



FREQUENTLY ASKED QUESTIONS

This document will provide you with answers to all the general questions which you need to ask when carrying out a supplier assessment.

PRIMUS OUWELFABRIEK B.V.

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PART ONE: COMPANY INFORMATION

Primus Ouwelfabriek B.V. (hereafter to be referred to as “Primus”) was founded in 1916. Since then, Primus has become a global leader in potato starch-based edible wafer paper solutions, which are marketed in many industries. Customer satisfaction and unrivalled product quality are key drivers for Primus, this is why we strive to be the best wafer paper producer on a daily basis. As many of our products are developed for the food chain and even for infant nutrition, we work according to the highest standards required by HACCP / BRC and IFS. Primus is also certified by SKAL and Kosher requirements. In order to ensure top quality and food safety Primus only purchase raw materials from vendors that we know and trust. The management team of Primus ensures that there are clear rules, efficient processes and effective structures within the organization. We strive to have an organization where everybody is proud to work for Primus, the unique world leader of wafer paper solutions.

For more information on Primus, its organization and vision, please visit

www.primuswaferpaper.com

	YES	NO
QUALITY POLICIES		
What quality policies have been defined:		
<ul style="list-style-type: none"> Mission & Vision <i>Please visit the Primus website where you will find more information about our Company</i> 	●	
<ul style="list-style-type: none"> Quality Policy <i>Food requirements, Management of Change, Crisis Management, Traceability</i> 	●	
QUALITY SYSTEMS		
Quality systems and standards meet the following regulations:		
<ul style="list-style-type: none"> BRC (British Retail Consortium) IFS (International Food Standard) Kosher Skal 	●	
RECALL OF PRODUCTS		
Are there appropriate recall procedures in place?		
<ul style="list-style-type: none"> Granting that documents can be traced back via product, packaging and batch code 	●	
<ul style="list-style-type: none"> Do you perform mock recall to test the recall process? 	●	

	YES	NO
<p>COMPLAINT MANAGEMENT</p> <p>Do you have a formal customer complaint process that guarantees commitment and responsibility, covering all products and logistics regardless of the nature of the complaint?</p> <p><i>A central Primus complaint procedure defines the process flow and responsibility of complaints handling. Complaints information, root cause analysis, and results of investigation are monitored via a central Primus complaint data base. The sales department is responsible for communicating with the customer. The quality department assures smooth processing, reports targets and results to the management team, suggests action plans to avoid recurrences.</i></p>		●
<p>APPROVAL PROCEDURE OF CHANGES</p> <p>Is there an approval and notification-of- changes program regarding major changes in manufacturing processes in place? All process and equipment changes are recorded and major ones are validated and documented. Management of Change (MOC) in place.</p>		●

	YES	NO
PRODUCT LABELLING		
Are finished product labels printed with text details in-house, showing the following information:		
• Name of Supplier	●	
• Name and batch number of the product	●	
• Quantity per unit	●	
• Best-use-before date (re-test date)	●	
• Storage conditions	●	
• Safety warning (when applicable)	●	
• Labels are in compliance with (EC) No. 1332/2008	●	
PRODUCT INFORMATION		
For specific product information, following documents are available:		
• Product Specification Sheet (PSS)	●	
• Material Safety Data Sheet (MSDS)		●
• Non GMO Statement	●	
• Kosher and Kosher for Passover (when applicable) certificates	●	
• Certificate of Analysis (COA) All round, not for specific batch	●	
RISK MANAGEMENT		
Do you perform risks assessment?	●	
Do you have a crisis management policy?	●	

PART TWO: SITE INFORMATION

GENERAL INFORMATION

NAME OF THE PRODUCTION SITE: PRIMUS OUWELFABRIEK B.V.

Address: Ambacht 8
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 The Netherlands
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	YES	NO
Is the site a mono production site?	●	
Does your site perform...		
<ul style="list-style-type: none"> • Planning <i>Global planning is performed in the central demand supply chain organisation in the Netherlands. Local scheduling is performed by the production plant.</i> 	●	
<ul style="list-style-type: none"> • Production 	●	
<ul style="list-style-type: none"> • Packaging 	●	
<ul style="list-style-type: none"> • Storage 	●	
<ul style="list-style-type: none"> • Sales and Marketing 	●	
<ul style="list-style-type: none"> • Distribution 	●	
Does the site guarantee...		
<ul style="list-style-type: none"> • On-site Quality Control and -Assurance 	●	
<ul style="list-style-type: none"> • Security-, Safety- and Environment Management 	●	
<ul style="list-style-type: none"> • Facility Management 	●	
<ul style="list-style-type: none"> • Research & Development 	●	

	YES	NO
Does the site provide a personnel training program, covering...		
• Standard operating procedure for training	●	
• BRC guidelines and SOPs	●	
• Regular updates of training documentation	●	
QUALITY UNIT		
Does the site have a separate QC/QA unit that is independent	●	
• In approval/rejection process (raw material/packaging components / product batches)	●	
• Specifications	●	
• Process Changes (in HACCP team)	●	
Is the site-QA unit responsible for...		
• Release of products (on customer request positive release is included)		●
• Documentation, investigation and customer complaints	●	
• Internal audits	●	
Is the site-QA unit involved in...		
• Rejection of non-conforming raw material and intermediates	●	
• Process deviation procedure, the investigation of failures and complaints	●	
• Evaluation, selection, approval and rejection of new suppliers/raw material	●	
• Return of non-conforming products	●	
• Supplier audits	●	
• Customer audits	●	
• Does the quality audit procedure guarantee pre-audit planning and post-audit documentation with respective corrective action to be taken?	●	

	YES	NO
HACCP		
HACCP system is in place	●	
What does the HACCP contain?		
Physical-, microbiological- and chemical contamination and allergen cross contamination are the hazards considered in the HACCP study.	●	
<ul style="list-style-type: none"> • Definition of hazards and risks for health quality 	●	
<ul style="list-style-type: none"> • Documented Critical Control Points (CCP) 	●	
<ul style="list-style-type: none"> • Critical Limits of each CCP 	●	
<ul style="list-style-type: none"> • Description of the monitoring procedure for each CCP 	●	
<ul style="list-style-type: none"> • Description of corrective actions when there is a noncompliance at a CCP 	●	
<ul style="list-style-type: none"> • An effective record system 	●	
<ul style="list-style-type: none"> • Regular audits 	●	
RAW MATERIAL		
Does Primus have a Vendor Evaluation program for the suppliers and ingredients used in the process, covering...		
<ul style="list-style-type: none"> • Raw material specification 	●	
<ul style="list-style-type: none"> • Inspection and analysis 	●	
<ul style="list-style-type: none"> • Periodic supplier audits (planning, documentation, follow-up) 	●	
<ul style="list-style-type: none"> • CoA or CoC 	●	
Does the site have written procedures in place for receipt, inspection, storage, identification, representative sampling, testing and disposition of raw materials?	●	

MANUFACTURING PROCESS

	YES	NO
EQUIPMENT		
Do the following instructions account for the site's production equipment:		
• Validated cleaning program	<input checked="" type="radio"/>	
• Validated calibration program	<input checked="" type="radio"/>	
• Procedure for the notification of production changes	<input checked="" type="radio"/>	
• Preventive Maintenance program	<input checked="" type="radio"/>	
WATER		
Does the site have a water purification system in place?		<input type="radio"/>
What types of water are used for manufacturing:		
• Well water		<input type="radio"/>
• Potable water (city water)	<input checked="" type="radio"/>	
• Softened water		<input type="radio"/>
• Purified water		<input type="radio"/>
• Distilled water		<input type="radio"/>
Does the site regularly check the water quality?	<input checked="" type="radio"/>	
AIR		
Does the site have an air-handling system in place?		
• In the manufacturing rooms?		<input type="radio"/>
• In the packaging rooms?		<input type="radio"/>
• Does the site regularly check the air quality (e. g. contamination, dust, and spray)		<input type="radio"/>

Does the site use compressed air according to ISO 8573; 2010 (class 1-4-1)



INSTRUCTIONS

	YES	NO
Does the site have written procedures in place regarding...		
Operation instructions and records	<input checked="" type="radio"/>	<input type="radio"/>
Process control instructions and records	<input checked="" type="radio"/>	<input type="radio"/>
Calibration instructions and records	<input checked="" type="radio"/>	<input type="radio"/>
Maintenance instructions and records	<input checked="" type="radio"/>	<input type="radio"/>
Cleaning instructions and records	<input checked="" type="radio"/>	<input type="radio"/>
Pest control and records performed by external contractor, control 8 times/year	<input checked="" type="radio"/>	<input type="radio"/>
Jewellery policy	<input checked="" type="radio"/>	<input type="radio"/>
Glass policy	<input checked="" type="radio"/>	<input type="radio"/>
Environmental monitoring system (temperature, humidity and microbiology)	<input checked="" type="radio"/>	<input type="radio"/>

BATCH SYSTEM

Are the products manufactured:

Continuously



Batch wise

Batch number has 5 digits. We have a “make to order” production strategy



	YES	NO
FOREIGN BODIES		
Can the site guarantee that vents in silos, tanks or other large containers are protected in order to prevent the entry of foreign bodies, insects and water?	●	
Does the site undertake the following measures to avoid risk of foreign bodies connected with metal, wood, fibers, fur, hair and plastic:		
<ul style="list-style-type: none"> • Sieves 	●	
<ul style="list-style-type: none"> • Wood control procedure (cal-p-06) 	●	
<ul style="list-style-type: none"> • Metal detectors 	●	
<ul style="list-style-type: none"> • Personal hygiene regulations 	●	
Does the site carry out routine checks in order to verify the good condition of its protection against foreign bodies?	●	
CLEANING AND HYGIENE		
Does the site's Hygiene Program in the production area cover the following points:		
<ul style="list-style-type: none"> • Usage of clothes and caps 	●	
<ul style="list-style-type: none"> • Garment instructions (including jewellery and objects) 	●	
<ul style="list-style-type: none"> • Definition of eating, drinking, chewing and smoking/non-smoking areas 	●	
<ul style="list-style-type: none"> • Regular drain cleaning 	●	
<ul style="list-style-type: none"> • Location of hand washing- and toilet facilities 	●	
Do operators and maintenance personnel receive training on the above Hygiene Program?	●	

DOCUMENTATION

	YES	NO
Does the site’s documentation system cover the following types of documentation:		
• Raw material specification	●	
• Standard Operating procedures (SOP) production and laboratory	●	
• Validation protocols	●	
• Facility engineering drawings	●	
• Policies (Corporate/Departmental)		●
• Finished products specifications	●	
• Stability protocols		●
• Batch productions	●	
Does the site keep records of significant changes and reason for change?	●	
Are deviations, incidents and rework of batches		
• Investigated	●	
• Approved	●	

	YES	NO
PACKAGING AND LABELING		
Does the site have written specifications, examining methods and cleaning procedures (where required) for packaging and labelling?	●	
Are packaging and labelling materials examined for suitability and correctness before Packaging operations?	●	
Is the packaging the site uses suitable for the contact with food? <i>Packaging used are in compliance with all relevant EU regulations for food contact.</i>	●	
Does the site exclusively use for primary packaging?		
Non-returnable package	●	
Reusable package		●
Does the site perform inspections on the labelling operation?	●	

	YES	NO
STORAGE		
Does the site have a suitably equipped area for:		
• Raw material	●	
• Intermediates	●	
• Finished products	●	
• Packaging material	●	
• Rejected material	●	
• Sampling	●	
Does the site apply the “First-in-first-out” system for raw materials?	●	
SHIPPING		
Does the site have written procedures for inspection of equipment before loading (cleanliness, absence of smell etc.)?	●	
Does the site have written procedures in place in order to verify shipping requirements?	●	
Is documentation enclosed in each shipment?	●	
Is the site capable and willing to provide customer with a Certificate of Analysis for every lot of product supplied to customers?		●
Does the site keep records of delivery:		
• By customer	●	
• By batch number	●	
• By order number	●	
Does the site have its own logistic department responsible for the transport of finished products?	●	

After loading, does the site seal the vehicles automatically?		<input checked="" type="radio"/>
	YES	NO
SAFETY, HEALTH AND ENVIRONMENT (SHE) REQUIREMENTS		
Is your site certified according to environmental norms? <i>According IFS/BRC standard</i>	<input checked="" type="radio"/>	
Does your company have a written environmental policy?	<input checked="" type="radio"/>	
Does your company have environmental audits?	<input checked="" type="radio"/>	
Do you act according to the local laws of environment	<input checked="" type="radio"/>	