Provisional Technical Specifications for

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LIPID-BASED NUTRIENT SUPPLEMENT FOR PREGNANT AND LACTATING WOMEN

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LNS - PLW

Version: **1, adopted 2021**
Replacing: **All drafts issued before 2020**
Date of issue: **08.02.2021**

This is a provisional specification for a pilot project and will be further reviewed based on project outcome.

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1. INTRODUCTION

1.1 Product purpose

LNS - PLW is a food for special dietary use that is intended to supplement the diet of pregnant and lactating women as part of a nutritional program. The product is intended to be eaten directly from the package with no necessary dilution, mixing or cooking. One sachet contains **75g of product**. One sachet per day is recommended for reducing risk of poor birth outcomes where diets have poor nutritional quality and for supporting recovery from malnutrition[1]. If one sachet per day is provided, the distribution of concurrent micronutrient supplementation (iron folic acid tablets or multi micronutrient supplements) can continue. In exceptional circumstances, programs may decide to provide two sachets per day, in which case concurrent micronutrient supplementation as mentioned above to the same women shall be halted.

1.2 Product type

LNS - PLW is a fortified lipid-based paste/spread that is individually packaged in robust sachets that are packed in sturdy cartons. **LNS - PLW** can be made with ingredients including heat treated oil seeds/pulses/cereals, sugar, milk powder, vegetable oils, defatted soy flour, maltodextrin, soy protein isolate, whey powder, salt, vitamins and minerals and additives.

1.3. Quality and safety

LNS - PLW shall be manufactured within a quality and food safety management environment in accordance with latest version of recognized international standards and best practices and/or guidelines, such as:

- Code of Hygienic Practice for Low-Moisture Foods: CAC/RCP 75-2015, of the Codex Alimentarius
- Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, of the Codex Alimentarius
- General principles for addition of essential nutrients to foods: CAC/GL 09-1987, of the Codex Alimentarius
- ISO 22000:2005: Food safety management systems

[1] https://www.who.int/news/item/07-11-2016-new-guidelines-on-antenatal-care-for-a-positive-pregnancy-experience; https://gatesopenresearch.org/documents/3-1498

- ISO/TS 22004 – Guidance on the application of ISO 22000:2005

2. INGREDIENTS

2.1 Generic requirements

LNS - PLW shall be manufactured from ingredients that are fresh, of good quality, free from foreign materials and substances hazardous to health, that comply with Codex Alimentarius or relevant regulations. In particular, the latest version of the following Codex standards and guidelines shall apply:

- Codex Stan 193-1995. In particular melamine shall remain below 2.5 mg/Kg in dairy source used
- Codex Stan 200-1995 for peanut
- Codex Stan 171-1989 for certain pulses
- Codex Stan 175-1989 for soy protein
- Codex Stan 210-1999 for oil and for oil used to produce shortening
- Codex Stan 212-1999 for sugar
- Codex Stan 207-1999 for sources of dairy protein
- Codex Guidelines CAC/GL 55 for vitamin and mineral premix
- Codex Stan 73-1981 for flavoring and antioxidants, including carry over from ingredients.
- Codex Stan 171-1989 for certain pulses grains
- Codex Stan 198-1995 for rice
- Food Chemicals Codex Specifications for maltodextrin
- Codex Stan 207-1999 for Milk Powders and Cream Powder
- Codex Stan 150-1985for Food Grade Salt
- Codex Stan192-1995 for Food Additives
- Codex Stan 289-1995 for Whey Powders

Additionally:

- The **LNS - PLW** supplier shall test melamine, at least once a year for each individual source of dairy protein used (either testing the skimmed milk powder or the final product).
- The **LNS - PLW** supplier shall test 3-MCPD, Glycidyl Esters and mineral oil[2] at least once a year for each vegetable oil used

2.2 Vitamin and mineral premix

LNS - PLW shall include a premix consisting of the vitamins and minerals described in Table 1. Suppliers should implement an effective food safety and quality management system for the premix, including supplier approval and premix quality control.

Additionally the premix shall:

- Be purchased from GAIN Premix Facility or any of the GAIN approved suppliers, as per the list available at the following link: http://gpf.gainhealth.org/suppliers/current-suppliers.
- Be delivered to the processor of **LNS - PLW** with a complete Certificate of Analysis. This document shall be presented to WFP with other documents for payment.
- Micronutrient premixes shall be stored as per manufacturer recommendations.

If the manufacturer would like to adapt the Vitamin premix, this will have to be discussed and agreed with WFP, and will have to be based on supporting data that show that the combination of raw materials, prescribed premix and specific processing steps results in a product of which the specific nutrient content is consistently outside the range of label value and max content (see table 2). An example of an adaptation that

[2] Hydrocarbons (MOSH and MOAH)

can be considered is higher inclusion of vitamins A and C to compensate for greater losses due to a specific heat processing step.

Table 1: Premix contribution and premix nutrient sources (approximate incorporation rate: 2.3%)

Nutrients	**Unit**	**Recommended nutrient sources[3] (/alternative options)**	**Nutrient added per 100g LNS +/-10%**
Vitamins			
Retinol (Vit A)[4]	mcg	Dry Vitamin A Palmitate / Dry Vitamin A Acetate	1155.9
Thiamin (Vit B1)	mg	Thiamine mononitrate / Thiamine hydrochloride	2.7
Riboflavin (Vit B2)	mg	Riboflavin	1.95
Niacin (Vit B3)	mg	Niacinamide	20.23
Pyridoxine (Vit B6)	mg	Pyridoxine hydrochloride	2.81
Folic acid (Vit B9)	mcg DFE	Folic acid food grade	660.5
Cobalamin (Vit B12)	mcg	Vitamin B12 (0.1 sd or 0.1% on mannitol)	4.01
Ascorbate (Vit C)	mg	Ascorbic acid fine powder	330.26
Cholecalciferiol (Vit D)	mcg	Dry Vitamin D3 (sd)	19.5
Dl-α tocopherol (Vit E)	mg	Dry Vitamin E acetate (50% dl-α tocopherol acetate)	53.58
Phytomenadione (Vit K)	mcg	Dry Vitamin K (5%)	119.31
Calcium (Ca)	mg	Di-Calcium Phosphate anhydrous / tricalcium phosphate	521[5]
Copper (Cu)	mg	Copper sulphate anhydrous / copper gluconate	1.07
Iodine (I)	mcg	Potassium iodide (10% trituration)	333.7
Iron (Fe)	mg	Ferrous sulphate monohydrate, dried / ferrous sulphate / ferrous fumarate (encapsulated or not) /NaFeEDTA,	30.66
Phosphorus (P)	mg	Di-Calcium Phosphate anhydrous / tricalcium phosphate	268.7[6]
Selenium (Se)	mcg	Sodium selenite / sodium selenate	94.41
Zinc (Zn)	mg	Zinc sulphate	20.64

[3] Other chemical forms may be acceptable after review of their potency and functionality. Suppliers should submit such information for WFP's review. For Niacin, nicotinic acid is prohibited because of its much lower safe upper limit (WHO Guidelines on food fortification with micronutrients, 2016) .

[4] Beadlet or spray dried form can be used assuming there is no carryover of antioxidants not approved in Codex.

[5] This is equivalent to a total of 1.4% Di-calcium phosphate: In final product Ca/P ratio should be 1-1.5, where 30% of P from plant sources and 100% from animal sources can be included in the estimate

3. PRODUCT SPECIFICATION

3.1 Generic requirement

LNS - PLW shall comply with the latest versions of the following guidelines or standards. Additionally, the supplier shall comply with relevant local regulations/standards.

- Framework and Specifications for the Nutritional Composition of a Food Supplement for Pregnant and Lactating Women (PLW) in Undernourished and Low-Income Settings, Report of an Expert Consultation held at the Bill & Melinda Gates Foundation, April 2017 [7]
- Codex Stan 193-1995 general standard for contaminants and toxins in food and feed
- Guidelines from Codex Committee on Pesticide Residues (CCPR)
- Recommendations from joint FAO/WHO expert meeting on tropane alkaloids, 2020

In addition,

- **LNS - PLW** shall be safe and suitable for human consumption. Additionally, its taste shall be suitable for consumption by pregnant and lactating women
- **LNS - PLW** shall be microbiologically stable with a water activity lower than 0.6
- **LNS - PLW** shall be free from objectionable matter; free from micro-organisms in amounts which may represent a hazard to health; not contain any substances originating from micro-organisms or any other poisonous or deleterious substances such as residues of hormones, antibiotics, pharmacologically active substances, anti-nutritional factors, toxic or noxious seeds[8] , heavy metals or pesticide residues, in amounts which may represent a hazard to health of the specific population group for which they are intended (pregnant and lactating women).
- **LNS - PLW** shall comply with requirements stated in Table 5 list of compulsory tests. Additionally, it shall contain a combined hyoscyamine/scopolamine (tropine alkaloids) concentration in dry food of less than 30ppb.
- Blend of oils shall be judiciously chosen in order to meet omega 3 and omega 6 requirements in the finished product and to minimize oil separation.

3.2 Nutritional value

LNS - PLW shall have a composition that is in line with Table 2 and Table 5.

[7] https://gatesopenresearch.org/documents/3-1498

[8] Crotolaria (Crotalaria spp.), Corn cockle (Agrostemma githago L.), Castor bean (Ricinus communis L.), Jimson weed (Datura spp.), Mexican Prickly Poppy (Argemone mexicana) and other seeds that are commonly recognized as harmful to health.

Table 2: Nutritional value at all points of time

Nutrients	Units	Min/100g	Label/75g[9]	Max/100g
Energy	kcal	510	XX[10]	590
Protein[11]	g	18.8	XX	22.2
Carbohydrate	g	30	XX	36.2
Lactose	g	-	-	9[12]
Total lipid (fat)	g	26	XX	39.3
n-6 fatty acids	g	3.2	XX	8.7
n-3 fatty acids	g	1.7	XX	2.1
n-6/n-3 fatty acid ratio	-	-	-	5
Added sugar	g	-	-	11.5
Vitamin A	mcg RE	733	550	1339
Vitamin B1 (Thiamine)	mg	1.6	1.2	3
Vitamin B2 (Riboflavin)	mg	1.73	1.3	2.4
Vitamin B3 (Niacin)	mg	19	14	24
Vitamin B6 (Pyridoxine)	mg	2.3	1.7	3.2
Vitamin B9 (Folate total)	mcg DFE	533	400	734
Vitamin B12	mcg	3.2	2.4	7.3
Vitamin C, total ascorbic acid	mg	133[13]	100	367
Vitamin D3	mcg	13	9.8	24
Vitamin E	mg aTE	29.3	22	53
Vitamin K (phylloquinone)	mcg	96	72	196
Calcium (Ca)	mg	667	500	1333
Copper (Cu)	mg	1.3	0.98	2.2
Iodine (I)	mcg	279	209	449
Iron (Fe)	mg	29	22	38
Phosphorus (P)	mg	400	300	933
Selenium (Se)	mcg	80	60	127
Sodium (Na)	mg	-	-	270
Zinc (Zn)	mg	20	15	27

3.3 Shelf life

Unless stated otherwise in the contractual agreement, **LNS - PLW** shall have minimum 24 months shelf life when stored under the conditions specified in the section Packaging and Marking Requirements (Table 4). At least one shelf life study per recipe should be initiated in line with WFP requirements[14] to confirm that:

- Food remains compliant with this specification (e.g. maximum and minimum defined in Table 2)
- There shall be no more than slight oil separation throughout the shelf life of the product

4. PACKAGING AND MARKING

4.1 Packaging

[9] Label values are derived from minimum nutrient values per 100g.

[10] All XX have to be filled by manufacturer, according to the specific formulation used. Please refer to codex standard in section 5.1 below for the full list of nutrients to be declared.

[11] Protein Digestibility- Corrected Amino Acid Score (PDCAAS) shall be minimum 0.9, calculated using the method provided in Dietary Protein Quality Evaluation in Human Nutrition (Report of an FAO Expert Consultation, 2011)

[12] Higher limit (9- 12 g/100g) can be allowed if suppliers can demonstrate food acceptability

[13] The value refers to product nutrients at the end of shelf life, after loss. Please refer to Table 5 for minimum Vitamin C value required at the time of purchase.

[14] https://foodqualityandsafety.wfp.org/

The product covered by the provision of this specification must be packed in appropriate packaging which safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product. The packaging material shall be made of substances which are safe and suitable for their intended use. They should not impart any toxic substance or undesirable odour or flavour to the product.

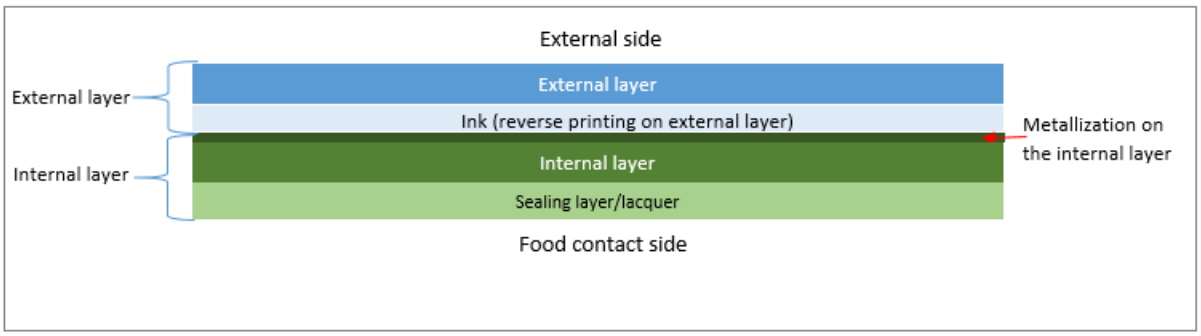
4.1.1 Primary packaging

LNS-PLW shall be packaged in food-grade flexible sachets, hermetically sealed and robust enough to prevent leakage and protect the product throughout its shelf life. Sachet material shall not represent a hazard for infants and young children when sachets is opened and put in contact with the mouth.

Sachets shall be:

- Food grade materials compliant with the last amendments of national regulations in the country of production (if not existing: compliance with EU or FDA legislations requested).
- Weight and quantity tolerance shall meet The International Organization of Legal Metrology International Recommendation OIML R 87 [15]
- Optimized shape to avoid space loss in the sachets and cartons
- Properly sealed with no leakages (test example: ASTM F2338 – 09, ASTM D3078 – 02 or equivalent)
- The sachet must have a feature to ease the opening (e.g. a tear notch)
- The sachets must be placed in an appropriate way in the carton box during the packing process to avoid packaging damage and product leakage
- Metalized film is a mandatory barrier, it must be away from the sealing layer and be protected by another layer (see Scheme 1 below)
- Reverse printing is mandatory (see scheme below)

Scheme 1: Example of film that would fit the required performances



4.1.2 Secondary packaging

LNS-PLW shall be packed in cartons suitable for the humanitarian supply chain, each carton containing 168 individual sachets with a net weight of 75g each. Cartons shall be:

- New, manufactured from well-constructed double walled corrugated board,
- With an edge crush resistance of 60ECT = 60 lbs/in eq 11 kN/m (ISO 3037) and a specific weight of 700 to 1000 grams per square meter.
- Fully filled for maximum strength.
- The fluting must be vertical, supporting the load
- The carton should be plain brown
- Dimensions adjusted to the load
- No stapling will be accepted

[15] OIML R 78 Quantity of commodity in pre-packages https://www.oiml.org/en/files/pdf_r/r087-e04.pdf, latest edition to be followed

4.1.3 *Stuffing of Containers and other transport vehicles*

If pallets are used inside containers: it is highly recommended to have 3 first bottom layers placed as column stacking, the rest can be interlocked (cross-stacking) for load stability. Pallet shall be wrapped in a suitable manner (locked to the pallet, enough containment force) and the cartons should be banded when necessary. The cartons shall be secured to pallets in order to prevent any damage to the contents or packaging during shipment. Pallet used should be strong enough to support the charge during transportation. The pallets are recommended to be heat treated as per ISPM 15 standards (methyl bromide fumigation is not allowed).

If no pallets are used inside container: dunnage (of strong sheets such as carton, plywood…) should be placed inside each container at every three layers of cartons to provide the required stacking strength. In addition, protecting material like air bag, carton, polystyrene, can be used. Also, kraft paper shall be adhered to all internal sides, door, and floor of container. Kraft paper also need to be placed on the top of packaging.

For shipping containers, unless fully shrink-wrapped pallets are used, and unless otherwise specified in the contract, it is highly recommended to place desiccant in container at appropriate location in order to absorb moisture.

If desiccant is required, supplier needs to use high quality desiccant and calculate the quantity of desiccant based on:

- Efficiency of desiccant
- Length of time in transit in container
- Container capacity

The following table provides a guideline on the quantity to be used.

Table 3: Guideline on the quantity to be used for calcium chloride-based desiccants:

Estimated days in container	20 ft container	40 ft container
15-59 days	9.00 kg	17.50 kg
60-89 days	11.25 kg	22.50 kg
90-120 days	13.50 kg	25.00 kg

Better alternative material can be used upon agreement with WFP.

Empty containers/vehicles shall be clean, pest free and free of damage, odours and previous cargo remains. Ventilation holes shall remain clear and unsealed.

4.2 Marking

LNS - PLW shall be labelled in accordance with latest version of recognized international standards and best practices and/or guidelines, such as

- Codex Stan 146-1985 - General standard for the labelling of and claims for pre-packaged foods for special dietary uses.
- Codex Stan 1-1985 - General standard for the labelling of pre-packaged foods

In addition **LNS - PLW** shall be labelled in an appropriate language as per Table 4 and artwork available on: https://foodqualityandsafety.wfp.org/ .

Table 4: Generic label requirement:

	Sachets	Inside leaflet (optional)	Outside box
Commercial name	Shall be kept simple and shall not reflect any medical purpose		
Product name	LNS-PLW Lipid-based Nutrient Supplement		
Target use	For Pregnant and Lactating Women		
Net weight	75g	-	168*75g
Nutrients content	"See technical data sheet"	Leaflet or box: in line with codex regulation and target defined in table 2	
Ingredient list	XX[16] **(allergen in bold** and "allergens warning: may contain traces of")		-
Preparation instruction	"Eat one sachet per day" + Generic pictogram that shows how food is eaten		-
Storage instruction	"Best stored below 30˚C, in a cool, dry place and in hygienic conditions, away from direct sunlight."		
Manufactured by: Name & address	XX		
Supplied by: Name & address*	XX		
Country of origin	Product of XX / Country of origin XX		
Manufacturer batch/lot number**	XX	-	XX
Production date (MM/YYYY)	XX	-	XX
Best Before end (MM/YYYY)	XX	-	XX
Other	"Consume in addition to daily diet" "It is strongly recommended to start breastfeeding immediately after birth, exclusively breastfeed during the first 6 months and continue until at least 24 months" "consume within 24 hours of opening" "Breastfeeding and pregnant woman" logo "No littering" logo	"Not for sale or exchange"	
Donor and WFP logo	-	as per contractual agreement	
Beneficiary feedback hotline (if required in the contractual agreement)	XX	-	XX

**: if different from the manufacturer*

***= supplier need to clearly describe the batch/lot size for the traceability of the product*

Templates for artwork available on: https://foodqualityandsafety.wfp.org/specifications

5. SAMPLING AND ANALYTICAL REQUIREMENTS

[16] All XX have to be filled by manufacturer.

As per contractual agreement, WFP can appoint an inspection company that will check, based on sampling plan defined below, that the food matches requirements specified in Table 5 and Table 6. Additional tests may be defined in case further quality assessment is required. The following sampling and analytical plans are currently utilized by WFP and shared only for suppliers' information. Suppliers should follow their own food safety and quality management plan. Additionally, WFP reserves the rights to change these plans at any time.

5.1 Sampling plan

Sampling frequency (lot size) will be defined based on the daily production of the producer.

- For producers with daily production equal to or greater than 100MT, the inspection lot size will be one day's production.
- For producers with daily production less than 100MT, the inspection lot size will be one week's production.

The following number of samples representative of the inspection lot will be sent to the laboratory:

1. One set of samples for analysis 1-5 in Table 5 and for retention analysis
2. Thirty samples for Salmonella analysis
3. Ten samples for Enterobacteriaceae analysis

5.2 List of analyses

Table 5: List of compulsory tests

No	Parameters	Limit	Method of analysis
1	Protein	18.8-22.2 g/100g	AOAC 991.20*
2	Lipid	26-39.3 g/100g	ISO 17189*
3	Vitamin C	172-367 mg/100g	EN 14130:2003*, AOAC 2012.21*, AOAC 985.33*
4	Iron (Fe)	29-38 mg/100g	AOAC 990.05* ISO 8294*
5	Total aflatoxin	Max 10 ppb	ISO 16050*
6	Salmonella	As per table 6	ISO 6579**
7	Enterobacteriaceae	As per table 6	ISO 21528-2***

**Minimum 12 individual sachets from 12 randomly chosen cartons to be mixed into 1 composite test sample by the laboratory*

*** 25 g analytical unit, samples may be pooled dry, by the laboratory, if lab method has been validated. The total analytical unit should be 750g*

**** 10 g analytical unit, no pooling*

Table 6: Microbiological criteria

Microorganisms	n	c	m	M	p-class
Salmonella	30	0	Absent in 25 g	n/a	2
Enterobacteriaceae	10	2	≤10 cfu/g	≤100 cfu/g	3

Where

- n: number of sample units;

- c: the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan;

- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality;

- M: a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality;

- p: 2 or 3 class plan