

Audit Report

Global Standard Packaging Materials Issue 6: August 2019

1. Audit summary			
Company name	ANL Plastics NV	BRCGS site code	1883448
Site name	ANL Plastics NV		
Scope of audit	In- and offline cast-extrusion of rigid foil, thermoforming and/or offset printing of (R)PET, PS, multilayer (R)PET and PP material for food and non-food applications. Trading of seal foil and laminated paper rings, thermoformed packaging (R)PET, PS, multilayer (R)PET and PP material for food and non-food applications. Outsourcing of assembly of cardboard and meat pads with own produced products.		
Scope exclusions	None		
Justification for exclusion	n/a		
Start date	2025-01-20	Finish date	2025-01-22
Re-audit due date	2026-01-24	Previous audit date	2024-01-19

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose an item	Choose an item		
Choose an item	Choose an item		

2. Audit results			
Audit result	Certificated	Audit Programme	Announced
Audit grade	A	Previous audit grade	A
Certificate issue date	2025-02-14	Certificate expiry date	2026-03-07
Number of non-conformities	Major against SOI of Fundamental	0	
	Critical	0	
	Major	0	

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2.Audit results		
	Minor	10

3.Company details			
Address	Hertenstraat 32 3830 Wellen		
Country	Belgium	Telephone	+32(0)12741595
Commercial representative Name	Vicky Verheyen	Email	Vicky.Verheyen@anlpackaging.com
Technical representative Name	Steven Beerten	Email	Steven.Beerten@anlpackaging.com

4.Company profile					
Plant size (square metres)	>25K sq.m	No. of employees	51-500	No. HARA Plans	1-3
Subcontracted activities	No				
Outsourced processes	Yes				
Other certificates held	Ecovadis silver				
Regions exported to	Europe Choose an item. Choose an item. Choose an item. Choose an item.				
Major changes or auditor observations since last BRCGS audit	2 extruders and 2 thermoforming machines away, 1 new extruder, 1 new thermoforming machines, on-line IV measuring equipment PET extruders;new compressor and new cooler				
Company description	The company was a family company with 3 sites (Poland, France and Belgium) and one site with commercial cooperation in Italy, but has (month of May 2021) been taken over by the Somater family group. The site is situated in Wellen (Belgium). The company was started in 1938 with wooden packaging for vegetables and fruit. In 1958 the company started with thermoforming of plastics. 191 FTE (+/- 80 FTE in				

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4. Company profile

	<p>main shift) are working on site 7/7, 24 hours a day, 5 shifts. 1 HACCP study and 32200 square meters built surface. 6 extrusion lines (of which 1 inline) and 14 thermoforming lines and 2 printing lines (small). Tools are made at the company and externally. Total group ANL >1 billion of units are formed a year with a turnover of 51 million euro in 2024 (72 million in 2023). AFSCA audit was 7 November 2024. The majority of the products are made for food contact. 85% plastics used: PP, (R)PET and PS. Outsourced process: Assembling of packaging made from 2 different parts. Assembling PP trays & meat pads</p>
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5. Product and process characteristics

Manufacturing Categories	<p>04 - Rigid plastics 05 - Flexible plastics 07 - Print processes Please select Please select Please select</p>
Products in production at the time of the audit	<p>Extrusion gold coloured RPET film, printing X-DS108Plateau108Rtopblack, protecting cover 250 X 300 X30 client Ca.114Qcover 500 pieces, mussel boxes ¼ euroH55 cristal</p>

6. Audit duration details

Total audit duration	21 hours	Duration of production facility inspection	9 hours
Reasons for deviation	Longer with 1.5h :Big site, long distances		
Next audit type selected	Unannounced		

Audit Duration per day

Audit Day	Date	Start Time	Finish time
1	2025/01/20	10:15	18:15
2	2025/01/21	08:50	18:15
3	2025/01/22	08:50	13:25

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Auditor information		
Auditor number	Auditor Name	Role
21907	Jan Corluy	Lead Auditor
Click or tap here to enter text.		Please select

Present at audit
 Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings

Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Steven Beerten, Quality manager	On site	On site	On site	On site
Yves Neven, CFO	On site			On site
Roderich Lemmens, Production manager tooling	On site	On site	On site	On site
Stefan Timmermans, Supply Chain coordinator			On site	
Vicky Pauwels, HR responsible			On site	On site
Vicky Verheyen, Commercial director	On site		On site	
Rik Peeters, Operations director	On site	On site	On site	On site
Matty Kurings, Quality engineer		On site		
Steve Gielen, Production supervisor extrusion		On site	On site	
Veronique Baldewijns, Teamleader thermoforming		On site	On site	

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Stefan Lafosse, Teamleader warehouse			On site	
Bart Vanspauwen, Maintenance supervisor			On site	
Vanessa De Wolf, QA engineer		On site	On site	
Sabine Gaens, printing operator		On site		
Patrick Vaes, Production supervisor thermoforming			On site	
Ellen Desteghe, assistant supervisor thermoforming			On site	
Abida Amirai/Sandra Careme- operator themoforming		On site		
Kim Lambrix- Vanessa Kaminski – HR employees			On site	
Tom Geerkens – Product developer			On site	
Peter Vissers_ purchasing			On site	
Jurgen Lopez Lopez – Warehouse manager			On site	
Johan Segers- Maintenance			On site	

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2024-01-17	BRCGS PM	announced
2022-11-21	BRGGS PM	unannounced

Document control

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CB Report number	141937		
Template Name	P609 Packaging Materials Audit Report Template v11		
Standard Issue	6	Template issue date	2022-02-15
Directory allocation	PackMat	Version	1.0

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Non-Conformity Summary Sheet

Major non-conformity against statement of intent of a fundamental requirement				
No.	Clause	Detail	Critical or Major	Re-audit date

Critical				
No.	Clause	Detail		Re-audit date

Major							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	1.1.2	A new plan was made for 2024 including KPI's, confirmation not given during yearly MR on 22/01/2024. No new plan product defined safety and quality FSC for 2024 was confirmed and implemented in 2024. Nevertheless, a lot of initiatives concerning FSC were realised e.g. formation day, a lot of quality trainings e.g. complaint metal parts, use on-line IV measuring equipment, 5 new internal auditors, formation on legislation/FOCOS.	The effectiveness of the actions done in 2024 to improve the product safety and quality culuture were reviewed, and conclusions taken as input for the plan for 2025. Deadline : 01/02/2025 Responsible : Steven Beerten	A product and safety culture plan for 2025 was made, based on the findings of the product safety and quality culture review, complaints and internal and external audits, Belgian legal requirements towards trainings. In addition, a quarterly formal review of this plan is scheduled for MT-members. Deadline : 05/02/2025 Responsible : Vicky Pauwels	Due to the swift changes in the company over the course of 2025, the initial plan could not be followed : certain activities were cancelled, new activities were defined and implemented. The initial plan should have been updated accordingly, but was not done.	2025-02-07	Jan Corluy

2	2.2.10	<p>CCP monitoring records are not always filled in like it should be/like it is described. Recording of CCP2 audit trail during this audit was also about another article and last reel production of audit trail was not produced on 27/09 but on 30/09. Via other evidence mistakes could be explained during this audit. Also, no start-up monitoring CCP2 on 30/09/2024 of reel 616755103.</p>	<p>Revision of the work instruction on filling in the CCP documents, and retraining of operators and teamleaders Deadline : 5/2/2025 Responsible : Patrick Vaes</p>	<p>Revision of the work instruction on filling in the CCP documents, and retraining of operators and teamleaders Deadline : 5/2/2025 Monthly check of CCP documents by Quality Manager planned. Deadline : 6/2/2025 Responsible : Steven Beerten</p>	<p>After discussions with operators and teamleaders, it was clear the requirement to fill in separate documents per production order was not fully understood</p>	2025-02-07	Jan Corluy
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3	3.5.4	<p>Follow-up of CA's was/is really improved (minor NC 3.6.1 former audit). There are actually no corrective actions overdue date. Only 64 open corrective actions at the moment of this audit. Nevertheless, it was assessed that follow-up of some minor NC's defined in internal audits is delayed. E.g. instruction release first production run IA 21/04/2023 still not finalised. CA 2024-047missing procedure blocking silo from IA 26/04/2024 not yet finalised.</p>	<p>Closing of the internal audit NC's as mentioned in the details of the non-conformity. In addition, closing of other long open internal audit NC's where possible within short period. Thirdly, review of all open audit NC's to make sure there is no open NC with a deadline longer than 3 months. Deadline : 6/2/2025 Responsible : Steven Beerten</p>	<p>Incorporate regular review times to check on the open CAPA points. In this way, actions can be taken in time to make sure open points are closed before the initial due date. In addition, the auditee will be instructed to have all audit points closed within 3 months. These instructions are incorporated in the audit report template. Deadline : 05/02/2025 Responsible : Steven Beerten</p>	<p>despite catching up on the number of open audit points, a number of points have remained open for too long. Deadlines could be moved too easily without consequence</p>	2025-02-07	Jan Corluy
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4	3.7.2	Supplier Zeller is supplying printing inks but this supplier is not approved. No evidence how this supplier is approved or how these are purchasings with sufficient guarantees what quality, legality and food safety is concerned. There is also no evidence how supplier Indurama (PCR PET) was approved: No GFSI certification, no external audit and no filled-in questionnaire. (several times requested by ANL).	<p>Make sure the supplier questionnaire is filled in and returned to ANL for both Zeller and Indorama.</p> <p>Deadline : 10/02/2025, ok 6/02/2025</p> <p>Responsible : Peter Vissers</p>	<p>Check the list of suppliers if there are other suppliers with missing questionnaires. Two suppliers were identified. Suppliers were reminded again, and information was received</p> <p>Deadline : 10/02/2025</p> <p>Responsible : Peter Vissers</p>	<p>For Indorama : the supplier was asked to fill in the questionnaire in august 2024. However, no answer was received, despite reminders from ANL's site. Note : for Indorama, the initial approval was based on the previous filled in questionnaire.</p>	2025-02-07	Jan Corluy
5	3.7.3	Supplier Zeller delivering printing inks is not evaluated after 2022 while this supplier is still delivering printing inks.	<p>Perform the supplier evaluation of Zeller, based on the returned questionnaire</p> <p>Deadline : 10/02/2025, ok 6/02/2025</p> <p>Responsible : Peter Vissers</p>	<p>Check for other articles with impact on quality and food safety which are not part of the supplier evaluation list</p> <p>Deadline : 01/02/2025</p> <p>Responsible : Quality Manager</p> <p>Outcome : all other articles with impact on quality and food safety are present in the supplier review of 2024</p>	<p>The supplier was not correctly recognized by the purchasing department as a supplier with impact on quality and food safety. Therefore, the supplier was not taken into account during the supplier evaluation of 2023 and 2024</p>	2025-02-07	Jan Corluy

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6	4.8.2	The upper side of preheating part of thermoforming line P922 was assessed as being dirty and greasy. There is a year plan 2024 for general cleaning of equipment. Frequency is defined as 2X/year but execution of this cleaning plan was incomplete e.g. cleaning of preheating units of all thermoforming lines was not performed in 2024.	Review cleaning of the preheaters, and clean the machines according to the reviewed instructions, after training of personnel Deadline : 06/02/2025 Responsible : Patrick Vaes	Review cleaning programme for 2025. In addition, create cleaning orders in the ERP system identical to production orders and maintenance orders (PO), and plan the cleaning tasks for 2025. Deadline : 10/02/2025 Responsible : Patrick Vaes	The intention to improve cleanliness of the machine was ok in making the yearly cleaning programme. However, the implementation was delayed (and in the end not executed) due to high output pressure and lack of personnel during the high season	2025-02-07	Jan Corluy
7	4.9.3.1	At the exit of preheating unit P922 flaking paint was assessed above running foil. Risk of (chemical) contamination of the foil.	Remove flaking paint from the preheater Deadline: 28/01/2025 Responsible : Patrick Vaes	Take measures to make sure paint is not flaking off again for this preheater. In addition, check all preheaters. Deadline : 05/02/2025 Responsible : Patrick Vaes In addition, update HARM-analysis on preheaters in thermoforming, based on the actions taken Deadline : 10/02/2025 Responsible : Steven Beerten	In the HARM-analysis, the presence of flaking paint coming off from the preheater was not recognized.	2025-02-07	Jan Corluy

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8	5.4.2	<p>To prevent foreign bodies in produced extrusion film (e.g. complaint about piece of metal in film) there is a magnet and a filter installed in extrusion heads. It is internally defined that these have to be monitored at least monthly for every extruder. It could not be demonstrated that this monitoring is taking place on weekly basis for every extruder. Week 04/09/2024 no magnet monitoring of PP extruder Bruckner and Kuehne. Last week no monitoring of magnet Viscotec 1 and Kuehne.</p>	<p>Review the current procedure for cleaning of filters and magnets. Then retrain personnel Deadline : 10/02/2025, ok 6/02/2025 Responsible : Steve Gielen</p> <p>Note : the frequency of cleaning is kept as it is : indication by the extruder, based on process parameters and working hours.</p>	<p>Daily check by supervisor if cleaning was needed, and if it was needed that it was done. This must be explicitly mentioned in the work instruction. Deadline : 10/02/2025 Responsible : Steve Gielen</p> <p>Review by Operations Director on monthly basis that this check is done.</p>	<p>The newer extrusion machines indicate when filters and magnets must be cleaned. Due to this new situation, operators no longer filled in the document. However, this created the situation that the effectiveness of cleaning cannot be verified correctly</p>	2025-02-07	Jan Corluy
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9	5.10.5	<p>There is a work instruction for checking incoming (bulk) trucks: WI_LEV_PROCES 3. There is also a form used for incoming control of bulk trucks P-LEV_PROCESS-doc1 1.12 but this is not always completely filled in e.g. section after delivering/loading e.g. delivery 21/01/2025. This form also has sections for delivery of pallets via trucks but this is actually not used anymore. In stead of this form stamp is put on CMR. This is not conforming WI_LEV_PROCES-3.</p>	<p>Review the procedure. In addition, make sure the documents used reflect the effective checks to perform. Deadline : 01/02/2025 Responsible : Jurgen Lopez-Lopez</p>	<p>From the audit date until the date for filing the CAPA plan to the audit body, check if the documents are correctly used. Deadline : 10/02/2025 Responsible : Jurgen Lopez-Lopez</p>	<p>Trucks were correctly checked according to the BRCGS requirements, but the procedure describing how to do so was not updated to the latest way of working</p>	2025-02-07	Jan Corluy
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10	6.1.5	There is no evidence/record of the training on the job as operator vacuum of new temporary employee AA.	<p>Review document F-HR-100 from 2019 Deadline : 01/02/2025 Responsible : Patrick Vaes</p> <p>Update procedure for HR-process after review of F-HR-100 Deadline : 10/02/2025 Responsible : Vicky Pauwels</p>	<p>The correct implementation of the document will be checked during the internal audit of chapter "personnel" of the BRCGS Packaging Materials V7</p> <p>As an example, the document was retrospectively filled in for operator A A</p>	<p>In 2019, a document was created for the evaluation of temporary workers in thermoforming. However, for the management at that time, it was not considered as valuable and it was never introduced</p>	2025-02-07	Jan Corluy
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Comments on non-conformities	
No comments	

Additional Modules/Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

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Detailed Section

1.	Senior management commitment
1.1	Senior management commitment and continual improvement
<p>The senior managers understand the importance of their commitment, both in attendance of the audit, and in management review. Sufficient evidence of the commitment to the implementation of the company policy is in place. The policy is signed by the whole directors team on 11/04/24 and new CEO, no changes. All required aspects are included. The policy is communicated to relevant staff by paper copy at all entrances.</p> <p>A FSC plan was made for 2023 defining actions per quarter. Actions on performance, training and awareness, appreciation employees and feedback and reaction on non conformities were made. This was based on the performance of the reviewed plan 2022. Fe. goals Q 2 : improving method how to deal with non conformities for maintenance department (postponed due to temporary lack of staff in Q department, Q3: mid term evaluation BRCGS , done, QA training day goal >95% presence, achieved. Plan is evaluated during quarterly meetings, as well as in yearly MR. A new plan was made for 2024 including KPI's, confirmation not given during yearly MR on 22/01/2024. No new plan product safety and quality FSC for 2024 was confirmed and implemented in 2024. Nevertheless a lot of initiatives concerning FSC were realised e.g. formation day, a lot of quality trainings e.g. complaint metal parts, use on-line IV measuring equipment, 5 new internal auditor, formation on legislation/FOCOS.</p> <p>Complete set of KPI's/objectives is defined. Quality objectives e.g. external complaints thermoforming (, average complaint handling time objective < 40 days, ok for plant ANLB, average 37, number of complaints 2024 (max. 50 related to product and packaging) : goal not achieved 179 in 2022, 195 in 2023, 179 in 2024 (94 complaints related to product & packaging + 18 foreign bodies) new KPI cost of non quality for 2023 +/- 135.000 euro, 2024 +/- 105000 euro, IA in time (month) 20/21 realised in 2024, RPT (within 10 days after audit) (about 50 % realised), CA's defined within 20 days after audit (About 50% realised in 2024)(Reported monthly, seen report December 2024. Also goals set / department: f.e. thermo man/machine hour target 1.89% (Target: 1,75) , achieved; scrap 3.5% , result 2023 2.5%, 2024: 2,19% time to produce target 96% - average above 99% (2024: 101,26%)</p> <p>The provided resources are adequate.</p> <p>The company is aware of the legal requirements e.g. via software FOCOS incl. automatic notification of changes in legislation and software for setting DoC-declarations..</p> <p>The recertification audit occurs on or before the audit due date 2025-01-25. Member senior management was present. See list 'Present at audit'. It is checked that NC's of previous audit are adequately resolved: 9 minors.</p> <p>There is one minor NC related to this section: 1.1.2: A new plan was made for 2024 including KPI's, confirmation not given during yearly MR on 22/01/2024. No new plan product defined safety and quality FSC for 2024 was confirmed and implemented in 2024.</p>	

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Nevertheless, a lot of initiatives concerning FSC were realised e.g. formation day, a lot of quality trainings e.g. complaint metal parts, use on-line IV measuring equipment, 5 new internal auditors, formation on legislation/FOCOS.

1.2 Management review

Seen prep of MR planned end of Jan. 2025 (exact date to determined), including HARM review complaints, internal audits, pest, ... demonstrates that the senior management is in control of meeting the requirements of the standard. Continuous improvement targets are established. There is also a SWOT analysis per process + a follow-up of related actions/process. Daily production meetings. 3 monthly HARA meeting. 2 monthly CAPA meeting Completion of actions is verified during monthly team meetings. The performances and objectives are part of the management review: seen M.R of 22/01/2024.

The review includes the evaluation of all items, including appropriate decisions and actions. Complete set of KPI's/objectives is defined. Quality objectives e.g. external complaints thermoforming (, average complaint handling time objective < 40 days, ok for plant ANLB, average 37, number of complaints 2024 (max. 50 related to product and packaging) : goal not achieved 179 in 2022, 195 in 2023, 179 in 2024 (94 complaints related to product & packaging + 18 foreign bodies) new KPI cost of non quality for 2023 +/- 135.000 euro, 2024 +/- 105000 euro, IA in time (month) 20/21 realised in 2024, RPT (within 10 days after audit) (about 50 % realised), CA's defined within 20 days after audit (About 50% realised in 2024)(Reported monthly, seen report December 2024. Also goals set / department: f.e. thermo man/machine hour target 1.89% (Target: 1,75) , achieved; scrap 3.5% , result 2023 2.5%, 2024: 2,19% time to produce target 96% - average above 99% (2024: 101,26%)

Complaints are reported monthly. Effective communication to appropriate staff is established: via meetings and hang-outs on white boards (seen in thermo and seen in extrusion). Management can demonstrate that actions have been verified and signed off as completed within the nominated timescales.

Besides the management review, Quality and Food Safety is addressed in monthly reports with directors' team, when issues a meeting will be asked. Employees are aware of the need to report any deviations to their team leader.

1.3 Organisational structure, responsibilities, and management authority

The company has a clear organisational structure and lines of communication for the effective management of product safety, legality and quality. An organisational chart, is available clearly demonstrating the management structure: rev 01-2025 consisting: CEO, sales & marketing director, finance & admin, production, HR, Quality. The responsibilities regarding management of product safety, legality and quality are clearly allocated, deputising is documented in back-up management F-GM-001, 2022-10-10. The effectiveness of operations is monitored by describe day to day monitoring; housekeeping inspections and discussed in daily meetings. The QA manager is responsible for implementation of the standard. Deputies N+1 and N+2 are mentioned on the job description. Responsibilities are described in job descriptions.

Employees are made aware of their responsibilities. The employees have access to the relevant work instructions and are kept informed of changes via update instructions and team meetings. There are also job descriptions available for all functions. Seen for QA engineer, extrusion operator, operator TF. The effectiveness of operations is monitored by day to day monitoring and shift-handovers.

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Non-applicable clauses	Click or tap here to enter text.
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2.	Hazard and risk management
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2.1	Hazard and risk management team
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The HARM/HARA team consists: quality manager (+ team leaders on demand) , operations director, quality engineers + extra members like project coordinator, product manager tooling, SHE coordinator.
 The team leader Steven Beerten is qualified through training by external consultant what HARM and trainings at former employers what risk analyses is concerned. The HACCP team is trained on HACCP principles. Last training was given to the HARM team on 08/02/2021 by consultant, training of new engineer LG 7/03/2024.

The members have specific and relevant knowledge: HARM/HARA was completely reviewed / process by responsible with coaching and training.

The team leader can demonstrate in-depth knowledge, education and experience. Training of all team members is achieved. Training records are available. See 2.1.1

2.2	Hazard analysis and risk assessment
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The company has a fully implemented and effective hazard analysis and risk assessment (HARA) in place. The hazard analysis and risk assessment includes In- and offline cast-extrusion of rigid foil, thermoforming, and/or offset printing of (R)PET, PS, multilayer (R)PET and PP material for food and non-food applications. Process steps like reception, storage, extrusion, thermoforming, printing and shipment, includes also outsourced and trading.

Following product group(s) are defined: (R)PET (with or without seal, with or without MAP), PP (with or without seal, with or without MAP), PS, printed, assembled.products (f.e. duobox)= outsourced

Process flow extrusion including rework (v7 18/01/2025), process flow inbound, process flow tooling, printing (17/01/2025), outsourced process Duobox (19/01/2025)

Recent flow diagrams verification Dec. 18th, 2024. Flow diagrams are verified on site, no changes.

The (HARA) team has identified and described all potential hazards and its potential source(s). Most relevant hazards: small perforations (MAP applications), breakage of finished products (in cooled / frozen conditions).

The necessary control measures to prevent, eliminate a product safety hazard or reduce it to an acceptable level are considered. Verified for e.g. product from trail: extrusion - thermoforming.

The Hazard Analysis and Risk Management plan (risk matrix 4x4) is well documented and includes inbound, storage, extrusion , thermoforming ,printing and shipment . Risk (K X E -1-7), red area (control measure CCP), orange area medium risk (control measure CP or PrP) and green area low risk no control measure necessary or PrP. No decision tree is used.

Suitable controls are determined. Controls other than CCP's are adequately covered by the PrP program and normal process controls. The company determined 2 CCP's: small holes in PP packaging (temp of thermoforming), breaking PET packings (IV value). The SSP reactor is not used for recycling/ purification but

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for quality purposes, already cleaned raw material is bought from other EFSA approved companies. Company did not apply anymore for EFSA approval.

Critical limits are set to identify whether the process is out of control. The critical limits are measurable and supported by clear guidance: CCP 1: no micro holes, critical max temperature depending foil type
 CCP 2 intrinsic viscosity of $\geq 0,78$ (SSP) critical value, post condensation, goal IV= 0.82 (and necessary process conditions: nitrogen flow > 650l/h, pressure < 15 mbar, temp reactor min 200°C).

For each CCP a monitoring system is defined to ensure compliance with critical limits. CCP2 daily measurement of IV (and hourly control of nitrogen flow, pressure and temp reactor); CCP1: hourly control of temperature thermoforming according to recipe.

The corrective action plan is defined for each CCP: CCP1: stop production and control products from last conforming control, CCP 2 increase holding/remaining time (when IV to low, previous product is reworked, and only new product available when holding/remaining time is correct)

The hazard and risk management system and prerequisite programmes are reviewed yearly and prior to any change. HARA team meeting every 3 months.

Review/verification of 18-12-2024. e.g.. change monitoring CCP 1 (Stop extruder Barmag 2), oPRP's, PrP's.

There is one minor NC related to this section: 2.2.10: CCP monitoring records are not always filled in like it should be/like it is described. Recording of CCP2 audit trail during this audit was also about another article and last reel production of audit trail was not produced on 27/09 but on 30/09. Via other evidence mistakes could be explained during this audit. Also, no start-up monitoring CCP2 on 30/09/2024 of reel 616755103.

Non-applicable clauses

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3.	Product safety and quality management
3.1	Product safety and quality management system
<p>The product safety and quality manual forms the basis for controls to produce safe and legal products, meet the requirements of the Standard and enable staff to be trained and informed. The manual is available in printed and electronic form. All procedures and work instructions enable their correct application by staff: Dutch and pictorial instructions. The relevant documents are readily available to relevant staff: e.g. process work instructions via hang outs on white boards and received production forms, more and more is done not on paper but online on machine; f.e. hourly pop-up Q checks need to be performed.</p>	
3.2	Document control
<p>The document control system ensures that correct versions of documents are available. Procedure document mgt v14 of 21/04/2023. The company has a manual and electronic document control system (WebISO). All documents have reference numbers, issue dates and are digitally approved. The documents are managed correctly.</p>	

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Of the following documents the reason for change of amendment and authorisation are available: different documents/procedure (see elsewhere in this report)

A system for secure storage and back-up is available daily and weekly back ups. (local and HO)

3.3 Record keeping

Genuine records are maintained. All necessary records are available and meet the criteria of the standard. Records are retained for 5 years. Hermes and Alois (own developed ERP system) has longer storage periods of data. Records in ERP cannot be alternated. Records are legible and genuine. The intended information is retrievable: papers related to product trail - inbound, checks extrusion - Webisio (quality checks thermoforming) - Alois (traceability records) The electronic records are stored securely and backed up.

The procedure for overall control of records is documented as part of Webisio system. A list of changes and when published is kept in the system (seen several documents during audit)

All necessary records are available and meet the criteria of the standard. Records are retained for 5 years

3.4 Specifications

Specifications are available and sufficiently detailed. A specification management system is in place that includes raw materials, semi-finished product, finished products, rework as well as cleaning and disinfection chemicals, lubricants. Specifications for raw materials and finished products are adequately detailed and include the parameters that are critical to the quality, safety and legality.

Following specifications were assessed and found appropriate:
Final product spec. AR00.32106.040 PP Cristal Plast- (20-01-2025- + DoC 18/10/2023)

Raw materials (+ DOC):

- PP T31 FCO32650 (05/08/2024)
- Resinex Affinity PL 1850 Polyolefin Plastomer (05/09/2023)

Specifications for cleaning chemicals include components, usage instructions and material safety data; checked for Interflon (Fin Clean All, H1)

Evidence of formal agreement of the finished product specifications was seen for trail product and new development (CRD)

Trademarks and logo's are approved by customers. Seen approval of BAT AR01.12779.000

Specification review is conducted at a minimum every 3 years or when changes occur.

3.5 Internal audits

The company is able to demonstrate that it verifies the effective application of the requirements of the Standard.

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A risk assessment is used to determine the internal audit programme. The risk assessment is part of review IA's on 10/01/2025. (extra IA concerning foreign bodies and follow-up CAPA list will be organised). The programme shows that every aspect is audited at least once a year; seen planning 2025. The following aspects are audited more frequently based on their risk: only when the number of NC's of previous audit is elevated, the frequency goes up to more than 1/year.

The scope of each internal audit is defined:

Internal auditors are independent and competent: Actually, the internal auditors are trained employees and there is one internal auditor from other site in Poland, these are trained last time on 01/03/2021, by external consultant. New training for 5 new internal auditor was finalised in 2024.

The internal audit reports comply with the requirements.

Results are reported to the relevant persons and departments. The corrective actions are defined and their completion is verified by QM:

- IA complaint handling and blocked stock on 26-04-2024: 5 NC's (CAPA 043-047)
- 30/11/2023 - f.e calibration planning was not followed (not enough staff - operator was trained, all done
- IA tooling & R&D by QA engineer QP 24/06/2024 (8 NC's)- CAPA 71-78 – 3 NC4S still open
- IA HARM/HARA – 05-12- by IW (plant mgr. Poland site) 2024 3 NC's: waste in process flow, foreign bodies enough in hazard analysis, incidents part of HARA.

The hygiene- and fabrication-based inspections are planned Glass breaking procedure weekly in the thermoforming department (S), conducted and recorded, monthly in extrusion by team leaders e.g. 7:10/2024 & 15/06/2024. Weekly 5S tours (including glass and hard plastic register checks) e.g. 10 & 17/01/2025. On top of that by process engineers every 3 months.

There is one Minor NC related to this section: 3.5.4: Follow-up of CA's was/is really improved (minor NC 3.6.1 former audit). There are actually no corrective actions overdue date. Only 64 open corrective actions at the moment of this audit. Nevertheless, it was assessed that follow-up of some minor NC's defined in internal audits is delayed. E.g. instruction release first production run IA 21/04/2023 still not finalised. CA 2024-047missing procedure blocking silo from IA 26/04/2024 not yet finalised.

3.6 Corrective and preventive action

The site uses the information from identified failures to make necessary corrections and prevent recurrence. A procedure for the completion of root cause analysis is documented, trends are taken into account . Discussed monthly.

The evaluation of the effectiveness of the root is checked, the conclusion is in compliance with the examined data sources: see complaints and internal audits.

3.7 Supplier approval and performance monitoring

The company has an effective supplier approval and monitoring system.

The supplier approval procedure is documented (P-AK_SPR of 6/01/2015
Every relevant supplier of goods or services is assessed based on risk and relevant requirements. No high risk suppliers, only low risk suppliers. Assessment verified for the suppliers related to product trail and others see specs reviewed.

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The supplier approval procedure is risk-based and includes the requirements : or GFSI certification or supplier audit or filled-in supplier questionnaire (+ traceability test). Suppliers also have to supply documentation (technical datasheet, MSDS, DoC (including SML, dual use additives) + contract and preferred supplier agreement. Final approval is done by purchase and QA department.
 Risk analysis performed on suppliers (no high risk suppliers) - score > 69% is low risk supplier. Risk is based on score between 0 and 20 points for product group, origin, economic profile, QMS, specs and DoC's). Seen for suppliers related to product trail.
 Some suppliers of raw materials are not GFSI certificated nor want to fill-in questionnaires e.g. Total but supply a whole list of documents (e.g. DoC PP granules 6/01/2025 comparable with the info of a supplier questionnaire and are also ISO9001 certificated e.g. Total till 15/10/2026.
 Also assessed filled-in questionnaire for supplier Unicol (pigments/colours)

The process of supplier performance review (last supplier evaluation on 16/04/2024) is based on risk and defined performance criteria specs/ certificate, service, quality and price.
 The evaluation records of the suppliers are checked of e.g. suppliers of the traceability test of this audit in Alois: E.g. To. 8/10, Indu. 8/10, Ma. 9/10, Uni. 8/10, Hob. 8/10, Wac. 8/10.

When the approval is based on questionnaires, this is reviewed every year.

An up-to-date list of approved suppliers is present and information is available for relevant staff, goods-receipt in Alois - no order can be placed when supplier is not in the system.

The company has a program in place to ensure that suppliers of raw materials have effective traceability systems implemented. This is verified through GFSI certification or questionnaires including traceability. For suppliers approved by questionnaires only, verification of the traceability system is carried out on first approval and then every 3 year, e.g. assessed for some of above mentioned suppliers.

The site knows the identity of the last manufacturer or packer e.g. raw materials supplied by trader Me. The approval is based on the information of the last manufacturer, packer or consolidator or on the relevant certification of the agent/broker.

All raw materials can be ordered at 2 or more companies. One back up is always provided so no real exceptions allowed, always CoA present when predefined in Q system.

There are 2 minor NC's related to this section 3.7.2 Supplier Zeller is supplying printing inks but this supplier is not approved. No evidence how this supplier is approved or how these are purchased with sufficient guarantees what quality, legality and food safety is concerned. There is also no evidence how supplier Indurama (PCR PET) was approved: No GFSI certification, no external audit and no filled-in questionnaire. (several times requested by ANL).

3.7.3. Supplier Zeller delivering printing inks is not evaluated after 2022 while this supplier is still delivering printing inks.

3.8 Product authenticity, claims and chain of custody

Systems are in place to minimise the risk of purchasing fraudulent or adulterated raw materials. Processes to access information on threats to the supply chain are in place trade associations, government resources, HO

A vulnerability assessment has been carried out and documented in VOED_SAFE_FRAUDE of 21/03/2024 resulting in a vulnerability plan. The plan is reviewed annually (last time 7/01/2025): based on parameters like

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availability, historical fraud, price, historical cooperation supplier, delivery performance. Only low risk raw materials identified. No changes last year.
 The following raw materials are identified as being a particular risk: none. Suppliers of PCR PET are most vulnerable but both suppliers (5Mor., Ind.) are RECYCLASS certified.

3.9 Management of subcontracted activities and outsourced processes

Following processes are subcontracted: fe Blankedale (assembling of trays & covers, eventually adding of meat pads in gastro). A risk assessment is done and documented. There are supplier agreements and/or contracts, assessed for clients of subcontractor Blankedale.
 There are supplier agreements and/or contracts. Assessed for clients of Blankedale, seen signed SWI 13/10/22 duabox, SLA 17/06/2022
 The subcontracted processes are part of the hazard analysis and risk assessment. Specifications are available: tray assembly
 The final release checks on finished work include normal quality controls
 Mechanisms to ensure traceability are maintained : GFSI certificate

3.10 Management of suppliers of services

Following services are contracted pest control, laundry, equipment maintenance (partly), transport & distribution, laboratory testing, tooling.
 The procedure for supplier approval includes the suppliers of outsourced services : same procedure as for products.
 Supplier evaluation is also yearly performed e.g. 16/04/2024 assessed for pest control provider (R), external transport (L), laundry (C) and lab (H).
 Reviewed contract is appropriate: transport (T), pest control (R), laundry (C)

3.11 Traceability

A system is in place for traceability. This includes traceability of raw materials such as PP, (R)PET and masterbatches, technical aids like anti-fog and anti-block agent, Al-wire and semi-finished products (film). Traceability is maintained by a software system. Masterbatches and additives are traced by stock movements (and registered on production forms), the batch number who is moved to production is considered to be in use.
 The traceability procedure is documented in Alois (software) and partially on paper (resins).
 Identification allows full traceability. All items in the production facility and warehouses are identified, where a major part of the system works in the warehouse with scanning technology.
 Limitations e.g. bulk materials are managed by date of use is noted on production form.
 Finished products can be identified by prod. code and batch code.
 The traceability system is tested yearly by the company together with recall test.including mass balance. The record of stock) the test contains; referenced documents, quantity check/mass balance, duration: 02-04-24 on AR00.24069.004 of pallet 054143040040063815 too high amount of phthalates produced on 18/01/2024 In other direction no issues
 The traceability system is tested during the audit:
 - AR00.32106.040 ¼ euro height 67 2100CC mussel tray:- order P161899659 produced between 25 & 27/09/2024 137088 pieces 32256 pieces scrapped, none in s - one client CF delivered all 30/09/2024.

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- Foil production 17/10/23 FL05.079.83.075 transparent PP + elastomer rder P158355326 (produced 5/09/2024) & P159378815 (produced 8/09/2024) 40% Rework material used of FC04.0407.
The test was completed in < 4 hours.
Rework material used is receiving a new batch code.

3.12 Complaint handling

An effective complaint-handling system is in use.
Complaints are recorded and investigated. Appropriate actions are identified. Complaints are handled conform procedure and standard:
There were 179 complaints in 2024, 94 concerning product and packaging + 18 concerning foreign bodies (6 metal, 2X fat, 2X blue parts, 2 X insect, 1 X glass) meat, other reasons are destacking, carton box too weak, breaking mussel boxes, price issues.

Following complaints were assessed during this audit:
-metal parts client Po.(complaint not justified based on metal analysis)
-metal part in plastic (dirty in extruder head)
- 3 running foreign bodies complaints (dirty, fat, screw)
- breaking mussel box (client DM) (one time wrong material (human mistake CA planned: RM to be scanned before use, other case still in investigation (Elastomer change)
Complaint data are analysed for trends by Q department, used to avoid recurrence and shared with relevant staff. Root cause analyses are conducted on all complaints.
Corrections actions running at the moment investigation installation metal detector, investigation elastomer.

3.13 Management of product withdrawals, and incidents and product recalls

The procedure and systems are documented in RAMPENPLAN 14/11/2024.
The procedure for product withdrawal, includes all requirements: RAMPENPLAN 14/11/2024. Since the last audit there were no withdrawals.
A clear definition of an incident and emergency situation is documented and communicated to relevant staff, RAMPENPLAN 14/11/24.
An up to date list of key contacts is available always in Alois. Since the last audit there were 2 withdrawals: metal parts in blister and breakage of mussel boxes.
The withdrawal procedure is tested yearly. The traceability system is tested yearly by the company together with recall test. including mass balance. The record of the test contains; referenced documents, quantity check/mass balance, duration: 02-04-24 on AR00.24069.004 of pallet 054143040040063815 too high amount of phthalates produced on 18/01/2024 In other direction no issues

Non-applicable clauses Click or tap here to enter text.

4. Site Standards

4.1 External standards

The site is fit for purpose.
Local and site activities are checked and have no adverse impact. There are no specific measures in place to protect the site from potential contaminants, flooding etc.
The external areas shall be maintained in good order. Any grassed or planted areas surrounding buildings shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced to avoid contamination of the product.

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External access points are secured by a lock e.g.: silos, pipework or other access points. No deviations spotted related to external drainage.
 External storage is adequately protected by outer packaging or covered.

4.2 Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas

A good level of tidiness and cleanliness in production areas are maintained.
 Interiors are kept in a good condition and clean. Walls are constructed of metal panels. Floor is in concrete.
 The risk assessment on windows is conducted. Precautions are taken by the use of plexi.
 Based on risk assessment lighting is protected with shatterproof covers or sleeves.(all protected) - relighting has been done most now LED
 Elevated walkways are designed and maintained effectively.
 Natural ventilation and via extra pest screened openings in summer periods

4.3 Utilities

Utilities are monitored effectively, e.g. water, compressed air.
 Based on risk assessment the water is verified as potable and supplied in sufficient quantity.
 Water is from the mains (source water for cooling tower water and thermo forming department) is softened and controlled by external company Aquatreat on monthly basis e.g. 5/11/2024. Or water is coming from a well and demineralised (extrusion department, cooling down of cooling tower but not in contact with product. Both origins are in closed systems and controlled.
 Besides that water is only used for hand washing and floor cleaning.
 Based on risk assessment microbiological and/or chemical water quality tests are completed : chemical monthly.
 Pressurised air is made by oil-free compressors (4) and is filtered.

4.4 Site security and product defence

A product defence plan is present. Procedure P-SAFE_Food-Defense of 17/01/2024 v10.
 The threat assessment plan assessed different areas: TACCP (inside) 4/12/2024 TAA (outside) 4/12/2024, reviewed 4/12/2024 and gates and badges are present - risks such as war in Ukraine (site Poland) are still taken into account.
 Authorised access of staff is ensured by badge.
 The access by employees (3 entrances), contractors and visitors is controlled: 1 entrance, gates are open from 8h30 to 17h - security pole needs to be opened by staff member. Visitors and contractors need to sign in at entrance.
 The staff is trained in site security: included in annual training.
 External storage tanks of raw materials are locked.

4.5 Layout, product flow and segregation

The layout and flow of processes and personnel are sufficient.
 The site maps show a complete overview: Extrusion, thermo forming rework and storage are all in segregated areas.
 The internal flows prevent cross contamination: extrusion, thermoforming rework and storage are all in segregated areas.
 Space for working and storage is sufficiently available. Warehouse stores finished product, raw and packaging materials; segregation is adequate.

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4.6	Equipment
<p>The design and construction of equipment is considered appropriate. The placement and positioning facilitate effective cleaning and maintenance. Sufficient place available. No New equipment to control CCPs installed: inline measurement of IV on some extrusion lines. There is also a commissioning procedure for new equipment e.g. Viscotec 3 E803 of 23/04/2024.</p>	
4.7	Maintenance
<p>An effective maintenance programme is in operation. Maintenance and condition monitoring is planned and conducted internally and/or by contractors: seen programme in Alois preventive and curative/corrective: machine P922 3 monthly preventive maintenance 7-11-2024 & 20/08/2024, extruder Viscotec 1/802 Sept. 2024 (corrective maintenance – control unit out of order), preventive maintenance 18/11/2024 and next planned 27/01/2025, SSP preventive maintenance week 48/2024 gas wash filter 2 weekly e.g. 13/01/2025 + hygiene clearance. Atlas Copco for compressors 13/11/2024, monthly control cooling towers by Aquatreat seen 5/11/2024.</p> <p>Following maintenance work, equipment is cleaned and inspected by authorised staff prior to use seen for machines/maintenance tasks mentioned above</p> <p>Temporary repairs are planned to be permanently repaired.</p> <p>The workshop is kept clean and tidy. Transfer of engineering debris to other areas is prevented; swarf mat, separate access.</p> <p>Contractors are adequately supervised by maintenance personnel.</p>	
4.8	Housekeeping and cleaning
<p>The site was found to be clean and tidy, a good level of housekeeping based on risk assessment was demonstrated. The cleaning procedures/ plans are based on risk assessment. They meet the requirements of the Standard. Cleaning is performed by production personnel and recorded. f.e seen on PVACALG D2433, machine P922, weekly schedule cleaning extrusion for Viscotec 1 & 2. Appropriate standard of cleaning is achieved.</p> <p>There is a list of approved cleaning chemicals based on MSDS, specifications, confirmation of suitability (including scent, taint and odour): available in closed cabinets list and instructions . Cleaning chemicals (labelled orange bottle, refilled by teamleader) are identified and stored in designated storage (closed cabinets). Restricted access and use only by trained personnel. Effectiveness is checked visually but once a year also swabbing TPC, yeast and molds, Listeria Monocytogenes, Salmonella.</p> <p>The environmental monitoring programme (VOED-SAFE_OMONITORING v5 21-04-2023) is in place. The last evaluation of the results did not show any significance which require action. Target organisms on environment -TPC 1X/year (13 points) 25/10/2024 (Max. 800 cfu on box spray).</p> <p>There is one minor NC related to this section 4.8.2: The upper side of preheating part of thermoforming line P922 was assessed as being dirty and greasy. There is a year plan 2024 for general cleaning of equipment.</p>	

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Frequency Is defined as 2X/year but execution of this cleaning plan was incomplete e.g. cleaning of preheating units of all thermoforming lines was not performed in 2024.

4.9	Product contamination control
4.9.1	Glass, brittle plastics, ceramics, and similar materials control

Based on risk assessment glass and other brittle materials are protected in open product, production, storage areas.

The glass handling procedure (including other brittle materials) is documented in P_BRC_ALG_GLAS V16 of 18/01/2025.

The glass register is checked weekly in thermoforming seen several weeks 2023, f.e 6/10/23, when issues remark to maintenance (nanometer machine 721, notification 468132) , ok week after
In extrusion this is done monthly seen week 50

The team leader is responsible for the course of actions to be taken when a breakage occurs. 3 glass incidents since previous audit: good follow-up e.g. screen breakage Kiefel.

4.9.2	Sharps and metal control
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The handling of (sharp) metal is documented. Knives used for slitting are stored in a secure yellow box. Every used knife is recorded. The use of snap-off blade knives is prohibited.

Tooling is checked during assembling and removing. seen checklist machine P561 DOC NR 86 v3

4.9.3	Chemical and biological control
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All chemicals (who are not a raw material) are stored separated in storage areas having restricted access e.g. cooling liquids, greasing, cleaning aids. Seen greasing, food grade approved, f.e Fin food lube, PN32, G150.

Restricted access and use only by trained personnel.

The following allergenic materials are present on site: none present. Raw materials, greasing aids, cleaning aids were assessed in HARA.

Personnel needs to clean clothes with air before entering production after break (allergens, smoke). A plan for the management of allergens is implemented. The plan is reviewed once a year (see HARA). No allergens present.

There is one minor NC related to this section: 4.9.3.1 At the exit of preheating unit P922 flaking paint was assessed above running foil. Risk of (chemical) contamination of the foil.

4.10	Waste and waste disposal
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The movement and flow of waste is established based on risk assessment.

Waste categorizing and segregation is applicable: shredded or put in waste containers, e.g. different kind of plastic materials PS, PP, PET. Selective collection of waste – communal waste / paper and carton

Trademark products are always shredded in mill and re- used in process or prior to collection by external party.

A third party is used for destruction trademarked materials, all is ground on site

4.11	Pest management
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No evidence of an infestation is found.
 The programme is clearly defined rodents, cockroaches, flying insects. Regular inspections are carried out 8 times / year (rodents), 6x / year flying insects + 1 supervision by external company Re.

The pest management is contracted to an external company.
 The service contract is clear. The inspection frequency is appropriate: seen 17/12/2024 (some mice infestation in vacuum), 22/10/2024 (nothing special), 24/09/2024 (nothing special). Supervision done 26/09/2024

All tox inside was replaced by radars 10/03/2023.

Pest management documentation and records are maintained and include the necessary information.
 Some incidents what rodents inside is concerned but no real infestation. Flying insects are increased in thermoforming department (CA are tested flies pot). 2 complaints related to this.
 A bait plan is available.

2 open actions at the moment of this audit-->both for pest control company Re.

Interviewed employees understood signs and the need to report any evidence.

Non-applicable clauses

4.2.2 No suspended ceilings
 4.11.3 Pest management is contracted to an external company.

5. Product and process control

5.1 Product development

The procedure for product development or modification is documented: prototype development v7.
 Customer requirements are documented and agreed: RFQ (request for quotation), CRD (Customer Requirement document).
 CCT meeting (cost calculation tool)
 a checklist is used for asking necessary info to the customer. Checklist is used for complex products.
 Design proposal/technical drawing is sent to customer for confirmation together with prototype and first products test are also sent. Both have been approved by customer by mail. Seen for AR00.36500.000 Cuv. Matadi Nordica V24- development and tooling in B TO00.36500.00.
 Sample is put in a Qbox (good and bad) at the line for operators.
 Customer requirements are documented and agreed in CRD and Alois software. First drawing 26/10/2023 next one 16/01/2024, prototype MO.0036500.002 OK for client 07/03/2024. Seen start up production 6/05/2024 – approval first production.

Production trials are documented and test results are validated.

The operating conditions and the required production parameters are established for each product: in Alois and checks in Webisio.

A procedure is in place to ensure that customer-specified requirements are met; compliance with CRD

5.2 Graphic design and artwork control

The necessary steps to meet the print and decoration requirements are determined.

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The artwork management procedure (including change management) is documented, seen BAT for AR01.12779.000 9/01/2025.

The use, storage and renewal off masters is controlled in Webisio.

5.3 Packaging print control

The printing process guarantees that printed information is fully legible and produced to customer specification.

Hazard analysis and risk assessment for printed packaging materials is carried out and controls are implemented: risk assessment is carried out and controls are implemented, examples: follow up of UV lamp (replacement after 1000h) for drying and visual check on text. Print plates are identified after cleaning and stored secured. Reference blue prints are kept. Extra lightning is provided for visual check (D50 lamps). Non conform printed material is destroyed before sending to waste.

5.4 Process control

The procedures, work instructions and process specifications are in place.

The team has identified and described all potential product defects and its potential source(s). Most relevant defects: thickness of film, dimensions, opacity (color), shapes at thermoforming. Checks are performed hourly. At start up and when maintenance was required release is done by team leader.

Process control points are identified: Most relevant parameter are thickness of film, dimensions, opacity (colour), shapes at thermoforming. Checks are performed hourly. At start up and when maintenance was required release is done by team leader.

The necessary control measures are considered. Verified for producttrail, days of audit.

Settings limits are set and documented e.g temperature extrusion, weight at inline extrusion, thickness of film.

Critical equipment settings can only be adjusted by teamleaders. Restrictions for protection are in place.

Bill of materials and process specification are available; seen for product from trail: all checks and BIM present.

At start up, after adjustments and periodically checks on quality parameters are done and documented: seen for trail and days of audit.

The clearance procedure is part of the start-up and documented: seen for trail and days of audits (see products in time of audit)

Process characteristics are reviewed when changes occur

The clearance procedure implemented, checked for production run: from trail, days of audit.

There is one minor NC related to this section: 5.4.2 To prevent foreign bodies in produced extrusion film (e.g. complaint about piece of metal in film) there is a magnet and a filter installed in extrusion heads. It is internally defined that these have to be monitored at least monthly for every extruder. It could not be demonstrated that this monitoring is taking place on weekly basis for every extruder. week 04/09/2024 no magnet monitoring of PP extruder Bruckner and Kuehne. Last week no monitoring of magnet Viscotec 1 and Kuehne.

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5.5 Calibration and control of measuring and monitoring devices

Measuring and monitoring equipment is properly calibrated.
 All relevant critical measuring equipment is identified and listed (DOC 7.06.05). All requirements are met: Seen results of micrometers (every member of personnel has one, when needed, seen fie 01-03-637 Nov. 2024), metal detector (only used in sorting department in case of incident) controlled on 12/04/2024; Gauss measuring equipment PCE-MFMM3000 s°n 6700731 on 5/03/2024, pyrometer thermoforming line P922 on 9/01/2025.

5.6 Product inspection, testing and measuring

The company {undertakes or subcontracts} critical inspection and analyses.
 Quality checks are carried out according to procedure. Hourly checks are conducted by operators and at start up by team leader e.g. In line measurements are used as indication for thickness and are verified with micrometer measurements.

Off-line quality checks are carried out e.g. IV (intrinsic value), only quality checks by operator like thickness, formation, good stacking. A system in place to remove any identified non-conforming product.

In-line testing of thickness in extrusion. Red light on machine is indicating that thickness is out of limit. Product is blocked or raw material defined as non-conforming.

The site can demonstrate that test results are reliable. In-line and on-line test methods are validated e.g. calibration of IV measuring equipment. Standardised methods are used where possible. Samples are stored to avoid degradation.

The external lab is ISO 17025 accredited (AB-079)for the assessed critical food safety analyses: migration tests

The laboratory is ISO/IEC 17025 accredited for the analyses critical to product safety or legality.
 6 migration tests (+ NIAS) planned-5 executed (mistake lab) on foil level done in 2024 - all conform - seen in detail PET brown NIR PCR no carbon black impact 20/08/2024.

5.7 Control of non-conforming product

Out-of-specification products are effectively managed. Blocked in system - separate location and/or label Procedure NCP v9 of 14/01/2021 is understood by personnel. Quality manager is authorised to decide on the final disposition. Products currently identified as out-of-specification: external complaint breakage mussel boxes (still in investigation), reel not good wound 62226457 lot. 154143940622264576 (for rework). Procedure is understood by personnel.

5.8 Incoming goods

Procedure for the intake of goods is in place; Incoming goods are checked in following way: visual inspection, seal for bulk material (also cleaning evidence is required), CoA's for polymers and other raw materials e.g. assessed for raw materials of traceability test during this audit and day 2 of this audit. Check of other than bulk are checked with a checklist. Records are available.
 Instructions are clearly understood by the involved personnel.
 Check include e.g. sampling, visual inspection, CoA, delivery notes. Records are available, see audit trail.
 Approval is achieved by acceptance confirmation at the intake stage.

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5.9 Storage of all materials and intermediate and finished products

Procedures to maintain product safety and quality during storage are based on risk assessment, segregation raw material , finished material all packed - where together raw material is stored only on ground location, always packed.
 Finished products are used/dispatched in date order.
 Packaging (including pallets) are protected from contamination and weather damage.
 Material intended for recycling shall be appropriately protected against contamination hazards.

5.10 Dispatch and transport

Effective procedures for dispatch and transport are in place.
 The procedure for the transport of products includes restrictions, security, what to do in case of breakdown or accident.
 Transport is contracted out. Vehicles are inspected before loading. Inspection records are maintained. Seen for trail (stamp present with checks done)
 The contract of a third-party contractor contains all specified requirements; seen for Transvenlo SLA and addendum product defence 6/12/2022, seen for Empol SLA 7/03/2022 and addendum 24/03/2022, Lux.(Year 2024-2025).
 The third-party contractors are not certified.

There is 1 minor NC related to this section 5.10.5:

There is a workinstruction for checking incoming (bulk) trucks: WI_LEV_PROCES 3. There is also a form used for income ng control of bulk trucks P-LEV_PROCESS-doc1 1.12 but this is not always completely filled in e.g. section after delivering/loading e.g. delivery 21/01/2025. This form also has sections for delivery of pallets via trucks but this is actually not used anymore. In stead of this form stamp is put on CMR. This is not conforming WI_LEV_PROCES-3

Non-applicable clauses	5.3.5.no composite printing
	5.6.9 no automated inspection equipment
	5.10.4 no company owned vehicles

6. Personnel

6.1 Training and competence: raw materials handling, preparation, processing, packing and storage areas

The company ensures that all personnel is demonstrably competent to carry out their activity.
 Interviews with several employees (see presence list) confirm the knowledge of their training; seen training Yearly refresher training half January 2025 (seen for several employees like SG, CV, AAH)
 Introduction training new employee AA 21/10/2024 (including quality , HARA? Safety, food defense etc...)
 Effective communication to relevant staff is established via meetings, hang-outs on white boards and via small movies.

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The competencies are reviewed during e.g team performance monitoring by line managers and individual evaluations. Also by reviewing of competence matrices.

There is one minor NC related to this section 6.1.5 There is no evidence/record of the training on the job as operator vacuum of new temporary employee AA.

6.2 Personal hygiene: raw materials handling, preparation, processing, packing and storage areas

The personal hygiene rules are based on risk assessment to prevent product contamination from personnel. The requirements are communicated to all personnel through rules present at entrance, pictograms. Compliance is checked regularly by 5S checks (monthly/weekly)

6.3 Staff facilities

Appropriate staff facilities are provided.
 All inspected hand washing facilities meet the requirements of the standard.
 Food brought into site premises is appropriately stored and eaten in a suitable area. Closed bottles
 Smoking is only allowed in designated areas. Blowers are available before entering production to eliminate potential presence of ashes/ food (allergens e.g. gluten in bread).

6.4 Medical screening

The company has procedures in place by which staff and visitors are fully informed of the health conditions so they are not a source of contamination for the products.
 Visitors and contractors are informed of the site's policies and the medical conditions that could lead to refuse entry: signing rules at entrance - visitor register
 Visitors and contractors are informed of the site's policies and the medical conditions that could lead to refuse entry : sign of at entrance after reading policy.

6.5 Protective clothing

Suitable protective clothing is worn in production areas.
 The procedures for protective clothing are based on risk assessment: shoes, protective glasses, coverings, snoods, hairnet, visitors coat.
 Protective clothing is removed on leaving production areas.
 The rules regarding the wearing of protective clothing are based on risk assessment and communicated rules signed at start up, present at entrance + pictograms
 clothing has been identified.
 Laundry is outsourced to an approved contractor CWS.

Non-applicable clauses

6.5.8 No home laundry.

Requirements for traded products

7.1 Approval and performance monitoring of manufacturers/packers of traded packaging products

Effective procedures for approval of the last manufacturer or packer of traded products are operated.

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The approval procedure is based on a complete and effective risk assessment if not GFSI certificated, included in general approval procedure see P_AK-SPR of 6/01/2025.

The approval procedure meets the requirements for certification and/or supplier audits: see 3.7

Records of the approval processes are maintained: seen for Chapo (by audit), sister companies all GFSI The approval and risk assessments are reviewed - during supplier assessment; Supplier Ada. Is GFSI certified: BRCGS packaging till 2026-01-17.

The performance criteria are defined and monitored yearly, criteria same as for raw material suppliers.

7.2 Specifications

Specifications meet legal requirements and assist customers in the safe usage of the product are maintained and available to customers.

Only 2 traded products e.g. PET/PE peel 55µm n°0538 of 17/05/2023, DoC of 22-01-2025 and e.g. AR03.00884.000 Visiopaq Viangro ring (12/08/2024) no food contact..

The company has a process in place to ensure that customer-specified requirements are met {specify} Specifications are reviewed when changes occur or at least every 3 years.

7.3 Product inspection and laboratory testing

Critical inspections and analysis for its traded products are identified: not evaluated as necessary by the company.

Visiopaq ring product is non-food contact.

No claims regarding status of products.

7.4 Product legality

Processes are in place to ensure that the products traded comply with the legal requirements in the country of sale.

The company has a process in place to remain up to date with the requirements comply with the legal requirements in the country of sale (only EU).

7.5 Traceability

The system ensures that products are adequately labelled or identified to facilitate traceability.

A system is in place for traceability for all batches of products, back to the last manufacturer or packer and forward to the recipients. Products are identified by via own label (name, prod. ref, unique pallet code, quantities, lotcode, date) which traceable to identification of traded goods supplier..

The traceability system is tested annually, and the results are recorded seen test 20/11/2024 AR0300884.000.

The traceability test including quantity check was completed in < 1 hour

Non-applicable clauses

7.3.3: No claims regarding status of products.

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Additional Module: Plastic Pellet Loss Prevention

10.1.1	Senior management commitment and control improvement
Click or tap here to enter text.	
10.2.2	Hazard analysis and risk assessment
Click or tap here to enter text.	
10.3.5	Internal audits
Click or tap here to enter text.	
10.3.6	Corrective and preventive action
Click or tap here to enter text.	
10.3.13	Management of incidents
Click or tap here to enter text.	
10.4.2	Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas
Click or tap here to enter text.	
10.4.4	Site security
Click or tap here to enter text.	
10.4.5	Layout
Click or tap here to enter text.	
10.4.8	Housekeeping and cleaning
Click or tap here to enter text.	
10.4.10	Waste and waste disposal
Click or tap here to enter text.	
10.5.8	Incoming goods
Click or tap here to enter text.	
10.6.1	Personnel: training and competence
Click or tap here to enter text.	

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Non-applicable clauses	Click or tap here to enter text.
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