

Audit Report

Global Standard Packaging Materials Issue 6: August 2019

1.Audit summary

Company name	National Flexibles Ltd	BRCGS site code	2113728
Site name	Bradford		
Scope of audit	The on-site slitting, rewinding, hot needle, perforation and outsourced processes of centre folding, gravure, digital and flexographic printing, lamination and die-cutting of PP, PE, PET (metalised and non-metalised), paper, aluminium, APET, OPA, EVOH, PVdC, polyamide iomer resin (Surllyn) films to produced reeled films, pouches and lids for food, pharmaceutical, consumer products (contact and non-contact).		
Scope exclusions	None		
Justification for exclusion	N/A		
Start date	2023-05-24	Finish date	2023-05-25
Re-audit due date	2024-07-09	Previous audit date	2022-07-07

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	Unannounced
Audit grade	AA+	Previous audit grade	AA
Certificate issue date	Select a date	Certificate expiry date	2024-08-20
Number of non-conformities	Major against SOI of Fundamental	0	
	Critical	0	
	Major	0	
	Minor	1	

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3. Company details

Address	2 Battlefield View, Birkenshaw, Bradford, BD11 2PT		
Country	United Kingdom	Telephone	01274 685566
Commercial representative Name	Mark Thompson	Email	mark@nationalflexibles.net
Technical representative Name	Caroline Clay	Email	caroline@nationalflexibles.net

4. Company profile

Plant size (square metres)	<10K sq.m	No. of employees	1-50	No. HARA Plans	1-3
Subcontracted activities	No				
Outsourced processes	Yes				
Other certificates held	ISO 9001:2015, ISO 14001:2015				
Regions exported to	Europe				
Major changes or auditor observations since last BRCGS audit	There have been no significant changes at the site during this report writing period.				
Company description	<p>The company was established over 40 years ago and became part of the Charles Baynes group in 1993. In 1998 Barry Twigg the current chairman undertook an MBO and National Flexible has evolved into a high-quality supplier of flexible films owned by its management and staff and is located on a light industrial estate in Birkenshaw, to the south-east of Bradford. The site supplies a wide range of laminated PE, PP, APET, metallised; APET, OPA, EVOH, OPP, LLDPE, PVdC plain and printed film primarily for UK and EU food customers. Films are</p>				

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4. Company profile

	<p>purchased, the artwork process is managed in-house. Printing, centre folding, die cutting and lamination is outsourced to meet customers' specific needs. Machinery on site includes slitting, rewinding and perforating equipment. Stock is held on site and called off by customers when required to give a rapid response. The site support and fund both on the job training and general interest training for all employees and have excellent staff engagement. The buildings comprise an area of 2,525 square metres. The site is entirely suited to the production and supply of food grade packaging products. There are 49 personnel operating a rotating 2-shift system and are no more than 35 staff on site at any one time. The site has developed and implemented compliance systems that meet the requirements of the BRCGS Standard version 6.</p>
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5. Product and process characteristics

Manufacturing Categories	05 - Flexible plastics
Products in production at the time of the audit	Clear films being slit from larger reels to smaller reels and packed. Job numbers 209818 & 208970.

6. Audit duration details

Total audit duration	12 hours	Duration of production facility inspection	4 hours
Reasons for deviation	None		
Next audit type selected	Announced		

Audit Duration per day

Audit Day	Date	Start Time	Finish time
1	2023-05-24	09:00	17:00
2	2023-05-25	09:00	13:30

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Auditor information

Auditor number	Auditor Name	Role
20106	Philip Parkin	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
Mark Thomson, Operations Director	On-Site	On-Site	On-Site	On-Site
Caroline Clay, Quality Manager	On-Site	On-Site	On-Site	On-Site
Toni Leach, QA assistant	On-Site		On-Site	On-Site
Joe Eyles – Machine Operator		On-Site		

GFSI Audit History

Date	Scheme/Standard	Announced/Unannounced
2021-07-01	BRCGS Packaging issue 6	Announced
2022-07-06	BRCGS Packaging issue 6	Announced

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Document control			
CB Report number	UK/BRC/084		
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

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Minor							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	3.10.1	The supplier approval questionnaire for Sprint transport had been signed by the service provider, without completing any of the questions, and this had been approved without subsequent review, which is not in accordance with the documented procedure.	SAQQ has been returned to Haulier for completing, returned, and reviewed and approved signed off by QA Manager.	The approved supplier list has been updated, and the review date has been set, to ensure reviewed and signed off within the correct timeline. A section has been added to the SOP014.3 list of Approved Suppliers to be completed after the supplier review has been completed. Supplier Assessment Questionnaire or Supplier Audit Non-Conformances included within performance review section of SOP014.2.1 service provider assessment.	Although the supplier questionnaire has been returned in January 2023, the QA review had not taken place, and had been filed in the Supplier file without review. Lack of systemised checking processes to ensure adequate completion of required documentation.	2023-06-15	Philip Parkin

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Comments on non-conformities

No significant issues observed & no NC trends identified.

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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 policy statement was found dated 24/03/2023 and authorised by the Managing Director. The document states the company's intention to ensure the safe & legal production of products and acknowledges the responsibility held by to company to its customers in this respect. Additional commitments include continual improvement of the management system & training of employees. The policy was last reviewed at Management Review for continued applicability and is communicated on notice boards seen in the employee entrance corridor. It is made available to customers on request and trained out at new employee induction.</p> <p>A product safety & culture plan has been established – QM001.2, issue 3 last reviewed 29/03/23.</p> <ul style="list-style-type: none"> - Defined activities involving all areas of the site include completion of a staff survey single topic toolbox talks covering the re-located locker rooms completed during November 2022. - Communication – The Company has completed a staff survey during January 2022 – not repeated since - Training – all staff have received product safety, basic food hygiene & product safety rationale awareness - Employee MZ (machine operative) – Food Safety & GMP training dated 05/01/2022 – provided by Techni-k – 72% with a 70% pass level. - Monthly quality report circulated to all employees – last report seen dated March 2023 – indication 27 complaints raised for the month – with 10 complaints deemed justified. - Staff recognition programmes are in place - Action plan how activities are to be undertaken and measured and timescales for completion – seen contained within QM001.2. - Weekend social event last held 28/01/23 - Staff retention is high at the site. - Review of effectiveness of completed activities held at Management Review dated 23/03/2022. <p>A range of objectives have been set by senior management Documented within Management Review. Objectives are posted on notice boards around the facility. Objectives were seen to reflect SMART principals and aim to maintain & improve performance across product quality, safety & legal related themes. They are communicated and monitored as an agenda point at Management Review and bi-monthly quality meetings, in addition to being seen displayed on the notice board. The following sample was reviewed. 2022 objectives roll over into 2023, with the target becoming incrementally improved over time.</p> <ul style="list-style-type: none"> - Customer Complaints <1.0% of sales orders raised, actual 1.22 for 2022 achieved – root cause being billing & admin – training needs assessment completed and evidenced in Management Review minutes. - AA grade for BRCGS audit, Grade AA achieve during 2022 audit. - Internal audits completed on time to schedule, achieved in 2022. - Customer complaints to be closed in 7 days, achieved 74.61% in 2022 – root cause delays in returning NCP & technical Colleagues abroad determined to be the root cause. - Food Safety refresher training for all employees. - Recalls and withdrawals – There has been no product withdrawal of recall incidents. 	

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The company has appointed a management representative who holds day-to-day responsibility for maintenance and improvement of the management system (employee CC – Quality Manager) and there is a Quality Assistant who acts as Deputy.

The company utilise BRCGS Participate & CEDREC as information sources to keep abreast of technical & legislative developments.

- Legislation Register – QM005.1 Last reviewed during January 2022 – seen to include reference to (EC) 1935/2004 & (EU) 2016/1416 – overall specific migration
- Site Statement of Compliance – dated 20/01/2023 (valid until 20/01/2026) - referencing compliance with 9EU No. 10/2011 inc. amendments 2020/1245 of September 2020 on plastic materials & articles in contact with food.
- Technical Data Sheet – for BOPP Co-ex dated 02/09/2020.

There is an electronic hard copy of the Standard is held and the audit was completed within the required window. The opening meeting was attended by Operations Director, Quality Manager & Quality Assistant and relevant employees & departmental managers were made available for interview throughout.

Previously raised audit non-conformances were reviewed (1 minor NC raised), with the site inspection and review of documentation verifying that there have been no reoccurring issues during this reporting period. The company has used root cause analysis in determining appropriate action to address the issues identified.

- NC1 – Operator not wearing blue plaster – no repeat issue noted during the site inspection.

The company use the correct BRCGS logo on the Company website. The current Certificate was seen to be available for download on the company website.

1.2 Management review

Management Review is undertaken annually and was last conducted on 23/03/23. In attendance were the following employees.

- GS – Managing Director
- MT – Operations Director
- SM – Lead Technical Engineer
- CC – Quality Manager
- AB – Operations Manager
- JE – Supply Chain Manager
- TL – Quality Assistant
- CB – Commercial Director
- CW – Customer Champion

The meeting followed a set agenda defined within SOP012.5 Quality Management Review, issue 7 dated 30/06/2022 and documented minutes evidenced the following topics as being covered.

- Previous management review documents, action plans and timeframes
- Changes in internal & external issues
- Customer feedback

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- Complaints
- KPIs
- Objectives
- Review of HARM system
- Results of internal, second-party and third-party audits
- The impact of any applicable legislative and certification scheme changes
- Incidents, corrective actions, out-of-specification results and non-conforming materials
- Resource requirements
- Supplier performance
- Performance against set objectives
- The effectiveness of the product defence and product fraud prevention plans

Actions resulting from management review included update & re-issue the quality policy, with responsibility allocated to employee T and with a timeframe for completion set at 31/03/23. A review of outstanding actions from the previous management review forms an agenda point.

Separate monthly quality management meetings are held attended by the QM, Operations Manager, Production Supervisor, Lead technical Engineer & Quality Assistant. The forum is utilised to discuss current & emerging issues, last completed 16/05/2023.

Issues of product safety, legality or quality are communicated directly to Production Shift Management, who escalate to the Operations Director by means of the documented internal NC reporting process. There is a whistleblowing Policy documented.

- QM048 – Whistle-Blowing Policy – issue 1 dated 02/09/20.

1.3 Organisational structure, responsibilities, and management authority

A current organisational chart is in place identifying roles and reporting channels, dated 31/01/23, with the most recent change being a restructure in January 2023. Responsibilities across the organisation are documented within individual employee job/role descriptions.

- Organisational Structure dated 31/01/23.
- Deputies for key roles – documented within SOP016.2 – Deputies – MD – employee GS, with the Sales Director – DD deputising.
- Responsibilities – Referenced within SOP016 Organisational Control, issue 13 dated 22/02/23 – including role descriptions for Managing director, Operations Director, QA Manager & QA Assistant

Employees are made aware of their responsibilities through induction and specific training provided covering each role/function, with refresher training taking place at 3-year intervals.

Non-applicable clauses

None

2. Hazard and risk management

2.1 Hazard and risk management team

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A multi-disciplinary HARA team is in place including the following employees, seen documented within The HARM Plan, with the Team Leader designated as the QA Assistant - TL)

- Employee TL (QA Assistant): HACCP Level 3 provided by High-Speed training, Cert. 1378358 dated 26/01/23.
- Employee SM (Technical Engineer): HACCP Level 3 provided by High-Speed, Cert. 2669959 dated 25/10/21.
- Employee AB (Production Operative): HACCP Level 2 provided by High-Speed training, dated 24/01/23.

Additional team members include employee AB – Operations Manager, JM – Warehouse Operative. The Technical Engineer brings a strong understanding of engineering, maintenance & materials science to the Group.

The HACCP study itself is applicable to the whole operation and encompasses all activities undertaken across the site – verified by the HACCP team on the product flow diagram - Man01, last reviewed 14/03/22.

2.2 Hazard analysis and risk assessment

The scope of the HARM analysis is documented within the HARM Plan and covers all process stages from receipt of enquiry, through to final despatch & customer returns. Products manufactured include slit film for direct contact applications. The scope is documented as The on-site slitting, rewinding, hot needle, perforation and outsourced processes of centre folding, gravure, digital and flexographic printing, lamination and die-cutting of PP, PE, PET (metalised and non-metalised), paper, aluminium, APET, OPA, EVOH, PVdC, polyamide iomer resin (Surlyn) films to produced reeled films, pouches and lids for food, pharmaceutical, consumer products (contact and non-contact).

The documented Hazard & Risk Analysis Plan which covers all slit products. The assessment includes consideration of the receipt of raw materials, product slitting, purchasing of raw material and printed film, packing & dispatch, including customer returns. The Company do not undertake any print or artwork activities in house. All print is outsourced through approved suppliers, as is responsibility for artwork origination & approval stages.

- HARM Plan 002, issue 2 – last reviewed 14/03/22.
- Product Description – documented within the Harm Plan Scope – page 9 of the HARM Plan – extruded single ply & polymeric films, plain or unprinted.

The plan details the inclusion within the study of foreign objects, chemical, microbiological contamination, waste & chemicals, allergens, functional hazards, migration, the suitability of raw materials for food use & origin and composition, misuse by the consumer, threat & vulnerability analysis & legislative requirements. The product description details the production of packaging for direct food contact and secondary applications in both plain & printed formats, which is outsourced to approved print providers, and details that only virgin polymer is used for food applications.

All Pre-requisite Systems are documented within a register – including supplier approval, site security, maintenance, personnel, cleaning & sanitation, calibration & pest management (not an exhaustive list).

- Allergens Policy – QM031, issue 6 dated 10/01/2023.

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There are Process Flows covering the entire operation from receipt of customer approved artwork, purchasing & receipt of raw materials through outsourced print, to despatch & delivery to customer including customer returns. The accuracy of the process flow is verified annually as an element of HARM review.

- Core Cutting Process Flow dated 14/03/2023.
- Customer Returns Process Flow dated 14/03/23.
- Plain Film process Flow dated 14/03/23.
- Slit To Stock Film, Pouches, Die-Cut Lids & Film Printed Abroad dated 14/03/2022.

The HARM Team has recorded all potential hazards likely to occur within the HARM Study, along with a calculation of the likelihood of occurrence (1 – 5) & severity of outcome (1 – 5) to arrive at a risk rating based upon a traffic light system. There follows a details description of the controls in place at each stage to reduce risk to an acceptable level and a further section detailing the actions to take if non-conformance is observed.

All identified risk have been scored low, with no CCPs identified.

The most recent HARM review was completed on the 13/03/2023, with all members of the HARM Team present. The review included a review of the operations, non-conformity, customer complaints, internal audit results, finished product testing, modifications & changes, process flow.

Non-applicable
clauses

2.2.9 – There are no CCPs.
2.2.10 – There are no CCPs.
2.2.11 – There are no CCPs.

3. Product safety and quality management

3.1 Product safety and quality management system

The Product Safety & Quality Management system consists of a Manual, sitting at issue 5, dated 28/09/22 that is aligned with the clauses of BRC, 9001:2015 & 14001:2015. The manual is complemented by a series of documented procedures & Policies. Evidence of review was seen recorded in and change log, with the most recent change being 16/05/23 requiring a change to the TACCP & VACCP. Management System documentation is in English, with all employees holding sufficient control of the language.

- Quality Manual Contents – System Documentation – issue 9 dated 06/09/2022.
- Standard Operating procedures – issue 9 dated 16/03/2023.

3.2 Document control

Documents are controlled in accordance with SOP018, issue 8 dated 25/11/21. Controlled documents include a table at the foot of each page detailing the document reference, issue date, issue number, prepared by & authorisation. All documents seen in use throughout the audit were correctly authorised and the most recent version. A document change register lists the most recent changes. Servers are backed-up daily to both on-site & off-site servers. Paper records are scanned for storage on protected servers.

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- Document Control – SOP018, issue 8 dated 25/11/21

3.3 Record keeping

Records examined during production tour & traceability test included maintenance, production, goods in etc. and were found to be legible appropriately authorised and retained in good order. No unauthorised changes to records were seen throughout the audit. The company's senior management have ensured that documented procedures are established and implemented to ensure that all records relating to product safety, legality, compliance, and quality are organised, maintained, stored, and easily retrievable. Record retention is set at a minimum of 3-years for all record types.

- SOP015 Quality Records – issue 6 dated 01/04/21

The following sample of records were reviewed during the traceability challenge.

- Technical Data Sheet: issue 1 dated 08/02/23 – detailing compliance with 1935/2004.
- BRCGS Packaging materials Cert. 10504095 Exp. 23/02/23.
- FSC Chain of custody certification: INT-COC-001458
- Completed Supplier Questionnaire; dated 18/08/2020 – next due August 2023.
- Outsourcing PO No. 403203 dated 15/02/23
- Quantity: 663kg of PL-C00841-006-VR1-R
- TCL order acknowledgement: dated 06/03/2023
- Flexo print Order acknowledgement: dated 15/02/23 – signed by the custome – employee HS on 15/02/23.
- Flexo Print Specification – Ref. PL-C00841-006-VR1-R
- Printed Goods-In: Goods-in note 403203 – Reg. YE14 NTA – 1 pallet – received by employee JM
- Goods In delivery note: No. 479297 dated 20/03/23 – referencing 403203.
- Checked by JM for vehicle clean & dry, outer wrapping intact, no odour or taint & pallets damage free.
- Incoming Printed Film Quality Check: completed by JM (warehouse operative) & JP (supply chain team member) checked for labelling, loose care, design repeat, correct colour to cromalin.
- Print Press Pass attended by the Company on 22/02/23.
- Printed retained sample seen – barcode 5024333251668

3.4 Specifications

Customer specifications are maintained for each item produced and include agreed requirements for colour, raw material type, print spec & thickness, along with defined performance criteria such as reel tension, slip & core diameter. Customer specifications are sufficiently detailed and include confirmation of raw materials grade, dimensions, and packing specification.

The following customer specifications were reviewed.

- Customer: OAR
- Product: Savour It Toast

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- Enquiry (SOPD4/2): dated 15/12/22 – quote No. 20494.
- Specification: 25gsm paper/25um heat sealable polyester, printed 5 colour flexo – width 330 – repeat 213.
- Proposal: dated 31/01/23 – quote ref. 20494
- Customer PO: email dated 30/01/23 from customer HS.
- Customer supplied artwork V1: Proof 12 dated 11/08/2021 – ink colours PMS 447, PMS 012, PMS process black
- Customer proof V2: Job No. 2302567 dated 02/03/23 – BBQ Chicked prod code PL-C00841-006-VR1-R
- Customer artwork approval dated 02/03/23 by RS.

Customer specifications are translated directly to outsourcing supplier specs used to generate the supplier purchase order, and internal slitting specifications which form the basis of the Work Instruction, with sign-off of the internal spec completed by the Technical Engineer. Specification review is completed on an order-by-order basis at sales order processing stage, with approval deemed to be receipt of customer Purchase order, in addition to artwork approval documentation. Changes to agreed product specification can only be made with prior input from the Technical Engineer. No manufacturers trademarks are applied to the packaging.

The site maintains a Statement of Compliance with respect to the products manufactured and Technical Data Sheets for each individual product/item. The document refers to, and acknowledges the main EU food contact regulations, although the site does not manufacture product for direct food contact applications.

- Site Statement of Compliance – dated 20/01/2023 (valid until 20/01/2026) - referencing compliance with 9EU) No. 10/2011 inc. ammendments 2020/1245 of Septembver 2020 on plastic materials & articles in contact with food.
- Technical Data Sheet – for BOPP Co-ex dated 02/09/2020.

Supplier raw materials and printed film specifications are held on file for all purchased film & raw materials in use and form an element of supplier approval procedures. Specifications include key performance parameters and an indication of the target range. Retained samples stored as a record of the final specification achieved.

- Supplier: TCL Packaging - Technical Data Sheet: issue 1 dated 08/02/23 – detailing compliance with 1935/2004.
- Outsourcing PO No. 403203 dated 15/02/23
- Flexo Print Specification – Ref. PL-C00841-006-VR1-R
- Printed retained sample seen – barcode 5024333251668
- Core Specification: Natflex RE76.6x10 – mandrel 76.6, moisture 10%, ply-series 100/102 dated 07/05/2022 authorised by JS.

3.5 Internal audits

Internal Audit is completed to a schedule referenced SOP012.1, issue 15 dated 27/03/2023 – Internal Audit schedule covering January 2023. The frequency of internal audit has been established based on risk which considered the severity & likelihood of failure to maintain requirements would have upon the business. The results of the risk assessment is documented on the Internal Audit Schedule, with GMP audits completed monthly, organisational Control audited on 2 separate occasions & Complaints audited quarterly, and all other

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elements, which cover the full scope of the Standard completed annually. Previous audit performance forms an input to the audit schedule decision making process.

The schedule was found completed in full for the 2022 year, with progress of the 2023 schedule on track to May 2023. Audit reports are completed using SOP012.2 Audit Report Form

- Audit Report dated 05/01/23 – covering Glass, Ceramics & Brittle Plastics audit – using Register SOP017.1.1, issue 21 dated 09/12/22 – completed by TL
- Findings: No NCs raised.
- Audit Report dated 06/01/23 – covering Traceability Exercise – raw materials to finished goods – completed by TL
- Findings: No NCs raised.
- Audit Report dated 11/01/23 – covering Supplier Approval – List of Approved supplier – completed by TL
- SOP014 – Supplier & Sub-Contractor Assessment, issue 9 dated 01/04/21.
- SOP14.1 – Supplier Assessment Questionnaire, issue 4 dated 13/08/20.
- SOP14.2 – Supplier & Outsourced/Sub-Contracted Processor Assessment, issue 4 dated 13/08/20
- SOP14.3 – List of Approved Suppliers Register, issue 4 dated 17/07/19
- Findings: No NCs raised.

When internal audit non-conformance is identified, a non-conformance report is raised and where appropriate, root cause analysis is completed, in addition to action to prevent reoccurrence. Audit reports were seen to include sufficient evidence of how conformance had been achieved. Internal audit is completed by a team of auditors to ensure impartiality, including - Caroline Clay Q.A Manager, Toni Leach QA Assistant and HACCP Team Leader & Scott McEvoy Head Technical Engineer, with no employee auditing their own area of responsibility. When NCs are raised, they are tracked to completion, including root cause analysis and action to prevent reoccurrence.

- Internal Audit Training – Employee TL – dated 29/04/2021 – completed by Advanced Food Safety.

Site inspections are completed at monthly intervals, covering offices, toilets, changing area/lockers, processing & packing area, storage area, canteen, racking & exterior. Issues are logged on each checklist detailed below, and the auditor notifies the process owner. Close-out is recorded using the same system, with verification of effectiveness of actions taken verified by the auditor.

- SOP023 - GMP Inspection Procedure – 002 dated 28/03/23
- Quarterly Hygiene Audit: completed 27/04/23 by AB
Covering: offices, toilets, changing area, processing & packing area, storage area, canteen, exterior area
Issues: None
Status: closed

3.6 Corrective and preventive action

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The documented corrective & preventative action procedure is referenced QM049. Instances of non-conformance are registered on the Customer Complaints Database on RADIUS and are allocated a unique reference number and investigated by the Quality Team. The company takes action to eliminate the cause of non-conformance. The actions to take are defined within documented procedure and include root cause analysis & preventative measures. Non-conformances are recorded on a system-based non-conformance report and actions taken are reviewed to ensure correct implementation & effectiveness through trend analysis presented at management review.

- QM049 – Complaints & Corrective Action Policy, issue 1 dated 07/09/20.
- SOP013 - Corrective & Preventive Action, issue 14 dated 17/02/23
- Minutes of Management Review dated 23/03/23.

- Ref 202300056 dated 03/03/23 – NCR Report FMG 005d
- Customer: B
- Product: LAM-C00051-001
- Issue: 2 reels of film found to be discoloured by customer
- Root Cause: acceptable manufacturing variation
- Corrective: unjustified complaint
- Preventative: unjustified complaint
- Status: Closed 03/02/23

- Ref 202300074 dated 22/03/23 – NCR Report FMG 005d
- Customer: BFG
- Product: BOPP/025/0380/T00029
- Issue: 300kg ordered – 500kg produced - -over acceptable tolerance
- Root Cause: order overpicked from stock item
- Corrective: customer agreed to keep product
- Preventative: Employees to use barcode readers to pick product
- Status: Closed 22/03/23

- Ref 202300085 dated 30/03/23
- Customer: SIP
- Product: PH-C00539-032-V02
- Issue: underdelivered by 100 pouches
- Root Cause: undersupply from original manufacturer
- Corrective: credit note 1270
- Preventative: Admin error, requiring greater care & attention
- Status: Closed 30/02/23

3.7 Supplier approval and performance monitoring

There is a supplier approval mechanism based upon risk, and documented within the HARM Study. All key suppliers/outsourcing partners hold GFSI Certification and only this pool of suppliers is used for food packaging products. Approved suppliers are entered onto the Approved Suppliers List. Supplier performance is reviewed as an agenda point at annual management review and supplier non-conformance is managed in accordance with the documented Corrective & Preventative Action procedures. The ongoing frequency of

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supplier approval is set at 3-year intervals. Certificates are updated annually and retained as documented information. Supplier performance is monitored ongoing and at Management Review.

- HARM Plan 002, issue 2 – last reviewed 14/03/22.
- SOP014 – Supplier & Sub-Contractor Assessment, issue 9 dated 01/04/21.
- SOP14.1 – Supplier Assessment Questionnaire, issue 4 dated 13/08/20.
- SOP14.2 – Supplier & Outsourced/Sub-Contracted Processor Assessment, issue 4 dated 13/08/20
- SOP014.3 – List of Approved Suppliers Register, issue 4 dated 17/07/19
- Minutes of Management Review dated 23/03/23.

The following supplier approval records were reviewed.

- Inner Core/Reels – supplied by Just paper Tubes Ltd – PO 403136 dated 27/01/23 – item T/W Cores 0370
- Incoming delivery note: dated 27/01/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free.
- Core Specification: Natflex RE76.6x10 – mandrel 76.6, moisture 10%, ply-series 100/102 dated 07/05/2022 authorised by JS
- ISO 9001:2015 Cert. No. 14127700 – Exp. 17/09/25
- Film Reel Bag supplied by AMG – PO 403156 dated 01/02/23 – 18 inch blue bag.
- Incoming delivery note: dated 07/03/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free – dated 07/03/23
- BRCGS certification – Polystar Plastics Ltd (original manufacturer) Cert. No PKG40169 Exp. 23/06/23
- Completed Questionnaire completed by AMG – dated 16/01/23 – confirming full traceability systems in place.
- Supplier: TCL Packaging
- Technical Data Sheet: issue 1 dated 08/02/23 – detailing compliance with 1935/2004.
- BRCGS Packaging materials Cert. 10504095 Exp. 23/02/23.
- FSC Chain of custody certification: INT-COC-001458
- Completed Supplier Questionnaire; dated 18/08/2020 – next due August 2023.
- Outsourcing PO No. 403203 dated 15/02/23
- Quantity: 663kg of PL-C00841-006-VR1-R
- TCL order acknowledgement: dated 06/03/2023
- Flexo print Order acknowledgement: dated 15/02/23 – signed by the customer – employee HS on 15/02/23.
- Flexo Print Specification – Ref. PL-C00841-006-VR1-R
- Printed Goods-In: Goods-in note 403203 – Reg. YE14 NTA – 1 pallet – received by employee JM
- Goods In delivery note: No. 479297 dated 20/03/23 – referencing 403203.
- Checked by JM for vehicle clean & dry, outer wrapping intact, no odour or taint & pallets damage free.

3.8 Product authenticity, claims and chain of custody

A documented vulnerability assessment is in place for each individual supplier which forms an element of the supplier questionnaire. The Company further process extruded & printed reeled film stock procured from

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GFSI suppliers, with the majority of risk managed through supplier pre-requisite programs. All stocks of film for food packaging applications is procured from suppliers holding appropriate GFSI Certification and the company insist on each supplier providing completing a vulnerability assessment which is evaluated prior to acceptance. All raw materials are received with appropriate documentation including delivery note/goods received & declaration of compliance.

The vulnerability assessment includes consideration of historical known supply issues & substitution, economic motivations, risk within the supply chain, availability of Declaration of Compliance demonstrating testing protocols & the nature of the material in terms of ease of manufacture. The Company monitor the RASFF Portal for emerging supply chain issues as an input to completion & review of the vulnerability risk assessment.

- Vulnerability Assessment – TACCP/VACCP 02, reviewed annually or when change occurs – last reviewed 16/05/23.

3.9 Management of subcontracted activities and outsourced processes

There is a supplier approval mechanism based upon risk, and documented within the HARM Study. All key suppliers/outsourcing partners hold GFSI Certification and only this pool of suppliers is used for food packaging products. Approved suppliers are entered onto the Approved Suppliers. Supplier performance is reviewed as an agenda point at annual management review and supplier non-conformance is managed in accordance with the documented Corrective & Preventative Action procedures. The ongoing frequency of supplier approval is set at 3-year intervals. Certificates are updated annually and retained as documented information. Supplier performance is monitored ongoing and at Management Review.

- HARM Plan 002, issue 2 – last reviewed 14/03/22.
- SOP014 – Supplier & Sub-Contractor Assessment, issue 9 dated 01/04/21.
- SOP14.1 – Supplier Assessment Questionnaire, issue 4 dated 13/08/20.
- SOP14.2 – Supplier & Outsourced/Sub-Contracted Processor Assessment, issue 4 dated 13/08/20
- SOP014.3 – List of Approved Suppliers Register, issue 4 dated 17/07/19
- Risk Assessment RA-BRC6-008 Outsourced Processes – last reviewed 09/06/22.
- Minutes of Management Review dated 23/03/23.

The following supplier approval records relating to outsourced processes were reviewed.

- Supplier: TCL Packaging
- Technical Data Sheet: issue 1 dated 08/02/23 – detailing compliance with 1935/2004.
- BRCGS Packaging materials Cert. 10504095 Exp. 23/02/23.
- FSC Chain of custody certification: INT-COC-001458
- Completed Supplier Questionnaire; dated 18/08/2020 – next due August 2023.
- Outsourcing PO No. 403203 dated 15/02/23
- Quantity: 663kg of PL-C00841-006-VR1-R
- TCL order acknowledgement: dated 06/03/2023
- Flexo print Order acknowledgement: dated 15/02/23 – signed by the custome – employee HS on 15/02/23.
- Flexo Print Specification – Ref. PL-C00841-006-VR1-R
- Printed Goods-In: Goods-in note 403203 – Reg. YE14 NTA – 1 pallet – received by employee JM
- Goods In delivery note: No. 479297 dated 20/03/23 – referencing 403203.

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- Checked by JM for vehicle clean & dry, outer wrapping intact, no odour or taint & pallets damage free.

3.10 Management of suppliers of services

There is a supplier approval mechanism based upon risk, and documented within the HARM Study. Approved suppliers of services to the Company are entered onto the Approved Suppliers List. Supplier performance is reviewed as an agenda point at annual management review and supplier non-conformance is managed in accordance with the documented Corrective & Preventative Action procedures. The ongoing frequency of supplier approval is set at 3-year intervals. Certificates are updated annually and retained as documented information. Service Level Agreements & terms & Conditions are in place for service providers. Supplier performance is monitored ongoing and at Management Review.

- HARM Plan 002, issue 2 – last reviewed 14/03/22.
- SOP014 – Supplier & Sub-Contractor Assessment, issue 9 dated 01/04/21.
- SOP14.1 – Supplier Assessment Questionnaire, issue 4 dated 13/08/20.
- SOP14.2 – Supplier & Outsourced/Sub-Contracted Processor Assessment, issue 4 dated 13/08/20
- SOP014.3 – List of Approved Suppliers Register, issue 4 dated 17/07/19
- Approval and Monitoring of Service Suppliers RA-BRC6-009 last reviewed 23/05/23.
- Minutes of Management Review dated 23/03/23.

The following supplier approval records relating to service providers were reviewed.

- Delivered by Sprint – SOP022.2 NF Delivery Criteria issue 8 dated 26/04/22 – signed by AF dated 03/01/23. – not completed correctly
- SOP022.1 3rd party Transport Breakdown Declaration & Contract – issue 6 dated 25/04/23 – signed by AF dated 03/01/2023.
- Pest Control service contract – Premier Pest Control - dated 30.10.2019 – rolling contract.
- Greenbank Recycling Solutions Ltd – Waste Carrier Registration – CBDU422007 – Exp. 31/01/25.

NC1 – 3.10.1: The supplier approval questionnaire for Sprint transport had been signed by the service provider, without completing any if the questions, and this had been approved without subsequent review and was not in accordance with the documented procedure.

3.11 Traceability

The traceability system in place was demonstrated to account for raw materials and outsourced printed film from Purchase Order, receipt at the site, through further processing/slitting and distribution to the customer, including secondary packing components such as film bags & reel cores. Raw material/outsourced printed film batch numbers are linked to the Works Order reference allocated to each production run. Several reel batches can be aligned with a specific customer purchase order to fulfil the required quantity. Reels of plain, or printed film and outworked WIP/ Products are delivered by suppliers and are identified by Batch Numbers, Reel I.D. Nos. Supplier Name and Country of Origin. All raw material reels are recorded on an electronically generated GRN system, allocated a batch number and bar coded and is the basis of traceability throughout the production process. Pouches and lids are boxed and labelled with batch numbers, supplier name and country of origin and a bar code attached after receipt. Operators attach bar code labels to every reel or box before wrapping and despatching. The Customer can identify the product from the bar code, box or reel label,

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pallet label and the delivery note. This information can be traced back to the original material used in the production of the product. Any product found to be defective would be identified and segregated from similar conforming product. Effective identification of raw materials, intermediate products, finished products, non-conforming products and quarantined goods was observed during the site assessment/traceability challenge. Outsourcing traceability is maintained.

No rework operations are performed with respect to customer returns. Non-conforming product is sent back to the original manufacturer or is scrapped and managed through Registered waste carriers.

- QM41 - Traceability Policy at issue 3, dated 31/01/23.
- SOP024 – Traceability, issue 1 dated 30/01/23.

An effective forwards traceability test from raw material was completed on 05/01/23 as an element of internal audit.

- RM supplier: T
- Purchase Order: 402883
- Order Confirmation: referencing PO402883
- Inventory:
 - 30396 – 561kg – job 208140
 - 30397 – 598kg – job 208140
 - 30398 – 631kg – job 208140-2
 - 30399 – 622kg – job 208140
 - 30400 – 580kg – job 208140-2 (517kg) & 208140 (71kg)
 - 30401 – 615kg – job 208140
 - 30595 – 486kg – job 208140
 - 30596 – 603kg – job 208140
 - 30597 – 615kg – job 208149

An effective backwards traceability test from finished product was completed on 06/01/23 as an element of internal audit.

Customer: W
Product WOPP-035-0315
Spec; 35um white OPP – 315mm wide
Shipment dated 24/11/22
Quantity: 686kg
Warehouse location: FG-A09-B27-L6
Produced under Job No. 100622
RM batch No. 29134
PO 402631

An effective traceability exercise was carried out as part of the audit against product – 25gsm paper/25um heat sealable polyester for customer OAR. The traceability challenge demonstrated that traceability to test data & samples is maintained.

- Customer: OAR
- Product: Savour It Toast
- Enquiry (SOPD4/2): dated 15/12/22 – quote No. 20494.

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- Specification: 25gsm paper/25um heat sealable polyester, printed 5 colour flexo – width 330 – repeat 213.
- Proposal: dated 31/01/23 – quote ref. 20494
- Customer PO: email dated 30/01/23 from customer HS.
- Customer supplied artwork V1: Proof 12 dated 11/08/2021 – ink colours PMS 447, PMS 012, PMS process black
- Customer proof V2: Job No. 2302567 dated 02/03/23 – BBQ Chicked prod code PL-C00841-006-VR1-R
- Customer artwork approval dated 02/03/23 by RS.

Outsourcing

- Supplier: TCL Packaging
- Technical Data Sheet: issue 1 dated 08/02/23 – detailing compliance with 1935/2004.
- BRCGS Packaging materials Cert. 10504095 Exp. 23/02/23.
- FSC Chain of custody certification: INT-COC-001458
- Completed Supplier Questionnaire; dated 18/08/2020 – next due August 2023.
- Outsourcing PO No. 403203 dated 15/02/23
- Quantity: 663kg of PL-C00841-006-VR1-R
- TCL order acknowledgement: dated 06/03/2023
- Flexo print Order acknowledgement: dated 15/02/23 – signed by the customer – employee HS on 15/02/23.
- Flexo Print Specification – Ref. PL-C00841-006-VR1-R
- Printed Goods-In: Goods-in note 403203 – Reg. YE14 NTA – 1 pallet – received by employee JM
- Goods In delivery note: No. 479297 dated 20/03/23 – referencing 403203.
- Checked by JM for vehicle clean & dry, outer wrapping intact, no odour or taint & pallets damage free.
- Incoming Printed Film Quality Check: completed by JM (warehouse operative) & JP (supply chain team member) checked for labelling, loose care, design repeat, correct colour to cromalin.
- Print Press Pass attended by the Company on 22/02/23.
- Printed retained sample seen – barcode 5024333251668

Raw Materials

- Inner Core/Reels – supplied by Just paper Tubes Ltd – PO 403136 dated 27/01/23 – item T/W Cores 0370
- Incoming delivery note: dated 27/01/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free.
- Core Specification: Nattflex RE76.6x10 – mandrel 76.6, moisture 10%, ply-series 100/102 dated 07/05/2022 authorised by JS
- ISO 9001:2015 Cert. No. 14127700 – Exp. 17/09/25
- Film Reel Bag supplied by AMG – PO 403156 dated 01/02/23 – 18 inch blue bag.
- Incoming delivery note: dated 07/03/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free – dated 07/03/23
- BRCGS certification – Polystar Plastics Ltd (original manufacturer) Cert. No PKG40169 Exp. 23/06/23
- Completed Questionnaire completed by AMG – dated 16/01/23 – confirming full traceability systems in place.

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Internal Production Order (Slitting & Perforation)

- W/O 209001
- Production Date 21/03/23
- Completed on ELDEC slitter/perforator
- Operator Start-Up Checks – recorded on the inspection pad – completed by employee MZ – checking for line hygiene prior to start-up, bins emptied, & surfaces clean (not an exhaustive list) in addition to operational checks including emergency stops & air lines.
- Line Clearance: completed by employee MZ dated 21/03/23 (Doc Ref. SOP 010.1) verified by SB – Production Supervisor.
- Production process Checks: completed on Doc. SOP010.2 – dated 21/03/23 / Job No. 209001 – completed by operator MZ – covering width, meter counter, weight, side reel profile & perforation.

Bill of Lading

- Shipment No 15641 dated 22/03/23
- Inventory ref. N20001414553 (full pallet – 67000603 impressions)
- Delivered by Sprint – SOP022.2 NF Delivery Criteria issue 8 dated 26/04/22 – signed by AF dated 03/01/23. – not completed correctly
- SOP022.1 3rd party Transport Breakdown Declaration & Contract – issue 6 dated 25/04/23 – signed by AF dated 03/01/2023.

Training

- Employee MZ (machine operative) – SOP10 – Production Control dated 04/07/22, SOP24 Traceability trained 30/01/22, Food Safety & GMP training dated 05/01/2022 – provided by Techni-k – 72% with a 70% pass level.
- Employee JP (supply chain team member) – SOP02 – Print Order New Design trained 28/02/23, SOP20 Trial Procedure trained 03/04/23, Basic Food Safety & Hygiene – provided by Vernor Wheelock dated 15/07/20.

3.12 Complaint handling

The documented complaints procedure is referenced QM049. Received complaints are registered on the Customer Complaints Database on RADIUS and are allocated a unique reference number and investigated by the Quality Team. The company takes action to eliminate the cause of non-conformance. The actions to take are defined within documented procedure and include root cause analysis & preventative measures. Non-conformances are recorded on a system-based non-conformance report and actions taken are reviewed to ensure correct implementation & effectiveness through trend analysis presented at management review.

- QM049 – Complaints & Corrective Action Policy, issue 1 dated 07/09/20.
- SOP013 - Corrective & Preventive Action, issue 14 dated 17/02/23
- Minutes of Management Review dated 23/03/23.

The following complaint reports were reviewed during the audit.

- Ref 202300056 dated 03/03/23 – NCR Report FMG 005d
- Customer: B
- Product: LAM-C00051-001
- Issue: 2 reels of film found to be discoloured by customer
- Root Cause: acceptable manufacturing variation

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- Corrective: unjustified complaint
- Preventative: unjustified complaint
- Status: Closed 03/02/23

- Ref 202300074 dated 22/03/23 – NCR Report FMG 005d
- Customer: BFG
- Product: BOPP/025/0380/T00029
- Issue: 300kg ordered – 500kg produced - -over acceptable tolerance
- Root Cause: order overpicked from stock item
- Corrective: customer agreed to keep product
- Preventative: Employees to use barcode readers to pick product
- Status: Closed 22/03/23

- Ref 202300085 dated 30/03/23
- Customer: SIP
- Product: PH-C00539-032-V02
- Issue: underdelivered by 100 pouches
- Root Cause: undersupply from original manufacturer
- Corrective: credit note 1270
- Preventative: Admin error, requireing greater care & attention
- Status: Closed 30/02/23

3.13 Management of product withdrawals, and incidents and product recalls

There is a documented Product Withdrawal and Recall procedure – SOP019, which includes written guidance of the type of event that would constitute an incident, which is trained out to staff at induction and refresher training. Examples listed in the procedure include glass or sharps contamination and chemical. The withdrawal procedure can be operated at any time, and the Sales Team hold a contact lists for customer and there are out-of-hours details of site staff. Any incident is recorded on an Incident Report and acted upon immediately.

A Product Withdrawal/Recall team has been established including the MD, Quality Manager, QA Assistant, Production and Technical Staff. Incident investigation include root cause analysis which is performed by the team. In the event of product withdrawal, affected stock is quarantined, the nature of the issue determined, quantities impacted and traceability of all materials, with actions assigned to Withdrawal/Recall Team Members with Customer Services / Sales and Key staff advised and briefed as required. External contact includes customers, who are notified of the need to quarantine held stock, with a requirement to notify the Certification body. Procedures include arranging transport for uplift of stock and disposal afterwards.

The Company undertake an annual Product Withdrawal test as an element of the Internal Audit schedule. The test records key timings at each key stage. Effectiveness of product withdrawal against the plan is assessed and recommendation of potential improvement implemented where agreed by the Team.

The following records were reviewed of the most recent Product withdrawal test. The test was deemed effective with no changes to the plan or procedures required – commencing 01/11/22 at 08:00 and closing at 09:19.

- Internal Audit – SOP019 Product Recall/tarting 01/11/22 at 08:30

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- Notification from from supplier of allergen contamination (scenario)
- Product Code: PL-C00398-018-01
- PO 402172 dated 04/05/2022
- Quantity received: 1145kg
- Traceability:
Shipping request 12435 dated 20/09/22 – 62kg
Shipping request 12693 dated 11/10/22 – 400kg
683kg remaining in stock
- Customer email dated 01/11/22 at 09:01
- Customer confirmation received ar 09:19

Non-applicable clauses

3.4.4 – There are no company or supplier trademarks printed to film.
3.8.3 – There are no materials at particular risk.

4. Site Standards

4.1 External standards

The site is located on a built-up trading estate located between Leeds & Bradford on the A650. Some areas of the site continue to remain undeveloped, and the Company is currently extending the on-site storage facilities available. There are large expanses of open land to the North, East & South of the company location and no other business adjoining. A Colour Printer & Textile organisation are located on the same estate. The business premises are owned by the Company Pension Scheme, and constructed from brick, which rises to one-third the height of the main structure, with the remaining area covered with single wall metal corrugate sheet cladding. A steel corrugated sheeted roof is fitted incorporating sky lights There are windows opening from the upper & lower floor offices. A glass faced reception leads to stairs up to the main meeting rooms, and key fob entry has been installed in the main reception doors used by all employees, visitors & contractors, with delivery drivers reporting to goods-in.

External areas are well maintained. Hard surfacing was seen in place around the outside perimeter where accessible. External drainage was found to be adequate with no evidence of standing water and drain covers are in place. No evidence was seen of external pipework entering the building which may provide for a possible entry point for pests. The external building fabric is well constructed, with the Company holding responsibility for the main structure upkeep & repairs There are no external silos or outside raw material or finished product storage. The building was unobstructed along all external walls. Two single roller shutter doors are used which are newly fitted and were found to be well sealed with no gaps evident. The wider site is fenced and there is an automatic security gate, and security cameras cover external areas. An intruder alarm is fitted, along with security lighting along all accessible sides of the building.

Externally, there are large areas for loading & unloading, along with storage of waste skips. No evidence was seen of release of waste into the environment. External traffic routes are surfaced with concrete maintained to an acceptable standard. General refuse materials are decanted from bins into designated skips outside, which were seen not to be overflowing, and no concerns have been raised by the contracted pest controller, who is approved via the standard site supplier approval procedures and is BPCA registered. Fabric inspections are carried out as part of GMP audits completed each month.

- Site Inspection completed 24/05/2023.

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- Risk Assessment - 4.1.1 Local Activities/ site location - RA-BRC6-012 dated 10/06/22 issue 2.
- Risk assessment - 4.1.3 Building fabrication - RA-BRC6-013 2 dated 10/06/22 issue 2.

Site inspections are completed at monthly intervals, covering offices, toilets, changing area/lockers, processing & packing area, storage area, canteen, racking & exterior. Issues are logged on each checklist detailed below, and the auditor notifies the process owner. Close-out is recorded using the same system, with verification of effectiveness of actions taken verified by the auditor.

- SOP023 - GMP Inspection Procedure – 002 dated 28/03/23
- Quarterly Hygiene Audit: completed 27/04/23 by AB
Covering: offices, toilets, changing area, processing & packing area, storage area, canteen, exterior area
Issues: None
Status: closed

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

All internal walls are painted brick and there is some use of metal steelwork within the construction. No evidence was seen of excessive dust build-up on higher level flat surfaces. Floors are of concrete construction, with no evidence of damage or loose chippings. There is firewall isolating the company offices from the production hall. All surfaces were seen to be newly painted and in excellent condition with a suitable surface to facilitate cleaning. All raw materials are stored in racking in a dedicated warehouse, waste is slit from the main film web and stored in bins awaiting recycling, or sent to general waste, which is performed off-site by a Registered waste carrier. There are no internal drain openings or windows which pose a risk of contamination. All lighting across the facility is protected LED and were seen to be suitable and sufficient. There are elevated walkways at some production equipment, and a mezzanine area is in place above production offices. The facility provides ample space for manufacturing & storage operations undertaken.

The production hall itself is an open-plan workspace containing a number of combined film slitting & perforating lines. Various worktables and workstations were seen in use, which were effectively sealed where appropriate, racking has been installed for raw materials & finished product. All reels of printed & unprinted film stock awaiting slitting are stored off the floor on wooden pallets, reels were seen covered with a /film when in storage. Ceilings are steel cladding with polycarbonate skylights. There are no suspended ceilings in production or storage areas. All areas of the factory are provided with good levels of working light. No evidence of glass or brittle plastic breakages were evident during the site tour. External doors were seen proofed against pest ingress.

- Site Inspection completed 24/05/2023.
- Risk assessment - 4.2.4 Glass windows – Further protection - RA-BRC6-014 dated 15/06/22 issue 2.
- Risk Assessment - 4.2.6 Elevated walkways - RA-BRC6-016 dated 16/06/22 issue 2..
- Risk Assessment - 4.2.8 Ventilation (Perf Machine) - RA-BRC6-015 dated 10/05/23 issue 2

Site inspections are completed at monthly intervals, covering offices, toilets, changing area/lockers, processing & packing area, storage area, canteen, racking & exterior. Issues are logged on each checklist

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detailed below, and the auditor notifies the process owner. Close-out is recorded using the same system, with verification of effectiveness of actions taken verified by the auditor.

- SOP023 - GMP Inspection Procedure – 002 dated 28/03/23
- Quarterly Hygiene Audit: completed 27/04/23 by AB
Covering: offices, toilets, changing area, processing & packing area, storage area, canteen, exterior area
Issues: None
Status: closed

4.3 Utilities

Water is used for cleaning purposes, hand washing, and is of potable quality. It is via mains supply, provided through Yorkshire Water. Compressed air does not come into direct contact with the product, and is utilised on machinery for operational control of valves and cylinders and is dried and oil separated. Based on risk assessment compressors are monitored and serviced to a schedule based on hours run. Compressed air is filtered to 0.01 micron and filters changed in line with manufacturers recommendations, with food grade lubricants used during maintenance. A Competent service provider is employed to undertake Statutory servicing of the compressed air systems utilised on the production lines.

- Compressor Servicing – completed by NC Air – Job No. 20212 – Mattie compressor Serial No. C9A4UP – completed 15/06/22.

4.4 Site security and product defence

There is a documented Site Security & Product Defence Plan referenced as QM010. The HARM Study includes reference to identified site security risks and a separate TACCP Risk Assessment has been completed and were reviewed, covering unauthorised entry & malicious intent. The risk assessment lists all identified risks & corresponding controls with employee awareness of relevant procedures covered within induction training material and documented within the Manual under section 4.4.

The minutes of Management Review summarise the effectiveness of the Product Defence Plan, with no incidents or breaches being recorded during this reporting period.

- QM010 Site Security & Food Defence Plan, issue 4 dated 02/09/20
- 4.4 Threat Assessment (documented within the product defence plan) VACCP/TACCP issue 4, last reviewed on 26/10/22, next due October 2023.
- Site Inspection completed 24/05/2023.
- Minutes of Management Review dated 23/03/23.
- HARM Plan 002, issue 2 – last reviewed 14/03/22.

A reporting system is in place at the main reception area including separate health questionnaire, which is completed by all contractors and visitors to the site. Employees use the same entry location. No evidence was seen of unauthorised entry points being used. The site is covered by 24-hour CCTV at the main access & exit point & at all four corners of the building, with the main entrance additionally protected by security key fob access & security lighting. An intruder alarm is fitted and armed outside working hours.

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The perimeter is secured by fences, and an automatic security gate is fitted. Persons wishing to gain access have to ring through to the main offices, register at the reception desk and fill in visitor's health questionnaire via iPad. They must wait for a member of team to allow access to the building and are accompanied at all times where practical.

4.5 Layout, product flow and segregation

There are Site Plans defining pedestrian movement, travel routes, locations of toilets, material routes, storage & waste routes within the main production hall & warehouse. Sorting is not undertaken and suspect scrap film is scrapped or sold on for less demanding applications through recycling.

- Site Plan – QM010.2 – Overall Site, issue 3 dated 21/03/23.
- Site Plan – QM010.3 – Pedestrian Flow, issue 2 dated 21/03/23.
- Site plan – QM010.4 – Product & Waste Flow, issue 1 dated 21/03/23.
- Site Inspection completed 24/05/2023.
- Risk Assessment 4.10 - Waste material & flow - RA-BRC6-009, dated 09/06/22, issue 2.

The process flow from goods-in, through production to, dispatch was found not to pose a risk to damage or contamination of the product and ample working space and storage has been provided to enable all operations to be carried out safely. Walkways were seen to be designated by nature of the single production line and floor markings. Outer packaging is removed in the main production hall within a designated area at the infeed to the slitters, film reels remain protected by nature of being tightly wound with the initial unwind scrapped. Separation was in evidence between raw materials, WIP and finished product.

4.6 Equipment

All production & warehousing equipment, including slitting/perforating and racking are designed for the intended purpose and maintained by a 3rd Party Specialist. The purchasing of machinery is controlled and subject to risk assessment through review of the HARM Study. No lubrication points were seen to be situated over the film web and the raw materials remain tightly wound until passing through the production line, subsequently re-wound, before being packing into blue food grade bags and stacked on pallets.

No unprotected notices were seen affixed to equipment (self-adhesive notices seen). A clean-as-you-go policy is in place and all cleaning equipment viewed located in designated areas close to each production line was plastic/wood handled and colour coded. Separate cleaning equipment has been purchased for cleaning toilets, which is stored in a separate locked cleaning cupboard located close to the offices. Wooden equipment is surface sealed and subject to regular inspection and cleaning to documented schedules. There has been no new equipment installed during this reporting period. Noticeboards do not have sharp loose fastenings and laminated notices are used throughout the site and are magnetic or self-adhesive.

- Site Inspection completed 24/05/2023.
- Risk assessment - 4.6.2 New Equipment Maintenance - RA-BRC6-019 issue 2 dated 10/05/23.
- QM017 Wood Policy, issue 4 dated 31/01/23.

4.7 Maintenance

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All equipment and plant are subject to a documented maintenance programme to reduce the risk of breakdown and serviced in line with OEM specifications. Planned maintenance is carried out by operators and recorded on pads.

- Operator Start-Up Checks – recorded on the inspection pad – completed by employee MZ – operational checks including emergency stops & air lines.

Maintenance records are recorded by individual machine. Third party specialist carry out servicing and breakdown activities and there is a recorded check of the machine to ensure it is clean and clear to resume production. The maintenance record system is paper-based and runs to a schedule for each machine. Temporary repairs/modifications using tape, cardboard, are only permitted in emergencies and where product contamination is not at risk. Modifications are subject to a time limit and are to be recorded and scheduled for correction on a Temporary Engineering Inspection pad, with the same system used to records when a permanent repair has been completed. No temporary repairs were observed during the site inspection, and no tools were seen left out that were not in use.

- Site Inspection completed 24/05/2023.
- Temp Repair Pad – ticket No. 156 – dated 28/07/22 – temporary repair to motor – K2 Line – approved by MT – closed out same day 28/07/22.

There is no engineering workshop. Contractors carrying out work fall under the jurisdiction of the Production Manager throughout their stay and are required to follow hygiene rules & sign-in procedures upon arrival at the site.

- Maintenance Plan – SOP010.3 – issue 6 dated 02/12/22 – covering item, location, service provider, inspection frequency, date completed, next due & responsibility.
- Compressor Servicing – completed by NC Air – Job No. 20212 – Mattie compressor Serial No. C9A4UP – completed 15/06/22.
- Slitter maintenance record – completed by M.J. Howard Technical Services – call out to replace bearing on rewind bar – Titan Slitter – dated 21/04/23.
- Slitter maintenance record – completed by M.J. Howard Technical Services – refix mountings of Kampf Unwind – Titan Slitter – dated 21/04/23.
- Compactor maintenance record – completed by Greenbank – service sheet dated 13/04/23

After maintenance activity there is a documented clearance, confirming that all contamination hazards & tools have been removed and that the line is safe to hand back to operations.

- Maintenance Clearance Log – Ref. SOP010.3.2 – issue 2 dated 25/04/23 – last entry dated 15/05/23 – Marshals – removal of hand tools – completed by engineer AC – checked by AB – signed & dated 15/05/23.

4.8 Housekeeping and cleaning

Good standards of housekeeping are maintained across all areas of the site. A clean-as-you-go policy is in place with operators responsible for the immediate area/line within which they work. The site has procedures detailing responsibility, methods, cleaning equipment to be used and verification of the effectiveness of cleaning activities undertaken. High level cleaning is carried out every 2-years. Cleaning of staff welfare and general factory areas, walkways, toilets, locker rooms, canteen & offices is carried out by

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an 3rd party cleaner and cleaning chemicals were seen stored in secure cleaner's cupboard. Cleaning equipment is segregated by area and colour coded.

- Site Inspection completed 24/05/2023.

General multipurpose cleaning chemicals are used in accordance with manufacturer's instructions and COSHH/MSDS records are maintained. Cleaning schedules were seen to be completed for all areas and machines. The sites does not use highly scented cleaning chemicals. Chemicals observed were close capped and used in accordance with manufacturer's instructions. Toilet equipment is stored separately and colour coded red.

- Risk Assessment - 4.8 Hygiene & Housekeeping Tasks - RA-BRC6-021 dated 15/06/22 issue 2.

Cleaning activities are planned monthly, and the following records were reviewed. Each record was seen to detail the frequency, responsibility, time allocated, safety precautions, cleaning equipment to be used, cleaning method & date.

- Compressor machine room monthly cleaning record – dated 10/05/23 – completed by employee JE – signed-off by employee S – covering floor cleaning, clean down compressor, ledge around compressor room.
- Warehouse monthly cleaning record – dated 26/04/23 – completed by employee C – signed-off by employee AB – covering strip curtains, loading bay, racking legs, lighting, floor isles, walls
- High-Level cleaning – completed by Clear Choice – completed 04/01/2023 – purchase order 403163.

A risk assessment has been completed within the HARA study to determine the need for environmental monitoring. The risk assessment considered that printed film is held in reel form with no product handling taking place, and with the reel edges trimmed during slitting. The product itself is not capable of supporting microbial growth.

- Risk Assessment - 4.8.5 Environmental Monitoring - RA-BRC6-022 dated 13/06/22 issue 3.

Site inspections are completed at monthly intervals, covering offices, toilets, changing area/lockers, processing & packing area, storage area, canteen, racking & exterior. Issues are logged on each checklist detailed below, and the auditor notifies the process owner. Close-out is recorded using the same system, with verification of effectiveness of actions taken verified by the auditor.

- SOP023 - GMP Inspection Procedure – 002 dated 28/03/23
- Quarterly Hygiene Audit: completed 27/04/23 by AB
Covering: offices, toilets, changing area, processing & packing area, storage area, canteen, exterior area
Issues: None
Status: closed

4.9 Product contamination control

4.9.1 Glass, brittle plastics, ceramics, and similar materials control

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The Company has completed a stand-alone risk assessment considering contamination risks from non-production glass, ceramics & brittle plastic.

- Risk Assessment - 4.9.1Glass, Brittle Plastic, Ceramics - RA-BRC6-014 -dated 15/06/21 issue 2.

All glass and brittle plastics that pose a potential product contamination hazard are controlled and recorded onto a glass register. Items not in the production or storage areas are excluded on the basis of risk. A Hygiene Incident Form is used to report breakages identified through site GMP inspection or by operators. In the event of breakage, a responsible person is placed in charge of the clean-up operation, ensuring that no other area is contaminated. All suspect products are quarantined, and any contaminated product disposed of. There have been no breakages reported during this reporting period.

- SOP017 - Sharps, Glass, Ceramics & Brittle Plastics, issue 6 dated 07/03/23.
- QM030 - Glass, Ceramics & Brittle Plastics Control Policy issue 3 dated 30/08/22.

The Register documents the item, location, number, type and condition. No unnecessary items of glass or brittle plastics were observed during the site inspection, and no broken glass or plastic was noted. All light tubing in the production and storage areas were observed to be shatterproof LED, and all EFK tubes are shatterproof. There are no windows which pose a risk. The Register is subject to regular inspection as an element of Internal Audit

- Site Inspection completed 24/05/2023.
- Audit Report dated 05/01/23 – covering Glass, Ceramics & Brittle Plastics audit – using Register SOP017.1.1, issue 21 dated 09/12/22 – completed by TL
- Findings: No NCs raised.

4.9.2 Sharps and metal control

Sharps & metal control has been considered as an element of the HARM Study and was reviewed during the site inspection. Control of sharps is documented within SOP017. The company do not use snap-off blades, only on-piece retractable blades were seen in use (in addition to machine blades issued to the slitting lines), and notice boards were seen free from drawing pins & staples. The procedure details that cutting tools shall not be removed from the company's premises and all knives in use are issued by the company and will be checked daily for condition and availability.

- Site Inspection completed 24/05/2023.
- HARM Plan 002, issue 2 – last reviewed 14/03/22.
- SOP017 - Sharps, Glass, Ceramics & Brittle Plastics, issue 6 dated 07/03/23.
- QM019 Metal Control Policy, issue 3 dated 30/08/22

The company maintain a store of new blades and complete a stock-take of blades available for issue at audit. Each blade issued is allocated a blade type reference and separate number and the issue date is recorded, which also records the return & disposal.

- Blade issue log – SOP017.5, issue 1 dated 07/03/23.
- 24/05/23 – Blade type M (machine blade) – 2 blades issued – 2 blades returned – 10 blades in situ – issued by employee JE.

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4.9.3 Chemical and biological control

Chemical & Biological Control has been considered as an element of the HARM Study & stand-alone risk assessment, and was reviewed during the Site Inspection. There is a Substance Inventory – COSHH Register, issue 3 dated 09/12/22 (last reviewed 18/05/23 by TL). The document lists all chemical substances in use across the site, the supplier, risk associated with the substance, the availability of supplier Safety Data Sheet, last review date, confirmation that the chemical continues to be in use and approval/authorisation by the Quality Team. All chemicals were seen stored in metal cabinets and manufacturer Safety data Sheets are held on film and subject to periodical review for updates. Biological hazards have been subject to documented risk assessment and are controlled via the Allergen Policy & HARM prerequisites covering Hygiene & Hand Washing. No strongly scented products were seen in use during the site inspection and no hazardous chemicals are in use.

- Site Inspection completed 24/05/2023.
- Risk assessment - Biological Control - RA-BRC6-023 dated 20/06/22 issue 2.
- Risk Assessment - Personal Hygiene - RA-BRC6-026 dated 20/04/23 issue 2.
- HARM Plan 002, issue 2 – last reviewed 14/03/22.
- QM031 Allergen Policy, issue 6 dated 10/01/23.

The following evidence of chemical control was reviewed.

- ARCO Super Professional Antiviral Disinfectant – MSDS dated 04/03/2020 – issue 1.
- ARCO Oxybac Foam Wash – MSDS dated 24/01/2020 – issue 1.1.
- ROCOL Foodlube Stray – MSDS dated 05/05/2022 – issue 9.2
- Prem Pest Control services – Ratimor Monitoring fresh bait – MSDS dated 13/03/23 issue 1.

4.10 Waste and waste disposal

Waste is removed from the site by Registered waste contractors and managed in accordance with legislative requirements. Process waste is controlled to prevent release into the environment and no issues were evidenced during the site inspection at external waste storage relating to risk of pest infestation or harbourage, with no issues reported by the visiting Pest Contractor. Suitable and sufficient refuse and waste containers are provided to handle the volume of waste generated, which was viewed stored in closed containers, not overflowing and in a clean condition. There is a register in place detailing Waste Contractors in the approved supplier's file. Waste containers were seen clearly marked across the sites. Plastic film waste is segregated for recycling and secure destruction of printed waste is carried out by an approved and licenced contractor.

- Site Inspection completed 24/05/2023.
- Risk Assessment - Waste Material & Flow - RA-BRC6-009 dated 09/06/22 issue 2.
- QM010.4 - Site Plan – Product & Waste Flow issue 1 dated 21/03/23.
- QM015 Waste & Disposal Policy issue 3 dated 30/08/22.
- Duty of care waste transfer – dated 02/05/23 – scrap packaging – GRN 002MAY23 – Accrued Plastics Ltd – CBDU137492 – Registration Exp. 02/05/25.
- Duty of care waste transfer – dated 27/04/23 – scrap paper – GRN 741769 – C&J Blackburn – CBDU87670 – Registration Exp. 14/02/25.

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- Destruction Certificate – Accrued Plastics Ltd – dated 13/06/22 – confirming destruction through extrusion.

4.11 Pest management

The company has a preventative pest management programme in place covering all areas of the site. A documented Policy is in place for the site.

- QM022 Pest Management Policy, issue 4 dated 11/01/21.
- Pest control risk assessment – seen dated 10/07/20 Revision 2 – reviewed at each Biologist visit.
- Risk Assessment - Pest Management scope/Frequency - RA-BRC6-025 dated 20/06/22 issue 2.
- Risk assessment – Infestations - RA-BRC6-025 dated 20/06/22 issue 2.

The programme is maintained by an external service provider – Premier Pest control Ltd, Registered BPCA Membership M15/683 Exp. February 2024. A Service Specification has been agreed, dated 03/05/29 issue 9, which includes 8 routine visits and 4 Field Biologist visit/audits, plus EFK servicing & any treatment as appropriate. Visit records confirmed attendance by the pest contractor on 15/04/23, 24/02/23 & 09/01/23 and continued throughout the previous year. The contractor is accompanied occasionally on visits by a member of staff.

- Service Specification – dated 03/05/29 – rolling contract
- Routine visit & EFK Service dated 05/04/23 – no activity internally or externally, EFK Tubes replaced & no recommendations.
- Routine visit dated 24/02/23 – no internal or external activity, no recommendations.
- Routine visit dated 09/01/23 – no proofing issues noted, site hygiene deemed extremely clean, site up to date with paperwork – no issues or recommendations.
- Pest Contractor SB – RSPH Level 2 Award in Pest Management dated 17/11/2015 Cert. 472871.

A site plan – dated 03/05/2023 is maintained indication the locations of all bait stations. Bait points were seen to be appropriately located and operational. External bait stations were tethered. During the site inspection all doors and possible entry points were seen effectively protected. Records of pest activity were reviewed and found to be comprehensive, they showed evidence of activity externally that the contractor had been acted upon. Details of the pest control products used were confirmed as non-toxic.

The company uses training material contained within QM022 Pest Management Policy & within on-line food safety training provided to all employees.

- Employee MZ (machine operative) - Food Safety & GMP training dated 05/01/2022.

There is a summary of pesticides in use which provides detail of the pesticide name, when & where used, quantity and initials of the Pest Contractor.

- Prem Pest Control services – Ratimor Monitoring fresh bait – MSDS dated 13/03/23 issue 1.

Non-applicable clauses

- 4.1.5 no raw materials stored outside.
- 4.2.2 no suspended ceilings.
- 4.2.3 no internal drains.

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- 4.2.4 no windows pose a risk.
- 4.2.6 no elevated walkways.
- 4.3.2, water, air, steam, ice or other gasses do not contact product.
- 4.4.3 no external tanks/silos.
- 4.7.7 no workshop.
- 4.8.5 no environmental monitoring.
- 4.9.2.4 No open noticeboards.
- 4.11.3 site does not undertake its own pest control.

5. Product and process control

5.1 Product development

Product development responsibilities fall under the Senior Team & Technical Engineer. Development activities generally revolve around existing film structures, that are reverse engineered around the Company's Outsource supply chain capabilities, all activities are covered within the HARM Study and stand-alone Product Design Risk assessment.

The site does not design and develop products in isolation, it advises customers on film types and application, and handles customer supplied artwork. The site clearly defines when a trial is required, and all development activities are documented in Trial Reports. Trials are undertaken at the customers site to verify the material in use during production situations. Changes to artwork are managed through the print order procedures with customers attending press passes, with proofs signed and retained by the site. Specifications for raw materials are established and agreed and Technical Specifications are created for all finished products. Specifications include critical use parameters including materials, size, colour and functionality. Samples are retained in line with Customers requirements. All changes to design requirements are approved by the customer, including changes to existing products. Production is carried out under defined operating procedures to produce a safe and legal product.

The following product development records were reviewed.

- Customer: WM
- Product: top & base web
- Enquiry date: 04/05/22.
- Customer Spec: 25um OPE laminated to 30um PE, in addition to a further trial covering 25um OPE to 50um PE.
- Special requirements & specific application documented on the enquiry form SOP D4/2 issue 002 dated 25/11/21.
- Trial PO – 402288 covering both 25um OPE laminated to 30um PE, in addition to a further trial covering 25um OPE to 50um PE.
- Specification (Technical Data Sheet) – Film code FP2310LT – Doc. No. TDS.AG.537 dated 03/09/23 – confirming suitability for direct food contact.
- Client Site based trial – completed on 12/05/23 – in attendance were the client maintenance engineer & SM – Head technical Engineer & LR – Area Sales Manager.
- Trial Report dated 12/05/23
- Conclusion: ongoing (trial deemed successful, no customer PO at this stage).

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5.2 Graphic design and artwork control

Approved artwork files are received from the Customer via email or FTP link. In house systems ensure artwork is checked and that final approval from the customer has been received prior to sending the order for printing and/or conversion at the selected outsourcing partner's site. All new jobs are allocated a unique reference number. The printed product is inspected and verified by the Customer Service Team on first receipt. Checks on incoming newly printed film are carried out using an approved artwork proof/standard on receipt of materials from outsourcing printers prior to despatch to the customer, to ensure no loss of essential information or mixing of products. Print suppliers hold BRCGS Certification, which provides reassurance that print equipment is suitably stored and identified.

The following artwork approval records were reviewed.

- Customer: OAR
- Product: Savour It Toast
- Enquiry (SOPD4/2): dated 15/12/22 – quote No. 20494.
- Specification: 25gsm paper/25um heat sealable polyester, printed 5 colour flexo – width 330 – repeat 213.
- Proposal: dated 31/01/23 – quote ref. 20494
- Customer PO: email dated 30/01/23 from customer HS.
- Customer supplied artwork V1: Proof 12 dated 11/08/2021 – ink colours PMS 447, PMS 012, PMS process black
- Customer proof V2: Job No. 2302567 dated 02/03/23 – BBQ Chicked prod code PL-C00841-006-VR1-R
- Customer artwork approval dated 02/03/23 by RS.

5.3 Packaging print control

Not applicable, the Company do not undertake any print activities.

5.4 Process control

The manufacturing process is controlled through the procurement of raw materials and printed film from approved suppliers and outsourcing partners who hold appropriate Certification, along with control of the operational environment within which the purchased film is further processed, in addition to critical machine settings and documented operator verification checks to ensure the finished product is consistently produced to the quality specified by Customers. Changes to product specification are captured through contract review at receipt of each new order and controlled in accordance with documented design, quotation, order processing & contract review procedures, in addition to a series of SOPs covering the manufacturing operations. Customer specifications and received Purchase Orders form the basis of the Work Instruction that accompanies each order through production and details the specification & tolerances permitted. The Work Instruction additionally records the results of Operator inspection and confirmation of line clearance prior to commencing makeready.

- SOP001 - Design & Quotation issue 10 dated 25.01.23
- SOP002 - Print Order – New Design issue 11 dated 27.02.23
- SOP004 - Pre Order Review issue 10 dated 27.03.23
- SOP005 - Order Processing & Contract Review issue 8 dated 27.03.23

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The Company has identified the process control points (those under its control – post print) where inspection is required and has established a quality plan detailing the inspection criteria and frequency based on historical and known process variance. Only authorised trained personnel have access to machine settings which are recorded on the Work Instruction. Each production run is approved against the documented specification available on screens located on each slitting line. Operator checks are in place at start-up/changeover, throughout the run and end of run. The company retain printed samples from each received outsourced production batch.

- SOP009 Production Scheduling and Planning issue 9 dated 01.04.21.
- SOP010 Production Control issue 14 dated 05.04.23 (including line clearance)

The following process control records were reviewed during the audit.

- Customer: OAR
- Product: Savour It Toast
- Enquiry (SOPD4/2): dated 15/12/22 – quote No. 20494.
- Specification: 25gsm paper/25um heat sealable polyester, printed 5 colour flexo – width 330 – repeat 213.
- Proposal: dated 31/01/23 – quote ref. 20494
- Customer PO: email dated 30/01/23 from customer HS.
- Customer supplied artwork V1: Proof 12 dated 11/08/2021 – ink colours PMS 447, PMS 012, PMS process black
- Customer proof V2: Job No. 2302567 dated 02/03/23 – BBQ Chicked prod code PL-C00841-006-VR1-R
- Customer artwork approval dated 02/03/23 by RS.

Outsourcing

- Supplier: TCL Packaging
- Technical Data Sheet: issue 1 dated 08/02/23 – detailing compliance with 1935/2004.
- BRCGS Packaging materials Cert. 10504095 Exp. 23/02/23.
- FSC Chain of custody certification: INT-COC-001458
- Completed Supplier Questionnaire; dated 18/08/2020 – next due August 2023.
- Outsourcing PO No. 403203 dated 15/02/23
- Quantity: 663kg of PL-C00841-006-VR1-R
- TCL order acknowledgement: dated 06/03/2023
- Flexo print Order acknowledgement: dated 15/02/23 – signed by the customer – employee HS on 15/02/23.
- Flexo Print Specification – Ref. PL-C00841-006-VR1-R
- Printed Goods-In: Goods-in note 403203 – Reg. YE14 NTA – 1 pallet – received by employee JM
- Goods In delivery note: No. 479297 dated 20/03/23 – referencing 403203.
- Checked by JM for vehicle clean & dry, outer wrapping intact, no odour or taint & pallets damage free.
- Incoming Printed Film Quality Check: completed by JM (warehouse operative) & JP (supply chain team member) checked for labelling, loose care, design repeat, correct colour to cromalin.
- Print Press Pass attended by the Company on 22/02/23.
- Printed retained sample seen – barcode 5024333251668

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Raw Materials

- Inner Core/Reels – supplied by Just paper Tubes Ltd – PO 403136 dated 27/01/23 – item T/W Cores 0370
- Incoming delivery note: dated 27/01/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free.
- Core Specification: Nattflex RE76.6x10 – mandrel 76.6, moisture 10%, ply-series 100/102 dated 07/05/2022 authorised by JS
- ISO 9001:2015 Cert. No. 14127700 – Exp. 17/09/25
- Film Reel Bag supplied by AMG – PO 403156 dated 01/02/23 – 18 inch blue bag.
- Incoming delivery note: dated 07/03/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free – dated 07/03/23
- BRCGS certification – Polystar Plastics Ltd (original manufacturer) Cert. No PKG40169 Exp. 23/06/23
- Completed Questionnaire completed by AMG – dated 16/01/23 – confirming full traceability systems in place.

Internal Production Order (Slitting & Perforation)

- W/O 209001
- Production Date 21/03/23
- Completed on ELDEC slitter/perforator
- Operator Start-Up Checks – recorded on the inspection pad – completed by employee MZ – checking for line hygiene prior to start-up, bins emptied, & surfaces clean (not an exhaustive list) in addition to operational checks including emergency stops & air lines.
- Line Clearance: completed by employee MZ dated 21/03/23 (Doc Ref. SOP 010.1) verified by SB – Production Supervisor.
- Production process Checks: completed on Doc. SOP010.2 – dated 21/03/23 / Job No. 209001 – completed by operator MZ – covering width, meter counter, weight, side reel profile & perforation.

Bill of Lading

- Shipment No 15641 dated 22/03/23
- Inventory ref. N20001414553 (full pallet – 67000603 impressions)
- Delivered by Sprint – SOP022.2 NF Delivery Criteria issue 8 dated 26/04/22 – signed by AF dated 03/01/23. – not completed correctly
- SOP022.1 3rd party Transport Breakdown Declaration & Contract – issue 6 dated 25/04/23 – signed by AF dated 03/01/2023.

5.5 Calibration and control of measuring and monitoring devices

The site identifies and controls all off-line measuring equipment used to monitor control points. There is a log (SOP008.1) which identifies the location, equipment, identification code and calibration due date. The equipment is only used by authorised personnel and protected against damage and adjustments through unauthorised use and employee training. The Quality Manager is responsible for ensuring the calibration provided completes calibration activities in-line with the relevant legal requirement/standard for the equipment. In event of failure, products made since the last clear point would be re-evaluated and any out of specification items rejected under the Control of non-conforming product procedure. Equipment is calibrated externally by recognised Service providers using equipment traceable to national standards.

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- Scales – Type EWS Junior – Serial No. 1124933 – Cert. No. 200538 – dated 19/04/23
- Scales – Type EFI Auto Count S50-KA2 – Serial No. 06181506 – Cert. No. 200534 – dated 19/04/23
- Scales – Type EFI Auto Count S50-KA2 – Serial No. 016181456 – Cert. No. 200516 – dated 19/04/23.

5.6 Product inspection, testing and measuring

Documented quality checks are carried out at start-up and reel changeover, these being bag width & length, seal integrity, seal width & perforations. Additional seal integrity visual checks are carried out throughout the run but not individually documented (checked across the product and summarised as being within spec on the works order). Documented checks are recorded on the Doc. SOP010.2 – dated 21/03/23. The validity of testing has been determined over time as knowledge of the equipment and process variability has increased. In the event that Non-conforming product is identified – a Non-Conformance Report QAS6.0 is raised and tracked to completion, including root cause analysis and action to prevent reoccurrence.

- SOP010 Production Control issue 14 dated 05.04.23 (including line clearance & product inspection).
- Internal Production Order (Slitting & Perforation)
- W/O 209001
- Production Date 21/03/23
- Completed on ELDEC slitter/perforator
- Operator Start-Up Checks – recorded on the inspection pad – completed by employee MZ – checking for line hygiene prior to start-up, bins emptied, & surfaces clean (not an exhaustive list) in addition to operational checks including emergency stops & air lines.
- Line Clearance: completed by employee MZ dated 21/03/23 (Doc Ref. SOP 010.1) verified by SB – Production Supervisor.
- Production process Checks: completed on Doc. SOP010.2 – dated 21/03/23 / Job No. 209001 – completed by operator MZ – covering width, meter counter, weight, side reel profile & perforation.

5.7 Control of non-conforming product

The documented non-conforming product procedure (SOP013) details that out of tolerance materials are labelled with a non-conforming product label. Identified non-conforming material is assessed by the Production Manager & Quality Team, and a decision taken to reject, accept by concession, depending on the severity, with the reason documented. defective product is recorded on a log and Radius MIS. Returned product is also recorded and labelled on hold. NCRs reviewed and reported as part of annual review.

- SOP013 Corrective & Preventive Action issue 14 dated 17.02.23.
- Minutes of Management Review dated 23/03/23.
- Destruction Certificate – Accrued Plastics Ltd – dated 13/06/22 – confirming destruction through extrusion

5.8 Incoming goods

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Raw materials may be received in accordance with the Good Inward procedure SOP011, Deliveries are visually checked for integrity & obvious signs of contamination, with acceptance recorded on delivery paperwork. Stock rotation is achieved, with some customers having a rolling stock of raw materials held at the site, with the remainder of raw materials purchased to fulfil a specific customer order, and the site MIS recording the date of receipt. Film stocks are accepted on the basis of incoming goods check, a supplier Declaration of Compliance, availability of Product Specification & suppliers holding appropriate Certification. Raw materials vulnerability & security has been considered within VACCP & TACCP Risk Assessments

- Risk Assessment - Incoming Goods inspection - RA-BRC6-028 dated 16.06.22 issue 2.
- SOP011 Materials Handling issue 017 dated 28.03.23
- SOP026 Imports Procedure issue 005 dated 16.11.22
- QM010 Site Security & Food Defence Plan, issue 4 dated 02/09/20
- Threat Assessment (documented within the product defence plan) TACCP issue 4, last reviewed on 26/10/22, next due October 2023.
- Vulnerability Assessment – TACCP/VACCP 02, reviewed annually or when change occurs – last reviewed 16/05/23.
- Outsourcing PO No. 403203 dated 15/02/23 - Quantity: 663kg of PL-C00841-006-VR1-R
- Printed Goods-In: Goods-in note 403203 – Reg. YE14 NTA – 1 pallet – received by employee JM
- Goods In delivery note: No. 479297 dated 20/03/23 – referencing 403203.
- Checked by JM for vehicle clean & dry, outer wrapping intact, no odour or taint & pallets damage free.
- Incoming Printed Film Quality Check: completed by JM (warehouse operative) & JP (supply chain team member) checked for labelling, loose care, design repeat, correct colour to cromalin.
- Incoming delivery note: dated 27/01/23 – received by CS confirming vehicle dry, no odour or taint & pallets damage free.

5.9 Storage of all materials and intermediate and finished products

All materials, work in progress and finished products are suitably protected and properly identified using a label with the relevant information. Storage is suitably controlled to protect the product from contamination (SOP011 Materials Handling Procedure) and malicious intervention through controlled access onto site. Procedures are in place to segregate raw materials, intermediate, and finished goods. Raw materials such as unprinted film is stored in reel form on pallets, and finished goods are stored in on shrink wrapped pallets. Waste film is compacted, with printed product scrapped and destroyed under controlled conditions, natural polymer film waste is sold on.

- Risk Assessment - Storage – External Holdings - RA-BRC6-031 - 21.06.22 issue 2.
- SOP011 Materials Handling issue 017 dated 28.03.23
- QM010 Site Security & Food Defence Plan, issue 4 dated 02/09/20
- Threat Assessment (documented within the product defence plan) TACCP issue 4, last reviewed on 26/10/22, next due October 2023.
- Vulnerability Assessment – TACCP/VACCP 02, reviewed annually or when change occurs – last reviewed 16/05/23.

5.10 Dispatch and transport

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Documented Procedure SOP011 & Policy QM037 refer. All finished goods are identified using a pallet card label and stretch wrapped. All products are suitably protected against the risk of taint, odour or malicious intervention sealed in blue food grade bags. Wooden pallets used are checked for damage and contamination and unacceptable pallets are removed. The product does not come into direct contact with the pallet. All delivery vehicles are subject to a documented hygiene-checking procedure with confirmation of cleanliness recorded on the despatch paperwork.

- Risk Assessment - Transportation of Materials (Inc chain of custody & 3rd party transport) - RA-BRC6-032 dated 16.06.22 issue 2.
- QM037 Transport Policy issue 004 dated 10.01.23
- SOP011 Materials Handling issue 017 dated 28.03.23
- QM010 Site Security & Food Defence Plan, issue 4 dated 02/09/20
- Threat Assessment (documented within the product defence plan) TACCP issue 4, last reviewed on 26/10/22, next due October 2023.
- Vulnerability Assessment – TACCP/VACCP 02, reviewed annually or when change occurs – last reviewed 16/05/23.

Non-applicable clauses

5.3 No printing completed on site.
5.6.3 No in line testing.
5.6.6 No in line testing.
5.6.9 No vision equipment.
5.6.10 No subcontracted analysis.
5.9.5 No packaging stored outside.
5.9.7 No hazardous chemicals.
5.10.4 no company vehicles.

6. Personnel

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

All employees are suitably trained and are subject to formal induction at the start of employment. New employees receive a Company Handbook covering smoking at work, substance abuse, whistle blowing, hygiene and other processes, specific task-based training & training relevant to product safety. A log/file is maintained which summarises the competence of all employees. All training material is in English, and it was confirmed that all employees have control of the language. Training provided to employees is recorded on training records – form SOP007.4, issue 3 dated 02/12/22. All staff interviewed during the evaluation had received suitable training commensurate with their role, demonstrated competence and were aware of the need to challenge unknown visitors as part of the food defence plan. In depth training is provided by machine manufacturers for new equipment when installed. Training records are maintained for all personnel and are controlled by HR Processes. Training needs are assessed on an ongoing basis and at Management Review.

- QM039 Training Policy issue 7 dated 31/01/23.
- SOP007 Personnel & Training issue 7 dated 24/02/23.
- Minutes of Management Review dated 23/03/23.

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The following training records were reviewed.

- Employee TL (QA Assistant): HACCP Level 3 provided by High-Speed training, Cert. 1378358 dated 26/01/23.
- Employee SM (Technical Engineer): HACCP Level 3 provided by High-Speed, Cert. 2669959 dated 25/10/21.
- Employee AB (Production Operative): HACCP Level 2 provided by High-Speed training, dated 24/01/23.
- Internal Audit Training – Employee TL – dated 29/04/2021 – completed by Advanced Food Safety.
- Employee MZ (machine operative) – SOP10 – Production Control dated 04/07/22, SOP24 Traceability trained 30/01/22, Food Safety & GMP training dated 05/01/2022 – provided by Technik – 72% with a 70% pass level.
- Employee JP (supply chain team member) – SOP02 – Print Order New Design trained 28/02/23, SOP20 Trial Procedure trained 03/04/23, Basic Food Safety & Hygiene – provided by Vernor Wheelock dated 15/07/20.

Training records were found to be sufficiently detailed and included the name, confirmation of attendance, date & signature of both the trainee and trainer.

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

The requirements for personal hygiene are set out in the Personal Hygiene & Jewellery Policy, which form the basis of induction & refresher training. Requirements have been subject to risk assessment within the HARM Study & stand-alone Personal Hygiene risk assessment Ref. RA-BRC6-026 dated 20/04/23, and were reviewed during the site inspection.

- QM012 Personal Hygiene & Jewellery Policy issue 6 dated 31/01/23.
- QM034 Plant Hygiene Policy & Procedure issue 7 dated 19/01/23.
- QM012.3 Hand Washing Procedure issue 1 dated 20/10/20.
- Site Inspection completed 24/05/2023.
- Risk assessment - Biological Control - RA-BRC6-023 dated 20/06/22 issue 2.
- Risk Assessment - Personal Hygiene - RA-BRC6-026 dated 20/04/23 issue 2.
- HARM Plan 002, issue 2 – last reviewed 14/03/22.

Information relating to the wearing of jewellery (plain ring/medical alert) was seen detailed within the Personal Hygiene Policy, as was guidance on fingernails & the wearing of perfumes or aftershaves, which are forbidden. Eating and drinking is only permitted in the canteen, Food seen stored in the canteen fridge was covered.

Hygiene Information is displayed on entry notice at reception and prior to site entry. All staff, visitors & contractors are required to wash their hands prior to entering the production area, after use of toilets, after eating or smoking, and after sneezing or coughing. Signage encouraging the washing of hands was seen at the entrance to production/reception and in the toilets. Hand washing products were found to be unscented, and hot water is available. No evidence was viewed of personal possessions being stored inappropriately throughout the audit and guidance on their storage is contained within the Personal Hygiene Policy. The company do not allow medicines to be taken into the production area. Visitors are assessed on a case-by-case basis and required to complete Health Questionnaire via iPad.

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- QM020 Visitor & Contractor Policy issue 5 dated 12/05/23
- QM020.1 Visitor / Contractor Hygiene & Safety Regulations issue 4 dated 27/04/21.

Wound dressings were seen to be blue in colour and controlled by First Aiders. Dressings are logged using form QM018.1, which records the item issued, issued to, issued by, reason, date, time, disposed of time, still intact upon leaving & initial/signature.

- QM018 Plaster Issue & Control Policy issue 4 dated 09/09/20.
- QM018.1 Plaster Issue Record issue 3 dated 09/09/20 – last issue dated 09/05/23 at 09:46 – issued to RC by RC – polaster No. RS1 – disposed of at home – verified by TL.

Site inspections are completed at monthly intervals, covering offices, toilets, changing area/lockers, processing & packing area, storage area, canteen, racking & exterior. Issues are logged on each checklist detailed below, and the auditor notifies the process owner. Close-out is recorded using the same system, with verification of effectiveness of actions taken verified by the auditor.

- SOP023 - GMP Inspection Procedure – 002 dated 28/03/23
- Quarterly Hygiene Audit: completed 27/04/23 by AB
Covering: offices, toilets, changing area, processing & packing area, storage area, canteen, exterior area
Issues: None
Status: closed

6.3 Staff facilities

Locker rooms are located close to the main entrance on the ground floor and can be accessed without entering the designated production zone. Two lockers have been provided for each employee involved in production for personal belongings, and separate clean protective clothing lockers are provided. Clean and dirty clothes were observed segregated and a separate locker/bin is located outside the locker rooms. There is controlled electronic fob employee access to the site.

The company policy is to prohibit the eating of food/confectionary, smoking & drinking across all areas of production and storage, including the locker area, and no evidence was seen that this policy was being flouted during the site inspection. No evidence was seen of items being inappropriately stored in lockers.

Smoking of cigarettes & vape devices is allowed at a designated outside location, which was observed clean & tidy, with suitable provision made for smoker's waste.

Suitable & sufficient hand washing facilities have been provided within all toilets & at the entrance to production, including appropriate signage to encourage correct employee behaviour, sufficient hot water and unscented soap, with paper towels provided.

The drinking of water is not permitted in production & storage areas, a canteen has been provided including a fridge, where all food was seen to be effectively sealed, with temperature of the fridge monitored and cleared out weekly.

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- Risk Assessment - Staff Facilities - RA-BRC6-026 dated 20/04/23 issue 2.
- QM038 Staff Facilities Policy issue 5 dated 25/05/22.
- QM038.1 Temperature Monitoring Record issue 1 dated 10/08/20.
- Site Inspection completed 24/05/2023.

6.4 Medical screening

Visitors must complete an electronic health questionnaire upon entry to the site. In the event of absence, employees attend a return-to-work interview with their direct line manager and complete a Return To Work from Sickness form. The Medical Policy & Return To Work procedure is trained out during new employee induction training. All personnel must report if they have been in contact with any infections, diseases etc.

- Risk Assessment - Medical Screening - RA-BRC6-033 dated 16/06/22 issue 2.
- QM020 Visitor & Contractor Policy issue 5 dated 12/05/23.
- QM020.1 Visitor / Contractor Hygiene & Safety Regulations issue 4 dated 27/04/21.
- QM019 Metal Control Policy issue 3 dated 30/0/22.
- QM012.2 Medical Screen Questionnaire issue 4 dated 31/01/23.
- QM012.1 Return to Work Interview Form issue 3 dated 30/08/22.

6.5 Protective clothing

The wearing of company supplied workwear is specified and communicated at induction, including polo shirts, trousers, safety shoes, hairnets & snoods. Clothing is permitted to be worn between all departments and personnel change into issued workwear upon arriving at the site. Company workwear is washed under contract by an external workwear provider - Ellis, and is monitored via site GMP Inspection. Garments are changed daily & washed weekly. There is a Procedure detailing the order in which work wear is to be put on. Site protective clothing covers the upper torso and does not contain external pockets or sewn on buttons. There are lockers provided for the storage of workwear for each employee, including effective segregation of workwear, with clean and dirty clothing seen segregated. Gloves are provided for certain tasks, they are controlled by means of QM016 - Glove Policy (blue nitrile).

- Ellis Laundry supplier questionnaire dated 03/04/23.
- Risk Assessment - Protective Clothing – Workwear - RA-BRC6-034 dated 16.06.22 issue 2.
- QM013 Workwear Policy issue 3 dated 20/10/20.
- QM016 Glove Policy issue 3 dated 20/10/20.
- QM013.1 PPE/Workwear Issue Form issue 3 dated 31/01/23.
- Site Inspection completed 24/05/2023.

Non-applicable clauses

6.3.10 – Drinking is not permitted in production or storage areas
6.5.8 – there is no home laundry

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Requirements for traded products	
7.1	Approval and performance monitoring of manufacturers/packers of traded packaging products
Not applicable	
7.2	Specifications
Not applicable	
7.3	Product inspection and laboratory testing
Not applicable	
7.4	Product legality
Not applicable	
7.5	Traceability
Not applicable	
Non-applicable clauses	Not applicable

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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

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Non-applicable
clauses

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