

	INTERAGENCY SPECIALISED FOOD PRODUCT QUESTIONNAIRE
	Ref. MSF: QA-NFOS-F1.1-2 / Ref UNICEF: DP 135 Annex 2 Version: 13 12/01/2021

Scope

This questionnaire shall be filled by specialized food **manufacturer** (one per product). It aims to get more details/information about the product and the controls implemented to prevent finished products from main microbiological, chemical and physical risks.

Product information

BRAND NAME (if applicable)			
Agency product reference number (if applicable)			
Product category: (several choices allowed)	☐ Treatment of severe acute malnutrition ☐ Humanitarian emergency ☐ Management of moderate acute malnutrition ☐ Nutritional Supplements ☐ Prevention of moderate acute malnutrition ☐ Other:		
Target beneficiaries (several choices allowed)	☐ Children from 6 to 12 months ☐ Adolescents ☐ Pregnant women ☐ Children from 12 to 24 months ☐ Adults only ☐ Lactating women ☐ Children from 24 to 36 months ☐ All people ☐ HIV and/or TB ☐ Other:		
Type and form	☐ Therapeutic milk (F75/F100) ☐ Paste ☐ RUTF (Ready to Use Therapeutic Food) ☐ Biscuit ☐ LNS (Lipid-based Nutrient Supplement) ☐ Powder ☐ Fortified blended food (eg Corn Soy Blend) ☐ Other form: ☐ Vitamin and mineral supplement powder (MNP) ☐ Other type:		
Principle ingredient / Base (e.g. : milk, maltodextrin, peanut...)			
Flavour (if different than principle ingredient)			
Primary packaging	☐ Sachet (grams) ☐ Tin (grams) ☐ Bag (grams) ☐ Other:		
Carton	Number of primary packaging per carton: (kg) Dimensions of carton (cm): length: / width: / height: Gross weight: <i>In case of secondary packaging:</i> Number of unit per secondary packaging: (kg) Number of secondary packaging per carton:		

Manufacturing site information

NAME:	
Address:	

Commitment

This questionnaire has been completed by:

Name(s)	
Function(s)	
e-mail(s)	

I hereby certify that the information given in this questionnaire and the attachments is correct.

Date:

Signature:

Outcome (to be filled by MSF / UNICEF / WFP)

Date sent		Manufacturer confidence level	☐ Low	☐ Medium	☐ High	☐ Very high
Date returned		Product risk	☐ low risk	☐ medium risk	☐ high Risk	

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RECOMMENDATIONS TO THE MANUFACTURERS

This questionnaire is a good tool for the preparation for an audit. It contains all the points approached during the MSF/UNICEF/WFP audit, and is based on the following standards (product depending):

- Codex alimentarius (http://www.codexalimentarius.net/web/index_en.jsp)
 - Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003
 - Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66 – 2008)
 - All standards linked to specific products for ingredients/raw materials and final products (ex : aflatoxins levels in peanuts, peroxide levels in vegetable oils, radioactive elements in milks, etc.) are detailed in the applicable Product Specifications Sheet (ref QA-NFOS-T:PSS+)
 - General Guidelines on sampling CAC/GL 50-2004
- Iso <http://www.iso.org/iso/en/ISOOnline.frontpage>
 - ISO 22000:2005: Food safety management systems – Requirements for any organization in the food chain
 - ISO/TS 22004 – Guidance on the application of ISO 22000:2005
 - ISO 9001:2000

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With reference to Ready to use Foods (RUF) such as RUTF, RUSF and other LNS products, MSF/UNICEF/WFP highly recommends the manufacturer to read the technical guidance:

- “Control of salmonella in low-moisture foods” and its annex, published by The GMA Association of Food, Beverage and Consumer Products Companies, in February 4, 2009.
<http://www.gmaonline.org/downloads/technical-guidance-and-tools/SalmonellaControlGuidance.pdf>

- -

For RUF containing peanuts, MSF/UNICEF/WFP highly recommends the manufacturer to read the following documents:

- US FDA – ‘The Changing Science of Peanut Butter’
http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=10&ved=0CIABEBYwCQ&url=http%3A%2F%2Fwww.ncagr.gov%2Fncfoodsafetyforum%2Fpresentations%2FDonald%2520Zink%2520-%25202009%2520Food%2520Safety%2520Forum.ppt&ei=eNUQUdfnLem00QXI0YHQCA&usg=AFQjCNHuf_TaCO34yz6961RBxeoY6gvdvg&sig2=JL9_YJO7XEFutx9YWl9faw&bvm=bv.41867550,d.d2k
- Thermal inactivation of Salmonella in peanut Butter Li Ma et al., 2009. J. Food Protect. 72:1596 – 1601

MSF/UNICEF/WFP highly recommends the manufacturer to read the technical guidance on micronutrient powders: Quality manual on Micronutrient Powders- A Guiding Document HF-TAG/UNIDO, 2014

PRODUCT SPECIFICATIONS

1.1. DESCRIPTION

Please describe the product (organoleptic properties: colour, flavour..), viscosity, homogeneity, granularity....

☐ Please provide your product Technical Data sheet (appendix 1)

1.2. NUTRITIONAL INFORMATION

/100g	
Energy:	Moisture content:
Proteins:	Water activity (Aw):
Lipids:	Fibres:
* n-6 fatty acids:	Ash:
* n-3 fatty acids:	PDCAAS*:
Carbohydrates: incl. free sugar:	Other : :

*Protein Digestibility-Corrected Amino Acid Score

1.3. VITAMINS AND MINERALS

Please fill **YOUR INTERNAL** finished product specifications in the following table. Your specifications shall be based on internal validation of the process (taking into account the effects of process on finished product) and trend analysis.

Minerals (per 100g)	min	max	mineral compound	Vitamins /100g	min	max	vitamin form
Mineral content.....				vitamin A.....			
Sodium.....				vitamin D.....			
Potassium.....				vitamin E.....			
Calcium.....				vitamin K.....			
Phosphorous.....				vitamin B1 (thiamin)...			
Magnesium.....				vit. B2 (riboflavin).....			
Iron.....				vitamin C.....			
Zinc.....				vitamin B6.....			
Copper.....				vitamin B12.....			
Selenium.....				vitamin B9 (folic acid)....			
Iodine.....				vitamin B3 (niacin).....			
Other:				vit. B5 (panthotenic acid)...			
				vitamin B7 (biotin).....			

2. INGREDIENTS / ACTIVE PRINCIPLE INGREDIENTS (APIs)

Please list all ingredients¹, quantities (in order of descending quantities per 100g or %) and their sources

Ingredient	Quantity	Supplier and Manufacturer if applicable	Country of origin

Are the following processes under your responsibility?

- ☐ peanut roasting
 ☐ sugar milling
 ☐ vitamins & minerals (premix) blending
 ☐ other:

3. PRODUCT SAFETY

The product shall not contain any substance originating from micro-organisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticides in amounts that may represent a hazard to health.

3.1. MICROBIOLOGY AND MYCOTOXINS

Please fill your finished product specifications for microbiology in the following table, where

- n: number of samples that must conform to the criteria
- 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: class plan

Microorganisms	Sampling plan and limits						Method
	unit	m	M	n	c	p	

¹ If pre-blended mix, please specify. For peanut based product, please specify roasted peanuts or peanut paste.



3.2. CHEMICAL SAFETY

How do you manage the pesticide and heavy metals levels in finished product?

How do you manage the nuclear radiation level (radioactivity) in finished product?

Do you manage other chemical safety risks (melamine, nitrites or any other)? Please describe.

☐ *Please provide the last available complete certificate of analysis (appendix 2): not more than 12 months old, and produced with the current manufacturing set-up and formula, including all parameters for product specifications: microbiology, mycotoxins as appropriate, pesticides: carbamates, organochlorine, organo-phosphorous and pyrethroid, heavy metals: arsenic, lead, mercury and tin; melamine; PAH (if applicable)... It shall be accompanied with a report discussing the results; trends analysis shall be implemented for all nutrients.*

Are you able to provide a “Non GMO certificate” for this product?

☐yes

☐no

If yes, ☐ *please provide it (Appendix 3).*

4. PACKAGING AND LABELING

Label language:

☐ Trilingual ☐ Bilingual ☐ only 1 language

Please specify (all languages)

☐ English

☐ French

☐ Arabic

☐ Spanish

☐ Russian

☐ Other:

4.1. PRIMARY PACKAGING

☐ *Please provide a picture(s) of the unit packaging or label artwork (with readable labelling and printing of batch number & best before date) (Appendix 4).*

Dimensions (mm):

Material:

Tear Notch / easy opening : ☐yes ☐no

Is the product packaged under protective atmosphere?

☐yes

☐no

If yes, how ?

Do you have in-process control on it? ☐yes, every

How?

☐no

Is the ink used food grade standard?

☐yes

☐no

☐NA

Performance: Oxygen Transmission Rate² (OTR) C³/m²/24H (at 23°C & 38 % RH):

Water Vapor Transmission Rate³ (WVTR) gms/m²/24h (at 38°C & 90 % RH):

☐ *Please provide (in Appendix 5) Certificate of Analyses to validate the above mentioned performance measurements and letter of compliance for food contact measurement.*

² As per standard ASTM - D3985

³ As per standard ASTM - F1249

4.2. CARTON

Is there a leaflet specifying nutritional composition of the product including minerals and vitamin content ? ☐yes ☐no

If yes, what is (are) the language(s)?

☐ *Please provide a copy(ies) of the leaflet (Appendix 6, one per language when applicable)*

Is the carton protected on the inside by a plastic bag to prevent any leakage of sachets from damaging other cartons? ☐yes ☐no ☐NA

Have you already tested the carton performance (Edge Crush Test⁴)? ☐yes ☐no
what is the result?

Carton type (American case, wrap around, ...):

Carton flap system : staples, glue, other:

Carton closing system : glue, tape, other:

How many stacked layers in static storage has the carton been designed for?

Information printed on the carton:

- ☐ Name and address of the manufacturer, packer, distributor, importer, exporter or vendor
☐ Country of origin
☐ Storage condition
☐ Weight ☐ Volume ☐ Numbers of units per carton.
☐ Batch number ☐ Best before date ☐ Production date

5. LOGISTIC INFORMATION

	Container 20'		Container 40'		By air
	Pallets	Bulk	Pallets	Bulk	
Number of pallets					
Number of cartons					
Number of units					
Total net weight					
Gross weight					
Dimensions (cm)					

6. REGULATORY SITUATION

6.1. IN THE COUNTRY OF MANUFACTURE

☐ Product registered and currently marketed.	License n°
☐ Product registered for marketing in the country of manufacturing but not currently marketed.	License n°
☐ Product registered for export only	License n°
☐ Product not registered	

6.2. IN OTHER COUNTRIES

☐ *Please provide the list of countries where the product is registered, with license number(s) (appendix 7).*

⁴ Measure in kN/m as per standard ISO 3037



6.3. PATENT/ LICENSE (RESTRICTED USE)

There is a patent/license limiting the use of this product in some countries? ☐yes ☐no
If yes ☐ *Please provide the list of countries where the product can/can not be use (appendix 8) .*

6.4. USE BY OTHER NGOs/ORGANIZATIONS

Is this product already used by other NGOs/organizations ? ☐yes ☐no
If yes Which one(s):

7. PRODUCTION

7.1. PRODUCTION CAPACITY

What is the maximum production capacity (in metric tons) for this product?

➔ Number of shifts per day:

➔ Number of day per week:

Is (are) there other product(s) manufactured in the same production line? ☐yes ☐no
If yes ☐ Please specify:

7.2. PROCESS

☐ *Please attach a description of the process (appendix 9): from raw materials reception to finished product, through a detailed flow chart. It shall indicate the quality controls performed during process (CCP, PRPs, OPRCs) and their key parameters -temperature, pressure, mixing time...*

7.2.1. Fortification

Do you have a written procedure for mixing/fortifying food? ☐yes ☐no
☐ *please provide a copy in appendix 10.*

Please detail the actions implemented and controls performed to check the fortification and homogeneity of the product:

Have you ever calculated the Coefficient of Variation of your fortification system? ☐yes ☐no
<http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator> (click on the calculator picture for the CV calculation form)

If yes, when was the last time?
☐ *please provide a copy of the results in appendix 11.*

Do you have a continuous fortification system? ☐yes ☐no
If yes, ☐ *please provide a copy of the calibration feeder procedure in appendix 10.*

Do you keep record of feeder calibration of fortification steps (quantity of premix added, frequency, etc...)? ☐yes ☐no

☐ *Please provide a copy of the procedure for fortifying/mixing and related production record(s) (appendix 10) Please provide results of trends analysis for the tracers and for all other nutrients (appendix 12).*

7.2.2. Heat treatment

Do you have a heat treatment in order to inactivate pathogens such as Salmonella? ☐yes ☐no

If yes, is heat treatment performed on the finished product? ☐yes ☐no

If not, please specify:

Was the heat treatment process validated with microbial challenge study on the finished product? ☐yes ☐no

☐ *Please attach the validation report (appendix 13).*

8. QUALITY ASSURANCE

8.1. HACCP

Has this product and its process undergone HACCP study? ☐yes ☐no

When was the HACCP System last updated?

Is there written procedures in place for the monitoring of each CCP, that includes:

- Process flow chart ☐yes ☐no
- Responsibility for control of CCPs ☐yes ☐no
- Critical limits (or specifications) ☐yes ☐no
- Test method ☐yes ☐no
- Frequency of checking ☐yes ☐no
- Recording of results ☐yes ☐no
- Corrective actions on process and product in case of non-compliance ☐yes ☐no

☐ *Please attach a description of the process (from raw materials reception to finished product) through a flow chart or figure in appendix 9. Indicate the key parameters (temperature, pressure, mixing time..., PRPs/OPRPs/CCP, and all the inspections performed during process).*

8.2. MONITORING OF INCOMING MATERIALS

Do you have a specific release procedure for incoming material? ☐yes ☐no

Who has authority to release incoming material?

☐ *Please list the ingredients, raw material (including packaging), technological auxiliaries and processing products used, and their monitoring plan in Annexes 1A & 1B of this questionnaire.*

8.3. INSPECTION DURING PROCESSING

☐ *Please list the test/checks performed during processing (weighing, mixing, packaging...) in the Annex 2 of this questionnaire.*

Are all those parameters recorded in a batch record documentation? ☐yes ☐no

Are the standards and acceptable limits available at the inspection post? ☐yes ☐no

In case of deviation, is the corrective action to be implemented defined in writing? ☐yes ☐no



Are the persons authorised to change parameters clearly defined? ☐yes ☐no

Are modifications of those parameters recorded? ☐yes ☐no

Are checks carried out to ensure that pack contents meet specifications? ☐yes ☐no

Is Foreign particle detection implemented on the final product? ☐yes ☐no

Which principle is used to control the integrity of the finished product (e.g sealing of the sachet)?

How long do you keep batch record?

8.4. INSPECTION OF FINISHED PRODUCT – PRODUCT RELEASE

☐ Please list in [Annex 3 of this questionnaire](#) the inspections made on the finished product (including microbiological and mycotoxins analysis) and the criteria for product release.

☐ Please provide a copy/example of certificate of analysis (appendix 14, as requested for each batch/lot delivered).

Do you have a specific release procedure for finished products? ☐yes ☐no

Who has authority to release the finished products?

How is the release status indicated (visually) and recorded (visually/electronically) for each product lot?

Is there a procedure of exceptional release? ☐yes ☐no

If yes Who is responsible for authorising it?

Is the customer informed? ☐ Systematically ☐ Never ☐ Sometimes: please specify

Do you keep retention samples of finished products? ☐yes ☐no

If yes For how long?

8.5. TRACEABILITY

How do you define a lot/batch?

What is the maximum size of a lot/batch (quantity and number of mixes)?

How is a given lot/batch identified (explain the coding)?

9. STABILITY STUDY AND STORAGE CONDITIONS

Do you perform stability study on representative batches:

- | | | |
|---|------------------------------|-----------------------------|
| - Long term stability study at 30±2°C for the claimed shelf life (real time studies). | ☐ yes | ☐ no |
| - Long term stability study at 40±2°C for the claimed shelf life (real time studies). | ☐ yes | ☐ no |
| - Accelerated data at 40±2°C for 6 months to support extrapolation of shelf life | ☐ yes | ☐ no |

Do you perform stability study with humidity controlled conditions?

☐yes

☐no

If yes Please specify:

Does the stability study verify organoleptic stability:

- Taste

☐yes

☐no

- Odour

☐yes

☐no

- Colour

☐yes

☐no

- viscosity

☐yes

☐no

- Product consistency and behavior

☐yes

☐no

- Stability of oils and fatty acids

☐yes

☐no

- Absence of oxidation

☐yes

☐no

Does the stability study verify nutritional value and nutrient stability: maintenance of a level of vitamin over or within specified levels for at least one water soluble and one fat soluble micronutrient?

☐yes

☐no

Does the stability study demonstrate absence of microbial growth?

☐yes

☐no

Based on the result of the stability study:

- What is the shelf life of the product?

- What are the recommended storage conditions?

☐ *Please provide a detailed report including the protocol and results of the stability study in Appendix 15.*

10. EFFICACY STUDY AND ACCEPTABILITY STUDY

Has this product already been used in MSF/UNICEF/WFP nutritional programmes?

☐yes

☐no

If NO Has a product with the same recipe produced by another manufacturer already been used in MSF/UNICEF/WFP nutritional programmes?

☐yes

☐no

If NO Has an efficacy study been perform?

☐yes

☐no

If yes, ☐ *Please provide a report including the method, number of patients, comparison with another product, duration, results in Appendix 16.*

Has an acceptability study been perform?

☐yes

☐no

If yes, ☐ *Please provide a report including the method, number of patients, comparison with another product, duration, results in Appendix 17.*

Is (are) there reference paper(s) published in nutritional/paediatrics journals?

☐yes

☐no

If yes, reference(s):

LIST OF DOCUMENTS TO PROVIDE

☐ This product questionnaire completed (for each product)

List of Appendixes. Please send all appendixes (*except the one in italic, only if applicable*), **by naming the documents with the appendix number, eg: “appendix 1, tech data sheet”**

- ☐ 1. The technical data sheet
- ☐ 2. Last available complete certificate of analyses, not more than 12 months old, and produced with the current manufacturing set-up and formula, including all parameters for product specifications: microbiology, mycotoxins as appropriate, pesticides: carbamates, organochlorine, organo-phosphorous and pyrethroid, heavy metals: arsenic, lead, mercury and tin; melamine; PAH (if applicable. It shall be accompanied with a report discussing the results.
- ☐ 3. *“Non GMO” certificate (if applicable)*
- ☐ 4. Picture(s) of the unit packaging or label artwork (with readable labelling and printing of batch number & best before date)
- ☐ 5. Certificate of Analyses to validate the packaging performance measurements (OTR, WVTR...) Letter of compliance for food contact measurement.
- ☐ 6. Copy of the leaflet
- ☐ 7. *List of countries where the product is registered, with registration details (reference, dates, etc...)*
- ☐ 8. *List of countries where the patent is applicable (where product can not be used)*
- ☐ 9. Description of the process (from raw materials reception to finished product) through a flow chart including: inspections performed during process (CCPs, PRPs, OPRPs) and the key parameters (temperature, pressure, mixing time...)
- ☐ 10. Copy of the procedure for mixing/fortifying and related production records, and/or copy of the calibration feeder procedure and related production records.
- ☐ 11. Results of the calculation of the coefficient of variation
- ☐ 12. Trend analysis for all nutrients (more detailed for tracers used for release)
- ☐ 13. Report for validation of heat treatment process, with microbial challenge study on the finished product
- ☐ 14. Copy/example of certificate of analysis as requested for each batch/lot delivered
- ☐ 15. Protocol and results of the stability study
- ☐ 16. *Protocol and results of the efficacy study*
- ☐ 17. *Protocol and results of the acceptability study*

List of Annexes:

- ☐ Annex 1 (A and B): Monitoring plan of ingredients, raw material (including packaging), technological auxiliaries and processing products used, and their monitoring plan
- ☐ Annex 2 (A and B): Test/checks performed during processing
- ☐ Annex 3 (A and B): Test/checks performed for finished product release



ANNEX 1 – MONITORING PLAN FOR THE INCOMING MATERIAL (INCLUDING PACKAGING)

Annex 1-A : Physical chemistry parameters + documentation

Ingredient material	Monitoring plan										Criteria for release?	
	Parameter	Method	Target	Max	Min	Frequency	CoA provided by the supplier ?	Analysed at reception?				
								Analysed upon receipt	Laboratory			Accredited
									(Int = internal Ext = external)			
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N
							☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ Y ☐ N	☐ Y ☐ N

Name and location (country) of the external laboratory(ies):



Annex 1-A: Physical chemistry parameters + documentation (continued)

Ingredient material	Monitoring plan										Criteria for release?	
	Parameter	Method	Target	Max	Min	Frequency	CoA provided by the supplier ?	Analysed at reception?				
								Analysed upon receipt	Laboratory (Int = internal Ext = external)			Accredited
							☐ Y ☐ N		☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☒ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	
							☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ Y ☐ N	☐ Y ☐ N	

Name and location (country) of the external laboratory(ies):

ANNEX 1 – MONITORING PLAN FOR THE INCOMING MATERIAL

Annex 1-B : Microbiological parameters:

Ingredients Raw material	Microorganisms	Sampling plan and limits							Method	CoA provided by the supplier ?	Analysed at reception?				Criteria for release?
		Frequency	unit	m	M	n	c	p			Analysed upon receipt	laboratory		Accre- -dited	
												(Int = internal Ext = external)			
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N
										☐ Y ☐ N	☐ Y ☐ N	☐ Int.	☐ Ext.	☐ yes	☐ Y ☐ N

Name and location (country) of the external laboratory(ies):

Annex 1-B : Microbiological parameters (continued)

Ingredients Raw material	Microorganisms	Sampling plan and limits							Method	CoA provided by the supplier ?	Analysed at reception?				Criteria for release?
		Frequency	unit	m	M	n	c	p			Analysed upon receipt	laboratory		Accre- -dited	
												(Int = internal Ext = external)			
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	
										☐ Y ☐ N	☐ Y ☐ N	☐ Int. ☐ Ext.	☐ yes	☐ Y ☐ N	

Name and location (country) of the external laboratory(ies):



ANNEX 2 – MONITORING PLAN DURING PROCESSING

Annex 2-A : Physical chemistry and other parameters

Semi finished product (SFP) / finished product (FP) / other	Monitoring plan								Criteria for release
	Parameter	Method	Target	Min	Max	Frequency	laboratory		
							(Int = internal Ext = external)	Accredited	
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no
							☐ Int. ☐ Ext	☐ Yes	☐ yes ☐ no

Name and location (country) of the external laboratory(ies):



ANNEX 2 – MONITORING PLAN DURING PROCESSING

Annex 2-B : Microbiological parameters

Where/what	Microorganisms	Frequency	Sampling plan and limits						Method	Laboratory		Criteria for release
			unit	m	M	n	c	p		Int/Ext	Accredited	
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
										☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no

Name and location (country) of the external laboratory(ies):



ANNEX 3 – FINISHED PRODUCT RELEASE

Annex 3-A : Physical chemistry parameters / documentation

Parameter	Method	Target	Min	Max	Frequency	Criteria for release	Laboratory (Internal/ external)	
							Internal/ external	Accredited
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes

Name and location (country) of the external laboratory(ies):



**Annex 3-A : Physical chemistry parameters / documentation
(continued)**

Parameter	Method	Target	Min	Max	Frequency	Criteria for release	Laboratory (Internal/ external)	
							Internal/ external	Accredited
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes
						☐ yes ☐ no	☐ Int ☐ Ext	☐ Yes

Name and location (country) of the external laboratory(ies):



ANNEX 3 – FINISHED PRODUCT RELEASE

Annex 3-B : Microbiological parameters:

Microorganisms	Frequency	Sampling plan and limits						Method	Laboratory		Criteria for release
		unit	m	M	n	c	p		Int/Ext	Accredited	
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no
									☐ Int. ☐ Ext	☐ yes	☐ yes ☐ no

Name and location (country) of the external laboratory(ies):