing, the following testing methods shall apply and will govern determinations as to whether or not the product meets the required specifications.

<u>Sample Table of Analytical Methods</u>		
[Note: This table must be modified to fit each product.]		
	<u>Test</u>	<u>Method</u>
Chemical	Moisture	AOAC 925.10
	Protein (N x 6.25)	AOAC 992.23
	Fat	AOAC 922.06
Physical	Particle Size Distribution	Method Reference TBD
Microbiological	Aerobic Plate Count	FDA-BAM, 8th Ed., Chap 3
	<i>E. coli</i>	FDA-BAM, 8th Ed., Chap 4
	<i>Salmonella</i>	FDA-BAM, 8th Ed., Chap 5

4.5 Test Result Precision

Instructions: Description of the precision which assay results should be reported. This paragraph is not all inclusive; other assays may be required and some assays may be deleted on a product by product basis to appropriately define that product.

[Note: Reporting test method precision will, by necessity, need to be included in deliverable C.3.3.5, standard analytical methods recommendations.]

4.6 Reporting Results

Instructions: This section should describe the process for reporting analytical results.

The contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results shall be evidenced by a Certificate of Analysis (COA). Copies of the original COA must be submitted as part of the invoice package. The COA shall provide the results of all tests specified. If quality discounts are provided in the contract, and the product to be delivered by the contractor falls within the quality discount table, those factors shall be identified on the COA.

All sample analysis may be performed by the supplier's own in-house laboratory. The analytical results of each sample must be reported on the COA, refer to Section 4.6.1.

4.6.1 Certificate of Analysis

Instructions: The COA should contain ALL parameters that are required to define the product and assure quality. Insert Certificate of Analysis table here.

4.6.2 Notification of Lots Failing to Meet Standards

Contractors shall notify the Government immediately of lots that fail to meet contract requirements.

4.6.3 Official Grade Certificates

For products which must meet official grading standards, official grade certificates (or copies thereof) shall be submitted with the payment invoice.

4.7 Lot Size Definition

Instructions: Define appropriate lot size used in commercial practice for the commodity specified. A sample statement defining lot sized follows.

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

Instructions: Define procedures and frequency for collecting representative samples from each lot to be used for assays representative of each lot. Alternatively, sampling plans may be included by reference to recognized sources.

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.8.1 Sample Collection

Instructions: This section shall describe sample collection procedures where required. Sampling procedures may be defined in this section or included by reference to standard procedures described elsewhere.

4.8.2 (Intentionally Blank)

4.9 Uniform Product

The contractor is responsible for ensuring that the commodity is uniform within a lot and between lots and substantially conforms to the required specifications.

4.10 Product Age

Instructions: The product age requirement may vary with the product.

4.11 (Intentionally Blank)

5 MANUFACTURER'S REQUIREMENTS

Instructions: This section is targeted for the supplier of the food item. It lists the requirements that must be met if they are to manufacture the product acceptable to the purchaser.

5.1 General Requirements

Instructions: Insert list of general requirements for manufacturers.

6 SPECIAL REQUIREMENTS

Instructions: If any item is not appropriate for the commodities processed, then state "None" or "Not applicable".

6.1 Pesticide Residues

Manufacturers must be able to demonstrate compliance to pesticide residue levels as provided in 40 CFR 180 through documented analytical results of pesticide residue testing within the previous six (6) calendar months.

6.2 (Intentionally Blank)

7 MANUFACTURER'S QUALITY ASSURANCE

Instructions: This section identifies manufacturer's quality programs and should consistent with current commercial practices.

7.1 Conformance to Specification

The material shall conform to the quality parameters specified herein. For characteristics not required to be reported on the Certificate of Analysis (or Warranty), a signed statement from the Contractor attesting to compliance shall be provided

7.2 Certificate of Warranty

A Certificate of Warranty shall provide warranty that the product complies with all specifications.

7.3 Third Party Audits

Manufacturers must have successfully completed sanitation and quality systems audits conducted by a qualified third-party within the preceding twelve (12) months prior to the date of the awarding of the contract.

7.4 Retained Samples

Contractors shall retain a portion of each composited sample collected during manufacturing (Section 4.9.2) of approximately two and one-half (2.5) pounds for a period of _[TBD]_ months. Retained samples shall be stored under conditions that will preserve the original condition of the sample, providing protection from insects, rodents, and avian pests as well as protection from excess heat or moisture damage.

7.5 Records Retention

Records of all ingredient, components, micronutrient premix certificates of analysis, and production batch records describing the process and any deviations from standard procedures shall be retained by the manufacturer for a period not less than twenty-four (24) months from the date of manufacture.

7.6 HACCP Requirement

Manufacturers must have developed and implemented a Hazard Analysis and Critical Control Points (HACCP) plan for the manufacturing process for delivering food aid commodities. The HACCP plan must be current, up to date, and reflect the actual manufacturing process used to produce the foods. Evidence of implementation and continuation of a HACCP plan must be provided by the manufacturer upon request.

7.7 Continuing Guarantee

The seller shall warrant that the material shall comply with all applicable provisions of the Federal Food, Drug and Cosmetic Acts, all other applicable federal laws and regulations and State and Local codes as amended and that such material is neither adulterated nor misbranded. A letter of Continuing Guaranty shall be furnished by the Contractor annually.

7.8 Right to Inspection

The Government reserves the right to inspect supplier's facilities. Qualification as an approved supplier and/or retention of approved supplier status may be contingent upon inspection of pertinent areas of the supplier's manufacturing facilities.

7.9 Good Manufacturing Practices

[PRODUCT NAME] shall be produced, packaged and stored in accordance with good manufacturing practices as described in 21 CFR 110 – Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food. Such evidence shall consist at a minimum of:

1. A copy of the Contractors Continuing Guarantee,
2. A statement from the Contractor(s) that they are in compliance with the Bioterrorism Act of 2002,
3. A statement from the contractor that they follow cGMPs,
4. A summary of the Contractors HACCP Plan,
5. A summary of the Contractors allergen management plan,
6. A copy of the Table of Contents of the contractor’s Quality Manual which shall include corporate policies and manufacturing procedures and practices,
7. Access to the Contractors most recent GMP/HACCP audit report,
8. Verified Trace & Recall Program.

7.10 FD&C Act Compliance

[PRODUCT NAME] and all ingredients used therein, must conform in every respect to the provisions of the “Federal Food, Drug and Cosmetic Act,” (21 CFR 9) as amended, and the regulations promulgated there under, including any Defect Action Level guidelines issued by the Food and Drug Administration (FDA) which may be applicable to this product. Shipments with counts in excess of the FDA Defect Action Level guidelines will be subject to rejection.

7.11 Currency of Specifications

Where the specifications refer to specific references (e.g. Standards of Identity, 21 CFR or Commercial Item Descriptions – AMS) and an updated specification has been issued by the responsible agency, it is the responsibility of the contractor to conform to the most current specifications available at the time the Invitation to Bid is issued.

7.12 (Intentionally Blank)

8 QUALITY DISCOUNTS

Instructions: This section should contain a description of the discounts schedule and references to the applicable Quality Sections above. Discounts may not apply to all commodities and should state “None” or “Not applicable” and subsections should be deleted.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications listed in Section 4.2, Chemical and Physical Properties, of this Commodity Requirement but falls within the discounts listed in the table in Section 8.2, the product may be delivered to Commodity Credit Corporation, but the purchase price will be reduced in accordance with the schedules of discounts in Section 8.2 for each 100 pounds (cwt.) of commodity delivered.

8.2 Schedule of Discounts

Instructions: Insert table of discount schedules specific to only those products to which discounts apply.

8.3 (Intentionally Blank)

9 REFERENCES

Instructions: This section lists USDA certification contacts, USDA analytical laboratory contacts, as well as sources of documents that may be referenced in the Commodity Requirement. Below are samples of references that may be included.

- A. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- B. *Salmonella* sampling requirements – Investigations Operations Manual 2007, Chap 4, Sampling Schedule, Salmonella sampling Plan:
http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule.html
- C. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscode/html/uscode21/usc_sec_21_00000346---a000-.html
- D. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- E. Soy Products CODEX STAN 175-1989
www.codexalimentarius.net/download/standards/325/CXS_175e.pdf
- F. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- G. (Intentionally Blank)

REVISED

Performance Language

Value Added Soy Products

This performance language document includes information that is intended to be inserted into the commercial products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

Any one of several products derived from processing whole, mature soy beans by removing the oil and/or part or nearly all of the carbohydrates. Products are classified on the basis of their protein content as soy flour, soy protein concentrates, and soy protein isolate. Soy flour may be further processed into textured soy flour products. Soy-Based Milk Replacer contains, at a minimum, 25% protein and 25% fat.

Commercial products described herein shall be the same products offered for sale in the commercial marketplace.

3 CLASSIFICATION

Solicitations for Bids for textured soy flour shall specify the granulation from:

1. ¼ inch (1.5 mm)
2. ¾ inch (20 mm)

4 FINISHED PRODUCT CHARACTERISTICS

4.1 Finished Product Analytical Requirements

Value added soy products must meet the requirements for soy protein products as defined in CODEX Standard 175-1989

www.codexalimentarius.net/download/standards/325/CXS_175e.pdf. Where the requirements for soy protein products in Section 4.2 are different from CODEX Standard 175-1989 the Requirements in Section 4.2 will take precedence. Upon request, manufacturers shall provide evidence that the Protein Digestibility Corrected Amino Acid Score (PDCAAS) which shall be not less than 85% of the reference casein.

4.2 Chemical and Physical Properties

Soy Flour, Defatted			
	Units¹	Minimum	Maximum
Particle Size Distribution		--	--
Through US Std. No. 100 sieve	%	95	--
Aerobic Plate Count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--

Soy Protein Concentrate			
	Units ¹	Minimum	Maximum
Particle Size Distribution		--	--
Through US Std. No. 100 sieve	%	95	--
Aerobic Plate Count	cfu/g	--	30,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--

Soy Protein Isolate			
	Units ¹	Minimum	Maximum
Particle Size Distribution		--	--
Through US Std. No. 100 sieve	%	95	--
Aerobic Plate Count	cfu/g	--	10,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--

Soy Milk Replacer			
	Units ¹	Minimum	Maximum
Protein (N x 6.25) ²	%	25.0	--
Moisture	%	--	8.0
Fat ²	%		30.0
Ash ²	%		8.0
Calcium	%	0.8	
Phosphorus	%	0.7	
Particle Size Distribution			
Through US Std. No. 100 sieve	%	95	--
Aerobic Plate Count	cfu/g	--	10,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--

¹ Percent weight basis.
² Moisture Free Basis

Textured Soy Protein			
	Units ¹	Minimum	Maximum
Protein (N x 6.25) ²	%	50.0	--
Moisture	%	--	10.0
Fat ²	%	--	2.0
Ash ²	%	--	6.5
Crude Fiber ²	%	--	5.0
Water Absorption Ratio	(w/w)	2.5:1	--
Particle Size Distribution			

Through US Std. 1/4 inch sieve	%	May vary as specified in invitation.	
Through US Std. 3/4 inch sieve	%		
Aerobic Plate Count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--
¹ Percent weight basis. ² Moisture Free Basis			

4.3 Grading Requirements

Not Applicable

4.4 Analytical Testing Methods

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.6.1 Sample Certificate of Analysis

Sample Certificate of Analysis Soy Flour, Defatted Modify as necessary for specific products.					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size		
Car/Truck ID:					
Lot Number:			Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS		Bags	
		Units¹	Limit	Test Result	Pass (Y/N)
Moisture		%	10.0 Max		
Protein (Nx6.25) ²		%	50.0 Min		
Fat ²		%	2.0 Max		
Ash ²		%	8.0 Max		
Crude Fiber ²		%	5.0 Max		
Particle Size Distribution					
Through US Std. No. 100 sieve		%	95 Min		
Aerobic Plate Count		cfu/g	50,000 Max		
<i>E. coli</i>		cfu/g	Negative to test		
<i>Salmonella</i> (Category II)		Presence / Absence	Negative to test		
Comments:					
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.					
Signature: _____			Date: _____		
Title: _____					
Telephone: _____					
FAX: _____					
¹ Percent weight basis.					
² Moisture free basis					

Sample Certificate of Analysis Soy Protein Concentrate Modify as necessary for specific products.					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size		
Car/Truck ID:					
Lot Number:			Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS		Bags	
		Units¹	Limit	Test Result	Pass (Y/N)

Sample Certificate of Analysis Soy Protein Concentrate Modify as necessary for specific products.				
Moisture	%	10.0 Max		
Protein (Nx6.25) ²	%	65.0 Min		
Fat ²	%	2.0 Max		
Ash ²	%	8.0 Max		
Crude Fiber ²	%	6.0 Max		
Particle Size Distribution				
Through US Std. No. 100 sieve	%	95 Min		
Aerobic Plate Count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis.				
² Moisture free basis				

Sample Certificate of Analysis Soy Protein Isolate Modify as necessary for specific products.					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size		
Car/Truck ID:					
Lot Number:			Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS		Bags	
		Units¹	Limit	Test Result	Pass (Y/N)
Moisture		%	10.0 Max		
Protein (Nx6.25) ²		%	90.0 Min		
Fat ²		%	2.0 Max		
Ash ²		%	8.0 Max		
Crude Fiber ²		%	0.5 Max		
Particle Size Distribution					
Through US Std. No. 100 sieve		%	95 Min		
Aerobic Plate Count		cfu/g	50,000 Max		
<i>E. coli</i>		cfu/g	Negative to test		
<i>Salmonella</i> (Category II)		Presence / Absence	Negative to test		
Comments:					

Sample Certificate of Analysis Soy Protein Isolate Modify as necessary for specific products.	
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.	
Signature: _____ Title: _____ Telephone: _____ FAX: _____	Date: _____
¹ Percent weight basis. ² Moisture free basis	

Sample Certificate of Analysis Soy Milk Replacer Modify as necessary for specific products.					
Invitation:			Pack Date:		
Export Contract VEPE:			Mill Point:		
Notice to Deliver VEPE:			Pack Size:		
Car/Truck ID:					
Lot Number:			Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS	Bags		
		Units¹	Limit	Test Result	Pass (Y/N)
Moisture		%	8.0 Max		
Protein (Nx6.25) ²		%	25.0 Min		
Fat ²		%	30.0 Max		
Ash ²		%	8.0 Max		
Calcium		%	0.8 Min		
Phosphorus		%	0.7 Min		
Particle Size Distribution					
Through US Std. No. 100 sieve		%	95 Min		
Aerobic Plate Count		cfu/g	50,000 Max		
<i>E. coli</i>		cfu/g	Negative to test		
<i>Salmonella</i> (Category II)		Presence / Absence	Negative to test		
Comments:					
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.					
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____		
¹ Percent weight basis. ² Moisture free basis					

Sample Certificate of Analysis Textured Soy Flour Modify as necessary for specific products.				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD, MT max)		
Contracted Quantity	MT	LBS	Bags	
		Units¹	Limit	Test Result
				Pass (Y/N)
Moisture		%	10.0 Max	
Protein (Nx6.25) ²		%	50.0 Min	
Fat ²		%	2.0 Max	
Ash ²		%	8.0 Max	
Crude Fiber ²		%	5.0 Max	
Particle Size Distribution				
Through US Std. 1/4 inch sieve		%	May vary as specified in invitation.	
Through US Std. 3/4 inch sieve		%		
Aerobic Plate Count		cfu/g	50,000 Max	
<i>E. coli</i>		cfu/g	Negative to test	
<i>Salmonella</i> (Category II)		Presence / Absence	Negative to test	
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____		Date: _____		
¹ Percent weight basis.				
² Moisture free basis				

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

4.10 Product Age

Unless otherwise specified in the solicitation, contract, or purchase order, the Value Added Soy Products shall be processed and/or packaged not more than 60 days prior to delivery to the purchaser.

9 REFERENCES

- A. Good Manufacturing Practices
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr110_07.html
- B. Soy Products CODEX STAN 175-1989
<http://www.codexalimentarius.net/search/advancedsearch.do>
- C. Microbiological Assay Methods, FDA-BAM
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>
- D. FDA Regulation, Title 21, Chapter 9, Subchapter IV, § 346a Tolerances and exemptions for pesticide chemical residues.
http://www4.law.cornell.edu/uscode/search/display.html?terms=Pesticide&url=/uscodes/html/uscode21/usc_sec_21_00000346---a000-.html
- E. Pesticide Residue 40 CFR 180
http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html
- F. (Intentionally Blank)

REVISED

Performance Language

Vegetable Oil

This performance language document includes information that is intended to be inserted into the Vegetable Oils/Fats template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

Commonly used commercial salad vegetable oils are covered in this Commodity Requirement. The sources of salad vegetable oils are: canola, corn, cottonseed, olive, peanut, safflower, soybean, sesame and sunflower seed oil. These vegetable oils consist mainly of any one oil, but blends of several commercial vegetable salad oils may be acceptable, if blends are permitted. Blends are defined by order of predominance of the composition.

3 CLASSIFICATION

Solicitations for Bids for vegetable oil shall specify the source of vegetable oil to be delivered. The salad oils, vegetable shall be Type I and shall be refined, bleached, and deodorized canola (rapeseed or low erucic acid rapeseed), corn, cottonseed, olive (refined), safflower, soybean, sesame, sunflower, or any other vegetable oil or combination of these oils.

4.1 Finished Product Analytical Requirements

The vegetable oil delivered shall meet the requirements for Type I Vegetable oil, Section 6.1 of the latest revisions and amendments for Commercial Item Description (CID) A-A-20091D (May 7, 200) at:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3006232>, except as these differ from chemical and physical requirements listed in Section 4.2 'Chemical and Physical Properties' which will take precedence. In addition, vegetable oil products shall be fortified with retinyl palmitate (vitamin A).

4.2 Chemical and Physical Properties

In addition to the chemical and physical requirements prescribed for Type I oil in Sections 5 and 6 of Commercial Item Description A-A-20091D, the following requirements apply:

Vegetable Oil Chemical and Physical Properties ¹			
	Units	Minimum	Maximum
Retinyl Palmitate (Vitamin A)	IU/g	60	75
Flavor	Organoleptic	7	--
AOM	hours	15	--
Flash Point	°F	620	--
Smoke Point	°F	420	--
Fire Point	--	670	--
Appearance	Visual	--	Clear to hazy
Color ²	Lovibond	--	3.0 R
Refractive Index (60 °C)	%	<i>Typical for source</i>	--
Saponification Value	mg KOH/g %	<i>Typical for source</i>	--
Unsaponifiable Matter (%)	%	--	1.5
Antioxidants (ppm) ³	ppm	--	200

Vegetable Oil Chemical and Physical Properties ¹			
	Units	Minimum	Maximum
Dimethylpolysiloxane (if added)	ppm	--	10 (if added)
Specific Gravity (25 °C)	g/cc	<i>Typical for source</i>	--
Insoluble Impurities	%	--	0

¹ Determination shall be made within seven days after packaging. Samples submitted for testing shall be in a completely filled container.
² Typical of source oil.
³ Maximum Of 0.06 percent free fatty acid will be acceptable if propyl gallate is added as an antioxidant.

4.3 Grading Requirements

Not Applicable

4.4 Analytical Testing Methods

[Note: a complete list of analytical testing methods reference will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

The test results for free fatty acids and moisture and volatile matter shall be reported to the nearest 0.01 percent. The test results for peroxide value and linolenic acid shall be reported to the nearest 0.1 meq/kg and one percent, respectively. The test results for Lovibond color, fat stability, and iodine value shall be reported to the nearest whole number. The test results for insoluble impurities shall be “detected” or “not detected”. The test results for the AOCS cold test shall be “pass” or “fail”. Any result not conforming to the analytical requirements shall be cause for rejection of the lot.

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Vegetable Oil				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD, MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
Salad Oil Source:				
	Units	Limit	Test Result	Pass (Y/N)
Retinyl palmitate (Vitamin A).	IU/g	60 min / 75 max		
Color ¹	5.25" Lovibond	<i>Typical of source</i>		
Free Fatty Acid	(% as Oleic)	0.05		
Peroxide Value	meq/kg	1.0		
Moisture	(%-KF)	0.06		
Flavor	organoleptic	7		

Sample Certificate of Analysis Vegetable Oil				
AOM	hours	5		
Cold Test ²	hours	5.5		
Appearance	Visual	Clear to brilliant		
Antioxidants (<i>if added</i>)	ppm	200		
Dimethylpolysiloxane (<i>if added</i>)	ppm	10		
Insoluble Impurities	%	none		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Typical of source: corn 3.0R, Soybean 1.0R ² Cold test is not required for peanut oil or soybean oil.				

4.7 Lot Size Definition

[Note: Recommendations for lot size definitions for the products contained in the template will be provided as Deliverable C.3.3.4.]

4.8 Sampling Procedures

[Note: Recommendations for sampling protocols for the products contained in the template will be provided as Deliverable C.3.3.1.]

5.1 General Requirements

All types of vegetable salad oils shall be clear and brilliant when held at 21.1 ° to 29.4 °C (70 ° to 85 °F). Heavy metal scavengers, antifoaming agents, and antioxidants can be added provided levels of use are in accordance with appropriate Food and Drug Administration regulations.

Vegetable oil shall have a light viscosity and shall not have a heavy oily mouth feel. It shall have a clean, fresh flavor and shall be free from rancid, beany, painty, sour, or other objectionable flavors or odors.

All ingredients shall be clean, sound, wholesome, and free from evidence of rodent or insect infestation. Vegetable oils shall be free from foreign material, such as, but not limited to, dirt, insect parts, hair, wood, glass, or metal.

8.1 Discounts

If the product to be delivered by the contractor does not meet the quality specifications of CID A-A-20091D, dated May 7, 2002, the commodity may be delivered; but the purchase price shall be reduced in accordance with the schedules of discounts for each 100 pounds (net weight) of product delivered in Section 8.2.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Color - Red			Excess Free Fatty Acid		
2.1 or 2.2		0.05	0.06 or 0.07	%	0.10
2.3 or 2.4		0.10	0.08 or 0.09	%	0.20
2.5 or 2.6		0.15	0.10 or 0.11	%	0.30
Excess Peroxide Value					
1.1 – 1.3	Meq/kg	0.35			
1.4 – 1.5	Meq/kg	0.50			

9 REFERENCES

A. Copies of the Official Methods of the American Oil Chemists' Society may be obtained from: American Oil Chemists' Society, P.O. Box 3489, Champaign, IL 61826-3489, telephone (217) 359-2344 or Fax (217) 351-8091.

<http://www.aocs.org/>

B. (Intentionally Blank)

Performance Language

Wheat-Soy Blend

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers wheat-soy blend (WSB) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Wheat-soy blend (WSB) is primarily used as a supplemental food for emergency rations, displaced persons assistance, weaning food in Maternal Child Health Programs (MCH) and other programs. WSB is composed of bulgur flour and wheat protein concentrate or straight grade flour and wheat protein concentrate, soy flour, defatted (toasted), soybean oil (refined, deodorized, bleached), a minerals premix and a vitamins and antioxidant premix.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or as an extender to other foods. The finished product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical, Physical and Microbiological Properties

Wheat-Soy Blend			
Chemical	Units¹	Minimum	Maximum
Moisture	%	--	11.0
Protein (N x 6.25) ²	%	20.0	--
Fat ²	%	6.0	--
Ash ²			6.6
Crude Fiber ²	%	--	2.5
Lysine	%	0.9	--
Vomitoxin	ppm	--	1.0
Micronutrients			
	Units	Minimum	Maximum
Iron	mg/100 g	14.7	30.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Material through US Std. No. 70 sieve	%	97.0	--
Microbiological			
	Units	Minimum	Maximum
Aerobic plate count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i>	Present /	Negative to	--

Wheat-Soy Blend			
	Absent	test	
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test	--
¹ Percent is on a weight/weight basis			
² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat, ash, crude fiber, lysine and particle size shall be reported to the nearest 0.1 percent. Results for vomitoxin shall be reported to the nearest whole number. Test results for iron shall be reported to the nearest 0.1 mg/100 g product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits. *Staphylococcus aureus*, coagulase positive, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test. Calcium and salt, if added as separate ingredients, shall be reported to the nearest 1 mg/100 g product

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Wheat-Soy Blend				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size:		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	_____ MT	_____ LBS	_____ Bags	
	Units ¹	Limit	Test Result	Pass (Y/N)
Moisture	%	11.0 Max		
Protein (N x 6.25) ²	%	20.0 Min		
Fat ²	%	6.0 Min		
Ash ²		6.6 Max		
Crude Fiber ²	%	2.5 Max		
Lysine	%	0.9 Min		
Vomitoxin	ppm	1.0 Max		
Iron	mg/100g	14.7 Min- 30.0 Max		
Vitamin A palmitate	IU/lb	8,400 Min – 16,000 Max		
Material through a US Standard No. 70 sieve	%	97.0 Min		

Sample Certificate of Analysis Wheat-Soy Blend				
Dispersibility	Essentially free from lumps or balling when mixed with water.	Pass/Fail		
Total Plate Count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Absent / Present	Negative to test		
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date: _____	
¹ Percent weight basis ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Wheat-soy blend shall contain bulgur flour and wheat protein concentrate or straight grade flour (cooked) and wheat protein concentrate; defatted, toasted soy flour, vegetable oil and vitamin mineral premixes at levels required to achieve the specified final product characteristics defined in Section 4.2 and shall be produced accordance with good manufacturing practices.

5.2 Formulation

Use of approved alternate ingredients (full-fat soy flour as a replacement for defatted soy flour) alters the formula percentages of ingredients and changes to the percentages must be made. The final product shall meet all requirements defined in Section 4.2.

Formulation		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Wheat Fractions		1458
Bulgur flour		[1058]
Wheat protein concentrate, enzyme inactivated		[400]
OR		
Straight grade flour (cooked)		[758]
Wheat protein concentrate		[700]
Soy Flour, Defatted, Toasted	21.9	400

Vegetable Oil	5.5	80
Mineral Premix	3.0	60
Vitamin Premix	0.1	2
Total	100.0	2,000

5.3 Ingredient Specifications

Ingredients listed in Sections 5.3.1 – 5.3.6 will be used in the preparation of wheat-soy blend.

Wheat shall be tested for vomitoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS) and any wheat testing higher than 2 ppm shall not be used in production of the commodity. The final product shall not contain more than 1 ppm of vomitoxin.

5.3.1 Bulgur Flour

Bulgur shall be milled in the United States from cleaned wheat of any of the classes defined in the “Official United States Standards for Grain,” (available at: <http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>) except mixed wheat and red durum wheat. The wheat will contain not more than 4.0 percent of damaged kernels. It will not be of distinctly low quality, light smutty, smutty, light garlicky, garlicky, weevily, ergoty, treated, musty, sour, or heated; and it shall not have any commercially objectionable foreign odor as these terms are interpreted and applied under the “Official United States Standards for Grain.”

The wheat shall be processed by washing, scouring, soaking in water, and cooking in water or in steam at atmospheric or higher pressures, then drying and partial debranning. The cooked product will be gelatinized but not dextrinized and have a translucent appearance. The partially debranned, cooked, and dried wheat will be cracked and further reduced in whole or in part to a flour-like fineness by grinding in suitable equipment.

5.3.1.1 Analysis

Bulgur flour shall conform to these requirements:

Bulgur Flour			
Assay	Units¹	Requirements	
		Min.	Max.
Moisture	%	---	11.5
Protein (Nx5.7) ²	%	12.0	--
Ash ²	%	---	1.8
Crude Fiber ²	%	--	2.0
Material through a U.S. Std No. 70 Sieve	%	97.0	--
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Wheat Protein Concentrate, Enzyme-Inactivated

Wheat protein concentrate shall be obtained from total millrun middlings derived from normal flour milling operations.

The wheat protein concentrate will be prepared by regrinding and sifting, fine-grinding and air classification, or other similar means of obtaining the desired fraction from the starting materials. Either the starting materials or the product after grinding and sieving will be heated in moist condition so as to inactivate enzymes, and to reduce any raw or bitter flavors, without significantly damaging the nutritive properties of the product as would accompany any toasting sufficient to cause color darkening. If desired, the protein concentrate may be heat processed in a mixture with straight-grade flour or wheat in the bulgur process.

The wheat protein concentrate may be combined with the wheat being processed into bulgur at a point in the process that provides for cooking of the two ingredients as a mixture, provided that the wheat meets all of the specifications listed for bulgur fiber content. However, in the subsequent milling and sifting process, a product shall be provided which, in combination with the other ingredients, meets all of the product specifications and particularly that for fiber content.

5.3.2.1 Analysis

The wheat protein concentrate shall conform to these requirements:

Wheat Protein Concentrate			
Assay	Units ¹	Requirements	
		Min.	Max.
Moisture	%	---	13.0
Protein (N x 6.25) ²	%	23.3	--
Fat ²	%	4.7	--
Ash ²	%	---	5.6
Crude Fiber ²	%	--	3.5
Lysine	%	1.0	--
Peroxidase Test		Negative to test	--
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.3 Wheat flour, straight grade, cooked

Straight-grade flour shall be milled from cleaned and normally scoured wheat.

The straight-grade flour shall comply with the Definitions and Standards of Identity for Wheat Flour, as defined under the “Federal Food Drug, and Cosmetic Act,” and regulations promulgated there under (21 CFR 137.105, found at: http://a257.g.akamaitech.net/7/257/2422/26mar20071500/edocket.access.gpo.gov/cfr_2007/aprqr/21cfr137.105.htm). This flour will be further processed in such a manner as to effect substantially complete gelatinization and moderate degradation of the starch, inactivation of enzymes, and essential freedom from a raw starch flavor or

odor, without significantly damaging the nutritive properties of the product as would accompany any toasting sufficient to cause color darkening. (If desired, the wheat flour may be processed in a mixture with wheat protein concentrate).

Straight-grade flour may be combined with wheat protein concentrate and processed as a mixture, if desired.

5.3.3.1 Analysis

The straight grade flour) shall conform to these requirements:

Wheat flour, straight grade, cooked			
Chemical and Physical Requirements			
Assay	Units ¹	Requirements	
		Min.	Max.
Moisture	%	---	14.0
Protein (N x 5.7) ²		11.0	--
Ash ²	%	---	0.56
Peroxidase Test		Negative to test	--
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.4 Soy Flour

5.3.4.1 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling.

5.3.4.1.1 Analysis

The soy flour, defatted (toasted) conform to these requirements:

Soy Flour, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (N x 6.25) ²	%	50.0	--
Fat ²	%	--	1.0
Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	

Odor	--	Neutral to nutty
Taste	--	Pleasant, neutral to slightly nutty
Texture	--	A homogeneous flour
¹ Percent on a weight/weight basis		
² Moisture-free basis		

5.3.4.2 Soy Flour, Full Fat

As an alternate to the use of 400 pounds of defatted soy-flour and 80 pounds of soybean oil, these products may be replaced with 480 pounds of full fat soy-flour. If additional soybean oil is required to attain minimum fat content specified for the blend, the additional oil will replace an equal amount of bulgur or straight-grade flour.

Soy flour, full fat shall be the screened, finely-ground product obtained from selected soybeans by cleaning, cracking, (optional) dehulling, tempering, cooking (full cook with color change to light yellow or golden buff), and cooling.

5.3.4.2.1 Analysis

The soy flour, full fat shall conform to these requirements:

Soy Flour, Full Fat			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (N x 6.25) ²	%	44.0	--
Fat ²	%	22.0	--
Crude Fiber ²	%	--	3.0
Ash ²	%	--	6.0
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.5 Soybean Oil

Soy oil, refined, deodorized, and stabilized, shall contain 0.005 percent citric acid added on the cooling side of deodorization. The soy oil shall comply with the requirements of the latest revisions and amendments for Commercial Item

Description A-A-20091D (May 7, 2002), <http://www.ams.usda.gov/fqa/aa20091d.htm>; type IV not winterized salad oil which is incorporated herein by reference.

Before addition to the product, the oil may be stabilized by the addition of butylated hydroxy anisole and butylated hydroxy toluene, each at a level of 2.5 mg. per 100 grams of formulated product. **Caution:** Antioxidant may be added to either the soy oil or to the vitamin antioxidant premix, but it shall not be added to both. [See Section 5.3.6.2]

5.3.6 Micronutrient Fortification

5.3.6.1 Mineral Premix

The minerals and vitamin premix shall not be combined and shall be added to the formulation separately.

The mineral premix shall contain the micronutrients listed in this Section, at the stated levels, and mineral premix identified as Option 1 shall be added to wheat-soy blend at the rate of sixty (60) pounds per 2,000 pound batch of finished product. The weight of other mineral premix options vary and any deviation in weight from 60 pounds shall be added or subtracted, as appropriate, from the total final product batch weight.

Weight of Minerals per 60 pounds of Premix

	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
	Lbs							
Calcium Phosphate, Tribasic	40.00			26.00	18.00	18.00		
Calcium Carbonate		36.00	36.00		12.00	12.00	10.00	10.00
Sodium Phosphate, Monobasic		32.00			16.00			
Calcium Phosphate, Dibasic				12.00				44.00
Potassium Phosphate, Monobasic			32.00			16.00		
Calcium Phosphate, Dibasic, Anhydrous							34.00	
Zinc Sulfate, Monohydrate ¹	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Ferrous Fumarate, FCC Grade, Purified	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Magnesium Oxide (MgO)	2.75	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Iodized Salt (0.007% I ₂)	16.25	16.25	16.25	16.25	16.25	16.25	16.25	16.25
Mineral Premix Total Weight, lbs	60.17	88.17	88.17	58.17	66.17	66.17	64.17	74.17

¹ Zinc sulfate heptahydrate (0.4 lbs) may be used as an alternative to 0.25 lbs zinc sulfate monohydrate.

If calcium and phosphorus ingredients and/or salt are added independently from a mineral premix, verification of the correct addition level must be documented, by assay, on the Certificate of Analysis.

5.3.6.2 Vitamin Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added to wheat-soy blend at the rate of two (2) pounds per 2,000 pound batch.

Weight of Vitamins per 2 Pounds of Premix

Vitamins	g
Thiamine mononitrate	2.5
Riboflavin	3.5
Niacin	45.0
Folic Acid	1.8
Pyridoxine hydrochloride	1.5
Calcium D-pantothenate	25.0
Vitamin B ₁₂	0.012
Butylated hydroxy anisole ¹	20.0
Butylated hydroxy toluene ¹	20.0
Ascorbic Acid (Stabilized, ethyl cellulose coated) ²	364
	IU
Vitamin A-Palmitate (Stabilized)	21,000,000
Vitamin D (Stabilized)	1,800,000
Alpha tocopherol acetate	68,000
Carrier ³	As Required to reach total weight of 2 lbs.
	Lbs
Vitamin Premix, Total	2.0

¹ If antioxidants (BHA and BHT) are added in the soy oil (Section 5.4), omit from this premix.
² Ascorbic acid (stabilized), ethyl cellulose (coated). Ascorbic acid content shall be not less than 364 g.
³ Soy flour, defatted (toasted) or starch to reach total weight.

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
11.1 or 11.2	%	0.10	19.9 – 19.8	%	0.10

11.3 or 11.4	%	0.20	19.7 – 19.6	%	0.20
11.5	%	0.35	19.5	%	0.35
Excess Crude Fiber			Excess Ash		
2.6 - 2.7	%	0.10	6.7 or 6.8	%	0.10
2.8 - 2.9	%	0.20	6.9 or 7.0	%	0.20
3.0	%	0.35	7.1	%	0.35
Deficient Fat			Excess Iron		
5.9 or 5.8	%	0.10	30.1 – 31.5	mg / 100 g	0.10
5.7 or 5.6	%	0.20	31.6 – 33.1	mg / 100 g	0.20
5.5	%	0.35	33.2 – 35.0	mg / 100 g	0.35
Insufficient Material Through U.S Std. No. 70 Sieve			Deficient Lysine		
96 or 95	%	0.10	0.8	%	0.10
94 or 93	%	0.20	0.7	%	0.20
92	%	0.35			

9 REFERENCES

- A. Bostwick consistometer sources: Fisher Scientific, catalog number 15-347-50, or VWR, cat No. 23270-004 or equivalent.

https://www.fishersci.com/wps/portal/SEARCHRESULTS?ru=http%3A%2F%2Fprodwcssserver%2Fwebapp%2Fwcs%2Fstores%2Fservlet%2FSearch&searchPref=no&position=search&preferProd=unchecked&searchType=Rapid&catalogCode=RE_SC&keyWord=15-347-50&catCode=ALL

OR

http://www.vwrsp.com/catalog/product/index.cgi?catalog_number=23270-004&inE=1&highlight=23270-004&from_search=1

- B. (Intentionally Blank)

REVISED

Performance Language

Wheat-Soy Milk

This performance language document includes information that is intended to be inserted into the Blended and Fortified products template. Applicable sections omitted from this performance language document may be found in the template.

2 SCOPE

This Commodity Requirement specification covers wheat-soy milk (WSM) produced for the food assistance programs.

3 CLASSIFICATION

Not applicable

4 FINISHED PRODUCT CHARACTERISTICS

Wheat-soy milk (WSM) is used as a supplemental food for emergency rations and displaced persons assistance, as a weaning food in Maternal Child Health (MCH) Programs and in other programs. WSM is composed of bulgur flour and wheat protein concentrate or straight grade flour and wheat protein concentrate, soy flour, defatted (toasted), non-fat dry milk, soybean oil (refined, deodorized, bleached), a minerals premix and a vitamins and antioxidant premix.

4.1 Finished Product Analytical Requirements

The product shall be of small particle size suitable for use as a dietary supplement for infants and children for serving as porridge, gruel, or as an extender to other foods. The finished product shall meet the chemical, physical, and microbiological requirements defined in Section 4.2.

4.2 Chemical and Physical Properties

Wheat-Soy Milk Chemical, Physical and Microbiological Properties			
Chemical	Units ¹	Minimum	Maximum
Moisture	%	--	9.5
Protein (N x 6.25) ²	%	20.0	--
Fat ²	%	6.0	--
Ash ²			6.6
Crude Fiber ²	%	--	2.5
Lysine	%	0.9	--
Vomitoxin	Ppm	--	1.0
Micronutrients			
	Units	Minimum	Maximum
Iron	mg/100 g	14.7	30.0
Vitamin A Palmitate	IU/lb	8,400	16,000
Physical			
	Units	Minimum	Maximum
Color, Munsell Color Std			
Containing Bulgur #1.1Y +7.88 /2.7	--	Identical to or lighter in grayish yellow beige	
Containing St. Grade Flour #2.5Y +8.26 / 2.8 (ST)		Identical to or lighter in pale yellow beige	
Material through US Std. No. 70	%	97.0	--

Wheat-Soy Milk Chemical, Physical and Microbiological Properties			
sieve			
Microbiological	Units	Minimum	Maximum
Aerobic Plate Count	cfu/g	--	50,000
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Salmonella</i>	Present / Absent	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test	--
¹ Percent is on a weight/weight basis ² Moisture free basis			

4.4 Analytical Testing Methods

[Note: appropriate analytical testing methods will be provided as deliverable C.3.3.8.]

4.5 Test Result Precision

Report all percentages on a weight basis. Results for moisture, protein (N x 6.25), fat, ash, crude fiber, lysine and particle size shall be reported to the nearest 0.1 percent. Results for vomitoxin shall be reported to the nearest whole number. Test results for iron shall be reported to the nearest 0.1 mg/100 g product. Vitamin A palmitate shall be to the whole number per pound of product. Aerobic plate count shall be reported to two (2) significant digits. *Staphylococcus aureus*, coagulase positive, *E. coli*, and *salmonella* should be reported as 'negative' (or 'positive') to test. Calcium and salt, if added as separate ingredients, shall be reported to the nearest 1 mg/100 g product

4.6.1 Certificate of Analysis

Sample Certificate of Analysis Wheat-Soy Milk				
Invitation:		Pack Date:		
Export Contract VEPE:		Mill Point:		
Notice to Deliver VEPE:		Pack Size		
Car/Truck ID:				
Lot Number:		Lot Quantity (TBD MT max)		
Contracted Quantity	MT	LBS	Bags	
	Units¹	Limit	Test Result	Pass (Y/N)
Moisture	%	9.5 Max		
Protein (N x 6.25) ²	%	20.0 Min		
Fat ²	%	6.0 Min		
Ash ²		6.6 Max		
Crude Fiber ²	%	2.5 Max		

Sample Certificate of Analysis Wheat-Soy Milk				
Lysine	%	0.9 Min		
Iron	mg/100g	14.7 Min- 30.0 Max		
Vitamin A palmitate	IU/lb	8,4000 Min – 00 Max		
Material through a US Standard No. 70 sieve	%	97.0 Min		
Total Plate Count	cfu/g	50,000 Max		
<i>E. coli</i>	cfu/g	Negative to test		
<i>Salmonella</i>	Absent / Present	Negative to test		
<i>Staphylococcus aureus</i> , Coagulase Positive	cfu/g	Negative to test		
Comments:				
I certify that this COA is true and that the samples taken and referenced herein came from the lot number shown on this form. This certification is executed with the full understanding of the provisions of 18 USC 1001 and 31 USC 3729.				
Signature: _____ Title: _____ Telephone: _____ FAX: _____			Date:	
¹ Percent weight basis ² Moisture free basis				

5 MANUFACTURER'S REQUIREMENTS

5.1 General Requirements

Wheat-soy milk shall contain bulgur flour and wheat protein concentrate or straight grade flour (cooked) and wheat protein concentrate; defatted, toasted soy flour, vegetable oil and vitamin mineral premixes at levels required to achieve the specified final product characteristics defined in Section 4.2.

5.2 Formulation

Use of approved alternate ingredients (full-fat soy flour as a replacement for defatted soy flour and soy oil) alters the formula percentages of ingredients and changes to the percentages must be made. The final product shall meet all requirements defined in Section 4.2.

Formulation		
Ingredients	Percent (w/w)	Pounds per 2000-lb Batch
Wheat Fractions		1252
Bulgur flour		[912]
Wheat protein concentrate, enzyme		[344]

inactivated		
OR		
Straight grade flour (cooked)		[654]
Wheat protein concentrate		[602]
Soy Flour, Defatted, Toasted	21.9	300
Nonfat Dry Milk		300
Vegetable Oil	5.5	80
Mineral Premix	3.0	60
Vitamin Premix	0.1	2
Total	100.0	2,000

5.3 Ingredient

Ingredients listed in Sections 5.3.1 – 5.3.7 will be used in the preparation of wheat-soy milk.

Wheat shall be tested for vomitoxin in accordance with procedures approved by Federal Grain Inspection Service (FGIS) and any wheat testing higher than 2 ppm shall not be used in production of the commodity. The final product shall not contain more than 1 ppm of vomitoxin.

5.3.1 Bulgur Flour

Bulgur shall be milled in the United States from cleaned wheat of any of the classes defined in the “Official United States Standards for Grain,” except mixed wheat and red durum wheat. Standards are available at:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=sq-ous>

The wheat will contain not more than 4.0 percent of damaged kernels. It will not be of distinctly low quality, light smutty, smutty, light garlicky, garlicky, weevily, ergoty, treated, musty, sour, or heated; and it shall not have any commercially objectionable foreign odor as these terms are interpreted and applied under the “Official United States Standards for Grain.”

The wheat shall be processed by washing, scouring, soaking in water, and cooking in water or in steam at atmospheric or higher pressures, then drying and partial debranning. The cooked product will be gelatinized but not dextrinized and have a translucent appearance. The partially debranned, cooked, and dried wheat will be cracked and further reduced in whole or in part to a flour-like fineness by grinding in suitable equipment.

5.3.1.2 Analysis

Bulgur flour shall conform to these requirements:

Bulgur Flour			
Assay	Units ¹	Requirements	
		Min.	Max.

Moisture	%	---	11.5
Protein (N x 5.7) ²	%	12.0	--
Ash ²	%	---	1.8
Crude Fiber ²	%	--	2.0
Material through a U.S. Std No. 70 Sieve	%	97.0	--
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.2 Wheat Protein Concentrate, Enzyme-Inactivated

Wheat protein concentrate shall be obtained from total millrun middlings derived from normal flour milling operations. The wheat protein concentrate will be prepared by regrinding and sifting, fine-grinding and air classification, or other similar means of obtaining the desired fraction from the starting materials. Either the starting materials or the product after grinding and sieving will be heated in moist condition so as to inactivate enzymes, and to reduce any raw or bitter flavors, without significantly damaging the nutritive properties of the product as would accompany any toasting sufficient to cause color darkening. If desired, the protein concentrate may be heat processed in a mixture with straight-grade flour or wheat in bulgur process.

The wheat protein concentrate may be combined with the wheat being processed into bulgur at a point in the process that provides for cooking of the two ingredients as a mixture, provided that the wheat meets all of the specifications listed for bulgur fiber content. However, in the subsequent milling and sifting process, a product shall be provided which, in combination with the other ingredients, meets all of the product specifications and particularly that for fiber content.

5.3.2.1 Analysis

Wheat protein concentrate shall conform to these requirements:

Wheat Protein Concentrate			
Assay	Units ¹	Requirements	
		Min.	Max.
Moisture	%	---	13.0
Protein (N z 6.25)	%	23.3	--
Fat ²	%	4.7	--
Ash ²	%	---	5.6
Crude Fiber ²	%	--	3.5
Lysine	%	1.0	--
Peroxidase Test		Negative to test	--
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.3 Wheat flour, straight grade, cooked

Straight-grade flour shall be milled from cleaned and normally scoured wheat. The straight-grade flour shall comply with the Definitions and Standards of Identity for Wheat Flour, as defined under the “Federal Food Drug, and Cosmetic Act,” and regulations promulgated there under (21 CFR 137.105, found at: http://a257.g.akamaitech.net/7/257/2422/26mar20071500/edocket.access.gpo.gov/cfr_2007/a/prqtr/21cfr137.105.htm). This flour will be further processed in such a manner as to effect substantially complete gelatinization and moderate degradation of the starch, inactivation of enzymes, and essential freedom from a raw starch flavor or odor, without significantly damaging the nutritive properties of the product as would accompany any toasting sufficient to cause color darkening. (If desired, the wheat flour may be processed in a mixture with wheat protein concentrate).

Straight-grade flour may be combined with wheat protein concentrate and processed as a mixture, if desired.

5.3.3.1 Analysis

Wheat flour, straight grade shall conform to these requirements:

Wheat flour, straight grade, cooked			
Assay	Units ¹	Requirements	
		Min.	Max.
Moisture	%	---	14.0
Protein (N x 5.7) ²		11.0	--
Ash ²	%	---	0.56
Peroxidase Test		Negative to test	--

¹ Percent on a weight/weight basis
² Moisture-free basis

5.3.4 Soy Flour

5.3.4.1 Soy Flour, Defatted (Toasted)

Soy flour, defatted (toasted) shall be the screened, finely ground product obtained from selected soybeans by cleaning, cracking, dehulling, tempering, flaking, defatting with hexane, desolventizing, deodorizing, toasting (full cook with color change to light yellow or golden buff), and cooling.

5.3.4.1.1 Analysis

The soy flour, defatted (toasted) shall conform to these requirements:

Soy Flour, Defatted (Toasted)			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	50.0	--
Fat ²	%	--	1.0

Crude Fiber ²	%	--	3.5
Ash ²	%	--	6.5
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	
¹ Percent on a weight/weight basis			
² Moisture-free basis			

5.3.4.2 Soy Flour, Full Fat

As an alternate to the use of 300 pounds of defatted soy-flour and 80 pounds of soybean oil, these products may be replaced with 380 pounds of full fat soy-flour. If additional soybean oil is required to attain minimum fat content specified for the blend, the additional oil will replace an equal amount of bulgur or straight-grade flour.

Soy flour, full fat shall be the screened, finely-ground product obtained from selected soybeans by cleaning, cracking, (optional) dehulling, tempering, cooking (full cook with color change to light yellow or golden buff), and cooling.

5.3.4.2.1 Analysis

The soy flour, full fat shall conform to these requirements:

Soy Flour, Full Fat			
Assay	Units ¹	Requirements	
		Min	Max
Moisture	%	---	10.0
Protein (Nx6.25) ²	%	44.0	--
Fat ²	%	22.0	--
Crude Fiber ²	%	--	3.0
Ash ²	%	--	6.0
Material through a U.S. Std. No. 100 Sieve	%	95.0	--
Nitrogen Solubility Index	--	10.0	30.0
Urease activity, increase in pH	--	0.05	0.15
Total bacteria count	cfu/g	--	50,000
Color	--	Light yellow to golden buff	
Odor	--	Neutral to nutty	
Taste	--	Pleasant, neutral to slightly nutty	
Texture	--	A homogeneous flour	

¹ Percent on a weight/weight basis
² Moisture-free basis

5.3.5 Nonfat Dry Milk

Nonfat dry milk (spray process) is to be furnished by the Government or contractor (as specified in the solicitation) and shall be U.S. Standard Grade or better as defined in Section 58.2528 of U.S. Standard for grades of nonfat dry milk (spray process), which is included herein by reference, found at http://www.ams.usda.gov/standards/NDM_02-02-01.pdf and in addition, shall meet the further requirements of this Section, and where they are different the requirements defined in this Section shall take president. Grading certificates shall be dated not more than 180 days prior to the date of manufacture of the corn-soy-milk.

Non-Fortified Nonfat Dry Milk			
Requirements Different than Grading Standards			
Chemical	Units ¹	Minimum	Maximum
Protein (N x 6.38) ²	%	30.0	--
Antibiotics		Negative to test	--
Whey Protein Nitrogen Classification, High Heat	mg/g Undenatured whey protein	--	1.50
<i>Salmonella</i> (Category II)	Presence / Absence	Negative to test	--
<i>E. coli</i>	cfu/g	Negative to test	--
<i>Staphylococcus aureus</i> , Coagulase positive	cfu/g	Negative to test	--
¹ Percent weight basis ² Moisture Free Basis			

5.3.6 Soybean Oil

Soy oil, refined, deodorized, and stabilized, shall contain 0.005 percent citric acid added on the cooling side of deodorization. The soy oil shall comply with the requirements of the latest revisions and amendments for Commercial Item Description A-A-20091D (May 7, 2002), <http://www.ams.usda.gov/fqa/aa20091d.htm>; type IV not winterized salad oil which is incorporated herein by reference.

Before addition to the product, the oil may be stabilized by the addition of butylated hydroxy anisole and butylated hydroxy toluene, each at a level of 2.5 mg. per 100 grams of formulated product. **Caution:** Antioxidant may be added to either the soy oil or to the vitamin antioxidant premix, but it shall not be added to both. [See Section 5.4.7.2]

5.3.7 Micronutrient Fortification

5.3.7.1 Mineral Premix

The minerals and vitamin premix shall not be combined and shall be added to the formulation separately.

The mineral premix shall contain the micronutrients listed in this Section, at the stated levels, and mineral premix identified as Option 1 shall be added to wheat-soy milk at the rate of sixty (60) pounds per 2,000 pound batch of finished product. The weight of other mineral premix options vary and any deviation in weight from 60 pounds shall be added or subtracted, as appropriate, from the total final product batch weight.

Weight of Minerals per 60 pounds of Premix

	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
	lbs							
Calcium Phosphate, Tribasic	40.00			26.00	18.00	18.00		
Calcium Carbonate		36.00	36.00		12.00	12.00	10.00	10.00
Sodium Phosphate, Monobasic		32.00			16.00			
Calcium Phosphate, Dibasic				12.00				44.00
Potassium Phosphate, Monobasic			32.00			16.00		
Calcium Phosphate, Dibasic, Anhydrous							34.00	
Zinc Sulfate, Monohydrate ¹	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Ferrous Fumarate, FCC Grade, Purified	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Magnesium Oxide (MgO)	2.75	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Iodized Salt (0.007% I ₂)	16.25	16.25	16.25	16.25	16.25	16.25	16.25	16.25
Mineral Premix Total Weight, lbs	60.17	88.17	88.17	58.17	66.17	66.17	64.17	74.17

¹ Zinc sulfate heptahydrate (0.4 lbs) may be used as an alternative to 0.25 lbs zinc sulfate monohydrate.

If calcium and phosphorus ingredients and/or salt are added independently from a mineral premix, verification of the correct addition level must be documented, by assay, on the Certificate of Analysis.

5.3.7.2 Vitamin Premix

The vitamin premix shall contain the micronutrients listed in this Section, at the stated levels, and shall be added to wheat-soy milk at the rate of two (2) pounds per 2,000 pound batch.

Weight of Vitamins per 2 Pounds of Premix

Vitamins	g
Thiamine mononitrate	2.5
Riboflavin	3.5
Niacin	45.0
Folic Acid	1.8
Pyridoxine hydrochloride	1.5
Calcium D-pantothenate	25.0
Vitamin B ₁₂	0.012
Butylated hydroxy anisole ¹	20.0
Butylated hydroxy toluene ¹	20.0
Ascorbic Acid (Stabilized, ethyl cellulose coated) ²	364
	IU
Vitamin A-Palmitate (Stabilized)	21,000,000
Vitamin D (Stabilized)	1,800,000
Alpha tocopherol acetate	68,000
Carrier ³	As Required to reach total weight of 2 lbs.
	lbs
Vitamin Premix, Total	2.0
¹ If antioxidants (BHA and BHT) are added in the soy oil (Section 5.4), omit from this premix. ² Ascorbic acid (stabilized), ethyl cellulose (coated). Ascorbic acid content shall be not less than 364 g. ³ Soy flour, defatted (toasted) or starch to reach total weight.	

Vitamin A stability testing shall be completed by the manufacturer or supplier of the vitamin premix. Manufacturers shall, upon request, provide documentation of such test results.

8.2 Schedule of Discounts

	Units	\$/cwt.		Units	\$/cwt.
Excess Moisture			Deficient Protein		
9.6 or 9.7	%	0.10	19.9 – 19.8	%	0.10
9.8 or 9.9	%	0.20	19.7 – 19.6	%	0.20
10.0	%	0.35	19.5	%	0.35
Excess Crude Fiber			Excess Ash		
2.6 - 2.7	%	0.10	6.7 or 6.8	%	0.10
2.8 - 2.9	%	0.20	6.9 or 7.0	%	0.20
3.0	%	0.35	7.1	%	0.35

Deficient Fat			Excess Iron		
5.9 or 5.8	%	0.10	30.1 – 31.5	mg / 100 g	0.10
5.7 or 5.6	%	0.20	31.6 – 33.1	mg / 100 g	0.20
5.5	%	0.35	33.2 – 35.0	mg / 100 g	0.35
Insufficient Material Through U.S Std. No. 70 Sieve			Deficient Lysine		
96 or 95	%	0.10	0.8	%	0.10
94 or 93	%	0.20	0.7	%	0.20
92	%	0.35			

9 REFERENCES

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- C. (Intentionally Blank)



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Deliverable C.3.2.3
Micronutrient Terminology

Background

The Commodity Requirement documents have undergone a number of modifications over the years that have resulted in inconsistencies in ingredient terminology. For example CSB13 describes one of the optional sources of calcium and phosphorus as both “di-calcium phosphate” and “dibasic calcium phosphate”, whereas the appropriate Merck Index terminology is “Calcium Phosphate, Dibasic Dihydrate.” Another example is tri-calcium phosphate which is identified in the Merck Index as calcium phosphate, tribasic and is known colloquially as ‘tri-cal’ phosphate.

The source of zinc specified in Commodity Requirement documents is zinc sulfate monohydrate (containing one H₂O molecule). Contained in the same table is the chemical formula for zinc sulfate heptahydrate (containing 7 H₂O molecules). Thus, there is a significant difference in the amount of zinc in the two forms, 33.6% and 16.7%, respectively. An often overlooked foot note in CSB13 and other similar fortified and blended foods allows the use of the heptahydrate form, however at a much increased level.

There also exists some confusion about the amount and form of micronutrients added to food aid products. For example, the Commodity Requirement documents for fortified and blended foods (e.g. CSB, CSM and others) specify the addition of ‘thiamine mononitrate’, a chemical compound, whereas the fortified food specifications (e.g. for wheat flour, cornmeal and others) specify addition of ‘thiamin.’ The thiamin moiety can exist in several forms, the chloride salt (thiamin chloride) and the nitrate salt (thiamin mononitrate) and each having a different amount of the ‘active’ thiamin component (e.g. 2.5 mg of thiamin vs. 2.5 mg of thiamin mononitrate are not equal in terms of their delivery of net active thiamin).

In 1996, USDA-ARS released a report describing a set of recommended nutrient specifications for food aid products.¹ USDA should confirm that the values in this ARS report are the amount of active nutrient levels desired in fortified blended foods. We recommend USDA enlist the expertise at USAID to identify the net active nutrient level and chemical form of each vitamin and mineral that should be added to title II foods.

¹ U.S. Department of Agriculture. (1996, Dec, 19). Report of a USDA ARS Task Group on Nutrient Standards for Grain Blends. USDA/ARS, Beltsville, MD: 1-22.

In order to update and provide uniformity to micronutrient nomenclature in Title II food aid commodities SUSTAIN recommends the following descriptions for micronutrients. In some cases, these recommendations were obtained from the Merck Index, a recognized chemical reference, while others follow the guidelines of the latest nutritional recommendations of IOM. We recommend that this nomenclature be used for all fortified foods.

Thiamin

There are a number of commercial thiamin compounds used in food fortification, each providing a different level of the ‘active’ nutrient. The typical compound used in fortification is ‘thiamin mononitrate.’ This form of thiamin is specifically designated in the Commodity Requirement documents ICSM3, WSB15, WSM10, CSB13, and CSM, whereas other Commodity Requirement documents specify ‘thiamin’ addition without designating the form (CM4, BWSF13, MF10, SFCM3, WFBF6, and SFSG13). SUSTAIN recommends that ‘thiamin mononitrate’ be the form of the micronutrient to be added to all applicable commodities and that this nomenclature be used in all relevant requirement documents. We also recommend the target level of thiamin be identified by USDA.

Folic acid

The current Commodity Requirement documents specify “Folic acid.” There are at least two forms of folic acid commercially available that differ in the amount of active folic acid. In consultation with industry experts, we recommend USDA specifically designate “Folic acid, USP” as the form to be added to Title II food aid products. Typically, USP contains 90.5% anhydrous folic acid.

While it is not yet common commercial practice to use DFE (Dietary Folate Equivalent), in its most recent publication on nutrients, the Institute of Medicine (IOM) is proposing changing the folic units from mg to μg DFE.² We therefore recommend USDA follow the IOM DRI Reference Intake guides.

Vitamin A

The term “vitamin A palmitate” is currently stated in Commodity Requirement documents. We recommend changing the nomenclature to “retinyl palmitate,” the scientifically correct terminology for the ester form of vitamin A and palmitic acid.³ The units in the current specification are stated as IU. The Institute of Medicine (IOM) is proposing to change units of vitamin A from “IU” to μg RAE (Retinol Activity Equivalents).⁴ We recommend using μg RAE/100g as a replacement of IU/lb in the specification.

Vitamin D

The term “vitamin D (stabilized)” is used in the current specification. This is a generic term that could either mean vitamin D₂ (ergocalciferol) or vitamin D₃ (cholecalciferol); thus, manufacturers could potentially be adding either form. Recent literature suggests that vitamin D₃

² IOM DRI Reference Intakes. Guiding Principles for Nutrition Labeling and Fortification. Washington, DC: National Academies Press; 2003.

³ Food Chemicals Codex, 4th Edition. Institute of Medicine. Washington, DC: National Academy Press; 1996.

⁴ IOM DRI Reference Intakes. Guiding Principles for Nutrition Labeling and Fortification. Washington, DC: National Academies Press; 2003

is superior in biological activity to vitamin D₂ and is more stable during storage. Therefore, SUSTAIN recommends the specifications state the preferred, biologically active, form as “vitamin D₃ (cholecalciferol).”

Vitamin E

The term “Alpha tocopherol acetate” is currently used in the Commodity Requirement specifications, and as stated, this terminology leaves it up to the manufacturer to choose whether to use either the less biologically active *all-rac-α*-tocopheryl acetate form (labeled as dl-*α*-tocopheryl acetate) that is typically used in foods, or the more active *RRR-α*-tocopheryl acetate form (labeled as d-*α*-tocopheryl acetate) which is *not* typically used in food products. Most food databases list vitamin E in the form of *α*-tocopherol equivalents (*α*-TE). The terminology should be changed to reflect the ester form e.g. from tocopherol to tocopheryl. In addition, IOM is recommending IU be changed to mg for vitamin E.⁵ We recommend that amounts be specified as “mg *α*-tocopherol equivalents (mg *α*-TE)” to ensure that the correct amount of vitamin E is added based on vitamin E activity.

Ascorbic acid

The current specification states “ascorbic acid (stabilized), ethylcellulose (coated).” As written, the specifications do not clarify whether the total amount to be added to a 2,000 pound batch (364 grams) is the weight of ascorbic acid or the weight of ascorbic plus the coating. The specification should clearly state the desired amount of ascorbic acid per unit of weight. The weight of coating material on the ascorbic acid should not be included in the target amount.

Tricalcium phosphate & other sources of calcium & phosphorus

Within the five Commodity Requirement documents containing optional formulas for delivering calcium and phosphorus, different terminology is used for the same ingredient. We recommend the terminology found in the Merck Index be used for chemical descriptions for all of the chemical names stated in the specification, as stated in Tables I and II. For example, the specification includes the terms “Dibasic Calcium Phosphate” and “Di-Calcium Phosphate” which should be renamed to the Merck Index term “Calcium Phosphate, Dibasic Dihydrate.”

The Commodity Requirements for CSB, CSM, ICSM, WSB and WSM allows eight formulation options for delivering calcium and phosphorus. However, these different formulations do not deliver the same quantities of calcium and phosphorus in the finished product; the calcium and phosphorus delivered by optional formula ‘F’⁶ is only 76% and 90.5% of the levels delivered by calcium phosphate, tribasic. SUSTAIN recommends the different formulations be adjusted to meet the desired levels of calcium and phosphorus in the finished products.

Zinc sulfate monohydrate

The current Commodity Requirement documents for fortified and blended foods specifies an amount of “Zinc Sulfate, Monohydrate (ZnSO₄ = approx 7H₂O).” The description in parentheses is not consistent with the nomenclature and should be deleted to maintain consistency with other specifications.

⁵ IOM DRI Reference Intakes. Guiding Principles for Nutrition Labeling and Fortification. Washington, DC: National Academies Press; 2003.

⁶ Commodity Requirement CSB13, http://www.fsa.usda.gov/Internet/FSA_File/csb13.pdf

Magnesium

The specification states “Magnesium Oxide (MgO).” SUSTAIN recommends deleting the chemical formula in parenthesis to maintain consistency with other specifications.

Table I – Current terminology and recommended revisions to terminology			
Current Specifications		Recommended Revisions	
Current Ingredient Terminology	Units	Proposed Ingredient Terminology	Units
Thiamin monoitrate [<i>sic</i>]	grams	Thiamin mononitrate	grams
Riboflavin	grams	Riboflavin	grams
Pyridoxine hydrochloride	grams	Pyridoxine hydrochloride	grams
Niacin	grams	Niacin	grams
Ca D-pantothenate	grams	Ca D-pantothenate	grams
Folic acid	grams	Folic acid, USP grade	µg DFE
Vitamin B12	milligrams	Vitamin B12	mg
Vitamin A Palmitate	IU	Retinyl palmitate	µg RAE
Vitamin D (stabilized)	IU	Vitamin D3 (cholecalciferol) (stabilized)	µg
Alpha tocopherol acetate	IU	Alpha-tocopheryl acetate	mg α-TE
Ascorbic acid (stabilized), ethylcellulose (coated), Soy flour, defatted (toasted) or starch to reach total weight; (additional soy flour may be added as a carrier, if desired)	grams	Ascorbic acid, (stabilized - ethyl cellulose coated)	grams, Ascorbic acid
Tri-Calcium Phosphate ²	lbs	Calcium Phosphate, Tribasic	lbs
Zinc Sulfate, Monohydrate (ZnSO ₄ =approx 7H ₂ O)	lbs	Zinc Sulfate Monohydrate	lbs
Ferrous Fumarate, FCC grade, purified	lbs	Ferrous Fumarate, FCC grade, purified	lbs
Magnesium Oxide (MgO)	lbs	Magnesium Oxide	lbs
Iodized Salt 0.007% I ₂)	lbs	Sodium Chloride, Iodized 0.007% I ₂)	lbs

Table II – Current terminology and recommended revisions to terminology		
Optional Calcium /Phosphorus Formulas	Current Terminology	Proposed Terminology
1A	Tri-Calcium Phosphate	Calcium Phosphate, Tribasic
1B	Calcium Carbonate	Calcium Carbonate
	Monobasic Sodium Phosphate	Sodium Phosphate, Monobasic
1C	Calcium Carbonate	Calcium Carbonate
	Monobasic Potassium Phosphate	Potassium Phosphate, Monobasic
1D	Tri-Calcium Phosphate	Calcium Phosphate, Tribasic
	Dibasic Calcium Phosphate	Calcium Phosphate, Dibasic Dihydrate
1E	Tri-Calcium Phosphate	Calcium Phosphate, Tribasic
	Calcium Carbonate	Calcium Carbonate
	Monobasic Sodium Phosphate	Sodium Phosphate, Monobasic
1F	Tri-Calcium Phosphate	Calcium Phosphate, Tribasic
	Calcium Carbonate	Calcium Carbonate
	Monobasic Potassium Phosphate	Potassium Phosphate, Monobasic
1G	Di-Calcium Phosphate Anhydrous	Calcium Phosphate, Dibasic, Anhydrous
	Calcium Carbonate	Calcium Carbonate
1H	Di-Calcium Phosphate	Calcium Phosphate, Dibasic Dihydrate
	Calcium Carbonate	Calcium Carbonate



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project

Contract AG-3151-C-07-0048

Deliverable C.3.3.1

Recommended Commercial Contractual Practices

Background/Summary

This report includes a summary of current commercial practices that are followed by both the agricultural commodity and processed food industries along with specific recommendations that USDA that can use to ensure that the quality of food aid products is consistent and will meet the requirements of intended recipients. In addition, the recommendations are designed to allow USDA to maintain and enhance the quality reputation of U.S. products provided to other countries.

Current Food Industry Practices for Commercial Contracts

This section summarizes current technical, quality and food safety practices underlying commercial contracts.

Legal and Regulatory Framework

The food industry's commercial principles, practices and contracts are founded on a legal and regulatory framework designed to ensure that foods manufactured, distributed and sold are fit for human consumption without causing harm. These legal and regulatory frameworks were developed from the 1938 FD & C Act and subsequent amendments, which mandated the implementation of Good Manufacturing Practices. Additional requirements have been added to the legal and regulatory framework from the 2002 Bioterrorism Act. In addition, the food industry is governed by the competitive desire to ensure that their products meet the needs and expectations of the consumer.

The development, implementation and enforcement of food laws and regulations are in a continuous state of evolution and will continue to evolve as new challenges arise in the production of food that is fit for human consumption. Examples of such challenges are the infection of food products by enteropathogenic *E. coli* O157:H7, and salmonella infections of vegetables and other foods. The food industry today has resulted in the concentration of various food commodities and processed foods in different parts of the country. The modern distribution system allows for the nationwide distribution of food which means that serious food borne diseases and contamination can rapidly spread to large sections of the population. The public health and economic costs of these problems dictate that the legal and regulatory framework has to keep pace with the changes in commercial practices in the food industry so that confidence in the safety of the food supply chain is maintained.

The food industry has adopted a multifaceted approach to ensure that foods and their processing conditions are safe and comply with the applicable laws and regulations; meet industry food quality standards; are packaged in suitable containers; and are distributed and stored under conditions which protect the integrity of the food in the distribution chain to the point of consumption by the end user.

The earliest quality system that the food industry was required to adopt under federal law and regulations were Good Manufacturing Practices (GMPs). GMPs regulations, which can be found in the Code of Regulations 21 CFR Part 110, cover:

- General Provisions,
- Buildings and Facilities,
- Equipment,
- Personnel,
- Production and Process Controls, and
- Defect Action Levels.

It should be noted that under section 110.19, “raw agricultural products” are excluded from GMP requirements in the CFRs. This would include the whole grains, legumes and pulses, which are currently included as USDA Food Aid Products.

On a worldwide basis the food industry has generally accepted that GMPs are the foundation on which other quality systems should be based. GMPs consist of a number of prerequisite components, including Standard Operating Procedures, Standard Sanitation and Cleaning Procedures, Standard Maintenance Procedures, Standard Sampling Plans, and Standard Quality Control and Quality Assurance Procedures. Figure 1 illustrates how GMPs are used as just one of the building blocks (pre-requisite programs) in conjunction with other programs in the continuing development of more rigorous food quality systems as they serve as the basis for Hazard Analysis and Critical Control Points (HACCP). HACCP is designed to systematically identify and assess hazards associated with the manufacture, distribution and use of food products and to define and implement preventative measures for their control.

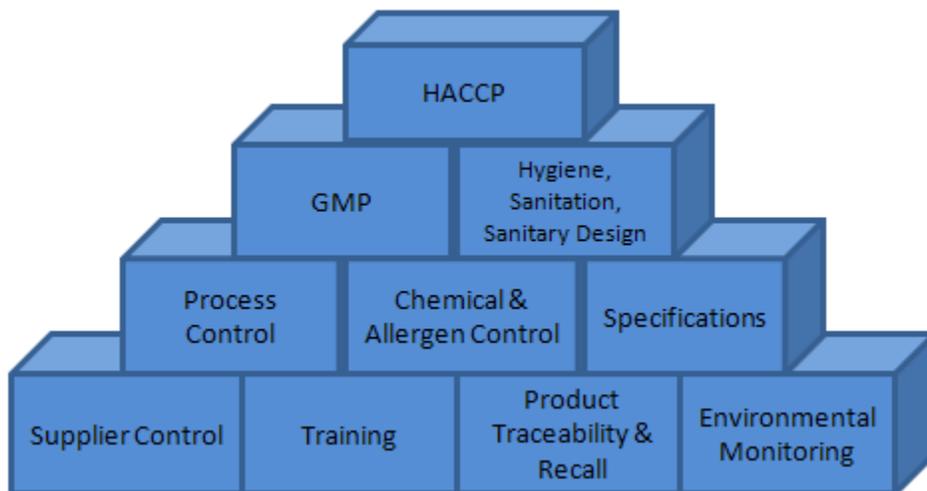


Figure 1. Prerequisite programs + GMPs => HACCP (ISO 22000) => Food Safety.

In the commercial food sector, food quality assurance now includes the implementation of HACCP systems. USDA regulations promulgated under the Code of Regulations cover mandatory HACCP plans for Meat and Poultry, Juices, and Seafood. In addition, the U.S. Food and Drug Administration (FDA) developed voluntary guidelines for HACCP systems for many sectors of the food industry such as the Dairy Industry, Food Service and Food Retail Industries.

At the international level many HACCP based food standards and systems now apply:

- ISO 22000 (section 67 pertaining to foods) Food Safety standard for HACCP.
- Canadian Food and Drug Regulations mandating official HACCP plans for Meat and Poultry, Eggs, Dairy Products, Fruits and Vegetables, Maple Syrup, Seafood and Low Acid Canned foods.
- HACCP regulations in many European countries, Australia and Japan.
- WHO/FAO Codex Alimentarius HACCP systems.

HACCP systems are implemented within a food company based on individual food product risks. For example, a company producing two different baked products such as breads and pastries in the same facility will have two separate HACCP plans, one for each product type. Despite commonalities with regard to raw materials and finished product storage and distribution, separate plans are needed because the processing systems for these two products differ substantially.

Globally competitive food companies have HACCP plans in place even though the legal framework only requires HACCP for specified foods and GMPs as a minimum. Nearly all companies that purchase both food ingredients and finished food products require that their suppliers have established validated HACCP plans as part of a supplier qualification process. Without validated HACCP systems in place many food companies are excluded from commercial transactions, even though HACCP may not be legally required.

In some countries, including Canada, the implementation of HACCP based systems is being driven back up the food commodity chain to the farm level. For example the Canadian Grain Commission (responsible for regulating the grain quality system) is in the process of introducing HACCP systems into the grain distribution system from the farm gate to the final delivery of grain to the customer at both the national and international level.

The Business Case for HACCP

HACCP has been shown to be a very effective system for reducing costs of production while improving the safety and quality of foods, both major forces driving its implementation. One of the cornerstones of the system is the development of Critical Control Points that must be consistently measured and recorded and that are not controlled by the use of GMPs (SOPs etc.) An example of this is milk processing where fluid milk is pasteurized before packaging and distribution. The two critical control points are the pasteurization temperature and the time through the pasteurizer.

The food industry recognizes that food safety requires an evolving, on-going system with structured and organized monitoring capability, open clear communications between suppliers and users, and full documentation and auditing of the process. In the majority of cases the food industry quality system exceeds the minimum requirements of the existing CFR regulations and standards because the economic benefits of doing so are great and the economic consequences of not meeting industry standards and practices are severe in terms of lost market share, sales revenues and consumer confidence.

Content of Current Commercial Practices in the Food Industry

The following are key components of current commercial contracts in the food industry for processed foods.

1. Supplier Qualification

Food companies now use a supplier qualification process that requires completing a questionnaire requesting specific information on candidate companies’ food safety and standard operating procedures and practices, including HACCP. Companies then draw up a short list and experienced and trained Quality Assurance (QA) staff conduct on-site audits. Sometimes a third party auditor, such as a recognized third party auditing organization (e.g. American Institute of Baking, Silliker Laboratories, and ABC Labs) may carry out the on site visit. The result is an Approved Supplier designation with 2-4 companies on the approved supplier list. In the case of multi-plant suppliers, each plant should be audited. There is an annual requalification process for suppliers based on the previous 12 months performance from both the commercial practices aspect as well as the suppliers performance related to quality and food safety.

2. Compliance Statements (a.k.a. Continuing Guarantee)

Suppliers are required to make a written statement that their process from raw materials to finished products conforms to the applicable laws and regulations and in the case of mandatory HACCP plans that the plans have been officially approved by the relevant government agency FDA or USDA. Compliance statements are renewed on a regular schedule established as part of the contract conditions, typically annually.

3. Quality systems

Suppliers are required to provide evidence that they have a documented quality system that meets GMPs as required by the U.S. Code of Federal Regulations or a HACCP plan. This will include the evidence of a Quality Manual covering GMPs, HACCP Plan and Audits (see Table 1 for complete list of components of a Quality Manual). It should be noted that suppliers of whole grains may have HACCP plans which do not have any Critical Control Points but which reference Standard Operating Procedures and GMPs as requirements. Some food companies use HACCP plans that are developed using software programs which can facilitate changes to the plan as the need arises. Suppliers are required to periodically demonstrate the effectiveness of their quality systems

Table 1. Typical Components of a Quality Manual.

Number	Component	Typical Sections*
--------	-----------	-------------------

1	General Provisions	Overview, Management Responsibility, Quality Policy, Food Safety/HACCP
2	Buildings and Facilities	Roofs, Windows, Floors, Walls, Pest Control program, raw material storage, finished product storage
3	Equipment	Equipment description, Operating instructions, Preventative Maintenance
4	Personnel	Training, Personal hygiene, Footwear, Clothing, Headwear
5	Production and Process controls	Production process layout, Equipment layout, Control points (temperature, pressure, time), Packaging and labeling, Product storage requirements, Distribution requirements, Maintenance schedules, sanitation and cleaning schedules
6	Quality control	Raw material specifications, packaging specifications, labeling specifications, finished product specifications, Quality Control procedures, laboratory Equipment, defect action levels
7	Product Recall	Recall Action plan document, product traceability system, product, Recall coordinator

*Note: This table is designed as guide and is not a comprehensive listing of the typical sections

4. Technical Specifications for Processed Foods

In commercial practice, the supplier is required to provide evidence of the quality parameters of the food to be supplied for each lot and or shipment. These will consist of chemical, physical and microbiological specifications. In some cases the specifications may be broken down into critical or major and minor specifications (see Table 2 below for an example of a Technical Specification for a food product). For example, a particular product may need to meet a protein quality parameter whose functionality is critical to the manufacturing process; this would represent a critical or major specification.

Foreign material, pesticide residues and radioactivity standards are normally included in the technical specifications. Certificates of Analysis (COA) from the supplier are included as part of the contract conditions and report the results of actual analyses for the defining parameters of the product. COA should also contain the specification limits as well as the analytical method used to conduct the assays. These may be from the supplier's own laboratory or from a contract laboratory. In the case of international trade there are additional certificate requirements that need to be included as part of the commercial practices, such as:

- Phytosanitary Certificates,
- Radiation Certificates (levels of radioactivity in the food particularly Strontium 90) in grains and milk products, and
- Fumigation Certificates.

Routine shelf life studies are also an important procedure contracted out by the food industry to ensure that the actual shelf life of the food product meets the specifications of the contract. Shelf-life testing is required to document that the product will be acceptable and meet all of the requirements at the end of the time designated either by “Best used by date” or manufacturing date plus a defined time interval. This is an ongoing activity in the commercial food industry as part of the Quality Assurance system. It is used to establish an information baseline for new products and to monitor trends for existing food products

Table 2. Example of a Technical Specification for a food product.

Section	Description
Introduction	Narrative describing the food and how it is made
Legal requirements	Laws and regulations covering the food
Ingredients	Raw materials, food additives, i.e. food processing additives, colors preservatives etc.
Chemical Specifications	Moisture, Protein, Carbohydrate, Fat, Additive levels, Fiber, Vitamins and Minerals, Pesticide residues, pH
Physical Specifications	Particle Size for solids, Viscosity for liquids, individual piece counts and weight range for each piece
Microbiological Specifications	Total Plate Count, Yeast and Molds, Coliform, Absence of pathogens such as <i>Salmonella</i> , <i>enteropathogenic E. coli</i> , <i>Listeria</i> , <i>Staph Aureus</i> , <i>Clostridium perfringens</i>
Organoleptic Specifications	Appearance, Color, Odor, Taste and texture
Packaging specifications	Size, packaging, packaging materials, stacking configuration in shipping containers, pallet configurations and sizing
Labeling specifications	Manufacturers name and address and contact information, Ingredient listing, Nutritional information, Best Before and/or production date readable to the consumer, country of Origin, Net Weight declaration
Storage and distribution conditions	Temperature range, others such as keep dry, store away from other potential contaminants such as petroleum products, perfumes, highly scented products
Quality Control Methods	List of applicable QC methods, including official methods

Packaging Specifications

The packaging and labeling specifications will cover the types of packaging used to protect the integrity of the food under normal conditions of storage and distribution until consumption or further processing (i.e. food ingredient). Durability and product protection afforded by the packaging materials must conform to the specifications agreed upon by the vendor and purchaser.

In the commercial sector, the food package label must meet the legal requirements for: Name of Manufacturer, Location and Address information of the Manufacturer, Contact information, Country of origin, ingredient declaration and nutritional information, Best Before date and/or date of production (readable by the consumer), Lot number, and bar code. Radio Frequency Identification RFID identification systems have started to be used in the food industry which

allows for electronic monitoring of the product through the food supply chain. These key requirements ensure that in the case of a recall the product can be properly identified, traced and disposed of safely. Proper production records will identify all product lots involved in the recall and reduce the cost of the recall.

Distribution and Storage Specifications

The distribution and storage specifications cover specific conditions during transportation and storage which define maximum temperature and humidity parameters, handling conditions of the products during transportation and storage, and the expected shelf life of the product stored under the conditions specified.

Third Party Audits

Suppliers are typically required to submit to third party quality audits which will cover the quality system as well as particular sections of the quality system such as sanitation audits. In the grain based food industry in the USA and Canada organizations such as the American Institute of Baking, Guelph Food Technology Centre (in Canada), ABC Labs and Siliker Laboratories are examples of contractors that carry out third party audits. The audits will include unannounced product verification checks to determine adherence to quality specifications and food safety requirements, i.e. microbiology.

Food companies buying processed foods expect that their suppliers will meet all the conditions that are agreed to in the contract. No price discounts are systematically given for products that do not meet the specifications listed above. If deliveries are not made by the agreed upon date then a discount may be negotiated between the supplier and customer to cover down time costs, demurrage costs, etc.

The use of third party quality audits as well as regular reviews of a suppliers’ performance are considered by the food industry as essential business practices. The frequency of third party audits and product verifications will depend upon the type of food and the supplier’s performance record. Typically either six (6) month or annual reviews are made. If the supplier consistently fails to meet the expected quality parameters and commercial performance it will be delisted as an approved supplier. Readmission as an approved supplier will require requalification under the Supplier Qualification scheme.

Periodic Review of Quality System

The food industry routinely carries out a routine review of all components of the Quality Assurance Programs, including GMPs, SOPs, processing specifications, ingredient specifications and finished product specifications. This is done as part of the HACCP requirements. Table 3 below describes typical frequencies of review that may be carried out for certain components of the quality system.

Table 3. Frequency of review for components of quality systems.

Component	Review Frequency
HACCP System	6 month or 12 months as changes occur in processing or product
GMPs	Annually or if production system is revised or modified

SOPs	Annually or if production system is revised or modified
Ingredient Specifications	Annually or each crop year
Finished Product Specifications	Annually
Quality control methods	Every 2 years or if the official method changes

Recommendations Appropriate for Food Aid

Commercial contract practices in the food industry have developed over time to guard against the cheapest or lowest cost supplier automatically becoming a qualified supplier. The final decision is usually made by a purchaser and is based on objective data and information on the suppliers past performance evaluated against pre-established criteria. History has shown the least cost supplier may not meet all the quality requirements as part of the tendering process or be able to provide a product or service in a consistent manner.

However in the public sector, procurement rules at times mandate the least cost supplier as supplier of choice without any regard to previous history of performance and quality of product and service. Because of its inherent risks, this practice should be critically reviewed.

Based on the points described above the following recommendations have been developed for consideration by USDA for Food Aid Products.

Processed Foods

1. Review existing specifications (part of current project) and modify Food Product specifications to require that food be processed at facilities under conditions that can ensure they are fit for human consumption at the final destination. USDA should review the specifications on an annual basis. More frequent reviews may be needed under certain circumstances (e.g. an ingredient is no longer available or crop conditions change).
2. Review existing specifications for packaging and labeling to ensure the integrity of the processed food by the time it reaches the beneficiaries. It should be noted that shelf-life testing is a normal part of the product development cycle.
3. For all processed food, implement the system used in commercial food industry contracts as specified above under the section Content of Current Commercial Contracts in the Food Industry.
4. Implement a product Traceability and Recall requirement for suppliers of all food aid products.
5. Include a requirement that suppliers' Quality systems provide information on the Technical Specifications of the Foods listed above in section 4.
6. Institute a system of Supplier Qualification which includes evaluations of the quality system at each manufacturing location as well as normal commercial and financial components. Develop defined criteria for supplier qualification approval.

7. Institute a system of qualified Third Party Audits for qualified suppliers with the cost of Third Party audits borne by the supplier. Require the qualified supplier to meet a minimum standard or rating on the basis of the Third Party Audit.
8. Use a qualified third party to review the current auditor training programs and employee qualifications so that the audits can be developed and conducted more effectively.
9. Establish an Interagency Task Force to review food aid product specifications, qualified supplier lists, supplier performance and supplier product quality on a regular basis.
10. Food aid products should be regularly monitored through an active verification program, which should include chemical, physical, microbiological and organoleptic (flavor/texture) parameters.

Whole Grain Foods

1. Issue specifications for Whole Grains that conform to existing published grade standards for grains, pulses and legumes. The specifications must include a maximum moisture specification requirement which is sufficiently low enough to prevent spoilage during storage and distribution. Fat rancidity will shorten the quality of milled whole grain foods and reduce shelf life of the products. In addition these specifications should require suppliers to attest that the food is fit for human consumption and that it meets the minimum foreign material and pesticide residue levels found in the CFRs and other USDA standards. Furthermore, the specifications and quality requirements; i.e. GMPs for suppliers of whole grains should be the same as for suppliers of fortified & blended products.
2. Evaluate the potential for including HACCP requirements for the specifications for Whole Grains.



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Deliverable C.3.3.2
Quality Control / Quality Assurance Practices &
Recommendations on the Use of Certificates of Analysis

Background & Summary

The specific components of quality systems are as varied as are food manufacturing systems and processes. However, common elements define all effective quality systems. Their implementation is integral to delivery of manufacturing productivity and cost control as well as product quality and safety. The purpose of this report is to outline quality control and assurance practices that should be used by food manufacturers to insure high levels of manufacturing and product quality and consistency. Every good quality program should contain a declaration of management's commitment to quality. This may be as simple as a line or two reinforcing quality practices or as complex as a multi-paragraph statement assuring employees and customers alike of the company's commitment to quality.

The preferred practice for quality systems is to design quality into the manufacturing process, starting with raw material specifications, process design and plant layout, appropriate standard operating procedures and controls, final product verification, sanitation and food safety practices and other systems designed for warehousing and transportation of quality products. Quality is best assured internally by integrating effective and efficient quality assurance procedures and systems across the manufacturing unit operations.

Section one, Practices for the Assurance of High Quality Levels, summarizes some of the essential components of a food manufacturing quality system. More thorough explanations of quality assurance programs can be found in numerous books and periodicals on the subject. Section two, Use of Certificates of Analysis, provides guidelines on the use of certificates of analysis to verify high quality levels.

Section 1

Practices for the Assurance of High Quality Levels

Assuring high levels of quality involves deliberate and systematic applications of technical methods and tools combined with cross-functional group dynamics and strong leadership. Some of the key elements of effective quality are outlined briefly below.

Analytical Measurements

Careful attention to analytical measurements and the quantification of analytical variability is essential to the assurance of quality. Methods must be defined and implemented to assure accurate and precise analytical measurements. Included should be procedures requiring that all laboratory instruments be calibrated and checked on a routine schedule. Calibration against known reference standards will provide assurance that the instrumentation is capable of readings that correctly indicate the true value and magnitude of the attribute being measured.

Analytical measurement accuracy and precision are not synonymous; accuracy is the ability to measure and report the true value of a measured attribute and precision describes the ability to make repeated measurements and obtain the same results. Repeatability and reproducibility are required to obtain precise analytical measurements repeatability refers to variation that is experienced when one operator uses the same measuring device repeatedly on the same sample. Reproducibility refers to variation experienced when different operators use the same measuring device on the same sample. A number of statistical tools can be used to assess analytical precision designed to quantify analytical repeatability and reproducibility. Reproducibility of a test will vary based on the assay being conducted and the matrix of the attribute being measured. The variability of stable easy-to-assay minerals (e.g. iron) and other components (e.g. proteins) common to processed cereal-based foods is indicated by the coefficient of variation (CV) and should range between 4 – 7%. However, the CV may run higher for more complex analyses in difficult to assay foods. For most practical purposes, the combined repeatability and reproducibility (overall precision) should have a CV of 10% or less. If the CV exceeds 10%, it may be necessary to use duplicate, triplicate or more testing to reduce the impact of variability on the overall decision making process.

Most commercial analytical laboratories have implemented internal quality controls and subscribe to proficiency testing programs as well as ongoing audits by independent third-parties. Food manufacturers should also subscribe to these basic quality assurance practices to ensure their analytical results are accurate and precise.

Raw Material

The opportunity to control product quality begins with the incoming raw materials used to manufacture foods. Criteria must be established and verification processes implemented to ensure quality, safety and uniformity of incoming raw materials and their conformation to specifications. This would include the following requirements:

- Approved specifications that define key chemical, physical, functional and microbiological attributes;
- Utilization of approved and qualified vendors;
- Incoming inspection, sampling and testing methods with defined acceptance criteria;
- An accompanying COA verifying that each lot has been checked by the supplier and complies with specifications,
- Defined raw material storage and handling procedures designed to maintain quality.

Acceptance sampling and testing requirements vary among different raw materials. The testing frequency should be based upon consideration of inherent risk associated with the raw material

or ingredient and the suppliers' past performance. Lower risk ingredients from reliable suppliers may be subject to less frequent testing. Based on acceptable past performance, practices such as 'skip-lot testing' may be introduced when manufacturers have demonstrated continual compliance to specifications and adequate internal quality systems to assure future performance and compliance to specifications. A thorough review of the suppliers' Certificate of Analysis (COA) is a very important element of quality control. The COA should provide reliable data demonstrating compliance to the specifications for chemical, physical, functional and microbiological parameters.

Standard operating procedures for transportation of raw materials should include guidelines for inspection of the transportation vehicle (e.g. truck, railcar or barge) upon arrival to assure seals are intact and correspond to seal numbers recorded on the Bill of Lading. Before accepting any raw material, the transportation vehicle should also be thoroughly inspected prior to unloading, to assure it is intact and undamaged. If problems are found, decision must be made relative to the risk and the shipment should be rejected if safety or qualities are compromised.

Process Design / Plant Layout

Processing equipment and the facilities housing food manufacturing should be designed to prevent contamination of the foods during production and for ease of effective cleaning. Sanitary design standards are part of the equipment and facility engineering design and procurement process. Plant layout and process flow should minimize the potential for cross contamination by separating raw materials and finished products.

The production area should be designed to prevent or mitigate foreign material contamination. The appropriate foreign material control devices such as sifters, sieves, metal detectors, magnets, filters must be installed at appropriate process steps and monitored by trained and knowledgeable personnel. Appropriate good manufacturing practices (GMPs) must be employed to minimize foreign substance contamination by the workforce (use of hairnets, no jewelry, buttons, shirt pockets for pens, pencils, etc.).

Process Variation

Manufacturing processes can usually be broken down into stages or unit operations. Unit operations can run in series or parallel, and they may contribute to variability which could impact finished product quality. It is advantageous to both manufacturer and consumer when product and process variability is minimized. Manufacturers benefit because process flow is more consistent with fewer interruptions, reducing downtime and increasing throughput. Consumers benefit, because each time they use the product it delivers a familiar experience resulting in increased consumer confidence, satisfaction and repeat sales. Process variation reduction techniques identified in the quality literature, including Six Sigma, can be used to bring performance at each unit operation closer to optimum process capability. As each unit operation feeds the next with lower variability, the total process variation is reduced, and conformance to specifications is more likely assured.

Standard Operating Procedures

A standard operating procedure (SOP) / process operating guidelines (POG) is a set of procedures that describe how routine activities are to be conducted from start-up to shut down.

SOPs can be defined as a set of instructions that standardize procedures to maximize product uniformity. Development of SOPs and their continued use is a critical part of a successful quality system. The term SOP may also include guidelines for completing, documenting and reporting results of analyses as well as directives for equipment and process operations. Acceptable quality programs must have a complete set of SOPs that are reviewed and updated on an ongoing basis.

Process Controls

Automated process controllers (PLCs) are used frequently to keep manufacturing processes on target. The most popular among them is the proportional-integral-derivative (PID) controller that automatically makes adjustments to operating equipment. As with all other measurement devices, PID controllers should be routinely checked and calibrated.

Final Product Verification

Verification of final product conformance to specifications requires a number of actions by the manufacturer. It is best conducted through a combination of rigorous process control and finished product analytical testing with a thorough review of process documentation and quality control records. The final product verification is reported to the customer (USDA, in the case of food aid purchases) via a Certificate of Analysis that provides documented evidence of the chemical, physical, functional and microbiological properties of each lot of product.

Control of Non-Conforming Product

Until all analyses are completed or if one or more assay does not meet specification, the product must be maintained under the manufacturers' control to prevent unauthorized distribution. Manufacturers must have clearly documented procedures for identifying and segregating non-conforming finished products and defined criteria for their eventual disposition.

Warehousing and Transportation Standards

Storage and transportation of raw materials and finished products are equally important and should be covered by written SOPs. Storage conditions should provide protection against contamination by insects, rodents and avian pests as well as prevention of quality deterioration and contamination hazards. Standard operating procedures should define maximum allowable temperatures and optimum humidity that will promote maximum product shelf-life. Transportation vehicles must be inspected and approved for use prior to loading finished food products.

Operator Training

An often overlooked part of the quality system is operator training. The quality systems elements previously outlined are most effective when operators responsible for task execution and corrective action have been effectively trained in job responsibilities. Operator training should consist of a demonstration of equipment (or laboratory instrument) operation followed by an adequate period of supervised use and then an evaluation of their skills in the task. To be thorough, operator training should include:

1. Training of all employees in food manufacturing plants in GMPs, Quality and Food Safety
2. Training of production staff, equipment operators and persons responsible for quality testing, according to a defined program to ensure proper performance of job tasks.

3. Training program requirements and content will be documented and conducted on a periodic basis to refresh skills.

Continuous Quality Improvement Tools

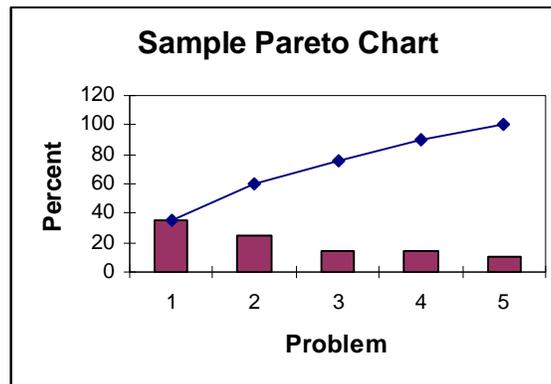
Process improvement is critical component of quality delivery. Teams work together on selected problems to identify root causes and implement corrective action plans. Moving process performance closer to capability is accomplished by careful “detective” work in which individual sources of variation are assessed for their impact on overall quality. There are many quality improvement tools available for this effort. The seven most popular continuous improvement tools are the following:

1. **Checklists / SOPs**

These are simple lists of items that should be verified before production is approved. Checklist items should document any elements necessary to deliver products that meet specifications including ingredients, process settings and flow rates, assuring the correct packaging material is being used, or other essential production parameter. Operators should routinely use the checklist on a step-by-step basis to verify that all job tasks are being addressed appropriately.

2. **Pareto charts**

These charts are histograms of defect types, reasons for downtime or other sources of process problems quantifying the frequency of occurrence. Bars representing each category of defect are arranged left to right to prioritize the most important problem sources. A Pareto chart often includes a line showing cumulative percent of problems; this aids in selecting problems to eliminate to achieve a targeted percent improvement.



3. **Cause and Effect Matrices**

This quality tool is similar to the popular “fishbone” diagram that classifies the causes of a problem into one of six categories: environment, methods, manpower, machines, materials and measurement, with one list for each category. Individual causes identified in brainstorming sessions are assigned subjective ratings by the quality improvement team for both importance and impact. The relative importance of each problem is calculated by multiplying the importance rating by the impact rating to assign a total score (see example

below). The six category lists are then combined and results displayed in descending order based on total score, providing teams with a prioritized list for corrective actions.

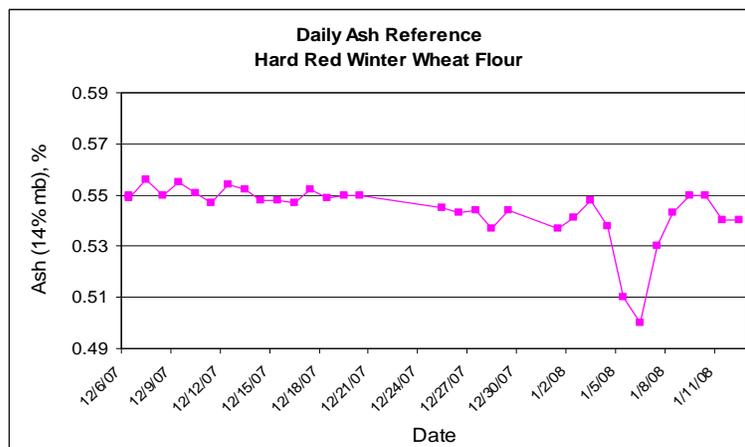
Cause & Effect Matrix
Category: Equipment

	Importance Scale	Impact Scale	Total Value	Ranking
Cause 1	2	9	18	4
Cause 2	3	0	1*	6
Cause 3	10	3	30	2
Cause 4	6	1	6	5
Cause 5	7	3	21	3
Cause 6	4	9	36	1

* Causes must have a numerical value to be included in the matrix.

4. Run charts

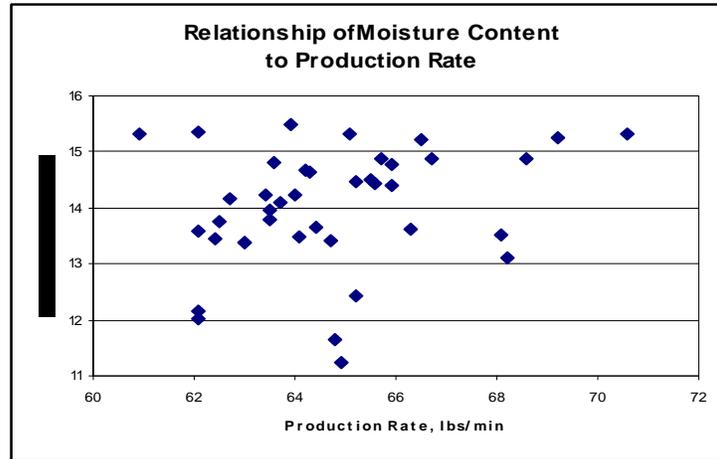
Graphical displays of data are easy to interpret and informative. Another quality improvement tool is the ‘run chart’ which is a simple data plot of a measurement response over time. In the example below, a single sample of wheat flour was tested daily for ash content (a daily instrument verification check) with the date plotted on the x-axis and the corresponding ash content plotted on the y-axis. It is easy to see from this chart that in late December 2007 a trend of decreasing measurement was initiated followed by a significant measurement upset in early January 2008. This visual tool often shows trends which might otherwise be overlooked when evaluating at data in a table format. A run chart can be a good first alert when key process indicators are trending towards an undesirable condition.



5. Scatter diagrams

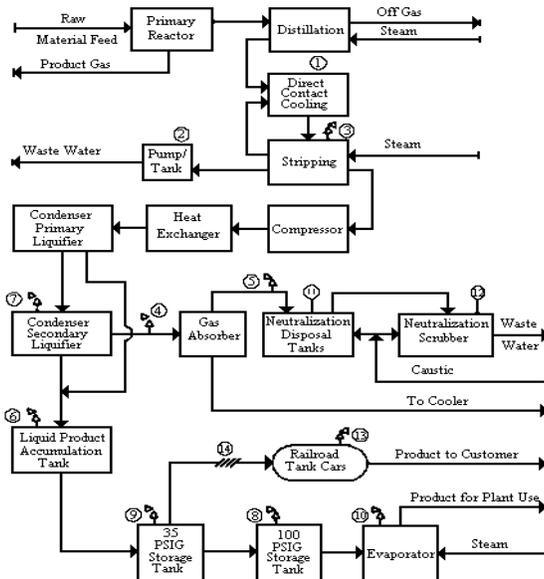
Scatter diagrams are used to detect relationships among variables. For example, process throughput rate might be related to finished product moisture, but the relationship is not readily apparent from data presented in table form. However, by plotting production rate on the horizontal axis against the corresponding moisture content on the vertical axis of a graph, relationships, if they are present, may be easily observed. Conversely, if there is no

relationship, the points appear as randomly placed dots. The scatter diagram might aid improvement projects to reduce variation by revealing that throughput rates above a certain level are likely to result in moisture problems.



6. Flow Diagram

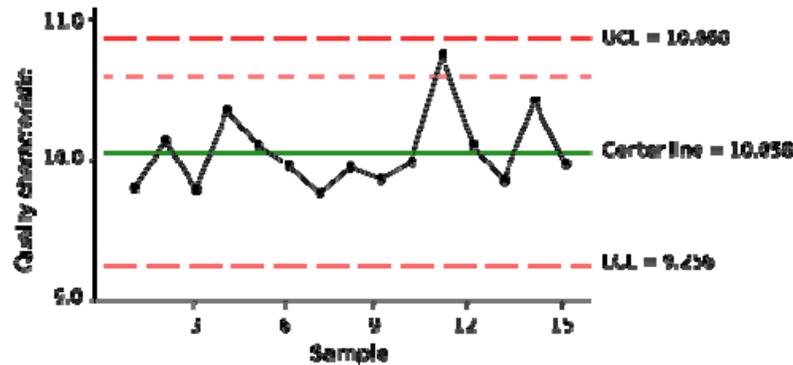
Process flow diagrams trace work in process through various unit operations and can be very informative, even for the most seasoned line operator. Flow diagrams shared by improvement team members can help create a common understanding of process improvement opportunities resulting in more informed process decisions. Flow diagrams are fundamental and process improvement is not likely without them.



Sample Flow Diagram. From: http://www.osha.gov/OshStd_gif/Block.gif

7. Control charts

Similar to run charts, control charts depict sequential observations of a process or product measurement, over time. Statistically calculated control limits on the graph indicate the points within which the process is considered to be stable. As the process exceeds those limits, there is an assignable source of variation causing process instability. As processes become unstable, the common reaction is to quickly make adjustments; this should be avoided until a trend has been confirmed by run rules. The real opportunity for continuous improvement provided by the control chart is detecting and preventing recurrence of process disturbances.



Sample Control Chart From: <http://en.wikipedia.org/wiki/Image:ControlChart.svg>

Corrective and Preventative Action

Corrective and preventative actions are integral parts of a quality program. These are changes implemented to resolve issues or problems identified through process improvement programs, internal audits or customer complaints. By utilizing the process improvement tools described above, it is possible to identify root causes of problems and take appropriate actions for correcting those problems and preventing future occurrences.

HACCP

A description of the fundamental requirements for Hazard Analysis and Critical Control Points (HACCP) was presented in deliverable C.3.3.1 (August 15, 2008) and only the major steps will be summarized here. The principle steps of the current HACCP model are¹:

1. Assemble HACCP Team
 - Develop a team that has the appropriate product specific knowledge and expertise to develop an effective food safety plan.
2. Describe Product
 - Develop a full description of the product including composition, chemical, physical, functional and microbiological properties.
3. Identify product use
 - This description should be based on product design criteria for specific uses.

¹ http://www.nsf.org/business/haccp/haccp_steps.asp?program=HACCP

4. Construct process flow diagram
 - Create a flow sheet that defines all steps of the operation.
5. On-site confirmation of flow diagram
 - Verify flow sheet accurately represents the process operations.
6. Conduct a hazard analysis
 - Identify potential chemical, physical, biological and pest hazards that may impact the safety of the product or process.
7. Identify Critical Control Points (CCPs).
 - Determine CCPs where positive process control actions can be implemented to reduce or eliminate potential hazards.
8. Establish Critical Limits for CCPs
 - Define limits at which corrective actions will be implemented.
9. Monitor CCPs
 - Implement procedures for ensuring compliance to critical limits.
10. Establish preplanned corrective actions
 - Develop action plan to implement when critical limits are reached.
11. Establish procedures for verification
 - Develop a protocol for evaluating success of corrective actions and monitor to assure compliance to acceptable critical limits.
12. Ensure proper documentation and record HACCP processes are maintained.

Implementation of the HACCP system involves the continual application of monitoring, record-keeping, corrective action procedures and other activities as described in the HACCP plan. Maintaining an effective HACCP system depends on regularly scheduled verification that is dependent on production frequency. The HACCP plan should be updated and revised as needed. An important aspect of maintaining a HACCP system is to assure that all individuals involved are properly trained in HACCP requirements so they understand their role and can effectively fulfill their responsibilities to ensure delivery of food quality and safety.²

GMP Compliance

Compliance to Good Manufacturing Practices (GMP) is one of pre-requisite quality programs that must be implemented as part of an effective HACCP plan. GMPs, as summarized in 21 CFR 110, are the minimum sanitary and processing requirements necessary to ensure the production of wholesome and safe food. They are an essential part of manufacturing operations and are intended to keep low-risk potential hazards from becoming serious enough to adversely impact the safety of foods produced.

GMPs guidelines include specific requirements for personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, process and controls, warehousing and distribution, and natural or unavoidable defects in foods for human use that represent no health hazard. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner appropriate for each individual business. GMPs, also referred to as 'cGMP' ('c' stands for current) state that manufacturers must employ up-to-date technologies and systems to comply

² <http://www.cfsan.fda.gov/~lrd/bghaccp.html>

with the Code of Federal Regulations. Systems and equipment used to prevent contamination, mix-ups, and errors, which may have been "top-of-the-line" 20 years ago, may be less than adequate by today's standards³

Recommendations – Practices for the Assurance of High Quality Levels

1. Food manufacturers should implement internal system to ensure optimized laboratory quality control of technical performance and subscribe to a proficiency testing program from a recognized third-party professional organization.
2. Specifications for both raw materials and products must be clear and concise and describe only those requirements necessary to define critical attributes of the ingredients or products.
3. Manufacturers should schedule regular objective third party audits.
4. Continuous process improvement techniques should be applied across the manufacturing system.
5. Acceptable quality programs must have a complete set of SOPs that are reviewed and updated on an ongoing basis.
6. Manufacturers must have a verifiable HACCP plan along with the necessary pre-requisite programs and adhere to GMPs.
7. Process data and quality improvement tools should be used to make data driven decisions for corrective and preventative actions to deliver continuous improvement.
8. Skip-lot testing⁷ may be introduced when manufacturers have demonstrated continual compliance to specifications and adequate internal quality systems to assure future performance and compliance to specifications.
9. The COA should provide reliable data demonstrating compliance to the specification for chemical, physical, functional and microbiological parameters.
10. Technical competency should be maintained through regular training programs to the state-of-the art for food safety and quality.

³ <http://www.fda.gov/opacom/morechoices/fdaforms/Fda-2966.pdf>

Section 2

Use of Certificates of Analysis

A certificate of analysis is a description of chemical, physical functional and microbiological characteristics of a product lot. When provided, a COA guarantees the product characteristics are as stated in the specification and that when appropriately sampled and tested for verification, equivalent analytical results should be obtained within the range of normal statistical error.

COAs listing the results of composite sample analyses for specification parameters only provide assurance of the product's averaged conformance to targets. It does not assure the within-lot variation is acceptable or that the entire product in a lot is within specification. It is quite possible that the average assay value of a lot is within acceptable limits while large quantities of product within that lot are not compliant to specifications. Composite sampling should only be used when both the supplier and customer have sufficient data to ensure that, 1) within-lot variation is sufficiently small to assure full compliance with specifications, and 2) within-lot variation is stable from one lot to the next.

It is the responsibility of the manufacturer to assure the customer that within-lot and between-lot variation remains small and stable. This should be done by a periodic examination of individual samples, as opposed to composite sample analyses. Control charts for the standard deviations are useful in this context. Evaluations should take place on a regularly scheduled basis.

Current practices by commercial food manufacturers require a certificate of analysis (COA), for each product lot, as a guarantee to customers that the products comply with specifications for all test parameters. COAs are advantageous in that they bring the manufacturers into partnership with their customers and ultimately the consumer.

Recommendations – Use of Certificates of Analysis

1. USDA should require a certificate of analysis for each lot of each food aid commodity purchased.
2. Certificates of analysis should report all information critical to assuring the lot conforms to the product specifications.
3. Certificates of analysis should contain appropriate chemical, physical, functional and microbiological requirements to ensure food safety and quality.
4. USDA should define requirements for COAs of all food aid products.
5. USDA should conduct routine over checks of COA results.
6. Sample COAs outlining the minimum data and information to be reported should be developed and issued by USDA.



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Deliverable C.3.3.3

Sampling and Testing Regime for Independent Verification of
Product Compliance with Contract Specifications

1. Purpose

1.1. Decision making with known risks

This report provides data tools for the objective determination of lot disposition. Exhaustive evaluation of each lot is not possible. Therefore, accept and reject decisions must be made on the basis of sampling, with attendant risk: acceptable lots will sometimes be rejected, and unacceptable lots will sometimes be accepted because of the uncertainties associated with sampling. The purpose here is to provide practical sampling plans whose risks to both manufacturer and consumer are known.

The sampling plans described in this document share philosophical and theoretical bases with those presented in the Codex Alimentarius Commission's document titled "CAC/GL 50-2004" which is available at http://www.codexalimentarius.net/web/index_en.jsp

The present plans have been simplified for ease of use and as a result, they may not always be exact in terms of stated probabilities. Sample sizes are intentionally held low in order to minimize sampling and analytical costs. In developing the plans, concessions were made to assure that manufacturers would not be pressed beyond their ability to deliver. Consequently, the protection against acceptance of out-of-specification commodities may not be as strong as one would wish. Inspectors should be encouraged to increase sample sizes within the guidelines offered below whenever they suspect that conformance to specifications may be lacking.

1.2. Data driven decisions

1.2.1. Variables and attributes

Generally when manufactured lots are inspected for conformance to specifications, resulting data are categorized into either "variables" or "attributes." Variables are those measurements that can be classified on a continuous scale – between any two levels there is an infinite number of other possible levels. Examples include moisture, fat, protein and ash. Attributes data, on the other hand, take the form of discrete values such as binary responses and counts; e.g., a sample is positive or negative to a test for *Salmonella*; there are 0, 1, 2 or 3 insect fragments in this sample.

1.2.2. Sampling

Sampling, as opposed to complete enumeration, is carried out to guide the lot disposition decision process. For sampling to be effective, it is essential that samples selected are representative of the manufacturer's lot in question. The goal is to assure that every unit of production in the lot has an equal chance of appearing in the sample.

Inspectors often believe intuitively that greater assurance of obtaining representative samples can be attained by stratifying the sampling by time or some other criterion such as warehouse location. Valid arguments for and against stratified sampling exist, but for the purposes addressed here, stratified sampling is acceptable.

1.2.3. Lot homogeneity

Generally it is assumed that manufactured lots of the commodities addressed here are uniform throughout. That is, on average, a determination made from a sample taken at the beginning of the lot is the same as a determination made from a sample taken at the middle and end. Similarly, samples taken from the top of a railcar are the same as those taken at the middle, bottom or elsewhere. If it is known that this assumption of lot homogeneity is not met, the manufacturer's lot should be divided into homogeneous sub-lots and disposition of each sub-lot should be determined separately.

1.2.4. Consistency with anticipated performance and sources of variability

All manufacturing processes exhibit variation, the sources of which are many and varied. Some, such as time, temperature and rate settings, are under manufacturing control while others, such as ambient humidity and raw material variation, are not. Still other sources of variation have less to do with the process than with how the process is seen. Analytical accuracy and precision fall into this category. These sources of variability influence lot disposition decision making.

Generally, manufacturing variability can be categorized into lot-to-lot variation and variation within a lot. Analytical variation is composed of bias (or lack of accuracy) and variance (or lack of precision). All sources of variability should be monitored carefully in order to assure the best possible decision making with regard to lot disposition.

To assure that manufacturing variability does not get out of hand, devices such as control charts are employed (see deliverable 3.3.2.). Likewise, control charts and check sample programs are employed, to assure that analytical precision and accuracy are maintained. These devices can help assure that manufacturing performance is consistent with specifications (e.g., sources of variation are minimized).

2. Basic concepts

2.1. AQL and RQL

When decisions regarding disposition of product lots are made under uncertainty, it is possible that some lots which are generally considered to be of high quality will be rejected while others which are generally considered of poor quality will be accepted. This is unavoidable, but the risks can be contained and can be limited by the choice of sample size. In this document, the

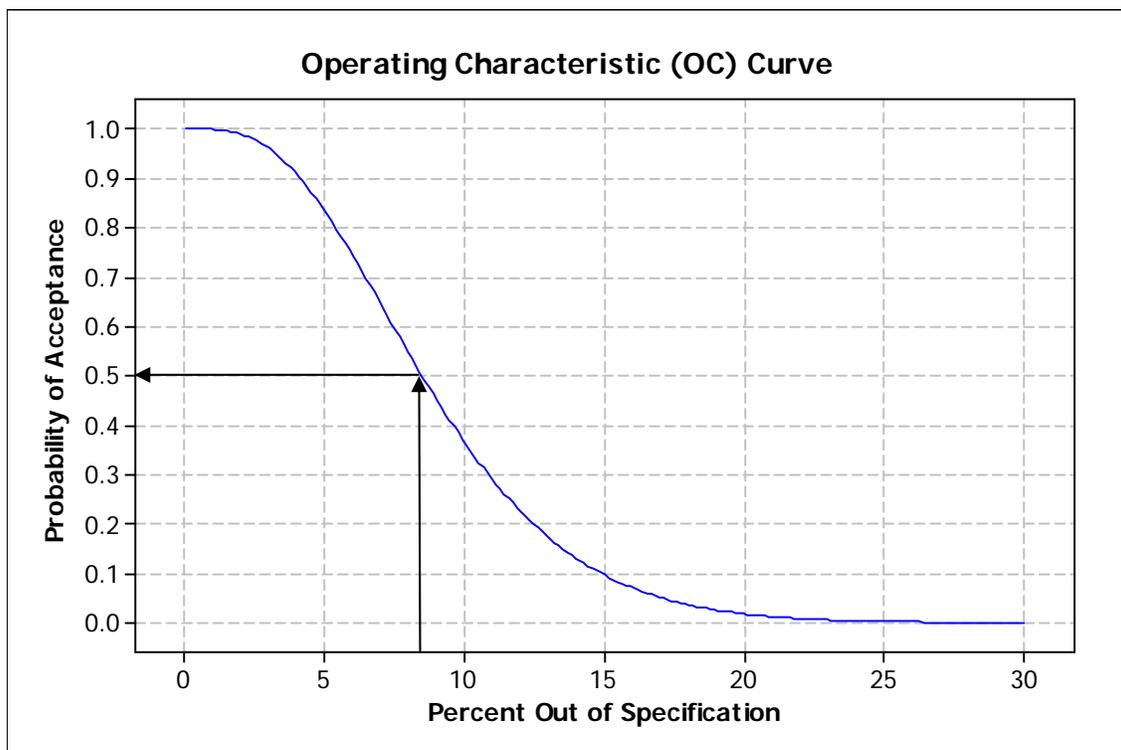
term “sample size” refers to the number of individual samples, not the quantity of product in each sample. Naturally, greater sample sizes are associated with lower uncertainty and, therefore, lower risks of incorrect decisions.

In devising sampling plans, a bargain is struck between producer and consumer. In effect, the consumer agrees to accept nearly all or approximately 95% of the product if the manufacturer produces at a certain specific average high quality level. This is called the Acceptable Quality Level or AQL. However, if the quality deteriorates so that it now averages at a certain specific low level, the consumer would like to detect the low quality level most or approximately 90% of the time. (This is the same as saying the consumer would accept the low quality level only 10% of the time.) That low quality level is then called the Rejectable Quality Level or RQL. Quality levels for both the AQL and the RQL are measured in percent out of specification.

2.2. Characterizing sampling plans

Sampling plans are generally characterized by a curve called an Operating Characteristic (OC) curve. It shows the probability of acceptance for all levels of quality graphically.

Figure 1. A General Operating Characteristic Curve



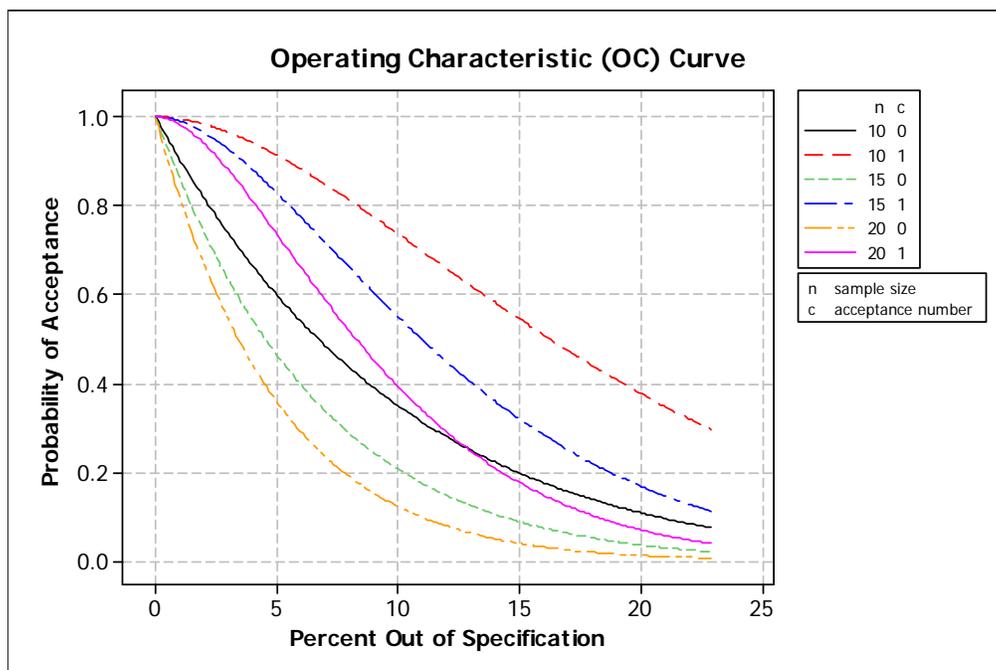
The AQL for the plan characterized by this curve is approximately 3%. If the manufacturer operates routinely so that only 3% of the manufactured product is outside the specification limits, then most or approximately 95% of the product lots will be accepted for consumption. Likewise, if the manufacturer operates so that as much as 15% of the product is out of specification, most of the time or 90% of the time the poor quality will be detected by the plan. It will be accepted and passed on to consumers only 10% of the time.

In this context, “percent out of specification” should be understood to mean the percent of the material within a given manufacturer’s lot that does not comply with the specifications. Within any production lot there is variation among individual samples. Larger variation will result in greater portions of the lot being out of specification than will be seen when the variation within a lot is small.

The AQL and RQL can be read directly from the OC curve, and so can the probabilities of acceptance of various other quality levels. One point of interest, for example, is the quality level where the burden of acceptance is shared equally by both producer and consumer. It is approximately 8%. At 8% out of specification, the probability of acceptance is roughly 0.5 (see Figure 1).

There are slight differences in the derivation and use of sampling plans for attributes and for variables. For attributes; e.g., foreign matter, insect fragments, the acceptance sampling plan is defined completely by the sample size and the acceptance number. Lot size need not enter in, but some published plans include it. We might state $n=15$ and $c=1$, meaning that 15 individual samples are to be taken, and if, in the 15 samples no defective units or only one defective unit is found the lot is accepted. If 2 or more defective units are found the lot is rejected. Figure 2 shows OC curves for attribute sampling plans with combinations of 10, 15 and 20 samples and acceptance numbers of 0 and 1. Notice that the $c=0$ plans are particularly demanding on the manufacturer in that they leave little room for error. Because of that, they should be used with caution and reserved for highly critical situations such as sampling for pathogens.

Figure 2. Examples of OC Curves for Attributes Sampling Plans



For variables such as protein, ash and moisture, the decision making process is a little more complicated:

Step 1. Calculate the mean, \bar{x}

$$\bar{x} = \frac{\sum x_i}{n}, \text{ where the } x_i \text{ represent the } n \text{ individual sample values.}$$

Step 2. Calculate the standard deviation

$$s = \sqrt{\frac{\sum x_i^2 - \frac{(\sum x_i)^2}{n}}{n-1}}$$

Step 3. Find the value of “k” that corresponds to the chosen sampling plan. See Section 3.2 and Table 3, below.

Step 4. Accept or reject the lot depending on the criteria in Table 1, below.

Table 1. Accept/Reject Criteria for Variables for Sampling Plans

	Only a lower specification limit (L) exists	Only an upper specification limit (U) exists	Both a lower (L) and an upper (U) specification limit exist
Accept the lot if:	$\bar{x} \geq L + ks$	$\bar{x} \leq U - ks$	$L + ks \leq \bar{x} \leq U - ks$

2.3. Sampling with individuals and sampling with composites

In order to estimate within-lot variation, it is necessary that individual samples be taken from the production lot in question and that they are analyzed individually. This practice runs counter to the practice of composite sampling where several samples are taken but mixed before only one chemical analysis is carried out. Composite sampling saves analytical costs and provides an estimate of the lot mean, but it provides no information on the variation within the lot. Therefore, it is not a useful practice for determining lot disposition.

A cost saving compromise can be reached, however. If an inspector has prior knowledge of within-lot variation for a given commodity and analyte, that information can be used as an estimate of current variation along with a current composite mean. The requirement for the use of the prior estimate of variation is that it be based on at least 30 individual observations taken over 3 or more production lots. Taking, for example, 10 observations from each of 3 lots would hold the same validity as taking 5 observations from each of 6 lots.

The historic within-lot standard deviation is defined as the ‘pooled’ within lot standard deviation calculated over the historic data:

$$s_p = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2 + \dots + (n_t - 1)s_t^2}{n_1 + n_2 + \dots + n_t - t}}$$

In this equation, n_i is the number of observations in the i^{th} lot, s_i^2 is the square of the standard deviation of the observations from the i^{th} lot, and t is the number of lots in the history.

For this compositing method to be valid, it is assumed that the manufacturing methods have not changed (have remained stable) since the last inspection data were gathered. If this assumption is not valid or if there is any doubt, individual samples should be taken in order to determine lot disposition.

3. Choosing a sampling plan

Sampling plans are chosen on the basis of whether the analyte in question is an attribute or a variable and on the degree of assurance of lot compliance needed. For attributes sampling, this document presents one plan with varying sample sizes. For variables plans, this document presents lists two AQL plans, one at 2.5% and one at 6.5%. The 2.5% AQL plans are to be used when the consequences of failure to comply with specifications are considered major. That is, failure to comply with specifications will cause performance failures and/or consumer distress. The 6.5% AQL plans are more lenient and are intended for use when failure to comply with specifications is considered minor. Minor issues are those which must be corrected but will not affect performance or consumer satisfaction directly.

Inspectors are encouraged to sample more extensively in either the 2.5% AQL or the 6.5% AQL category by increasing the sample size when grounds for suspicion exist. Increasing the sample size would be warranted when, for example, the inspector observes violations of Good Manufacturing Practices (GMPs) or the inspector notices unsanitary conditions in the manufacturing facility.

A third category of inspection is needed for microorganisms. Sampling plans for microorganisms are treated separately in Section 4.

3.1. Attribute plans

The attributes plans are shown graphically in Figure 3 and numerically in Table 2. (There are small differences between the graphical and tabulated probabilities due to slight differences in distributional assumptions.) All plans use an acceptance number of $c=1$, meaning that the lot in question should be accepted if the number of defective samples is 0 or 1, but rejected if the number of defective samples is 2 or greater. The choice of sample size is up to the inspector. However, it should be recognized that increased sample sizes, while more expensive, provide greater consumer protection.

Figure 3. Operating Characteristic Curves for Attribute Sampling Plans

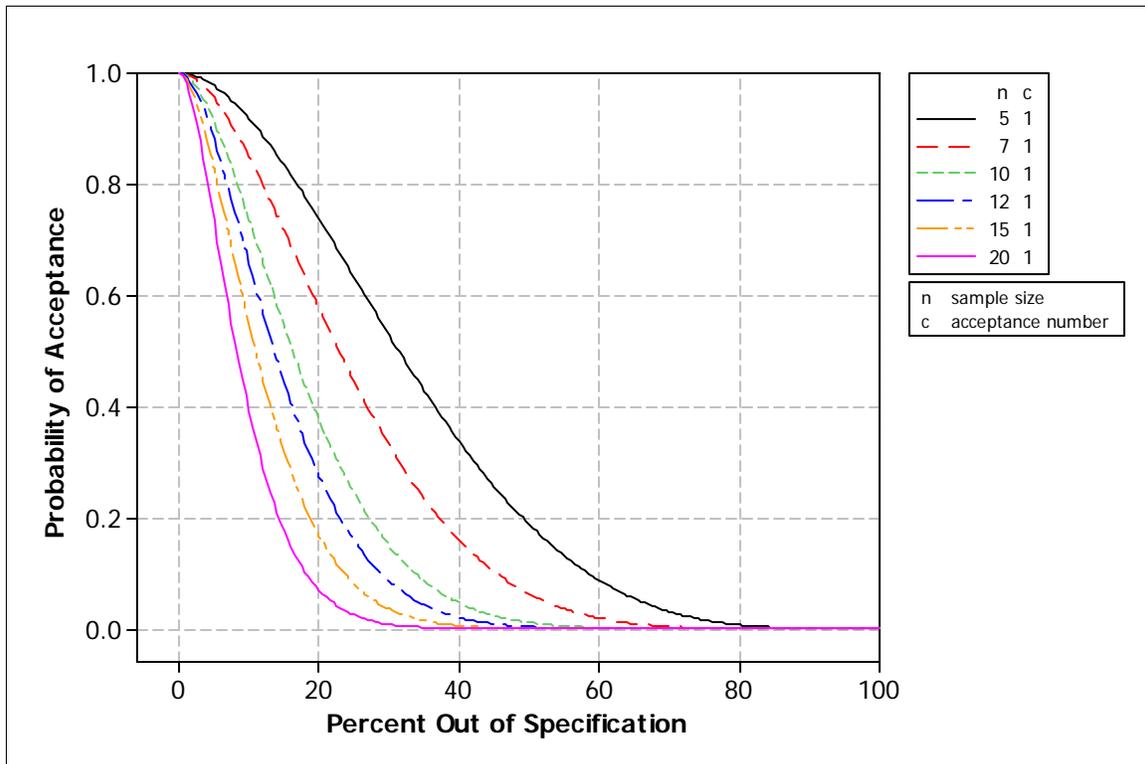


Table 2 Attribute Sampling Plan Probabilities

Sample Size	True Proportion Out of Specification	Probability of Acceptance	Sample Size	True Proportion Out of Specification	Probability of Acceptance
5	0.05	0.974	12	0.05	0.878
5	0.10	0.910	12	0.10	0.663
5	0.15	0.827	12	0.15	0.463
5	0.20	0.736	12	0.20	0.308
5	0.25	0.645	12	0.25	0.199
5	0.30	0.558	12	0.30	0.126
5	0.35	0.478	12	0.35	0.078
5	0.40	0.406	12	0.40	0.048
5	0.45	0.343	12	0.45	0.029
5	0.50	0.287	12	0.50	0.017
7	0.05	0.951	15	0.05	0.827
7	0.10	0.844	15	0.10	0.558
7	0.15	0.717	15	0.15	0.343
7	0.20	0.592	15	0.20	0.199
7	0.25	0.478	15	0.25	0.112
7	0.30	0.380	15	0.30	0.061
7	0.35	0.298	15	0.35	0.033
7	0.40	0.231	15	0.40	0.017
7	0.45	0.178	15	0.45	0.009
7	0.50	0.136	15	0.50	0.005
10	0.05	0.910	20	0.05	0.736
10	0.10	0.736	20	0.10	0.406
10	0.15	0.558	20	0.15	0.199
10	0.20	0.406	20	0.20	0.092
10	0.25	0.287	20	0.25	0.040
10	0.30	0.199	20	0.30	0.017
10	0.35	0.136	20	0.35	0.007
10	0.40	0.092	20	0.40	0.003
10	0.45	0.061	20	0.45	0.001
10	0.50	0.040	20	0.50	0.000

3.2. Variables plans

The 2.5% and 6.5% AQL variables plans are shown graphically in Figures 4 and 5, respectively, and combined in Table 3. As in the case of attributes plans, the choice of sample size is up to the inspector. However, it should be recognized from Figures 4 and 5 and from Table 3 that increased sample sizes, while more expensive, provide greater consumer protection.

Figure 4. Operating Characteristic Curves for 2.5% AQL Variables Sampling Plans

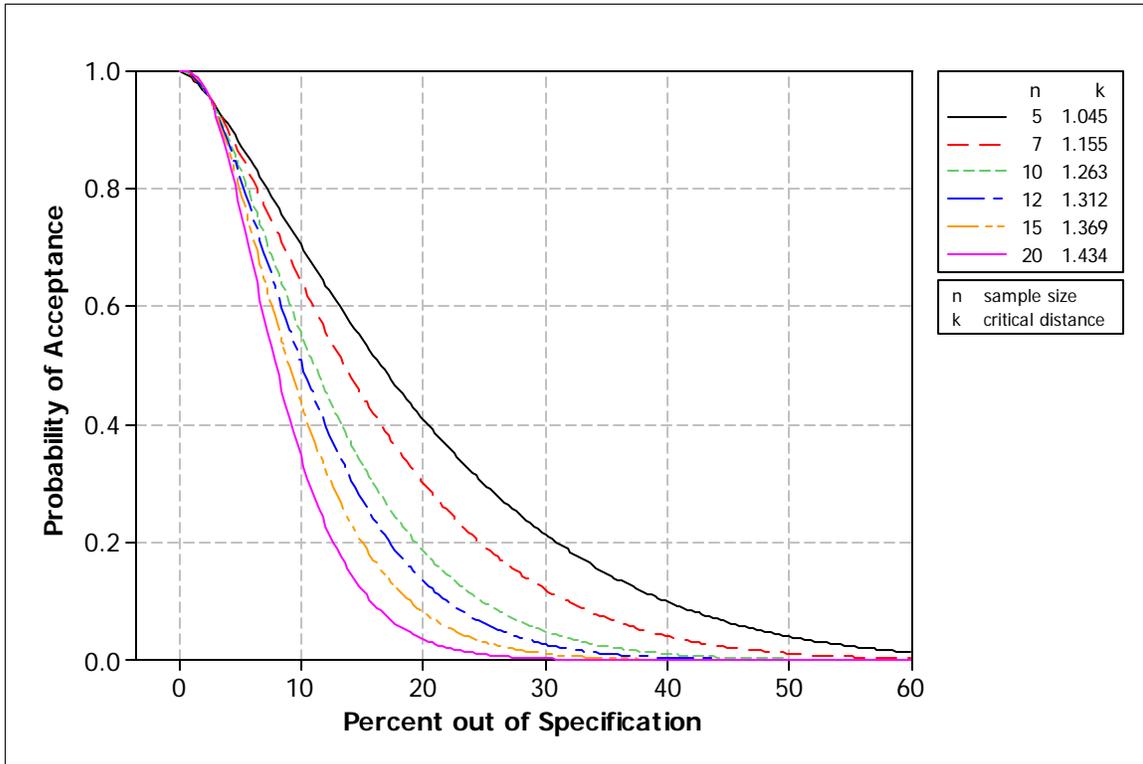


Figure 5. Operating Characteristic Curves for 6.5% AQL Variables Sampling Plans

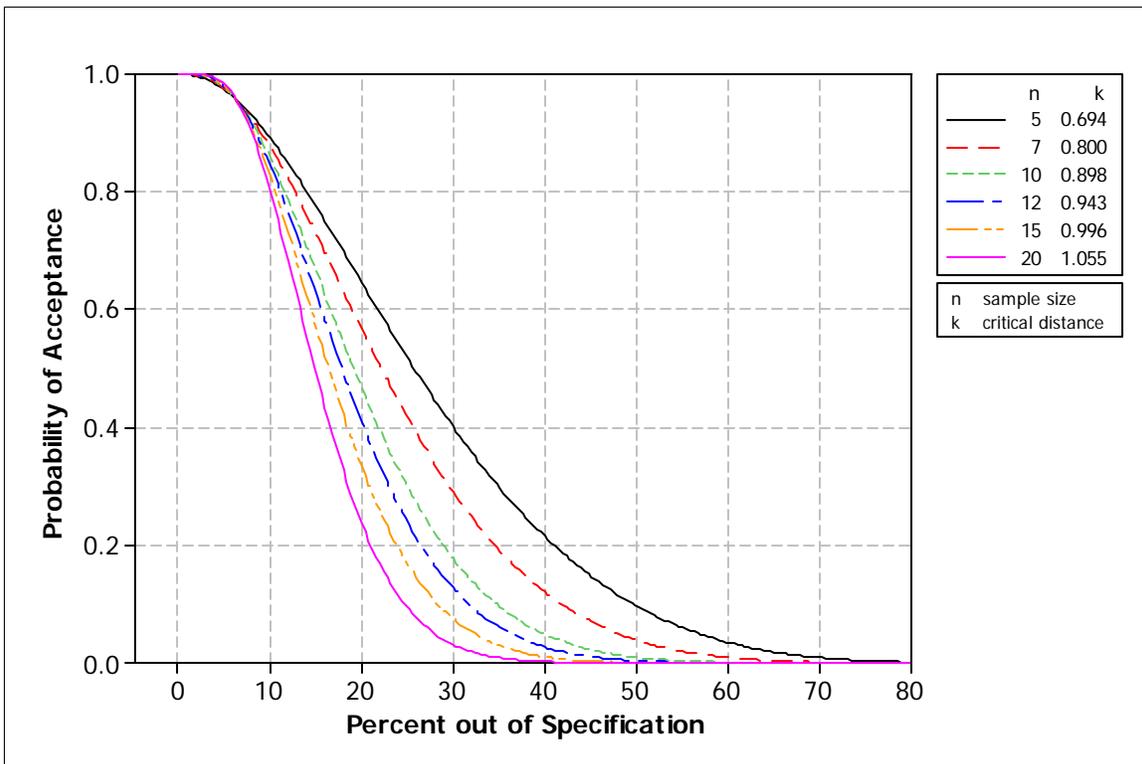


Table 3. 2.5% and 6.5% AQL Variables Sampling Plan Probabilities

Sample Size(n)	2.5% AQL Plan				6.5% AQL Plan			
	Critical Distance(k)	Percent Defective	Probability Accepting	Probability Rejecting	Critical Distance(k)	Percent Defective	Probability Accepting	Probability Rejecting
5	1.045	2.5	0.953	0.047	0.694	5	0.974	0.026
5	1.045	5	0.875	0.125	0.694	6.5	0.954	0.046
5	1.045	10	0.704	0.296	0.694	10	0.892	0.108
5	1.045	15	0.544	0.456	0.694	15	0.777	0.223
5	1.045	20	0.409	0.591	0.694	20	0.648	0.352
5	1.045	25	0.299	0.701	0.694	25	0.52	0.48
5	1.045	30	0.213	0.787	0.694	30	0.403	0.597
5	1.045	35	0.148	0.852	0.694	35	0.301	0.699
5	1.045	40	0.099	0.901	0.694	40	0.216	0.784
5	1.045	45	0.064	0.936	0.694	45	0.149	0.851
5	1.045	50	0.04	0.96	0.694	50	0.098	0.902

Table 3 (continued). 2.5% and 6.5% AQL Variables Sampling Plan Probabilities

Sample Size(n)	2.5% AQL Plan				6.5% AQL Plan			
	Critical Distance(k)	Percent Defective	Probability Accepting	Probability Rejecting	Critical Distance(k)	Percent Defective	Probability Accepting	Probability Rejecting
7	1.155	2.5	0.954	0.046	0.8	5	0.976	0.024
7	1.155	5	0.858	0.142	0.8	6.5	0.954	0.046
7	1.155	10	0.641	0.359	0.8	10	0.878	0.122
7	1.155	15	0.449	0.551	0.8	15	0.731	0.269
7	1.155	20	0.301	0.699	0.8	20	0.57	0.43
7	1.155	25	0.194	0.806	0.8	25	0.419	0.581
7	1.155	30	0.12	0.88	0.8	30	0.292	0.708
7	1.155	35	0.071	0.929	0.8	35	0.193	0.807
7	1.155	40	0.041	0.959	0.8	40	0.121	0.879
7	1.155	45	0.022	0.978	0.8	45	0.071	0.929
7	1.155	50	0.011	0.989	0.8	50	0.039	0.961
10	1.263	2.5	0.953	0.047	0.898	5	0.978	0.022
10	1.263	5	0.833	0.167	0.898	6.5	0.953	0.047
10	1.263	10	0.554	0.446	0.898	10	0.859	0.141
10	1.263	15	0.332	0.668	0.898	15	0.669	0.331
10	1.263	20	0.186	0.814	0.898	20	0.469	0.531
10	1.263	25	0.098	0.902	0.898	25	0.302	0.698
10	1.263	30	0.049	0.951	0.898	30	0.179	0.821
10	1.263	35	0.023	0.977	0.898	35	0.098	0.902
10	1.263	40	0.01	0.99	0.898	40	0.05	0.95
10	1.263	45	0.004	0.996	0.898	45	0.023	0.977
10	1.263	50	0.002	0.998	0.898	50	0.01	0.99
12	1.312	2.5	0.953	0.047	0.943	5	0.979	0.021
12	1.312	5	0.818	0.182	0.943	6.5	0.953	0.047
12	1.312	10	0.504	0.496	0.943	10	0.848	0.152
12	1.312	15	0.272	0.728	0.943	15	0.63	0.37
12	1.312	20	0.134	0.866	0.943	20	0.412	0.588
12	1.312	25	0.062	0.938	0.943	25	0.241	0.759
12	1.312	30	0.027	0.973	0.943	30	0.128	0.872
12	1.312	35	0.011	0.989	0.943	35	0.062	0.938
12	1.312	40	0.004	0.996	0.943	40	0.027	0.973
12	1.312	45	0.001	0.999	0.943	45	0.011	0.989
12	1.312	50	0	1	0.943	50	0.004	0.996

Table 3 (continued). 2.5% and 6.5% AQL Variables Sampling Plan Probabilities

Sample Size(n)	2.5% AQL Plan				6.5% AQL Plan			
	Critical Distance(k)	Percent Defective	Probability Accepting	Probability Rejecting	Critical Distance(k)	Percent Defective	Probability Accepting	Probability Rejecting
15	1.369	2.5	0.953	0.047	0.996	5	0.981	0.019
15	1.369	5	0.796	0.204	0.996	6.5	0.953	0.047
15	1.369	10	0.435	0.565	0.996	10	0.83	0.17
15	1.369	15	0.199	0.801	0.996	15	0.575	0.425
15	1.369	20	0.082	0.918	0.996	20	0.336	0.664
15	1.369	25	0.031	0.969	0.996	25	0.17	0.83
15	1.369	30	0.011	0.989	0.996	30	0.076	0.924
15	1.369	35	0.003	0.997	0.996	35	0.03	0.97
15	1.369	40	0.001	0.999	0.996	40	0.011	0.989
15	1.369	45	0	1	0.996	45	0.003	0.997
15	1.369	50	0	1	0.996	50	0.001	0.999
20	1.434	2.5	0.953	0.047	1.055	5	0.983	0.017
20	1.434	5	0.764	0.236	1.055	6.5	0.953	0.047
20	1.434	10	0.342	0.658	1.055	10	0.804	0.196
20	1.434	15	0.119	0.881	1.055	15	0.496	0.504
20	1.434	20	0.035	0.965	1.055	20	0.24	0.76
20	1.434	25	0.009	0.991	1.055	25	0.095	0.905
20	1.434	30	0.002	0.998	1.055	30	0.032	0.968
20	1.434	35	0	1	1.055	35	0.009	0.991
20	1.434	40	0	1	1.055	40	0.002	0.998
20	1.434	45	0	1	1.055	45	0	1
20	1.434	50	0	1	1.055	50	0	1

To use the variables acceptance sampling plans, an inspector chooses the AQL, either 2.5% or 6.5%, and the sample size. Then the inspector examines the data from the analyzed samples and calculates the mean and the standard deviation (as in Section 2, ii), above. The decision to accept or reject is made using the provisions of Table 1, above.

Example: the one-sided upper specification limit (U) for all purpose flour is 14.0%. An inspector, suspicious of lack of attention to quality, inspects 10 samples from a given lot and carries out separate moisture analyses for each sample. The inspector uses a 6.5% AQL plan. For 10 samples, the critical distance, k, is 0.898. The 10 moisture values obtained from the sampling are: 13.9, 14.1, 13.8, 14.5, 13.9, 13.5, 15.1, 14.1, 12.0 and 13.5. The mean, \bar{x} , of these 10 samples is 13.8%, and the standard deviation, s, is 0.80%. From Table 1, the inspector calculates:

$$U-ks = 14.0 - (0.898)(0.82) = 13.26.$$

Because the mean moisture, 13.8%, is greater than the calculated U-ks of 13.26, the lot cannot be accepted.

4. Sampling for micro-organisms.

The International Commission on Microbiological Specifications for Foods (ICMSF) has published sampling plans for acceptance or rejection of manufactured lots based on estimated microbiological load. Among these are two-class attributes plans and three-class attributes plans.

Two-class attributes plans define a maximum concentration of organisms, m . Any sample with a concentration larger than m is considered to be defective while samples with lower concentrations are non-defective. The calculation of underlying probabilities is slightly different from those used in the development of the attribute sampling plans described above, but for most practical purposes, the 2.5% and 6.5% AQL sampling plans described above can be used.

Three-class plans define another parameter, M , which is a maximum that no sample may exceed. This is in addition to the maximum, m , for samples. The sampling attribute plans given above can also be employed in this case, recognizing that the lot is rejected if any sample has a microbiological load exceeding M . This part of the three-class sampling plan is similar to a sampling plan having acceptance number equal to 0. In most cases, that is not desirable, but in the case of pathogens, it is essential.

Salmonella sampling is often treated as a special case. The ICMSF generally recommends taking multiple 25gram samples to determine lot disposition. OC curves are displayed based on varying sample amounts in total grams. A standard is defined as zero colony forming units (CFUs) in 100g of product. The probability of finding no CFUs in 10, 25 gram samples or 250 grams is calculated using Poisson probabilities. The Poisson density is:

$$f(x) = e^{-np} (np)^x / x!, x = 0,1,2,3\dots,$$

but it reduces to

$$f(0) = e^{-np}$$

when the number of CFU's permitted in the sample is 0. If we seek detection of as many as 1 CFU/100g, then in a sample of 250 grams, whether derived from 25, 10g individual samples or 250, 1g samples is

$$f(0) = e^{-\frac{250(1)}{100}} = e^{-2.5} = 0.082$$

This means that if we take a sample of 250g and find no Salmonella CFUs, we can be 1-f(0) or 91.8% confident [that is, 100% times (1-0.082)] that there are no CFUs in the batch represented by the sample. The following table shows the confidence levels corresponding to various sample sizes.

Table 4. Sample sizes and Resulting Confidence Percentages for a Salmonella Sampling Plan.

Number of 25g samples	Total grams	Confidence of 0 CFUs in the lot
5	125	71.35
10	250	91.79
15	375	97.65
20	500	99.33
25	625	99.81
30	750	99.94
35	875	99.98

It seems unlikely that such small amounts of product could provide such great confidence, but it must be remembered that the basis for the plan is the common practice assumption of a standard of zero CFUs in 100 grams of product. Changing the base would change the confidence levels.

5. References

Codex Alimentarius, General Guidelines on Sampling CAC/GL 50-2004.
<http://www.codexalimentarius.net>

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SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Deliverable C.3.3.4
Recommended Lot Sizes for Food Aid Commodities

Background

The Free Online Dictionary¹ defines a batch as “a quantity required for or produced as the result of one operation.” In food (and other) manufacturing, a batch defines a quantity of product that has uniform content, characteristics and physical properties. Throughout this recommendation, the term ‘lot’ is used and should be considered synonymous with ‘batch’.

Definition of a lot by food manufacturers can take many forms and has several purposes. A lot defines the amount of product that is represented by a Certificate of Analysis (COA) and the results of analyses that accurately represent that batch. Manufacturers must collect representative samples from a lot upon which analyses are conducted and the results thereof are reported on the COA to the purchaser. Results reported on the COA should conform, in every detail, to the previously agreed upon product specifications. Identification of a lot is usually some variation of an alphanumeric code and is the basis for tracking a batch from production to delivery to the final consumer.

In the context of food manufacturing, defining a large quantity of product as a single lot has both positive and negative aspects and is a balance between reward and risk. By defining a lot as a large quantity of product, the reward to manufacturers involves reduced interruptions (batch code and/or label changes) and reduced sampling and testing to comply with COA requirements. However, defining a large quantity of product as a single lot puts that large quantity at risk for recall if issues with quality or safety are found. The SUSTAIN technical team has made a significant effort to obtain information on the typical lot size for food aid commodities. The resources tapped include individuals working for companies producing food aid products and resources in companies producing similar products, commodity groups representing various industry segments, USDA’s own resources within GIPSA/FGIS, and the SUSTAIN technical team’s personal knowledge and experience.

Industry Practice

Designation of a quantity of product to declare a lot varies among product categories and the type of process system. In the processing of packaged foods, a lot may be defined as the quantity

¹ <http://www.thefreedictionary.com/batch>

of product produced on a single process line during one eight (8) hour shift. Highly processed foods (soy protein isolates) and foods dry blended from multiple ingredients, which are blended to achieve a high level of within batch uniformity may designate one blender load as a batch. Thermally processed foods (e.g. canned tuna) that use a static retort may designate a single retort load as a batch. However, when a continuous retort is used, a defined time interval may be the characterizing limit for a lot, usually the quantity produced during one shift on a single production line.

For a number of milling related industry segments, and specifically flour milling, where bulk shipments are made, the common lot unit is one transportation vessel, either one truck load (ca. 50,000 lbs.) or one railcar (ca. 180,000 lbs.).

Containerized shipments are generally restricted to the smaller, 20-foot containers' that have a normal capacity of 44,000 lbs. (400, 50 kilo bags). 'Bulk container shipments' could contain containers fitted with a grain door, containing up to 54,000 lbs.

The USDA handbook² describes several examples of commodity lot sizes for commodities from which Table I was reproduced.

Table I – Maximum Lot Sizes	
Commodity	Lot Size
Dry Corn, Oat, Soybean, Sorghum, and Wheat Products	500,000 (225,000 kg)
Vegetable Oil, Shortening and Syrup	80,000 primary containers or one truck or railcar for bulk product
Pasta and Margarine	150,000 (76,500 kg)
Products containing Milk	180,000 (81,000 kg)

Lot sizes in Table II are, for the most part, based on input from the industry segments or representatives from companies supplying food aid products. The milling sector was generally helpful and provided useful information.

SUSTAIN experienced difficulty obtaining cooperation from some industry segments, some commodity groups and individuals for the simple information on typical commercial lot sizes. The initial requests for obtaining information on typical lot sizes were made concurrent with the requests for information on recommended quality parameters during January and February 2008. To date, several unfulfilled requests for information remain. Where industries/companies were not forthcoming with information on lot sizes, estimates in Table II are based on their respective experiences and knowledge of the SUSTAIN team, for similar industries and products.

Recommendations

- Lot size shall not exceed the quantity designated in Table II.

² Processed Commodities Handbook, Chapter 2 – Sampling, USDA-FGIS 8/1/94, page 2-4

- For commodities such as CSB, WSB, wheat flour, cornmeal and similar products, a single lot shall not exceed the quantity stated in Table II and that quantity shall be produced on a single manufacturing process system (i.e. line) within twenty-four (24) consecutive hours.
- Products such as dehydrated soup mixes, canned salmon and similar products shall be the quantity produced during a single “shift” (typically 8 hours) on one production line.
- A lot shall be declared upon a significant interruption in the manufacturing process system. Breaks in processing to clear blockages or other minor mechanical repairs would not require designation of a new lot.
- A complete certificate of analysis shall be required for each lot.

Table II – Recommended Lot Sizes for Food Aid Commodities		
Commodity Categories	FSA Commodity Requirement ID	Recommended lot size Not to Exceed (NTE, lbs)
Blended and Fortified Foods		
<i>These products are fortified with 7 micronutrients.</i>		
a. All Purpose Wheat Flour/ Bread Flour	WFBF4	1 railcar NTE 180,000
b. Bulgur / Soy Fortified Bulgur	WBSF11	1 railcar NTE 180,000
c. Cornmeal	CM3	1 railcar NTE 180,000
d. Instant Corn-Soya Masa Flour	MF10	1 railcar NTE 180,000
e. Soy Fortified Cornmeal	SFCM3	1 railcar NTE 180,000
f. Soy Fortified Sorghum Grits	SFSG13	1 railcar NTE 180,000
g. Value Added Soy Products defatted flour soy protein concentrate soy protein isolate soy milk replacer textured soy protein)	VASP4	NTE 50,000 NTE 12,000 NTE 50,000 NTE 12,000 NTE 50,000
<i>These products are fortified with 18 micronutrients.</i>		
h. Corn-Soy Blend	CSB13	1 railcar NTE 180,000
i. Corn Soy Milk	CSM3	1 railcar NTE 180,000
j. Instant Corn Soy Milk	ICSM3	1 railcar NTE 180,000
k. Wheat Soy Blend	WSB15	1 railcar NTE 180,000
l. Wheat Soy Milk	WSM10	1 railcar NTE 180,000
Whole or Partially Processed Grains		
m. Barley	BAR4	1 Truckload NTE 50,000
n. Bagged Whole Grains [Corn, sorghum, soybeans, wheat]	KCBG8	1 railcar NTE 180,000
o. Buckwheat (Groats, Grits, Flour)	BWP4	1 Truckload NTE 50,000
p. Dry Edible Beans (11 types of beans and Peas)	DEB4	1 Container NTE 50,000
q. Milled Rice	MR20	1 railcar NTE 180,000

Table II – Recommended Lot Sizes for Food Aid Commodities		
Commodity Categories	FSA Commodity Requirement ID	Recommended lot size Not to Exceed (NTE, lbs)
r. Peas and Lentils (whole dry peas, split peas, lentils)	PL4	1 Container NTE 50,000
s. Bulk Soybean Meal (common product of commerce)	None	500,000
Commercial Products		
t. Dehydrated Potato Products (several options)	DPP4	The quantity obtained during one (1) eight-hour shift from a single production line.
u. Dehydrated Soup Mix (several options)	DSM5	The quantity obtained during one (1) eight-hour shift from a single production line
v. Non Fortified Nonfat Dry Milk	DME2	1 Truckload NTE 50,000
w. Canned Pink Salmon	None	The quantity obtained during one (1) eight-hour shift from a single production line
Vegetable Oil/Fats		
x. Vegetable Oil (Soybean and vegetable)	VO11	1 Truckload NTE 60,000
y. Bulk Oil (Crude, Degummed Soybean; Fully Refined Soybean Oil; Crude Corn Oil; Crude Sunflower Seed) and Tallow	BOT1	1 Truckload NTE 60,000
z. Corn Oil	CO4	1 Truckload NTE 60,000
aa. Refined Sunflower Seed Oil	SFSO4	1 Truckload NTE 60,000

Contract AG-3151-C-07-0048
 Blended and Fortified Products

Assay	Units	All Purpose Flour	Bread Flour	Bulgur	Soy-Fortified Bulgur	Cornmeal	Soy Fortified Cornmeal	Instant Corn-Soy Masa Flour	Soy Fortified Sorghum Grits	Corn-Soy Blend	Corn-Soy-Milk	Instant Corn-Soy-Milk	Wheat-Soy Blend	Wheat-Soy Milk
Chemical - Proximate														
Moisture	%	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10	AOAC 925.10
Protein	%	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	--	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23
Fat	%	--	--	AOAC 922.06	AOAC 922.06	AOAC 922.06	AOAC 922.06	AOAC 922.06	AOAC 922.06	AOAC 922.06				
Ash	%	AOAC 923.03	AOAC 923.03	AOAC 923.03	AOAC 923.03	AOAC 923.03	AOAC 923.03	AOAC 923.03	AOAC 923.03	--	--	--	AOAC 923.03	AOAC 923.03
Crude Fiber	%	--	--	AOAC 962.09E	AOAC 962.09E	AOAC 962.09E	AOAC 962.09E	--	AOAC 962.09E	AOAC 962.09E	AOAC 962.09E	AOAC 962.09E	AOAC 962.09E	AOAC 962.09E
Chemical - Other														
Vitamin A	IU/lb	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06	AACC 86-06
Calcium	mg / 100g	AOAC 985.01	AOAC 985.01	AOAC 985.01	AOAC 985.01	AOAC 985.01	AOAC 985.01	AOAC 985.01	AOAC 985.01	--	--	--	--	--
Iron	mg / 100 g	AOAC 999.11	AOAC 999.11	AOAC 999.11	AOAC 999.11	--	AOAC 999.11	AOAC 999.11	AOAC 999.11	AOAC 999.11	--	AOAC 999.11	AOAC 999.11	AOAC 999.11
pH	pH units	--	--	--	--	--	--	AOAC 940.22	--	--	--	--	--	--
Lysine	%	--	--	--	--	--	--	--	--	--	--	--	AACC 07-01	AACC 07-01
Physical / Functional														
Particle Size	%	--	--	AACC 66-20	AACC 66-20	21 CFR 137.250,	21 CFR 137.250,	AACC 66-20	AACC 66-20	AACC 66-20	AACC 66-20	AACC 66-20	AACC 66-20	AACC 66-20
Physicochemical														
Falling Number	Sec	AACC 56-81B	AACC 56-81B	--	--	--	--	--	--	--	--	--	--	--
Microbiological														
Aerobic Plate count	cfu/g	--	--	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3				
Coliform, E. coli	cfu/g	--	--	--	--	--	--	--	--	--	--	--	--	--
Salmonella	Present / absent	--	--	--	--	--	--	--	--	FDA-BAM, 8th Ed., Chap 4				
Staph aureus, cp	cfu/g	--	--	--	--	--	--	--	--	FDA-BAM, 8th Ed., Chap 5				
Mycotoxins														
Aflatoxin, Qualitative	Positive / Negative	--	--	--	--	AOAC 993.16	AOAC 993.16	AOAC 993.16	--	AOAC 993.16	AOAC 993.16	AOAC 993.16	--	--
Aflatoxin, Quantitative	ppb	--	--	--	--	AOAC 972.26	AOAC 972.26	AOAC 972.26	--	AOAC 972.26	AOAC 972.26	AOAC 972.26	--	--
Vomitoxin, Test kits	2 ppm Max	Neogen 8330.	Neogen 8330.	Neogen 8330.	Neogen 8330.	--	--	--	--	--	--	--	Neogen 8330.	Neogen 8330.

Commercial Products

Assay	Units	Dehydrated Potatoes	Dehydrated Soup Mix	Non-Fortified Nonfat Dry Milk	Canned Pink Salmon	Soy Flour	Soy Concentrate	Soy Isolate	Textured Soy Protein	Soy Milk Replacer
Chemical - Proximate										
Moisture	%	AOAC 934.06 [1]	AOAC 934.06 [1]	AOAC 927.05	--	AOAC 925.10				
Protein	%	AOAC 992.23	AOAC 992.23	AOAC 992.23	--	AOAC 992.23				
Fat	%	--	--	AOAC 932.06	--	AOAC 945.39				
Ash	%	--	--	AOAC 930.30	--	AACC 08-16				
Crude Fiber	%	--	--	--	--	AOAC 962.09F				
Chemical - Other										
Reducing sugars	%	AOAC 906.03 [2]	--	--	--	--	--	--	--	--
Sulfite content	ppm	AOAC 990.28	--	--	--	--	--	--	--	--
Salt	--	--	--	--	AOAC 976.18	--	--	--	--	--
Sodium	--	--	AOAC 984.27	--	AOAC 969.23	--	--	--	--	--
Calcium	--	--	--	--	--	--	--	--	--	AOAC 984.27
Phosphorus	--	--	--	--	--	--	--	--	--	AOAC 984.27
Monosodium Glutamate	%	--	AOAC 970.37	--	--	--	--	--	--	--
Physical / Functional										
Particle Size	%	--	--	--	--	AACC 66-20				
Scorched Particles	mg	--	--	ADPI [4] Page 30	--	--	--	--	--	--
Physicochemical										
Titratable Acidity (lactic acid)	%	--	--	ADPI [4] Page 33	--	--	--	--	--	--
Protein Dispersibility Index	%	--	--	--	--	AACC 46-24	AACC 46-24	AACC 46-24	--	--
Nitrogen Solubility Index	%	--	--	--	--	AACC 46-23	AACC 46-23	AACC 46-23	--	--
Urease	pH units increase	--	--	--	--	AACC 22-90	AACC 22-90	AACC 22-90	--	--
Trypsin Inhibitor	--	--	--	--	--	AOCS Ba 12 -75	AOCS Ba 12 -75	AOCS Ba 12 -75	--	AOCS Ba 12 -75
Solubility Index	%	--	--	ADPI [4] Page 32	--	--	--	--	--	--
Whey Protein Nitrogen Classification	L, M, H	--	--	[5]	--	--	--	--	--	--
Water Absorption Ratio	%	--	--	--	--	--	--	--	TBD [6]	--
Microbiological										
Aerobic Plate count	cfu/g or MPN	FDA-BAM, 8th Ed. Chap 3	AOAC 966.23	FDA-BAM, 8th Ed. Chap 3	--	FDA-BAM, 8th Ed. Chap 3				
Coliform	cfu/g or MPN	FDA-BAM, 8th Ed., Chap 4	AOAC 966.24	FDA-BAM, 8th Ed., Chap 4	--	FDA-BAM, 8th Ed., Chap 4				
<i>E. coli</i>	cfu/g or MPN	FDA-BAM, 8th Ed., Chap 4	AOAC 966.24	FDA-BAM, 8th Ed., Chap 4	--	FDA-BAM, 8th Ed., Chap 4				
<i>Salmonella</i>	resent / absen	FDA-BAM, 8th Ed., Chap 5	AOAC 994.04	FDA-BAM, 8th Ed., Chap 5	--	FDA-BAM, 8th Ed., Chap 5				
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	--	--	FDA-BAM, 8th Ed., Chap 12	--	--	--	--	--	--
Yeast	cfu/g	FDA-BAM, 8th Ed. Chap 18	AOAC 997.02	--	--	--	--	--	--	--
Mold	cfu/g	FDA-BAM, 8th Ed. Chap 18	AOAC 997.02	--	--	--	--	--	--	--
Reduced Sulfite Anaerobic Clostridium	cfu/g	--	AOAC 976	--	--	--	--	--	--	--
Reduced Sulfite Anaerobic Clostridium	cfu/g	--	AOAC 976	--	--	--	--	--	--	--
Antibiotic	Present / absent	--	--	[3]	--	--	--	--	--	--

References

[1] This assay requires a combination of AOAC 934.06 (first paragraph) and the paragraph below:
 6.3.4 Examination for moisture. Weigh to the nearest 0.1 mg, two, approximately 2-gram, samples
 of the ground, screened material (that portion which has passed through the 20 mesh screen and has

Assay	Units	Dehydrated Potatoes	Dehydrated Soup Mix	Non-Fortified Nonfat Dry Milk	Canned Pink Salmon	Soy Flour	Soy Concentrate	Soy Isolate	Textured Soy Protein	Soy Milk Replacer
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been collected on the 40 mesh screen) into tared, dry, aluminum weighing dishes approximately 50.8 or 63.5 mm (2 or 2-1/2 inches) in diameter and 19.1 mm (3/4 inch) in depth with tight-fitting covers. Place the dishes with cocked lids in a vacuum-oven and dry for 6 hours at 70 degrees Centigrade under a pressure of not more than 100 mm of mercury. During drying, admit to the oven a slow current of air (approximately 2 bubbles per second), dried by passing through concentrated sulfuric acid. Remove the dishes, place the lids on tightly, and allow them to cool in a desiccator before weighing. Calculate the percent of moisture in the original samples and report the average of the two samples.

[2] This assay requires a combination of AOAC 906.03 or AOAC 923.09 and the paragraph below:
 Further preparation of sample for reducing sugars test. Weigh 25 grams of potato granules or ground, sieved material into a 250 mL centrifuge bottle, add 75 mL of water, mix, and allow to stand for ½ hour. Add 100 mL of 95 percent ethyl alcohol plus 1 gram of calcium carbonate. Heat in a hot water (90 degrees Centigrade) bath for 1 hour while stirring frequently. Centrifuge sample at 1,500 rpm for 10 minutes and decant the liquid portion into a 600 mL beaker.
 Repeat extraction three more times, each time using 75 mL of 80 percent ethyl alcohol, heating in the hot water (90 degrees Centigrade) bath for 15 minutes while stirring frequently. Centrifuge at 1,500 rpm for 10 minutes and decant the liquid into the 600 mL beaker. Evaporate combined extracts on a steam bath to a volume of 50 to 75 mL. Quantitatively transfer extract into 250 mL volumetric flask with hot distilled water, cool, add 10 mL of saturated, neutralized lead acetate 4/, and bring to volume. Filter liquid through No. 2V Whatman or equivalent filter paper into a 250 mL Erlenmeyer flask containing about 4 grams of potassium oxalate. Mix filtrate thoroughly and allow precipitate to settle. To remove excess lead, add a few potassium oxalate crystals. Decant liquid through No. 2V Whatman or equivalent filter paper into a 250 mL glass-stoppered Erlenmeyer flask. Reagents used shall be American Chemical Society Reagent Grade.

[3] Standard Methods for the Examination of Dairy Products, R.T. Marshall , ed

[4] Methods of Analysis of the American Dairy Products Institute Bulletin 916, 2002

[5] US Standards for Grades of Nonfat Dry Milk (Spray Process) USDA, AMS-Dairy Division, Feb 2001

[6] Functional to be defined.



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Deliverable C.3.3.5

In fulfillment of deliverable C.3.3.5, SUSTAIN has reviewed current testing indices and organoleptic performance elements. Where specific tests or assays are required of vendors to demonstrate compliance with contract specifications, we have recommended one accepted standard analytical method for full compliance with micronutrient requirements.

Attached is a MS Excel[®] workbook containing the recommended assay procedures for the major components listed on product definition and/or sample certificate of analysis for the food aid products. The products and the recommended analytical procedures are divided on to four separate pages of the workbook, one for each of the four categories of food products identified by USDA. The summary is intended to be used to identify approved methods for the key analytes identified in the performance language documents.

Each worksheet contains the major analytes listed along the left hand vertical column and the products as column headings across the top. The intersecting 'cell' contains the recommended analytical procedure for that analyte in that food matrix. Not all assays listed are required for every product and those assays that are neither required nor applicable for a particular product are denoted by a dash in the corresponding cell.

In some instances in the performance language documents (previously submitted), references are made to other sources of product definition (e.g. US Grading Standards for Non-fat dry milk) that identify appropriate analytical procedures; those have not been reproduced in this summary.

CONFIDENTIAL
 Contract AG-3151-C-07-0048
 Deliverable C.3.3.5 Recommended Analytical Procedures for Vegetable Oils-Fats

Contract AG-3151-C-07-0048
 Vegetable Oils-Fats

Assay	Units	Vegetable Oil Products	Corn Oil	Sunflower Seed Oil	Bulk Oil & Tallow
Antioxidants (<i>if added</i>)	ppm	AOCS Ce 6 -86	--	AOCS Ce 6 -86	--
Air Oxygen Method	hours	AOCS Cd 12 -57	AOCS Cd 12 -57	AOCS Cd 12 -57	AOCS Cd 12 -57
Appearance		Visual	Visual	Visual	--
Cold Test	hours	AOCSCc 11-53	AOCSCc 11-53	AOCSCc 11-53	AOCSCc 11-53
Color	Lovibond	AOCS Cc 13e-92	AOCS Cc 13e-92	AOCS Cc 13e-92	AOCS Cc 13e-92
Dimethylpolysiloxane (<i>if added</i>)	ppm	AOCS Cd 24 -95	AOCS Cd 24 -95	AOCS Cd 24 -95	
Fat stability (OSI)	hours	AOCS Cd 12b-92	AOCS Cd 12b-92	AOCS Cd 12b-92	AOCS Cd 12b-92
Flash Point	° F	--	--	--	AOCS Cc 9a -48
Flavor	organoleptic	AOCS Cg 2 -83	AOCS Cg 2 -83	AOCS Cg 2 -83	--
Free fatty acids	(% as Oleic)	AOCS Ca 5a-40	AOCS Ca 5a-40	AOCS Ca 5a-40	AOCS Ca 5a-40
Halphen Test (Crude Sunflower Seed oil)		--	--	--	AOCS Cb 1 -25
Insoluble Impurities	%	AOCS Ca 3a-46	AOCS Ca 3a-46	AOCS Ca 3a-46	AOCS Ca 3a-46
Iodine value		--	AOCS Cd 1d-92	AOCS Cd 1d-92	--
Linolenic acid	%	--	--	--	AOCS Ce 1c-89
Moisture and volatile matter	(%-KF)	AOCS Ca 2d-25	AOCS Ca 2d-25	AOCS Ca 2d-25	AOCS Ca 2d-25
Oleic Acid [1]	% of TFA	--	--	AOCS Ca 5b.71	AOCS Ca 5b.71
Peroxide value (PV)	meq/kg	AOCS Cd 8-53	AOCS Cd 8-53	AOCS Cd 8-53	AOCS Cd 8-53
Phosphorous	%	--	--	--	AOCS Ca 12a -02
Retinyl Palmitate	IU/g	AOAC 960.45	AOAC 960.45	AOAC 960.45	--
Saponification Value	Mg KOH/g %	--	--	AOAC 960.45	AOAC 960.45
Unsaponifiable Matter (%)	%	--	--	--	AOCS Ca 6a -40

References

[1] Applicable to mid oleic sunflower seed oil.

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Contract AG-3151-C-07-0048

Deliverable C.3.3.5 Recommended Analytical Methods for Whole or Partially Processed Grains

Contract AG-3151-C-07-0048

Whole or Partially Processed Grains

Assay	Units	Barley	Buckwheat Bagged Whole (Groats, Flour & Grits)	Dry Edible Beans	Milled Rice	Peas & Lentils (Whole Dry Peas, Split Peas & Lentils)	Soybean Meal
Chemical - Proximate							
Moisture	%	AACC 44-15A	AACC 44-15A	AACC 44-15A	AACC 44-15A	AOAC 44.17	AOCS Ba 2a-38
Protein	%	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOAC 992.23	AOCS Ba 4e-93
Ash	%	--	--	AOAC 923.03	--	--	--
Fat	%	--	--	--	--	--	AOCS Ba 3-38
Crude Fiber	%	--	--	AOAC 962.09E	--	--	AOCS Ba 6-84
Chemical - Other							
Urease	pH increase	--	--	--	--	--	AOCS Ba-9-58 ²
Physicochemical							
Protein Dispersibility Index	%	--	--	--	--	--	AOCS Ba-10-65 ²
Physical / Functional							
Color		--	--	TBD	--	--	--
Aroma		--	--	TBD	--	--	--
Flavor		--	--	TBD	--	--	--
Particle Size	%	AACC 66-20	--	AACC 66-20	--	AACC 66-20	--
Microbiological							
Aerobic Plate Count	cfu/g	FDA-BAM, 8th Ed. Chap 3	--	FDA-BAM, 8th Ed. Chap 3	--	FDA-BAM, 8th Ed. Chap 3	FDA-BAM, 8th Ed. Chap 3
Coliform	cfu/g or MPN	FDA-BAM, 8th Ed., Chap 4	--	FDA-BAM, 8th Ed., Chap 4	--	--	--
<i>E. coli</i>	cfu/g or MPN	FDA-BAM, 8th Ed., Chap 4	--	FDA-BAM, 8th Ed., Chap 4	--	--	FDA-BAM, 8th Ed., Chap 4
<i>Salmonella</i>	Present / Absent	FDA-BAM, 8th Ed., Chap 5	--	FDA-BAM, 8th Ed., Chap 5	--	FDA-BAM, 8th Ed., Chap 5	FDA-BAM, 8th Ed., Chap 5
<i>Staphylococcus aureus</i> , coagulase positive	cfu/g	--	--	FDA-BAM, 8th Ed., Chap 12	--	--	--
Yeast & Mold	cfu/g	FDA-BAM, 8th Ed. Chap 18	--	--	--	--	--
Mycotoxins							
Vomitoxin	ppm	AOAC 986.18	--	AOAC 986.18	--	--	--
Non Grading Factors							
Test Weight	lbs/bu	--	FGIS Methods	--	--	--	--
Dockage	%	--	FGIS Methods	--	--	--	--

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Contract AG-3151-C-07-0048

Deliverable C.3.3.5 Recommended Analytical Methods for Whole or Partially Processed Grains

Assay	Units	Barley	Bagged Whole Grains	Buckwheat (Groats, Flour & Grits)	Dry Edible Beans	Milled Rice	Peas & Lentils (Whole Dry Peas, Split Peas & Lentils)	Soybean Meal
US Grain Grading Standards		FGIS Grading	FGIS Grading	--	FGIS Grading	FGIS Grading	FGIS Grading	--
Purity	%	--	--	Typically Grain grading factors, but no US grading standards exist for buckwheat	--	--	--	--
Whole Groats (Retained on US Std 7/64' round hole sieve)	%	--	--		--	--	--	--
Unhulled kernels	%	--	--		--	--	--	--
Whole groat	%	--	--		--	--	--	--
Foreign material	%	--	--		--	--	--	--
Mineral matter	%	--	--		--	--	--	--
Insect infestation (live insects)	Count	--	--		--	--	--	--
Insect infestation (dead insects)	Count	--	--		--	--	--	--



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USDA Food Aid Quality Project
Contract AG-3151-C-07-0048
Deliverable C.3.3.7
Analytical Cost Estimates

The original scope of deliverable § C.3.3.2 was to “*Recommend a scientifically valid commodity sampling and testing regime to certify vendor compliance with commodity specifications.*” Due to the lack of data upon which a scientifically valid sampling plan could be based, with the agreement of USDA, confirmed in modification 0004 to contract AG-3151-C-07-0048 effective July 17, 2008, the scope of deliverable § C.3.3.2 was modified to read “*Recommend a minimum standard by which a vendor will ascertain that its internal commodity specification compliance certification procedures are equal or superior to the standard.*” Similarly, in the same modification, deliverable § C.3.3.3 was modified to read “*Recommend a sampling and testing regime of sufficient rigor and based upon defensible data analysis for USDA to employ for independent verification of product compliance with contract specifications at point of delivery to the U.S. government.*”

Included as part of deliverable § C.3.2.2 (Performance Language for the food aid products) were recommendations for minimum testing by the manufacturers and reporting of results on a certificate of analysis (COA). These recommended analyses define the minimum level of testing required to assure the product sample tested meets the specified parameters defined in the Commodity Requirement documents.

The cost estimates included herein for conducting product analyses are based on the average analytical costs posted on the websites of four commercial, for profit, analytical laboratories (Table I). Some analyses listed in the COA (e.g., dispersibility of CSB in water) are not routinely conducted by commercial laboratories. Cost estimates for conducting these special tests were either provided by laboratories or based on costs for comparable analyses.

The *Special Requirements* defined in the Commodity Templates (Section 6) are common practices in the commercial food sector; manufacturers must have an ongoing pesticide residue testing program and where required, ‘official’ grain grade certificates. The recommended *Manufacturer’s Quality Assurance* (section 7) of the templates includes requirements for third party audits, lot sample retention, HACCP and GMP programs, all of which are also typical requirements for the commercial sector. All companies providing background information for deliverable C.3.2.2 reported having such programs already in place that would meet the requirements of the recommendations. No new costs are envisioned.

Provided in Table II are estimated costs of engaging a commercial, for profit, laboratory to conduct the testing required for reporting of product characteristics on certificates of analysis

(COA). As noted, testing recommendations in the individual performance language documents are consistent with contemporary commercial practices.

The cost of conducting compliance verification testing using a predetermined Acceptable Quality Levels described in deliverable § C.3.3.3 (the cost of conducting *all* analyses listed on the COA) would be a multiple of the estimated cost times the number of samples required to achieve USDA's desired level of probability of rejecting defective lots. When conducting verification testing, USDA may want to consider only those assays that define the product or those analytes for which there may be a concern (vitamin A and iron).

Recommendations:

1. Manufacturers should be required to conduct assays and report findings for all components / attributes listed on the sample COAs that were included in the respective performance language documents submitted as deliverable § C.3.2.2.
2. Verification testing of randomly selected lots should consist of all assays / attributes listed on the Certificate of Analysis.
3. Alternatively, USDA may assay only those components / attributes for which there is a cause or need to conduct additional verification testing.

Table I
Typical Analytical Costs

Chemical	\$	Mycotoxins	\$
Ash	16.38	Aflatoxin, Qualitative	53.33
Calcium	21.67	Aflatoxin, Quantitative	66.00
Crude Fiber	12.33	Vomitoxin	54.75
BHA	70.00	Vomitoxin (DON)	36.00
BHT	70.00		
Fat (Acid Hydrolysis)	26.50	Microbiological	
Fat (Ether Extraction)	18.00	Coliform (MPN)	16.00
Fat, Dairy	50.00	E. coli (MPN)	16.00
Falling Number	32.00	Mold	14.00
Iodine	200.00	Salmonella	22.63
Iron	20.25	Salmonella - 375 g	70.00
Lysine	103.00	Staph. aureus Coagulase Positive	17.75
		Staph. aureus Coagulase Positive –	
Moisture	12.00	Confirmation	20.00
Moisture and volatiles	25.00	Total Aerobic Plate Count	13.83
NSI	39.00	Yeast	20.00
Protein Dispersibility Index	38.50	Yeast & Mold	15.25
Pesticides Organo-Phosphate Screen	105.00		
Pesticides Chlorinated Hydrocarbons	96.67	Fats & Oils	
pH	16.38	AOM	30.00
Protein	14.38	Antioxidants (if added) each	70.00
Reducing Sugars	80.00	Cold Test	20.00
Retinyl Palmitate	63.75	Flash Point	70.00
Salt (from soluble chlorides)	31.88	Free Fatty Acid	15.00
Sulfite	152.00	Insoluble Impurities	10.00
Sulfur dioxide	152.00	Iodine Value	25.50
Titratable Acidity	22.00	OSI	57.50
Urease	8.00	Peroxide Value	19.50
Vitamin A Palmitate	61.67	Saponification Value	35.00
Zinc	21.67		
		Grading / Inspection	
Physical / Functional		Dockage	6.50
	Lab		
Appearance	Observation	Foreign Material	2.50
Bulk Density	18.50	Grade (Includes FM on Wheat)	13.00
Color	15.00	Grade Additional Factors	6.50
Color, Munsell	15.00	Grade Chalky Kernels	4.50
Consistency (Bostwick)	13.00	Sanitation (Extraneous & Frags)	58.00
Dispersibility	27.00	Sanitation (Foreign Material)	58.00
Granulation	17.00	Test Weight	13.00
Lovibond Color	22.50		
Tortilla	50.00		

Table II
Estimated Cost of Analysis to Complete One
Certificate of Analysis for Each of the Products Listed

Fortified and Blended Foods	\$	Whole or Partially Processed Grains	\$
Corn-Soy Blend	311	Barley	167
Corn-Soy-Milk	326	Milled Rice	130
Instant Corn-Soy-Milk	295	Bulk Soybean Meal	162
Wheat-Soy Blend	408	Bagged Whole Grains – Wheat	53
Wheat-Soy Milk	390	Bagged Whole Grains – Corn	53
		Bagged Whole Grains – Sorghum	53
		Bagged Whole Grains – Soybeans	53
Milled Products		Dry Edible Beans	27
All Purpose Wheat Flour	178	Peas and Lentils	27
Bread Flour	178		
Bulgur	238		
Soy-Fortified Bulgur	264		
Cornmeal	259	Commercial Products	
Instant Corn-Soy Masa Flour	256	Dehydrated Potatoes	579
Soy Fortified Cornmeal	294	Dehydrated Soup Mix	42
Soy Fortified Sorghum Grits	277	Non-Fat Dry Milk	290
		Canned Pink Salmon	113
		Soy Products - Soy Flour	206
Vegetable Oil		Soy Products – Concentrate	174
Corn Oil	398.75	Soy Products - Isolate	162
Vegetable Oil	373.25	Soy Products - milk replacer	232
Bulk Oil & Tallow	135.00	Soy Products - Textured Soy Protein	259
Sunflower Seed Oil	367.75		



SHARING SCIENCE & TECHNOLOGY TO AID IN THE IMPROVEMENT OF NUTRITION

USDA Food Aid Quality Project

Contract AG-3151-C-07-0048

Deliverable C.3.3.8

Procedures for Identifying Acceptable Commercial Analytical Laboratories

Background

A study conducted by the Global Environmental Monitoring Scheme of the WHO on the performance of laboratories that provide data on food contamination (136 laboratories in 21 countries using their preferred methods) found that only 60% reported accurate results for trace metals in milk powder, 41% for pesticides in spinach powder, 43% for nitrate in spinach powder and 88% for aflatoxin in nut-based animal feed.¹ SUSTAIN conducted an inter-laboratory round robin to determine the variability of the analysis of vitamin A, the marker for vitamin premix addition to fortified and blended foods. The calculated coefficient of variation was a very large 35%, with only two of sixteen laboratories capable of analyzing blind samples accurately and precisely. Thus, there is a critical need to better identify laboratories that can accurately and precisely measure analytes of interest in defined food matrices.

The results of analytical measurements from different laboratories and at different times should be consistent results and the methodologies/equipment used should be appropriate for the intended purpose. Laboratories conduct analyses to fulfil specific customer requirements. If results are not fit for purpose then performing the analysis is a waste of time and money. If a laboratory knows, or suspects, that results are unreliable then it will incur the costs associated with repeating the measurements. The release of unreliable results to customers carries a risk and therefore a potentially more significant cost to the laboratory.

Valid measurements and agreement between laboratories can be achieved by implementing a set of basic principles. The six principles of Valid Analytical Measurement (VAM) provide a framework to enable organizations to deliver reliable results first time, every time, and achieve bottom line improvements through increased operational efficiency and reduction in risk.

Principle 1 - Analytical measurements should be made to satisfy an agreed requirement.

Principle 2 - Analytical measurements should be made using methods and equipment which have been tested to ensure they are fit for purpose.

¹ I. Mueller-Harvey, 2003, Food, Agric & Enviromt. 9 – 11.

Principle 3 - Staff making analytical measurements should be both qualified and competent to undertake the task.

Principle 4 - There should be a regular independent assessment of the technical performance of a laboratory.

Principle 5 - Analytical measurements made in one location should be consistent with measurements made elsewhere.

Principle 6 - Organizations making analytical measurements should have well defined quality control and quality assurance procedures.”²

Discussions with food processors revealed that the amount of pre-qualification required of a contract analytical services laboratory is related to the size of the company. One small company stated that if it was something they do not assay in-house, they generally select a laboratory that is “close by” with little or no consideration given to the laboratory’s capabilities. Another small company (milling) stated they “use a laboratory (identified to this interviewer) that is well known to the industry and has good turn-around time.” One major company stated they have an extensive prequalification program to determine the laboratory’s capability and conduct follow up verifications to assure consistently accurate and precise results.

For this deliverable SUSTAIN also interviewed contract analytical services laboratories to determine how they select laboratories for sub-contracting analytical work. Depending upon the matrix and the intricacies/complexity of the analyses, a single laboratory may not be capable of adequately conducting all of the required analyses, hence multiple laboratories may be required to conduct all analyses.

One overriding message from participants was that the laboratories should be pre-qualified before the need for their services arises. The emergence of a problem is not the right time to identify an appropriate analytical laboratory for contract services from among candidate facilities with no prequalification.

Laboratory Accreditation

A search of web-sites yielded a plethora of organizations offering laboratory accreditation. There are many laboratory accreditation bodies world-wide with differing requirements, thus making direct comparisons difficult. Without a thorough investigation, the value of these various accreditations is difficult to evaluate. Requirements for accreditation range from the stringent documented procedures specified in ISO 17025 to mere requests for ‘accreditation’ submitted on the laboratory’s company stationary.

Perhaps the most widely known laboratory accreditation is ISO 17025 which “specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling.” It covers testing and calibration performed using standard methods, non-standard

² <http://www.nmschembio.org.uk/GenericArticle.aspx?m=108&amid=1285>

methods, and laboratory-developed methods. “It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.”³ ISO accreditation is specific to individual analytical methods for which accreditation was sought and approved and not an accreditation of the laboratory in general. It is somewhat misleading for laboratories that describe *themselves* as “ISO Certified.” If ISO 17025 accreditation is one of the laboratory selection criteria, it is the responsibility of the entity contracting for analytical services to verify that analyses of interest are in fact ISO certified. Further, to paraphrase the words of representatives from two different commercial laboratories, being ISO 17025 certified is no guarantee that you are going to obtain the true value, only that the laboratory will conduct a specific analysis the same way each time.

ISO 17025:2005 guides development of management systems for laboratory quality, administration and operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it to confirm or recognize the competence of laboratories. ISO requirements focus on documented procedures. ANNEX A, attached, contains a sample table of contents for ISO accreditation is specific to individual analytical methods for which accreditation was sought and approved and not an accreditation of the laboratory in general. Since obtaining each certification is costly and time-consuming, some laboratories obtain certification for a few assays and then claim to be “ISO Certified”, giving the impression that all assays are ISO compliant.

Another laboratory accreditation applicable to food testing is USDA’s FSIS Accredited Laboratory Program (ALP). The ALP accredits nonfederal analytical chemistry laboratories to analyze meat and poultry food products for moisture, protein, fat, and salt content and/or certain classes of chemical residues. Currently the specific chemical residues are chlorinated hydrocarbons (CHC), polychlorinated biphenyls (PCB), sulfonamides, nitrosamines, and arsenic. This program defines minimum proficiency levels that laboratories must maintain for continuation of accreditation.⁴ Accreditation is based on successfully analyzing an initial 36 sample qualification set. Continued accreditation is contingent upon maintaining minimum proficiency in ongoing samples analyses, assaying a minimum number of samples assayed weekly, successful analyses of blind samples, and other criteria. Since this accreditation program is focused on meat and poultry, it is not applicable to cereal grain-based foods.⁵

The American Association for Laboratory Accreditation (A2LA) is a nonprofit, non-governmental, public service membership society. The mission of A2LA is to provide comprehensive services in laboratory accreditation and laboratory-related training. Its focus covers a wide range of analytical disciplines including foods.⁶ Laboratory accreditation is based on internationally accepted criteria for competence (ISO/IEC 17025:2005). A2LA also offers programs for accreditation of inspection bodies, proficiency testing providers, reference material producers and product certification bodies. Resources contacted for this report commented as follows on A2AL accreditation:

1. An expensive proposition

³ http://www.iso.org/iso/catalogue_detail?csnumber=39883

⁴ http://www.fsis.usda.gov/Science/Accredited_Laboratories/index.asp

⁵ http://www.fsis.usda.gov/Science/Accredited_Laboratories/index.asp

⁶ <http://www.a2la.org/>

2. Generally not for agricultural materials testing
3. No guarantee of capability in testing food products

Laboratory Proficiency Programs

Proficiency testing is a widely-used quality tool. Laboratory proficiency programs usually involve a group of peer laboratories that conduct similar analyses in similar matrices and compare results. A number of organizations and professional societies offer proficiency testing programs for subscribers to their respective check sample programs for the testing of agricultural materials. AOAC International, AACC International and AOCS are some organizations that provide proficiency testing programs and conduct a statistical analysis of the results of check sample reports. There are different criteria for defining laboratory proficiency including, but not limited to z-scores⁷ and cusum analyses. Laboratories that consistently report within predetermined limits are awarded proficiency recognitions.

Standards for proficiency vary among organizations providing such services. Laboratories participating in the AACC International check sample / proficiency testing program (multiple laboratories testing aliquots of the sample) are given a 'Superior' rating if they have an adjusted z-score for the preceding year of less than 1. A 'Satisfactory' rating is applied to laboratories that have adjusted z-scores of less than 2. Gilbert and Patey⁸ define laboratories with z-scores between -2 and +2 as satisfactory. The National Veterinary Services laboratory, when evaluating the presence or absence of an analyte (e.g. salmonella) states that "to pass the proficiency test, laboratories must fall in the area of the Poisson distribution curve in which it is estimated that 95% of their most correct peers would lie."⁹ In the case of the National Veterinary Services laboratory, we note that the measures being compared are discrete, while the other laboratories are working with continuous measures. Thus, a specialist proficient in evaluating laboratory performance must evaluate the laboratory's performance over sufficient observations to assure statistical compliance to minimum performance standards.

Recommendations

Seldom is any one laboratory equipped to conduct extensive analyses on a wide range of food matrices, thus multiple laboratories may be required to obtain the desired analytical services. Identifying suitable contract analytical laboratories is a task similar to vetting manufacturers and suppliers of other goods and services. A number of steps should be taken. Following is a compilation of suggestions, including input from industry partners and contacts.

1. Evaluate the reputation of the laboratory by seeking referrals from those working in the related industry. The food industry has developed a base of knowledge concerning the capabilities of testing laboratories. Some companies have developed approved vendors

⁷ The number of standard deviations from the mean, usually a scale of 0 – 3.

⁸ John Gilbert and Alan L Patey 1998 IUPAC, Pure g! Applied Chemistry70,2309-2312 Laboratory proficiency testing programmes

⁹ http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/PTSummEIA.pdf

lists, which include analytical services, but this is no guarantee that the lab will provide accurate and precise results on an ongoing basis; that will need to be verified through satisfactory proficiency testing results and/or submitted samples with known level of analytes.

2. Conduct a business analysis to make certain this is an acceptable company backed by sufficient financial resources to remain a viable entity during the expected term of service. If the laboratory or parent company is financially unstable, it may not be a viable business entity throughout the duration of the contract. This is also an opportunity to evaluate the business relationships and organizational make up of the laboratory and determine if it is part of a larger entity that could influence the outcome by engaging a broader range of technical resources.
3. Conduct a 'paper audit' to ascertain a laboratory's capabilities. This may be completed using a questionnaire to obtain the necessary background information on the laboratory's accreditations, standard operating procedures, internal quality control, proficiency testing, and other relevant topics. (A sample survey instrument is provided in Annex B.) Responses from the paper survey must be evaluated by specialist(s) proficient in laboratory operation and quality systems to ascertain the completeness and appropriateness of their responses.
4. Ongoing determination of the laboratory's capability of producing accurate and precise results from performance testing conducted by a recognized organization (e.g. AOAC, AACC and others) on check samples in matrices similar to the product of interest. Evaluation of laboratory performance results must be conducted by specialist(s) proficient in analytical methodology and statistical data analysis. Minimum acceptable proficiency, as defined by z-score should be less than ± 2 .

Alternatively, or if the laboratory does not have a sufficient length of performance history, the entity contracting for analytical services may want to submit its own qualification samples to laboratories for their own evaluation of accuracy and precision. A set of qualification samples would need to be created with a series of known levels of the analyte(s) of interest in a matrix representing the food product of interest. Preparing qualification samples to assure the analytical results are representative is challenging. The facility designated to prepare the samples must obtain representative materials and prepare a blend that has the ingredients uniformly distributed throughout, using mixing equipment which may not be available in all laboratories. In the case of a qualification set comparable to CSB, this would require obtaining the ingredients, preparing the blends, conducting sufficient analyses to assure the analytes of interest are evenly distributed through the test batch and that levels are equivalent to the target.

The prepared blend to be used for qualification samples must be sampled and sufficient assays conducted to assure homogeneity and uniformity of key analytes throughout. Once the samples are prepared they must be stored and shipped in a way that prevents degradation of labile analytes (e.g., vitamin A).

Qualification of laboratories must be ongoing to assure the laboratory remains capable and qualified. Recommendations from experts state that blinded (analyte levels are unknown to the recipient laboratories) qualifications / proficiency verification samples should be repeated on a regular quarterly basis.

5. Engage a specialist proficient in evaluating laboratory operations and quality systems to conduct a site visit to verify the accuracy and validity of the information reported in the questionnaire. This on-site visit must be conducted by someone proficient regarding laboratory equipment / instrumentation, standard operating procedures for laboratories, analytical methodologies, and good laboratory practices. Items to evaluate during a site visit include, but are not limited to:
 - a. Verify the laboratory actually exists (not a contractor submitting samples to a third party),
 - b. Laboratory has the necessary equipment,
 - c. Staff counts are consistent with the preliminary audit survey,
 - d. Stated accreditations are current,
 - e. Proficiency testing is current.

ANNEX A

Sample ISO 17025 Quality Manual¹⁰ Table of Contents

1. Introduction
2. Scope
3. Definitions & terminology
4. Management Requirements
 - a. Organization
 - b. Quality System
 - c. Document control
 - d. Review of contracts
 - e. Subcontracting
 - f. Purchasing
 - g. Service to client
 - h. Complaints
 - i. Control of non-conforming work
 - j. Improvements
 - k. Corrective actions
 - l. Preventative actions
 - m. Control of quality records
 - n. Internal audits
 - o. Management review
5. Technical Requirements
 - a. General
 - b. Personnel
 - c. Accommodation
 - d. Test methods and validation
 - e. Equipment
 - f. Measurement traceability
 - g. Sampling
 - h. Test items
 - i. Quality Control
 - j. Reports / calibration certificates

¹⁰ <http://17025.homestead.com/iso.html> and <http://www.quality.co.uk/custpage.htm>

ANNEX B

SAMPLE CONTRACT LABORATORY PRELIMINARY AUDIT

All information provided here is held in strict confidence

Instructions: Complete all questions. Responsible person must sign the last page. Return completed and signed form via FAX to: _____

Laboratory Name	
Mailing Address	
Person with overall responsibility	
Contact Person	
Phone Number	
Fax Number	
E-Mail	

Attach additional pages if necessary.		
General		
G1. What types of materials are tested at this facility? (indicate approximate percentages)	Material	Percentage
	Food & agricultural	
	Environmental	
	Pharmaceutical	
	Other _____	
G2. List the 25 highest volume tests performed at this facility.	Attach separate sheet	
G3. List certifications, accreditations, and licenses held by your lab. Provide copies of each accreditation or certification or registration listed. (Attach sheet(s) as needed)		
G4. Is your laboratory inspected by regulatory agencies? If so, list date of last inspection and agency.		
G5. List Professional and Scientific Organizations that either this facility or facility management is a member of.		
G6. Name of Parent Company responsible for this laboratory facility (if facility is wholly owned, state "none").		
G7. Does the laboratory have a computer based Laboratory Information Management System? If yes, list the LIMS vendor.		

ANNEX B

Personnel			
P1. How many personnel are employed at this facility?	Function		Number
	Laboratory/Technical		
	Administrative/QA		
P2. What is the number of average years of laboratory testing experience of laboratory/technical staff?			
P3. What percentage of laboratory personnel having secondary or post-secondary education or professional training?	Level		Percentage
	Secondary (High School)		
	Technical Training		
	Technical degree (Bachelor degree or equivalent)		
	Higher degree (Masters degree or higher or equivalent)		
P4. Are records available documenting the proficiency and training of all technical staff? (Yes/No)			
Facilities and Equipment			
F1. Approximate square feet (or square meters) of facility devoted to laboratory testing.			
F2. Approximate linear feet (or meters) of laboratory benches.			
F3. Number of laboratory fume hoods.			
F4. Major Equipment Inventory: List number of each type of equipment currently in use in this laboratory facility. Add other types as needed.	Equipment Type		Count
	GC		
	HPLC		
	Atomic Absorption Spectrophotometer		
	ICP/AES or ICP/MS		
	GCMS		
	LCMS or LCMSMS		
	Muffle Furnace		
	Oven		
	Floor Mount Centrifuge		
Temperature Controlled Incubators			
Test Methods			
M1. Specify scope of testing offered in Attachment I.	See Attachment I		
M2. Do you have a laboratory method validation protocol in place?			
Quality Assurance			
Q1. Is there a written laboratory quality policy?			
Q2. Is there a written laboratory quality manual?			
Q3. Are control charts used to monitor performance of all tests listed in the Scope of Testing (Attachment I)?			
Q4. How long are records maintained of all original observations (raw data)?			
Q5. Are all test results reviewed by a second person qualified to evaluate the data?			
Q6. How often are laboratory balances calibrated and by whom?			
Q7. How often are laboratory automated pipets calibrated and by whom?			
Q8. Do laboratory records document the			

ANNEX B

	person performing the test and the person reviewing the data?	
Q9.	Is there a laboratory protocol for dealing with test non-conformance including notifying all customers of questionable test results?	
Q10.	Describe the laboratory protocol for reporting test results when replicate tests are conducted on a sample.	
Q11.	Do certificates of analysis (test reports include:	Report Content (Y/N)
		Lab Facility Name
		Lab Facility Address
		Lab Facility Phone Number
		Sample description
		Test results with units
		Test Method Reference
		Name of lab performing any subcontracted tests
	Name of person responsible for all report content	
Q12.	List all Proficiency Testing Programs in which the laboratory participates including specific proficiency samples tested.	
Q13.	How are samples assigned a unique identifier when received?	
Q14.	Describe the laboratory confidentiality policy.	
	Microbiology Specific QA	
Q15.	Describe the lab disinfection program. Include how and how often disinfection is verified.	
Q16.	Describe the personnel hygiene program. Include how and how often disinfection is verified.	
Q18.	Describe media prep. Are batches traceable to media lot no., weight, autoclave run, QC data?	
Q19.	Describe the media QC program. Negative and positive controls? Is QC run on media prior to use?	
Q20.	Is the water tested for suitability?	
Q21.	How is the autoclave performance monitored?	

ANNEX B
Attachment I
Scope of Services

Chemistry	Test Offered? (Y/N)	Reference	Lab Operating Procedure in Place? (Y/N)
Moisture, air oven			
Moisture, vacuum oven			
Moisture, Karl Fisher			
Crude Protein			
Ash			
Crude Fat, petroleum ether extraction			
Crude Fat, acid hydrolysis extraction			
Fat, from fatty acids (GC)			
Crude Fiber			
Vitamin A			
Vitamin E			
Thiamin			
Riboflavin			
Vitamin D			
Folic Acid			
Biotin			
Niacin			
Pyridoxine (vitamin B6)			
Cyanocobalumin (vitamin B12)			
Aflatoxin, qualitative screen			
Aflatoxin, HPLC			
Vomitoxin, qualitative screen			
Iron			
Calcium			
Sodium			
Chloride			
Salt			
Phosphorus			
Zinc			
Lead			
Arsenic			
BHA/BHT			
TBHQ			
Propyl Gallate			
Sulfite (residual)			
Sugar Profile			
Total Starch			
Dietary Fiber			
Urease			
Trypsin Inhibitor			
Protein Dispersibility Index			
Nitrogen Solubility Index			
Total Free Fatty Acids			
Titrateable acidity			
Iodine Value			

ANNEX B

Unsaponifiabiles (fats and oils)			
Insolubles (fats and oils)			
Fat Stability			
OSI (fat stability)			
AOM (fat stability)			
Linoleic acid			
Oleic acid			
Fatty Acid Profile			
Peroxide Value			
TBA test			
Anisidine Value			
Lysine			
Complete amino acid profile			
pH			
Microbiology			
Aerobic Plate count			
Total Coliform,			
E. coli			
Salmonella			
Staph aureus, cp			
Yeast & Mold			
Physical Tests			
Falling Number			
Particle Size (screen)			
Flash Point (oils)			
Color			
Water Absorption Ratio			