



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)	<input type="checkbox"/> Treatment of severe acute malnutrition	<input type="checkbox"/> Humanitarian emergency	
	<input type="checkbox"/> Management of moderate acute malnutrition	<input type="checkbox"/> Nutritional Supplements	
	<input type="checkbox"/> Prevention of moderate acute malnutrition	<input type="checkbox"/> Other:	
Target beneficiaries (several choices allowed)	<input type="checkbox"/> Children from 6 to 12 months	<input type="checkbox"/> Adolescents	<input type="checkbox"/> Pregnant women
	<input type="checkbox"/> Children from 12 to 24 months	<input type="checkbox"/> Adults only	<input type="checkbox"/> Lactating women
	<input type="checkbox"/> Children from 24 to 36 months	<input type="checkbox"/> All people	<input type="checkbox"/> HIV and/or TB
	<input type="checkbox"/> Other:		
Type and form	<input type="checkbox"/> Therapeutic milk (F75/F100)		
	<input type="checkbox"/> RUTF (Ready to Use Therapeutic Food)		
	<input type="checkbox"/> LNS (Lipid-based Nutrient Supplement)		
	<input type="checkbox"/> Fortified blended food (eg Corn Soy Blend)		
	<input type="checkbox"/> Vitamin and mineral supplement powder (MNP)		
	<input type="checkbox"/> Other type:		
Principle ingredient / Base (e.g. : milk, maltodextrin, peanut...)			
Flavour (if different than principle ingredient)			
Primary packaging	<input type="checkbox"/> Sachet (grams)	<input type="checkbox"/> Tin (grams)	<input type="checkbox"/> Bag (grams)
	<input type="checkbox"/> 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	<input type="checkbox"/> Low	<input type="checkbox"/> Medium	<input type="checkbox"/> High	<input type="checkbox"/> Very high
Date returned		Product risk	<input type="checkbox"/> low risk	<input type="checkbox"/> medium risk	<input type="checkbox"/> high Risk	



CONTENTS

RECOMMENDATIONS TO THE MANUFACTURERS	3
PRODUCT SPECIFICATIONS.....	4
1.1. DESCRIPTION	4
1.2. NUTRITIONAL INFORMATION	4
1.3. VITAMINS AND MINERALS.....	4
2. INGREDIENTS / ACTIVE PRINCIPLE INGREDIENTS (APIS).....	5
3. PRODUCT SAFETY	5
3.1. MICROBIOLOGY AND MYCOTOXINS	5
3.2. CHEMICAL SAFETY	6
4. PACKAGING AND LABELING.....	6
4.1. PRIMARY PACKAGING	6
4.2. CARTON.....	7
5. LOGISTIC INFORMATION.....	7
6. REGULATORY SITUATION	7
6.1. IN THE COUNTRY OF MANUFACTURE	7
6.2. IN OTHER COUNTRIES	7
6.3. PATENT/ LICENSE (RESTRICTED USE)	8
6.4. USE BY OTHER NGOs/ORGANIZATIONS.....	8
7. PRODUCTION	8
7.1. PRODUCTION CAPACITY	8
7.2. PROCESS	8
7.2.1. <i>Fortification</i>	8
7.2.2. <i>Heat treatment</i>	9
8. QUALITY ASSURANCE	9
8.1. HACCP	9
8.2. MONITORING OF INCOMING MATERIALS	9
8.3. INSPECTION DURING PROCESSING	9
8.4. INSPECTION OF FINISHED PRODUCT – PRODUCT RELEASE	10
8.5. TRACEABILITY	10
9. STABILITY STUDY AND STORAGE CONDITIONS	10
10. EFFICACY STUDY AND ACCEPTABILITY STUDY.....	11
LIST OF DOCUMENTS TO PROVIDE	12
ANNEX 1 – MONITORING PLAN FOR THE INCOMING MATERIAL (INCLUDING PACKAGING)	13
ANNEX 1 – MONITORING PLAN FOR THE INCOMING MATERIAL	15
ANNEX 2 – MONITORING PLAN DURING PROCESSING	17
ANNEX 2 – MONITORING PLAN DURING PROCESSING	18
ANNEX 3 – FINISHED PRODUCT RELEASE	19
ANNEX 3 – FINISHED PRODUCT RELEASE	21



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

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>

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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=eNUQUdfnLem00QXIoYHQCA&usg=AFQjCNHuf_TaCO34yz6961RBxeoY6gvdyg&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.....				viamin 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

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

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, nitrates 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, organophosphorous 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)?
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:

- | | | | | | |
|--|--|--|---------------------------------|---|---|
| <input type="checkbox"/> Name and address of the manufacturer, packer, distributor, importer, exporter or vendor | <input type="checkbox"/> Country of origin | <input type="checkbox"/> Storage condition | <input type="checkbox"/> Weight | <input type="checkbox"/> Volume | <input type="checkbox"/> Numbers of units per carton. |
| <input type="checkbox"/> Batch number | | | | <input type="checkbox"/> Best before date | <input type="checkbox"/> 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

<input type="checkbox"/> Product registered and currently marketed.	License n°
<input type="checkbox"/> Product registered for marketing in the country of manufacturing but not currently marketed.	License n°
<input type="checkbox"/> Product registered for export only	License n°
<input type="checkbox"/> 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 used (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 days 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 $30\pm2^\circ\text{C}$ for the claimed shelf life (real time studies). yes no
- Long term stability study at $40\pm2^\circ\text{C}$ for the claimed shelf life (real time studies). yes no
- Accelerated data at $40\pm2^\circ\text{C}$ 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 | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| - Odour | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| - Colour | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| - viscosity | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| - Product consistency and behavior | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| - Stability of oils and fatty acids | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| - Absence of oxidation | <input type="checkbox"/> yes | <input type="checkbox"/> 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 performed? 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 performed?

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



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	
								<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int. <input type="checkbox"/> Ext. <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N
								<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int. <input type="checkbox"/> Ext. <input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> Y <input type="checkbox"/> N
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Annex 1-A: Physical chemistry parameters + documentation (continued)

Ingredient material	Parameter	Method	Target	Max	Min	Frequency	CoA provided by the supplier ?	Analysed at reception?			Criteria for release?	
								Analysed upon receipt	Laboratory			
									(Int = internal Ext = external)	Accredited		
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							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
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							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
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							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
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							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
							<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N



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					
												(Int = internal Ext = external)	Accre- dited				
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> 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			laboratory						
											Analysed upon receipt	(Int = internal Ext = external)	Accre- dited				
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			
										<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Int.	<input type="checkbox"/> Ext.	<input type="checkbox"/> yes <input type="checkbox"/> N			

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



ANNEX 2 – MONITORING PLAN DURING PROCESSING

Annex 2-A : Physical chemistry and other parameters

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



ANNEX 2 – MONITORING PLAN DURING PROCESSING

Annex 2-B : Microbiological parameters

Where/what	Microorganisms	Sampling plan and limits						Method	Laboratory		Criteria for release
		Frequency	unit	m	M	n	c		Int/Ext	Accredited	
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
									<input type="checkbox"/> Int. <input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no

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



ANNEX 3 – FINISHED PRODUCT RELEASE

Annex 3-A : Physical chemistry parameters / documentation

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



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

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



ANNEX 3 – FINISHED PRODUCT RELEASE

Annex 3-B : Microbiological parameters:

Microorganisms	Sampling plan and limits						Method	Laboratory		Criteria for release	
	Frequency	unit	m	M	n	c		Int/Ext	Accredited		
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no
								<input type="checkbox"/> Int.	<input type="checkbox"/> Ext	<input type="checkbox"/> yes	<input type="checkbox"/> yes <input type="checkbox"/> no

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