



Audit Report
Global Standard Packaging Materials Issue 6: August 2019

1.Audit summary						
Company name	Film and Foil Solutions Limited BRCGS site code 7725375					
Site name	Haydock	Haydock				
Scope of audit	Perforation, macro punching, folding, slitting and rewinding (Outsourced print process) of OPP, BOPP and PET to produce film on reels. The slitting and rewinding of Kraft paper onto reels for food, consumer and retail products (North building). All products (Contact and non-contact)					
Scope exclusions	OPP, BOPP and PET reeled film (Wet Gloss, Thermal Gloss, Wet Matt, Thermal Matt, Wet Silk, Thermal Silk, Wet Anti-Scuff, Thermal Anti-Scuff, Wet Temptation, Thermal Temptation) at Bauer Warehouse					
Justification for exclusion	Differentiated by supplier branded outer packaging, manufacturing process (Log splitting) and processed and stored in Bauer warehouse					
Start date	2024-01-22 Finish date 2024-01-23					
Re-audit due date	2025-02-11 Previous audit date 2023-01-17					

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	2025-03-24		
Number of non-conformiti	es	Major against S	OI of Fundamental	0		
Critical			0			
Major			0			
		Minor		1		

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3.Company deta	3.Company details				
Address	North Building North Florida Road Haydock WA11 9UB				
Country	United Kingdom	Telephone	44 01942 727151		
Commercial representative Name	Paul Rice	Email	Paul.rice@filmfoil.com		
Technical representative Name	Steven Walsh	Email	steven@filmfoil.com		

4.Company prof	file					
Plant size (square metres)	<10K sq.m	No. of employees	1-50	No. HARA Plans	1-3	
Subcontracted ad	ctivities	No				
Outsourced proc	esses	Yes				
Other certificates	held	None				
Regions exported to None Choose an item. Choose an item. Choose an item. Choose an item.						
Major changes of observations sind audit		Since the last evaluation there have been no changes at the site				
Company descrip	The site is part of Coral Products PLC group The site was originally set up to provide over winding film tape for the electrical component industry before expanding into the food and consumer sectors. There is a dedicated and experienced Management Team at site, at this is reflected by the ongoing success and development of the plan The nature of the business is the perforation, slitting folding and rewinding of a range of purchased films for food, consumer and retain		e food and am at site, and ent of the plant. ding and			

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4. Company profile

products customers on 8 slitting machines, 2 with hot needle perforation unit and one with a punch unit 2 centre fold machines,& core cutter The process of printing is outsourced to a third-party company. The site infrastructure is adequately maintained and suitable for the products manufactured at the site, some products come into direct food contact. To this end, the site has been audited and approved for supply to Tesco.

The site is 3,147m² in total North Building 1036m² North Extension 260m² South building 741m² Keedwell 1110m²

There are 24 employees working a 2-shift system with 9 on site at any one time.

The site also operate an additional warehouse (Bauer (4 miles away) where industrial film is split, but this is outside the scope of the audit The company has developed procedures and systems that are in compliance to meet the requirements of the BRCGS issue 6 Packaging Materials

5.Product and process characteristics	
Manufacturing Categories	02 - Papermaking 05 - Flexible plastics Please select Please select Please select Please select
Products in production at the time of the audit	Slitting, punching, & rewinding of plain & printed BOPP films

6.Audit duration details				
Total audit duration	12 hours	Duration of production facility inspection	4 hours	
Reasons for deviation	Compliant with P606			
Next audit type selected	Announced	Announced		

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Audit Duration per day					
Audit Day	Date	Start Time	Finish time		
1	2024-01-22	08:00	12:00		
2	2024-01-23	08:00	16:00		

Auditor information				
Auditor number	Auditor Name	Role		
20349	Cameron Keith	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

N. /1.1. T		0:: 1		
Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Bob Jenkins, Site Director	On-site	On-site	On-site	On-site
Paul Rice, Finance & Commercial Director			On-site	
Jason Butler Production Manager	On-site	On-site	On-site	On-site
Steven Walsh, Quality Manager	On-site	On-site	On-site	On-site
Andrew Goodyear, Machine Operator		On-site		
Mark Helsby, Machine Operator		On-site		
Colin Forber, Despatch		On-site		

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GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced
2022-02-03	BRCGS Packaging issue 6	Announced
2023-01-17	BRCGS Packaging issue 6	Announced

Document control					
CB Report number	UK/BRC/505				
Template Name	P609 Packagin	P609 Packaging Materials Audit Report Template v11			
Standard Issue	6	6		ate issue date	2022-02-15
Directory allocation	PackMat	Vers	sion	1.0	

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Non-Conformity Summary Sheet

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

Critical					
Re-audit date					

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

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Mino	or						
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	6.2.3	Unauthorised personal mobile phone noted on work station in production slitting dept	Andy Goodyear has been retrained in the personal hygiene procedure doc 6.1.1 iss 3 and paragraph 2 in particular has been reaffirmed. Document resigned understood by A. Goodyear	To Prevent re-occurrence all staff have been retrained in the rule that mobile phones shall not be taken into Production without Management permission. Doc NC 01 Memo attached showing staff signatures to show agreement.	A. Goodyear was aware of the rule and had taken it into production against his training and signage. The signage was clear, and Andy was aware of the rule. He chose to disregard it.	2024-01-26	C Keith

Comments on non-conformities

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Additional Modules/Head Office Non-Conformity Summary Sheet

Critical Cri				
No	Clause	Detail	Re-audit date	

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

Minc	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

The company has established a Product Safety, Quality Management Policy which includes a commitment to produce safe & legal products and also commits to a program of continuous improvement. The policy is, signed by Site Director

The policy is reviewed during the annual Management Review meeting and is communicated to all employees through notice boards and via the induction process

The company has developed a product safety and quality culture plan which has includes a continual improvement culture for product safety and product quality. The plan is reviewed 6 monthlies for the effectiveness of the implementation.

The plan consists of internal and external complaints and reviews for improvements with quality reviews with both internal personnel and external parties

Internal and external parties and how that influences the sites processes and activities

The plan is viewed as part of business reviews six monthly with senior management on an ongoing basis for its implementation and effectiveness. This includes feed-back and KPI monitoring from customers and suppliers, employee engagement and feedback. Additional training as identified for personnel; more focus on product safety objectives as part of the sites overall KPI's. Initiate a user-friendly feed-back communication system between employees and senior management

As this is a culture plan and total implementation is not instantaneous to ensure its implementation is sustainable the plan is scheduled to be fully sustainable over a three-year period Next review June 2024 {6 monthly}

The business has a business plan inclusive of objectives for the site

There are product safety, legality and quality objectives in place at the site

The site has reviewed the 2022-23 KPI's and 4 out of 5 objectives from 2022-2023 were achieved 1 failed targets

No. of complaints target 47 actual 54

Issue due to complaints not being passed from sales office to Quality dept

Customer complaints now being raised for all customer issues raised {better reporting at site}

Reduce internal quarterly inspections reduce NC's by 10% target <2 NC's per month actual 2 per month. These are being or have been addressed by the site such as incorrection information being supplied to process the orders

2023-2024 KPI's

Pass BRCGS audit min Grade A in 2024

Customer Complaints NCR reduction by target of <49 per year {previous year 54}

Reduce internal NC 's by 10% <6 per annum {previous year 7}

Maintain internal quarterly inspections at <2 NC's per month previous year 2}

The team review the system quarterly to ensure compliance to targets is being attained; this is supplemented with an annual management review.

The site has provided the necessary resources required to effectively implemented the processes of the system by employing a Consultant to ensure that the site is compliant with the required standards. Targets are communicated to Production staff via Senior Management and are monitored throughout the year and reviewed via the Management Review process. Objectives displayed on company notice boards

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There is a dedicated member of staff SW Quality Manager who has responsibility for maintaining the BRCGS Standard, with support from BJ Site Director BRCGS Deputy

There is also resource provision in the form of production personnel who are heavily involved in maintaining the BRCGS Standard, such as the production Planner and operatives. The BRCGS team are fully supported by Senior Management at site.

The site senior management provide resources for the site with investment in equipment, personnel and company infrastructure to be able to be compliant with the standard

The site ensure they are compliant and up to date with scientific and technical developments, industry codes of practice, relevant legislation applicable to country of manufacture and use of product and any changes in the standard and or protocols published by the BRCGS this is managed via Quality Manager SW.

The Company use Techni-K, & BRCGS participate, & various suppliers also supply information.

Products are compliant with UK & European legislation

produce & flow wrap for in store bakeries etc.

The company ensures materials are safe for use and has a Statement of Compliance is in place for all products produced at the site which is sent to Customers on request.

Statement of Compliance {SOC} dated 14.2.2023 rev 5 signed by B Jenkins Site Director Product specification sheets also confirm compliance and are produced for each individual product. All products are manufactured on site, sold within the EU, and conform to current legislation such as EU10 and amendments up to 2023/1442, EC1935/2004/EC, 2023/2006, 94/62/EC other packaging being of a secondary nature paper used for inter-levees for metal sheets

Suppliers Statements of Compliance also confirm the above.

Migration testing is undertaken on the raw materials by the suppliers

Majority of products at site are in direct contact with food stuffs such as the lidding films for confectionary,

There is a genuine copy of the current BRCGS Packaging Materials standard issue 6 at the site.

The audit has been carried within the required scheduled date prior to 11.2.2024 {Unannounced}

The Site Director, Quality Manager, & Production Manager were present at the opening & Closing meetings, and all relevant personnel were on site and available during the assessment.

The site holds a genuine electronic copy of the issue 6 of the BRCGS standard and utilises the BRCGS website to ensure it is kept up to date with any changes to the standard, or protocol. Including position statements

Non-conformance are created from customer complaints, external audits, second-party audits, third-party audits, internal audits and are reviewed at monthly meetings with attendees including the senior management.

Root cause analysis is evident in the closure of the reports both internally and external issues. There were 5 minor N/C's raised during previous audit that required root cause analysis to prevent a recurrence

Root cause analysis is used by the site as required to determine the corrective and preventive actions to be implemented for any customer complaints, internal NC, or third-party audit findings.

The site uses the BRCGS Logos on company stationary

Product Safety, Quality Management Policy dated 6.6.2023 signed by Site Director Bob Jenkins Product safety and QMS policy signed briefing document for training on policy by SW

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Quality Culture Procedure plan
Quality Culture review minutes 22.12.2023
Management Review Meeting minutes 2.6.2023
Company objectives 2023- 2024
Site Statement of Compliance {SOC} dated 14.2.2023 rev 5 signed by B Jenkins Site Director
Copy of Current issue 6 standard
Position statement P618 v4

1.2 Management review

There is an annual Management Review Meeting undertaken at the site.

Present at the meeting were senior members of the Senior Management Team

Sales & Marketing Director Tony Quazi

Site Director Bob Jenkins

Finance Director Paul Rice

Quality Manager Steven Walsh

Production Manager Jason Butler

Colin Forber Logistics Team Leader

The minutes were reviewed during the assessment and the agenda items were found to meet the requirements of the standard and included: -

Previous management review and action plans – time frames

Results of internal and external audits

Customer performance indicators complaints and feedback

Effectiveness of root cause analysis and corrective actions implemented

Review effectiveness of HARM – risk management system and prerequisites

Impact on legislation and certification scheme changes

Incidents, corrective actions, out of specification results and NC materials

Resource requirements

incidents, root cause and corrective actions for non- conformances

Review targets of set objectives – KPI's & reasons why objectives have not been met to understand the root cause and use the findings to set the future years objectives and assist with continual improvements at site Effectiveness of the Product Defence and product fraud prevention plans.

Detailed report produced including the data reviewed.

Any actions are addressed with responsibility and due dates assigned.

Minutes are circulated to all attendees with action points allocated to designated personnel.

The review process reviews objectives and re-defines them where necessary.

Site issues are resolved via the Control of Non-conforming Product procedure.

Any issues of product safety, legality or quality will be brought to the attention of the dept manager who can escalate any issue to the Production Manager Site Director or Quality Manager for resolution

Evidence

Management Review Meeting minutes 2.6.2023

Incident reporting procedure 3.1.3 issue 2 dated 1.9.2020

1.3 Organisational structure, responsibilities, and management authority

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Organisational structure Shows organisational structure and reporting lines on site with clearly allocated responsibilities for the management of activities to ensure product safety, quality, and legality is clearly conveyed and understood by the managers responsible.

There are allocated and documented deputies for key roles in the business

The roles and responsibilities are documented for each position to ensure quality, product safety and legality is maintained with deputies assigned to the role

Organisational structure

Managing Director Ian Hillman

Site Director Bob Jenkins

Finance Director Paul Rice

Sales & Marketing Director Tony Quazi

Quality Manager Steven Walsh

Production Manager Jason Butler

Colin Forber Logistics Team Leader

Production Planner Jake Stuart

Machine Operatives

Logistic Operators

Work instructions are documented for operations and the training system process at site is linked to job functions and descriptions.

System Designated Manager for the BRCGS is SW Quality Manager.

SW Quality Manager HACCP training via Effective Control Keith Ogden 1.5.2018 Cert No. 1054 (5-18)

Steve is supported, and in his absence deputised by Bob Jenkins Site Director BRCGS deputy

Bob Jenkins CIEH HACCP training 9.9.2004 Cert No. 495875

Organisation chart shows designated deputies to define who can make decisions on product safety, legality, and quality.

All personnel are made aware of their responsibilities by receiving an induction course which is followed by job specific on-the-job training, work instructions and procedures are available at the point of use.

Roles and responsibilities are documented for each position listed on the organisational chart with deputies assigned to ensure quality, product safety and legality is maintained

Dept managers deputises for each other

Production Support Manager & Production Planner deputise for each other

There are job descriptions in place

There are work instructions in place for the operations carried out at site detailing employee responsibilities {readily available to operators}.

Job description include quality and product safety requirements

Evidence

Viewed job descriptions for Jason Butler Production Manager

Organisation Chart issue 6 dated 11.2.2023

Work instructions 5.4.1 issue 4 slitting and perforation process control

SOP73 blade changing instructions

Non-applicable clauses

None

2. Hazard and risk management

2.1 Hazard and risk management team

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The Hazard & Risk Analysis Team consists of multi skilled personnel that have responsibilities covering Technical, engineering/ maintenance, production operations and customer services

HARM Team Leader is Steven Walsh Quality Manager.

HARM Team Deputy is Bob Jenkins Site Director (also looks after maintenance)

Kay Halliwell production Operative

Paul Rice Finance Director

Jake Stuart Planning Supervisor

Keith Ogden Effective Control Ltd Company Consultant

It is the sites responsibility to maintain the day to day management of the system

Consultant KO ECL & Quality Manager advises team members re updates in requirements via a team

approach with minimum annual management meeting. Day to day updates to ensure any changes to manufacturing / customer requirements are always attained. Team have extensive knowledge of industry.

The other team member provides input and information for the team to evaluate

The members of the team have undertaken HARA awareness training and certificates / training records are on file.

The team are kept updated by any changes in the factory through daily and weekly meetings which cover customer requirements and during the management review meetings

HARM review meetings and providing and any training as required.

Evident

HARM training records

Steven Walsh Quality Manager HACCP training via consultant K Ogden 1.5.2018 Cert on file Bob Jenkins internal HACCP training via S Walsh Quality Manager 15.6.2022 Cert on file Bob Jenkins CIEH HACCP training 9.9.2004 Cert No. 495875

Colin Forber Logistics Team Leader internal HACCP training via S Walsh Quality Manager 9-10.5.2023 Cert on file

Liam Whittle Production Operative internal HACCP training via S Walsh Quality Manager 9-10.5.2023 Cert on file

Paul Rice Finance Director HACCP training via consultant K Ogden 24-25..6.2015 Cert on file Jason Butler Production Manager internal HACCP training via S Walsh Quality Manager 10-11.5.2022 Cert on file

Consultant K Ogden Effective Control Ltd BRCGS Registered Consultant Advanced Food Hygiene CIEH HACCP Cert No. 03775 9.9.1993

2.2 Hazard analysis and risk assessment

There is a documented Hazard and Risk Analysis in place at the site that identifies hazards relating to product safety and legality with controls established and put into place to manage the hazards, by either elimination, or reduction of the hazard to an acceptable level

The scope of the study is addressed in the section "Terms of Reference" and includes all stages of site operations and traded goods from raw material receipt, operational processes of sealing slitting- rewinding, boxing, to delivery of finished goods to the customer covering, quality, product safety and legality requirements.

The Hazard & Risk Management team have many years' experience in manufacturing & conversion of flexible films for food packaging with knowledge of

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Historical known and foreseeable hazards that nay have an impact on product safety with specific processes and raw materials

legislative requirements

industry technical developments, production equipment constraints,

Relevant codes of practice

Intended use of the product (if known by the company)

Industry known quality defects that could affect quality or product safety and customer requirements.

Relevant legislation is listed EC1935/2004; EC2023/2006 & EU10/2011 and amendments to 2020/1245. Products are both decorated and plain packaging products for Film is used as direct food contact packaging, as packaging for contact food packaging products & non-food contact products

There are composition details in the study i.e. raw materials including OPP, BOPP, PET films, and kraft papers

The process flow shows the following process steps

Receipt of Product specification

Receipt of artworks from customer (no printing on site) Out sourced

Raw materials receipt {No additives of inks or adhesives}

Raw material storage

Slitting, perforating punching, folding, and rewinding

Out sourcing of printing

Line Clearance

In Process inspection

Pallet wrapping

Storage of finished goods

Despatch

Customer Returns

The flow chart is reviewed at least annually or if a significant issue – incident arises and any deviation to the current process

The analysis is inclusive of

Microbiological Hazards

Chemical contamination Taint and odour, Component transfer, Allergens (No inks varnishes or adhesives) Virgin & recycled materials in use as per customer specification

Unintended migration of substances from the packaging materials or other hygiene sensitive product Defects that effect functional integrity

Defects critical to consumer safety

Foreseeable misuse by the customer {single use only products as detailed in sale contract of items} Foreign objects {Physical contamination}

Potential for Malicious intervention {site security & product defence risk assessment}

Food fraud or substitution {product vulnerability risk assessment}

There is no functionality claims for the packaging produced at the site

The HARA system in place is managed by Prerequisite programmes that effectively reduce or eliminate each product safety hazard to an acceptable limit

There are no CCPs identified in the study

Prerequisites are inclusive of

Personal Hygiene

Environmental Hygiene

Integrity of Plant & Equipment

Control of NC Materials

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Glass / Brittle Plastics Contamination Control

Storage

Building Fabric & Equipment Maintenance

Pest Control

Process Quality Control Procedures

Potential for Malicious intervention {site security & product defence

Potential for product fraud - material substitution (product vulnerability

Hazards are assessed for each step in the process considering all required sources, including potential for migration of substances from the packaging into the product.

Control measures are documented. Risk for likelihood (1-3) and severity (1-3) are assessed and risk rating is calculated to categorise the risks

Risk rating 1-3 = Low {Prerequisite managed}

Risk rating 4-6 = Medium {QMS procedural controls as appropriate }

Risk rating 7-9 = High risk put through Codex Alimentarius decision tree to establish if CCP, Establish and implement additional controls to effectively manage hazard

Highest rating identified being a risk rating of <3 in the study "Low risk" hazard

Any product found to be outside of the specification requirements is controlled via the NC product procedure inclusive of corrective actions to be taken Including quarantining of the product to prevent their goods being released until their specification parameters relating to quality, product safety and legality have been established

The company have operating documents that manage the pre-requisite requirements. The prerequisite programmes are monitored via the internal audit programme in place at site.

The study is reviewed as a minimum annually or on changes to process, product composition change, product failures and finished product recalls from consumers (including system tests), complaints, product recall or withdrawal, any failure identified from the review of the prerequisite controls, results from internal or external audit findings, or prerequisites identifying a deficiency, and any new industry developments that have a potential impact associated with materials process or product

No product withdrawals or recalls since the last BRCGS audit

Evidence

HARA study issue 8 dated 2.6.2023

HARA review 2.6.2023

Internal audit schedule 2023 - 2024

Site standards internal audit report including prerequisites 5.12. 2023

Production operations internal audit report including prerequisites 22.6.2021

Malicious intervention and product defence - site security risk assessment reviewed 2.6.2023 Product defence & Product Fraud- vulnerability risk assessment reviewed 2.6.2023

Product Defence plan reviewed 2.6.2023

Non-applicable

2.2.9 No CCP's clauses 2.2.10 No CCP's

2.2.11 No CCPs

3. Product safety and quality management

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3.1 Product safety and quality management system

There is a fully implemented Product Safety and Quality Management system in place designed to meet the BRCGS Standard for Packaging Materials Issue 6 requirements.

The system is logical, addresses the clauses of the BRCGS standard, is fully implemented and incorporates the HARM study. The QMS is updated and maintained by the Quality Manager

Docs are easily navigable on the system

The system is in hard copy & electronic format and is accessible to all key personnel on site. Individual Policies, Procedures, and work Instructions are in place that support the system.

The system is in English, there are other nationalities at site, but all speak and write fluent English.

The effectiveness of the system is reviewed during the annual Management Review Meetings and opportunities for improvement are implemented, as necessary.

The system is also reviewed when any changes to the company's processes or procedures occur, changes to the standard and is subject to internal audits.

Master copies of documents are maintained in hardcopy for site personnel and also in electronic format and backed up daily to prevent loss or malicious intervention

The BRCGS representative and Site Director have the only access to change documentation within the QMS system. The system is constantly updated to reflect the requirements of BRCGS issue 6 for packaging materials

Evidence

Quality Management System on Company drive addressing Quality, Product Safety, and Legality requirements.

Document Control Register

Management review meeting minutes dated 2.6.2023

3.2 Document control

There is a detailed document control procedure in place at the site that manages documents that are part of the sites product safety and quality management system.

Master documents are maintained in hard copy and also in soft copy the on the site server

Documents are assigned a unique document reference, issue letter, and date of issue.

Authorised documents are assessable by the Quality Manager & consultant.

Quality Manager removes obsolete hard copy documents and replaces with new versions as required Old version electronic documents are archived

An amendment record is maintained at the end of each document and the change recorded Master copies of documents are maintained in hardcopy for site personnel

Electronic format documents and records are backed up daily to prevent loss or malicious intervention to Google Drive off site server by the site's IT department

Evidence

Document Control Procedure 3.2, Issue 2, dated 13.7.2020 Document Master List 3.6, Issue 2 dated 5.1.2021

3.3 Record keeping

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There is a record control procedure in place at the site

Records pertaining to product safety, quality and legality are well maintained on site, legible, readily available, and retrievable, this was verified as part of the vertical audit and during site tour and admin records cross checks carried out

In the event of a record requiring an alteration the change is authorised with initials by the person making the alteration. Alterations can only be made by departmental managers or other senior managers on site.

Records reviewed
Customer purchase order
Customer invoice
Works order
Raw material purchase order
Receipt inspection
Product quality checks
Picking list
Vehicle inspection
Delivery Note
Audits
Customer Complaints
Pest control records
Cleaning records

Access is restricted to electronic records with password controls in place.

The site maintains a table listing the various records used on site.

Records are retained for minimum 3 years which relates to the useable life of products as used by their customers.

Some hard copy documents are scanned and archived after 12 months such as Quality production documents and housekeeping inspection records and retained indefinitely

{electronic records are backed up to onsite and off-site servers to prevent loss and malicious intervention and retained indefinitely} by the site.

Evidence

Record Keeping Procedure 3.3, Issue 2, dated 13.7.2020

Viewed various quality, production, cleaning, delivery purchasing records as part of vertical audit and during tour of the site

3.4 Specifications

Raw material, and finished goods specifications are held on file as part of the supplier approval and assessment programme at site.

Product specs are maintained on the sites MIS system and created as part of the new product development system. The system requires password protected login and it has a server backup.

Product Specifications are reviewed as part of the sales order process with material specs reviewed as part of the ongoing supplier assessment process.

Approved specifications are received from customers for the site to manufacture

Raw material specification & food contact information were reviewed as part of audit

No manufacturers trademarks are applied to the packaging, only printed graphics as per customer approved artwork

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The order processing procedure entails conducting a specification review on each order by sales staff. All changes or amendments to existing specifications are reviewed by Sales, Production and technical departments for consideration and possible implications and all must be approved

There is a site declaration of compliance for food packaging products supplied

Site SOC stating nature of materials used type and manufacturer in the packaging supplied, details virgin material currently no PCR materials in the packaging specification, date of issue 15.2.2022, any limitations of use, useable life of packaging as applicable if relevant, legislation compliance with EC1935/2004; EC2023/2006, EC/94/62, & EU10/2011 and amendments to 2023/1442

Example Specification Product Item No. FF182 v4 Job No. 14882

Customer Baker & Baker

Description 750mm x 2400m 25µm OPP for punching 3 lane punching 8mm holes 100mm between holes Slit from master reel 1520mm

No PCR material used in the product

The document has no expiry date {Not appropriate}

The document has no reference to useable life of the packaging {Not relevant}

Specification approved 13.4.2023 for suitability by customer

The specifications have relevant legislation information as per individual item

Specifications are sent to customers for approval by email

The site SOC as a minimum is reviewed annually or sooner if composition change occurs or legislation changes

Specifications are reviewed for each order as part of the sales order process with customers.

Order Acknowledgement are sent to customers that details any requested changes.

Any changes in specifications are agreed with customers documented and communicated to relevant site personnel

Specifications are backed up to off site server to prevent loss and malicious intervention

Evidence

Viewed product specifications maintained on the sites MIS system

Viewed spec for Westpak

Spec No. item code FF182 v4 {Film with punched 8mm holes 100mm between holes on reel } Raw material BOPP code 25AMBOPP345

Raw material specification

Specification for BOPP material HHT 18-40µm supplied by Nahar poly Films {Spec sheet confirms suitable for direct contact food use}

Spec dated 10.3.2022

SOC for material 15.9.2022

Site SOC dated 14.2.2023 rev 5 signed by B Jenkins Site Director stating nature of materials used type and manufacturer in the packaging supplied, details virgin material currently no PCR materials in the packaging specification, date of issue 14.2.2023, any limitations of use, useable life of packaging as applicable if relevant, legislation compliance with EC1935/2004; EC2023/2006, EC/94/62, & EU10/2011 and amendments to 2023/1442

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3.5 Internal audits

There is a documented schedule of internal audits at the site for 2023-2024

The schedule covers all site activities and risks associated with the process and has considered previous audit performance and all processes are audited as a minimum annually

There is Corrective action tracker in place showing responsibility, issues logged actions tracked and completed on time.

Procedures are in place that are required to implement the standard and any applicable modules The internal audits have a defined scope for the activity & sections of the HARA food safety plan

The schedule is fully audited minimum once per annum

The schedule covers the HARA product safety plan

Supplier approvals, Corrective actions, and verifications

Prerequisite programmes

Product defence and product fraud plans {Product authenticity claims and chain of custody}

The audits cover product defence and product vulnerability - fraud plans, suppliers review and deficiencies, machinery cleaning, corrective actions, and verifications

Internal audits are carried out by competent personnel that are independent of the activity or process being audited

The internal audits identify conformance as well as non-conformity as found

Root cause analysis is utilised to resolve any NC raised and the Quality Manager is the responsible person to ensure any identified corrective and preventative measures are implemented

Site hygiene standard audits conducted monthly that include cleaning and housekeeping performance {The frequency has been based on risk}

Site building standards audits conducted monthly with consideration for risks identified from the building condition or equipment condition {The frequency has been based on risk}

Internal audit procedure issue 3 dated 28.8.2020 Internal audit schedule 2023- 2024

Trained internal auditors

Steven Walsh internal audit training via KO Effective Control Ltd 2019 Jake Stuart internal audit training via KO Effective Control Ltd 2019 B Jenkins Internal audit training via SGS 25th Nov 2008 Course No. A17283

Internal audits viewed

Pest Control audit dated 5.12.2023 Conducted by SW Quality Manager 0 NC's raised

Good practice referenced in audit

Production audit dated 26.1.2023 Conducted by SW Quality Manager

2 minor NC's raised relating to signatures on paperwork not completed (operatives briefed at time of audit)

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Job for W/O 11336 reviewed Good practice referenced in audit

Sharps audit dated 5.12.2023 Conducted by SW Quality Manager No NCR's raised Good practice referenced in audit

Internal audits audit dated 7.6.2023 Conducted by BJ Site Director No NCR's raised Good practice referenced in audit

Glass – Brittle plastics audit dated 5.12.2023 Audit carried out by SW no issues raised

G&BP Inspections carried out quarterly seen inspections 6.12.2023 & 5.4.2024 in production depts and Keedwell Warehouse

Hygiene audit 5.12.2023 by SW 3 minor NC's raised

1 relating to blades left on workbench

2 relating to paint on floor peeling

The issues have been rectified and closed out December 2023

3.6 Corrective and preventive action

The site has procedures for implementing - completing root cause analysis and corrective actions to determine preventative measures to prevent a recurrence of the non-conformity and implement ongoing improvements at the site

Non-Conformance reporting uses 5Y & Fishbone root cause analysis techniques with corrective and preventative measures applied as applicable to the complaint

There are systems in place to identify any significant trends in non-conformities at the site

The site has not had any non- conformities raised that put the safety, legality integrity or quality of the product at risk

There have been no product withdrawals to assess

Results of internal audits, and $2^{nd} - 3^{rd}$ party audits have raised NCR's for root cause analysis to be applied.

The site implements RCA to internal issues and external customer complaints, dependent on the nature of the issue raised and the severity of the complaint

The site has no inline test equipment

In the event of any RCA being utilised the measures implemented are reviewed for effectiveness by the production management and quality dept {This would also be included as topic for discussion on the management review, and on the sites action tracker}

Evidence

Customer Complaint D228 dated 20.11.2023

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Issue film winding loose on reel

Complaint viewed at evaluation

Issue due to machine speed increased and the rewind tension section on the machine was not capable of retaining tension at the speed the machine was run at; equipment has since had the speed limiter re set as to the speed this machine can run at

Complaint closed out 4.12.2023 by SW

Control of Non-Conforming product procedure 5.7 Issue 2 date 23.11.2020

Corrective Action - root cause analysis procedure 3.6 issue 1 dated 1.9.2020

Root Cause Analysis 5 Why Analysis system in place

Management review meeting minutes 2.6.2023 ref root cause analysis implementation and effectiveness

Product Withdrawal & Recall Procedure 3.12 Issue 3 dated 1.9.2020

Incident reporting procedure 3.13 issue 1 dated 1.9.2020

3.7 Supplier approval and performance monitoring

There is a documented supplier approval and appraisal procedure with on- going monitoring assessment programme at the site based on risk

The process covers materials and any outsourced process as applicable

There are currently no subcontracted production processes by the site

There is outsourcing of printing to a BRCGS certificated site

The suppliers to site have BRCGS Certification for the materials they supply, and the site confirm the certification is valid using the BRCGS web site

There is an approved up-to date supplier register in place at the site on the sites MIS system and is accessible to the senior management team at site

Key materials have supporting food contact documentation on file. Key materials conform to EU legislation requirements.

Suppliers are performance monitored by the site and discussed at the management review meeting and reviewed with questionnaire as a minimum 3 yearly

The suppliers being BRCGS certificated have traceability processes in place

Main suppliers are long standing established international suppliers with good supply history.

Purchase orders for approved suppliers only.

Details of specification for materials on file or available from supplier's web site.

The procedure in place takes into consideration for in the event of a supplier not being BRCGS certificated an exemption may be granted by the Site Director

On the basis

Certificate of analysis

Statement of compliance

Trail order

Enhanced vigilance and product checking

Company looking to attain certification to the BRCGS standard

Evidence

Supplier Approval Procedure 3.7 issue 2 dated 29.7.2020

Approved Supplier's Register data base on MIS system

Supplier questionnaire 3.7.1 2 issue 2 dated 22.6.2020

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Nahar Poly Films Ltd India

Questionnaire dated 24.5.2023

BRCGS Certificated by DNV Site code 10008630 Expiry 9.6.2024

Validated on BRCGS web site 13.7.2023

Statement of compliance to EC/1935/2004, EC/2023/2006, & EU10/2011 and amendments dated 15 9.2022

Alupol BOPP Film supplier

Questionnaire dated 29. 6.2023

BRCGS Certificated by TUV Rhineland Site code 1322187 Expiry 9.3.2025

Validated on BRCGS web site 23.5.2023

Statement of compliance to EC/1935/2004, EC/2023/2006, & EU10/2011 and amendments

Superfilm BOPP Film supplier

Questionnaire dated 8.6.2023

BRCGS Certificated by DQS Site code 1591560 Expiry 8.12.2024

Validated on BRCGS web site 9.12.2023

Statement of compliance to EC/1935/2004, EC/2023/2006, & EU10/2011 and amendments

West Coast Corrugated box supplier

Questionnaire dated 2.5.2023

ISO 9001:2015 Certificated via NQA cert No. 1436 Cert Expiry 1.3.2024

Traceability exercise to be carried out within 3-year cycle

Blue bag supplier Aintree Plastics LDPE

Questionnaire dated 6.6.2023

BRCGS Certificated via UK Food Certification Site code 6385113 Expiry 14.6.2024

Validated on BRCGS web site 14.6.2023

Statement of compliance to EC/1935/2004, EC/2023/2006, & EU10/2011 and amendments

3.8 Product authenticity, claims and chain of custody

The site has conducted a risk assessment for product Authenticity, claims & Chain of Custody

The assessment has considered

Historical evidence of substitution

Potential substitution making it more economical and potentially more profitable

Purchasing from approved suppliers [limit access to gain access to potentially substitute products within supply chain}

Prevent sale of products to food companies that might lead to the sale of products unfit for human consumption

Prevent sales of product within the supply chain from unknown source of origin {nature of product} Prevent sales of counterfeit product with unknown provenance {Prevention of substitution by testing of materials from supply source upstream by manufacturers}

Risk of brand abuse by incorrect disposal of waste product

The materials supplied have migration test information for suitability even though there is no know history of substitution Materials are compliant with EU legislation

The plan is under constant review by the site to reflect any changes that may have an impact such as changing economic factors or market intelligence that raises the risk of product vulnerability Evidence

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HARA study issue 8 dated 2.6.2023

Product defence & Product Fraud- vulnerability risk assessment reviewed 2.6.2023 Product Defence plan 2.6.2023

3.9 Management of subcontracted activities and outsourced processes

The site does not subcontract any of its production process They do however outsource printing to BRCGS certificated companies as they don't have the facility inhouse. Customers are aware the site has no printing capability at site

In the event the site subcontracted any production process operations it would be conveyed to the customer being supplied it was a subcontracted process.

The company purchasing the product has the responsibility to inform the brand owner as the site has no direct contact with the brand owners.

There are currently no subcontracted processes in place

If this changed traceability would include the subcontracted section of the process

There is no decoration of products at site outsourced operation

If the site moved to subcontracting any section of the process the final release of products would be the responsibility of the site and not the subcontractor to ensure product safety quality and legality have been upheld and not compromised.

If subcontractors were used in the production process going forward.

The subcontractor would need to be BRCGS certificated

Traceability would be challenged as part of the BRCGS evaluation process

Evidence

Supplier Approval Procedure 3.7 issue 2 dated 29.7.2020 covers supplier evaluation and continual monitoring Approved Supplier's Register data base on MIS system Supplier guestionnaire 3.7.1 2 issue 2 dated 22.6.2020

Webflex print supplier

Questionnaire dated 24.5.2023

BRCGS Certificated by QAIC Site code 6051053 Expiry 29.1.2024

Statement of compliance to EC/1935/2004, EC/2023/2006, & EU10/2011 and amendments

Tipografic Print supplier

Questionnaire dated 25.5.2023

BRCGS Certificated by QAIC Site code 1720341 Expiry 27.3.2024

Statement of compliance to EC/1935/2004, EC/2023/2006, & EU10/2011 and amendments

3.10 Management of suppliers of services

Purchasing and goods reciept procedure also covers service suppliers, evaluation and continual monitoring

The vendor assessment SLA's considers service suppliers legality, suppliers' ability re compliance to service provision being provided, potential risks to product safety, and product quality.

Consideration has been given to product vulnerability and product defence as per risk assessments in place

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The site has Service Level agreements in place with suppliers of key services which includes but limited co; Pest Control, transport, waste management, calibration, laboratory services, consultants for product safety – product quality, storage – dispatch activities, laundry services.

Evidence

Supplier Approval Procedure 3.7 issue 2 dated 29.7.2020 covers supplier evaluation and continual monitoring Approved Supplier's Register data base on MIS system

Supplier questionnaire 3.7.1 2 issue 2 dated 22.6.2020

Pest Control provider NWPC Itd pest Control

NWPC ltd pest Control Ltd are members of the NPTA Membership No. 852 Exp 15.4.2024

SLA in place 8 routine 1 biologist and 4 EFK services with annual tube change

EFK CTA as appropriate based on risk.

Transport services provider

M & S Transport

RHA terms and conditions applicable

Haulier agreement doc 5.8.1 issue 2 dated 16.9.2020 signed by M Kennedy for M & S Transport dated 11.1.2023

Waste services provider
Fresco Environmental Ltd
Waste Registration No. CBDU44197 expiry 21.10.2024

Calibration services provider
Accurate weigh Company
EWS Scales
Location production hall centre fold machine
Model Junior
Site No. of scales No.5
Capacity 100kg / 0.05Kg
Serial No. 1145346

Calibrated 21.12.2023 to National standards Cert No.JH/10011/23

3.11 Traceability

There is a documented traceability procedure in place that can trace raw materials back and forward of the supply chain Covering Process Control, Identification & Traceability.

Each order placed is assigned a unique Job Number. Orders are placed against the unique Job description (customer code / description is used). Documents relevant to each job are kept in the Job bag providing traceability to raw material batches, quality, and production records.

The Job Number is used for traceability and this number is shown on, boxes & pallets
The system is tested as a minimum annually for suitability forward and reverse of the supply chain

The traceability is inclusive of raw material and finished products (no intermediate products due to the process, non- conforming material, and any quarantined items from the process.

Customers can easily identify their products via labels and delivery notes. Delivery notes carry the product description, the quantity, the date of manufacture Customer name.

Traceability tests are undertaken and documented annually as a minimum.

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There is no reworking of products at site any out of specification material is scrapped and removed by waste contractor

The testing of material is traceable to batch lots and retained by the site for inspection as requested

The site has conducted traceability exercises forward, reverse, product withdrawal trace exercises the timings were recorded and completed within a 4 hrs window

Evidence

Traceability procedure 3.9 issue 3 dated 10.9.2021

Forward & reverse trace exercise 16.6.2023 (in conjunction with product mock withdrawal exercise)

2 reel of material that had a potential contamination issue mock sinario

Material used

Customer Countrystyle Foods Customer PO No. 167897

Site Sales O/No. 5928

W/O 13666

Material print outsourced to Webflex (Site Po No. 1633)

Print Ref PDF 6165946 V1

Site Supplied raw material to Webflex {2 reels}

Printed Material received from Webflex at site 13.6.2023 Delivery Note Ref PID No. 13179

Slit on Elite No. 1 machine 14.6.2023

Manufactured 44 reels 5312kgs

Qty delivered 28 rolls 546 Kgs

Product Delivered to customer on 15.6.2023

Delivery Note No. 8659

Remaining 16 reels were delivered to same customer on Customer PO No.168762, Site S/O No. 6029

Delivered on 16.6.2023 Delivery Note No. 8656

Raw material

Description Alupol BOPP 25um material

Product Code FFBOBOPP-25-KG

PO No of film 1591 on 12.5.2023 (Supplier Alupol)

Qty received 23 reels Goods in No. PID13114 26.5.2023

Traced 2 reels from the delivery

Roll No. 430144835/429510/2/7 & Roll No. 430144835/429510/3/4 used in W/O 13666

Material from the batch was used in other customer orders

Customer Countrystyle Foods PO No. 168762 W/O No. 13488

Customer Countrystyle Foods PO No. 169297 W/O No. 13657

Full traceability established

Customer Contact Jackie Wilson

Exercise started at 15.45pm finished 16.59pm {carried out in conjunction with prod withdrawl exercise}

Traceability was challenged during the evaluation.

Customer Paragon Ltd

Customer PO/No. NOT182485 dated 623.11.2023 {for delivery 4.12.2023}

Site Sales O/No. 6922

Description Rolls of 145mm x1500m X 50µm PET Clear material {Unprinted}

Product Item No. 50PET-ED7R1-KG

Qty ordered 5 rolls Job No. 15368

Material JBF Bahrain Film Supplier

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Material PO No. 1380
GRN No. film 13951 recieved on 26.10.2023
1 reel from delivery used
Reel No of film used 6A23A129RCR2
Slit on Elite 1 on 27.11.2023
Qty 5 rolls produced
Qty delivered 5 rolls on 1.12.2023
Delivery Note No. 9799
Haulier MS Transport
Vehicle Hygiene checks carried out prior to loading by CF
Full traceability confirmed

3.12 Complaint handling

The complaint handling procedure is defined in Non-Conformity, Preventative and Corrective action Product Procedure and fully addresses the requirements of the standard.

All complaints are recorded, investigated and evidence of effective close out is documented using root cause and corrective - preventative action.

The Customer complaint register is an excel spreadsheet on the shared drive administered by the Quality Manager.

In the event of root cause analysis being necessary for any failures identified the corrective and preventative measures implemented are reviewed for effectiveness {This is also a topic for discussion on the management review}

Non-Conformance reporting is inclusive of a requirement for 5Y root cause analysis to be carried out with corrective and preventative measures applicable

There have been 54 customer complaints at the site 2023 Customer Complaints target 2024 <49

The Quality Manager is the responsible dedicated person to investigate any complaints in conjunction with dept Managers and conducts the root cause analysis and ensures the identified corrective and preventative measures are implemented. The Quality Manager reviews the effectiveness of the implemented actions Any trends as identified are reviewed at monthly management meetings for correction and also at annual management review meeting

Evidence

Customer Complaint D228 dated 20.11.2023

Issue film winding loose on reel

Complaint viewed at evaluation

Issue due to machine speed increased and the rewind tension section on the machine was not capable of retaining tension at the speed the machine was run at; equipment has since had the speed limiter re set as to the speed this machine can run at

Complaint closed out 4.12.2023 by SW

Customer Complaint D229 dated 4.12.2023

Issue short delivery of product

Complaint viewed at evaluation with RCA and corrective measures applied

Incorrect qty of rolls put on delivery note 150 instead of 123

This customer has consecutive orders and operative selected the qty for the next order delivery 150 instead of 123

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The Logistics Supervisor is now checking random orders to reduce the potential of another wrong qty is entered on the delivery note by operatives

Customer credited for the 27 reels originally invoiced for

Complaint closed out 4.12.2023

Control of Non-Conforming product procedure 5.7 Issue 2 date 23.11.2020

Corrective Action - root Cause analysis procedure 3.6 issue 1 dated 1.9.2020

Root Cause Analysis 5 Why Analysis system in place

Management review meeting minutes 2.6.2023 ref root cause analysis implementation and effectiveness Action tracker data base showing responsibility, issues logged actions tracked and completed on time

3.13 Management of product withdrawals, and incidents and product recalls

Product Recall & withdrawal Procedures in place at the site

The procedure identifies roles and responsibilities.

Team of Site Director, Production Manager, Sales, Quality Manager

Procedure describes the process steps and responsibilities during product withdrawal.

The procedure describes the three phases of investigation, communication, and containment.

The Site Director& Sales Manager is responsible for customer contact.

The Quality Manager completes the traceability and root cause investigation in conjunction with departmental managers and Co-ordinates the event with logistics. Any regulatory body notifications as required by Site Director in conjunction with Quality Manager.

The procedure states actions and responsibilities should a customer recall a product.

The site has not been involved in any withdrawals or recalls since the last audit.

The system is operation 24 - 7 with lists of personnel & contact numbers available.

Incident report guidance

The site provides documented guidance on incidents within the procedure

It includes examples of potential incidents e.g.

glass breakage, chemical and biological contamination, sharps, pest control hygiene, personal health issues, malicious contamination, or sabotage

Failure of digital cyber security- attack or failure

Disruption to production and warehousing activities

Disruption to key services i.e. water energy, transport, machinery failure, staff availability and communication systems

Products that may have been released from site that could have be affected by an incident that occurred

There is a detailed incident reporting system in place

There have been no incidents reported since the last audit

The systems in place are suitable and sufficient to effectively manage an incident to prevent the product being released due to a hygiene, product safety, or quality incident at the site that could have affected, the product

The site manufactures generic products with brand markings as required by customer

The product withdrawal procedures in place at the site covers any brand owners print decorated products It identifies key responsibilities and timings

Identifies key personnel

Communication plans

Methods of informing customers

Regulatory bodies as required

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The site products have not been involved in any product recalls
If this event occurred the site would assist with traceability information as required

The system is tested as a minimum annually

Results of tests or product withdrawals are used and reviewed to implement any corrections or improvements as necessary

Evidence

Product Withdrawal & Recall Procedure 3.12 Issue 3 dated 1.9.2020

Incident reporting procedure 3.13 issue 1 dated 1.9.2020

Incident guidance included in training induction pack

Control of Non-Conforming product procedure 5.7 Issue 2 date 23.11.2020

Product withdrawal exercise carried out 16.6.2023 (in conjunction with Forward & reverse trace exercise)

Supplied material that had a potential contamination issue mock sinario

Customer Countrystyle Foods

Customer PO No. 167897

Site Sales O/No. 5928

W/O 13666

Print Ref PDF 6165946

Qty delivered 28 rolls 546 Kgs

Product Delivered to customer on 16.6.2023

Delivery Note No. 8659

Raw material

Description Alupol BOPP 25um material

Product Code FFBOBOPP-25-KG

PO No of film 1591 on 12.5.2023 (Supplier Alupol)

Material used

Roll No. 430144835/429510/2/7 & Roll No. 430144835/429510/3/4

Customer Contact Jackie Wilson confirmed they could trace the material as supplied on 16.6.2023 PO No.

Exercise started at 15.45pm finished 16.59pm {carried out in conjunction with prod withdrawl exercise}

Non-applicable clauses

3.4.4 No manufacturers trademarks or logos

3.7.6 Materials purchased from manufacturers not agents or brokers

3.11.5 No reworking performed outsourced or subcontracted

4. Site Standards

4.1 External standards

The site is situated in a commercial area of Haydock with no neighbouring activities posing any risk of product contamination.

The building fabric is brick skin with steel cladding walls.

The building is being adequately maintained in a suitable condition.

The site has perimeter fencing and gates that and are secured out of business hours.

There are security cameras and security lighting in place.

Grounds are being adequately tended

There is a clean and unobstructed area along the external walls of the buildings

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Refuse materials are in designated skip locations for general waste and plastic for recycling is segregated stored appropriately.

The external traffic areas for loading are tarmac & concrete with a section designated for staff parking of vehicles.

The building is adequately proofed to prevent pest ingress, ingress of water or any other potential contaminates

External drainage is via mains systems and suitable for requirements; it has protective drain covers in place to prevent pest ingress.

There is no unsealed access pipework at the site

There is no external storage of products

Evidence

Site tour 22.1.2024

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

Fabric construction steel integral frame and brick base with internal sealed painted concrete floors, and steel cladded or painted brick - block walls. Steel cladded roof with skylights

There are no suspended ceilings at site in production or storage areas

There are no internal drains that require protection from pest ingress or odour

There are no glass or brittle plastic windows that pose a risk to the product

The HARA study has likelihood and severity risk assessed the non-production glass at site and established the controls in place are suitable and are being adequately managed.

There are no elevated walkways at the site that pass over production lines

Lighting both high and low level have protected fluorescents bulbs installed in production and warehouse areas and EFK units have shatterproof bulbs

Ventilation is of natural provision and suitable for operations

Evidence

Site tour 22.1.2024

4.3 Utilities

Water at site is of potable quality it is supplied by local water authority it is of potable quality mains supplied and treated to prevent contamination

The site has conducted a risk assessment as part of the HARA to determine the microbiological and chemical quality of water, steam ice, air, compressed air or other gasses that come into the direct contact with the packaging requires monitoring. And that they don't pose a risk to product safety, quality, and that they comply with legal regulations.

Water does not come into direct contact with the products during operations Water is used for cleaning at site.

Compressed air is used in the manufacturing process but does not come into direct contact with the product it operates control valves on the equipment. Compressed air is filtered, oil separated and dried.

Evidence Site tour 22.1.2024

HARA study issue 8 dated 2.6.2023

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Potable water supply analysis by United Utilities

Compressor service including air filter changes by ACE Air Compressors & Equipment Ltd with service carried out 25.9.2023

4.4 Site security and product defence

There is a site security risk assessment in place which is reviewed at the HARA review meeting; it is reviewed as a minimum annually or sooner if changes occur at site.

There have been no high risks identified.

There is one secure entry point for employees from the car park.

The site uses an intercom system for entry in reception, CCTV and security lighting in place

All visitors and contractors must report to reception and follow the signing in procedures.

All visitors and contractors are supervised whilst on site.

Signage is clearly displayed for unauthorised areas.

There is a site security product defence plan in place

All visitors sign in and out of the premises, accompanied by staff member host and staff are encouraged to report or challenge any unidentified or un-accompanied personnel. Staff are trained in the site security arrangements as part of refresher induction training.

There are no external silos at the site

Evidence

Site tour 22.1.2024

HARA study issue 8 dated 2.6.2023

Product defence & Product Fraud- vulnerability risk assessment reviewed 2.6.2023

Product Defence plan 2.6.2023

Site security procedure training records {Induction refresher training}

4.5 Layout, product flow and segregation

There is a site plan in place that Identifies

Access points for personnel

Travel routes for personnel, raw materials, {No WIP} and finished goods

Staff facilities

Route for removal of waste from the vicinity

Production & process flow

Storage areas.

The process flow from intake to despatch is designed so as to minimise the risk of contamination or damage to products

There is adequate and sufficient working space and storage maintained sat site so as operations at site are carried out without compromising product safety in hygiene conditions

External packing is removed from materials in designated location prior to it being used, it is away from the equipment to prevent any cross contamination

There are designated lines painted as walkways to gain access to the various locations at site with barriers in place to guide people to and from the materials and machinery production area after entering the factory.

The routeways at site are logically designed and easy to follow.

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Evidence Site tour 22.1.2024 HARA study issue 8 dated 2.6.2023

4.6 Equipment

The equipment is designed specifically for its intended purpose.

The manufacturing equipment at site consists of 8 slitting machines, 2 with hot needle perforation unit and one with a punch unit, 2 centre fold machines, & core cutter; wrapping machinery and materials handling equipment

The machinery is a selection of modern and refurbished older machinery that is adequately maintained. The equipment has a steel frame and metal covers, some powder coated, some painted that is easy to clean,

and to maintain.

If new equipment is ordered the specification reviewed before purchase order placed and performance criteria agreed.

Newly commissioned equipment instigates a maintenance programme and cleaning programme to be generated as part of the machinery testing and validation process. The area for the machinery installation is cordoned off to prevent product contamination.

There has been no new equipment since last evaluation

No wooden equipment noted during the audit in production or storage areas apart from wooden pallets Notices displayed on the machines are laminated

Evidence Site tour 22.1.2024 Site Plan dated 21.1 2021

4.7 Maintenance

There is a documented programme of condition-based maintenance with maintenance schedule in place covering all items of production equipment and plant critical to product safety legality or quality to reduce any breakdowns and reduce risk of any potential contamination

Monthly checks are carried out by operators, for general maintenance lubrication and basic maintenance Third party manufacturer engineers operating under the control of Operations Manager, conduct any other maintenance tasks required

There is an annual service regime on the equipment

There is no offline testing equipment in use at the site that is adjustable and requires re calibration after maintenance activities

The condition-based system has taken into consideration items that are critical to product safety quality and legality such as the machine heating elements and bearings, these are monitored to prevent potential contamination and equipment failure

Tools after use are removed and placed in toolbox or wall racks adjacent to the machinery. There is a documented line clearance of maintenance equipment after tasks are carried out

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No temporary engineering was noted during the audit on equipment;

In the event of temporary engineering being required in an emergency situation, it is to be done so as the product was not potentially put at risk of contamination and the temp- repair would be recorded, and subjected to correction in an agreed set time frame.

There is a small engineering workshop on site that poses no potential contamination risk to production or storage areas at site with swarf mat provision in place.

Contractors working at site are monitored by host the Production Manager or site Engineer Maintenance contractor's sign in the visitors log for contractors.

Evidence

Site tour 22.1.2024

PPM Schedule 4.7.1 issue 4 dated 10.3.2022

Maintenance Clearance sheet 4.7.3 issue 4 dated 31.1.2023

PPM Maintenance of Eldec 1 slitting - perforating machine on 15.9.2023 by BJ with engineering line clearance completed.

PPM Maintenance of Eldec 2 slitting - Punching machine on 27.10.2023 by BJ with engineering line clearance completed by BJ

Breakdown repair on Eldec 3 Electrics tripping out on machine 7.9.2023 Loose connection on wires repaired by BJ on 8.9.2023 engineering line clearance completed by BJ

Compressor service including air filter changes by ACE Air Compressors & Equipment Ltd with service carried out 25.9.2023

Model Bodge C25 Compressor

S/No. 5079849

Job No. 10446

Hrs run 48156

Engineer Steve

4.8 Housekeeping and cleaning

The company have a clean as you go policy in place to maintain standards of housekeeping on site.

The cleaning programme at site has been based on risk

Weekly machine cleaning requirements are documented for each machine.

Machine cleaning tasks are carried out by operators and listed on the weekly cleaning checklist documented for each machine.

Staff facilities are cleaned by contract cleaning company and verified By BRGS Designated Manager High level cleaning has been undertaken and the site is very- clean

Cleaning instructions detail Responsibility for cleaning Area to be cleaned Frequency of cleaning

Method of cleaning

Cleaning materials to use

Cleaning record with operative signature of cleaning being carried out

Verification of cleaning by Manager

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Cleaning equipment for welfare areas is stored away from production cleaning equipment.

Cleaning chemicals are fit for application suitably labelled and used as per manufacture directions

They are stored in a separate secure cupboard in closed lidded containers

There are no strongly scented chemicals in use in the production or storage areas that could taint, or odour contaminate the products

Equipment used for toilets is colour coded red and stored in separate cleaner's cupboard.

A risk assessment has been carried out as part of the HARA study in relation to environmental monitoring i.e. cleaning operations being effective to minimise the risk of microorganisms existing on the packaging and that they may be detrimental to products.

The assessment concluded that based on risk an environmental monitoring program is not required

The site has no vehicles {all third party}

Evidence

Site tour 16.1.2023

HARA study issue 7 dated 2.6.2022

Cleaning schedule sheet issue 3 dated 17.2.2021

Welfare area cleaning records dated 14.1.2024 by DP with verification by JB

Perf & Slitting machine Eldec 1 cleaning records 22.1.2024 cleaned by KT with verification by JB

Punching machine Eldec 2 cleaning records 22.1.2024 cleaned by MY with verification by JB

Multi- purpose antibacterial cleaner in use Hygenol Enyguard MSDS on file v10.7

Chemical register COSHH

4.9 Product contamination control

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

Glass & Brittle plastics have been risk assessed at site as part of the sites HARA study

There is a register of glass and brittle items at site

The frequency of inspection is based on risk to the product {monthly}

Cleaning or replacement of items is conducted so as not to minimise the potential to contaminate the products

Items of glass and brittle plastics not in production areas have been considered by the site and are evaluated on a risk basis for potential contamination of products produced

Protected lighting installed in production / warehouse area fluorescents with protected covers.

Flying insect devices have shatterproof EFK tubes.

There is an incident reporting procedure –process in place used for Glass & brittle plastics, sharps, spillages, etc.; no breakage incidents recorded at site in last 12 months noted in file.

Incident procedure includes full clearance process & investigation with documented report of the event held on file.

In the event of a breakage the dept manager coordinates the incident event. This is then reported into designated manager.

Evidence

Site tour 22.1.2024

HARA study issue 8 dated 2.6.2023

Glass & Brittle plastics procedure 4.9.1.2 issue 1 dated 13.4.2018

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Glass & brittle plastics registers in place by machines and area

Glass - Brittle plastics audit dated 5.12.2023

Audit carried out by SW no issues raised

G&BP Inspections carried out quarterly seen inspections 6.12.2023 & 5.4.2024 in production depts and Keedwell Warehouse

4.9.2 Sharps and metal control

There is a documented policy for the control and use of sharp implements at site to prevent contamination inclusive of knives and blades used on site

Sharps are issued 1 for 1 basis by dept manager or Team Leader

Used blades are placed in closed yellow sharps containers

Snap off blades are not used at site

Martor safety knives, in use at the site

No sharp items were noted as uncontrolled during the evaluation site tour

There are no open notice boards in production packing or storage areas of the site

There are no single securing fastenings such as drawing pins or staples being used at the site

Evidence

Site tour 22.1.2024

Sharps policy - procedure 4.9.2 issue 2 dated 2.9.2020

Knives challenged

Knife 31 owner AG matched knife register details

Knife 29 KB matched knife register details

4.9.3 Chemical and biological control

The company have a register and an approved chemical list for purchasing in place.

Substance material data sheets are maintained and readily available along with substance technical specification sheets

No strongly scented chemical products noted at site

Chemical containers are labelled, and decanted chemicals identified in their respective containers Chemical containers are secured with caps- lids when not in use.

Chemicals are stored in secure cupboard when not in used {small containers < litre}

Larger quantities are stored in chemical cupboard with access restricted to authorised personnel Chemicals are used only by trained site personnel

The site has used hazard & risk principles to assess control & manage any potential microbiological contamination and any potential allergen risks as part of the sites HARA study

Evidence

Site tour 22.1.2024

HARA study issue 8 dated 2.6.2023

Multi- purpose antibacterial cleaner in use Hygenol Enyquard MSDS on file v10.7

Chemical register COSHH

4.10 Waste and waste disposal

Waste & Waste Control:

Waste management systems meet legal requirements of England

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There are identified bins for waste materials at site

Waste polythene trim is removed from site for recycling by Licensed registered waste carrier

General waste is segregated in identified general waste bins and decanted into external skip which is removed by Licensed registered waste carrier. The bins are cleaned as required to reduce any contamination

Il sites waste streams are effectively managed in identified containers and removed accordingly with recycling the main priority.

Trademarked printed products with decoration or brandings are destroyed as part of the waste recycling process; majority of products at site are generic with no branding or decoration {Printing is outsourced}

Trademarked waste products manufactured at the site are remove by registered licensed waste providers

External storage of waste material is in skip with lid in designated location to minimise the potential of attracting pests; The area is cleaned for any debris each time the skip is emptied

Evidence

Site tour 22.1.2024

Waste services provider is Fresco Environmental Ltd (all waste steams)

Waste Registration No. CBDU44197 expiry 21.10.2024

4.11 Pest management

There is a preventative pest management programme in place at the site covering all areas of the site under the site's jurisdiction.

Consideration has been given in the programme to acknowledge different periods of the year may have increased pest activity with appropriate measures implemented to ensure the site is adequately protected In the event of additional pest activity is noted it is recorded by the pest control management provider, the additional necessary measures implemented, and the preventative pest plan programme reviewed to include the additional requirements as or when deemed appropriate by the competent pest control provider. The sites pest control management is contracted to a competent pest Control company who are members of the NPTA

There is a Contract Agreement in place with the Pest control company

There are 8 routine visits, 1 biologist visits and 4 EFK inspections covering rodents flying & crawling insects including catch tray analysis and annual tube changes.

The frequency of visits has been based on risk assessment and documented accordingly

Procedures are documented in the pest control hard copy file.

The risk assessment would be subject to review if or when

Any changes to building or production process occurred that could have an impact on the pest control management programme and if Any significant pest issues occurred at the site

The site premises are adequately proofed to prevent potential pest ingress with seals and expandable foam seals. Cable entry points and ducting entry points are sealed.

There are no opening windows that require protective screening.

The external building doors are proofed and sealed with strips at the base.

There are protective door fly screens in place as a deterrent for entry by birds or flying bats etc. There are no canopies at site that have a potential for birds nesting or roosting.

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In the event of an infestation the pest control company would be contacted to assess the situation in conjunction with the site management team and immediate actions implemented as required If there was any potential contamination or damage to products, they would be quarantined awaiting a decision on disposition and their release.

In the event of an infestation of flying insects the site will request an analysis of the catch trays to help identify any potential problem areas.

The site utilises a risk-based approach {risk assessment} when there has been a subsequent increase in activity to determine with the pest provider "competent persons" the necessary actions to eliminate the hazard.

There is an authorised site plan signed and dated up to date in place identifying the clearly numbered marked pest control devices

bait stations, traps, and EFK units and their locations

A register of pesticides along with safety data sheets is present in the file, example being Detex nontoxic Blocks.

Employees are aware of the signs of pest activity and must report any such activity to a Manager or Supervisor.

Pest Control awareness training has been delivered to all employees including with training records retained on site.

The reports indicate the system is working effectively and no issues of pest activity were noted at the evaluation

Evidence

Site Tour 22.1.2024

NWPC ltd pest Control Ltd who are members of the NPTA Membership No. 852 Exp 15.4.2024 Site bait plan in place signed and dated 15.9.2023 identifying the numbered bait stations, traps, and EFK units and their locations

SLA in place dated 8 routine 1 biologist and 4 EFK services with annual tube change MSDS Detex & Deadline Non- toxic bait

The last routine visit took place on 9.1.2024 by J Thompson no signs of rodent activity issues recorded access to baits in two locations difficult to access

Last Biologist visit took place on 11.1.2023 by J Huyton proofing issues recorded for attention these have been addressed by site and signed off {Biologist booked for 19.12.2023 PO No. 1968 delayed due to illness of pest controller rescheduled for Jan 2024}

Last EFK visit 9.1.2024 Bulbs changed in EFK units May 2023

{All units were noted as in working condition at evaluation}

J Huyton Biologist training via Killgerm 16.5.2000

J Thompson Technician RSPH level 2 in pest control 31.3.2016 Cert No. 494233

G Noon Pest Control Training Technician via Paragon 7.12.2004

S Dunlop BPCA Diploma level 2 in pest control 25.8.2011 Cert No. 8538

Pest Control R/A reviewed 11.1.2023

Pest Control Procedure 6.1.4 issue 1 dated 15.4.2018

Pest awareness carried out & training records retained on site

Non-applicable clauses

- 4.1.5 No external storage of Raw materials
- 4.2.2 No Suspended ceilings
- 4.2.3 There are no internal drains that require protection from pest ingress or odour
- 4.2.6 There are no elevated walkways at the site adjacent to or that pass over production lines
- 4.4.3 No external silos or intake pipes

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4.8.5 No environmental monitoring

4.9.2.4 No open noticeboards in production, packing and storage areas

4.11.3 Use 3rd party pest control company

5. Product and process control

5.1 Product development

Design and Development; is documented at site inclusive of an agreed specification as part of establishing customer requirements for new products.

Customer provides the details and specifies material requirements (substrate) and dimensions.

An excel spreadsheet is completed with all relevant information required by the office.

Packaging design assessment of sites capability is completed by Planning Manager for production

Any critical parameter requirements such as hole sizes and perforation arrangements and spacings, recycled material No migration testing by site, to be conducted by the customer to ensure legal requirements are upheld.

The site only slits and perforates – punches holes in materials and has applicable material DOC's for the raw material suppliers used.

The site doesn't currently conduct product trials due to the nature of their operations just slitting punching and perforating of products as required on already approved materials specified or supplied by their customers

If one was required due to material change requirements or processing methods – equipment change it would be conducted so as to ensure the process capability at site was appropriate to the required quality parameter stipulations for the product and that product safety quality and legality were not compromised Product technical specifications are agreed with customers before products are produced at site. The products may have decoration or brand references {also approved by customers with pdf artwork supplied} Third party outsourced printing

Process settings on the site's machinery and operating conditions at site enable products to be manufactured to required quality parameters and are safe and legal

New products relate to size changes of products;

Any material change is undertaken by the customer and the material extrusion provider and is not under the scope of the sites capability

The details include

1. How will product be slit, perforated - punched

Material gauge

- 2. Material type and origin i.e. virgin or material with recycled content
- 3. Application of use food, hygiene sensitive or non food

An Item Code is created on the sites MIS system for each new product usually using the customer product code with the Product description added.

This contains all information relevant to the product and any customer specific requirements or criteria for monitoring, which references to the design specification drawing file number, creating a product spec for the production process.

This information is maintained on the MIS system for future runs and used to generate the Works Instruction which is attached to the front of each job bag.

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A Set-up sheet is created on the first run and retained in the job bag along with approved samples for future runs.

Samples are retained for each job.

The packaging specification review is completed.

Details recorded include; Customer details, Project title, Description, Material details, Process details – dimensions, width and length, perforations, punching, bag format, packing format

The design procedure is inclusive of transferring customer specification details onto the sites MIS system. The information is checked for accuracy

Specifications are agreed via email with customers and by order acknowledgements after any updates to specification

The process details any testing requirements

If any requested changes to the product specification had a potential detrimental effect the customer would be informed accordingly prior to the production of the item

New equipment is validated as required with any equipment settings referenced for process manufacturing being detailed on works order job bag

Evidence

Reviewed new product development procedures at evaluation 5.1.1

Specifications and Contract Review procedure Issue 2 dated 14.7.2020

5.2 Graphic design and artwork control

The site outsources print as required.

Artwork pdf is received as approved, electronically, from customers and passed to the Operations Manager for technical assessment and suitability to print. The artwork is then sent to the print supplier to print the film. The operations manager is responsible for checking printed film received from the supplier.

Evidence

The two print companies used are both BRCGS Certificated as ref in supplier's clause 3.9 in this report Artwork approval for pdf design Artwork No. 61659461 v1 approved 29.9.2023 by Customer A Clarke Countrystyle

Description ASDA Wheatsheaf

PDF matched to incoming material at site by Sales & Marketing Director TQ on 29.9.2023

5.3 Packaging print control

No printing operations undertaken at site {outsourced}

Evidence

Site Tour 22.1.2024

HARA study issue 7 dated 2.6.2023

5.4 Process control

The company has undertaken a review of the full manufacturing process, as part of the HARA study. There are documented work instructions and procedures with process specification s in place to ensure effective QMS operations of process and products manufactured are within the required customer parameters

The HARA study has identified and detailed potential product defects that could arise at each step of the process that could have an impact on the finished product

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These include product quality defects, defects that may have an impact on the functional integrity, and the performance of the finished product when being used, defects that could enable the product to be produced outside of the customer prescribed quality requirement parameters.

There are identified manufacturing process control points within the process documented in the process specification

Equipment settings at site; that may have an impact on product safety or legality are conducted by trained authorised personnel only i.e. the site senior machine setter operative or dept manager.

These are documented on Job Specification sheets and machine program sheets which are generated for each production run.

Critical settings are documented and include but are not limited to

Machine speeds, tensions, dimensions. Temperatures etc

Machines are automatically recipe controlled.

The equipment is not password protected but operational personnel have been instructed not to touch the equipment settings and the actual screens to access the settings are relatively complicated to access without being trained on the programmes.

The Bill of Materials and specification for the product being produced is part of the works order documentation

The works order contains a record of the production batch and checks that are carried out at start up and every reel change during production operations or when any equipment adjustments are made to ensure consistency of products being produced are within the agreed quality parameters of the product technical specification. Documented inspections are filed with the with the works order.

There is a documented line clearance process in place recorded as part of process change over The process is inclusive of responsibilities of personnel to carry out

Identifies areas of special note where materials may still be present – trapped

Validation of line clearance process

Line clearance sign off to commence production

In the event of a change a new specification is raised and new unique number on system.

Revalidation of quality plan to ensure conformity to specification, verification via inspection regime to ensure quality product safety and legality are maintained

Evidence

Site tour 22.1.2024

HARA study issue 8 dated 2.6.2023

Process Control procedure Slitting, Perforation, Punching 5.4.1 Issue 4 dated 28.6.2021

Line Clearance procedure 5.4.7 issue 4 dated 28.6.2021

Inprocess inspection checks on Elite 2 slitting machine

Job No. 1300 slitting 70μm PET clear film reel 14255mm slit into 9 reels at 138mm wide x 1000metres Master Reel No. S924661-3/4

Material batch GI No.14255. Material supplier JBF

Quality checks and line clearance by AG Verified by SW

Inprocess inspection checks on Eldec 2 punch -slitting machine

Job No. 115728 S/O No. 7100

Punching 3 lanes of 8mm holes

Master reel No. BDB1503958 25µm OPP

Quality checks and line clearance by MH Verified by JB

Inprocess inspection checks on Eldec 1 -perforating slitting machine

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Job No. 14882 S/O No. 6675

Slitting from 1520mm to 2 x 750mm wide x 2400m reels, with P30 strip 100mm centre of slit reels

Master Reel No. BDK1502063

Quality checks and line clearance by MH Verified by JB

5.5 Calibration and control of measuring and monitoring devices

The site calibrates equipment used to monitor manufacturing control points that may have an impact of products produced in relation to quality product safety and legality

There is a documented calibration procedure in place supported with calibration details of equipment in use. The equipment is held in designated locations and sealed so as prevent any unauthorised adjustments, mis use, damage, and deterioration

The equipment in use has details of

The items location

The item serial No.

Calibration date and next due date

Equipment for calibration is conducted by trained personnel as a minimum annually based on risk and any adjustments made as deemed required by inspection check carried out

Calibration is performed either internally or by recognised Calibration houses that use equipment traceable to National Standards. or internal calibration to designated work instructions

In the event of equipment operating out of defined parameters the dept manager is informed who liaises with quality dept and the equipment is removed for repair or replacement as applicable

Any failure of equipment instigates an assessment of the potential risks to product produced since the last known correct specification parameter was being achieved, this will entail products to be quarantined and re inspected to ensure product safety, quality or legality has not been compromised

Root cause analysis is carried out to understand why the equipment failed and what corrective or preventative measures are required to be implemented to reuse the potential of a recurrence; and to assist in continual improvements of the process.

Evidence

Register of calibrated equipment, dated 18.12.2020. Calibration Procedure Issue 3 dated 7.9.2020

Calibration services provider
Accurate weigh Company
EWS Scales
Location production hall centre fold machine
Model Junior
Site No. of scales No.5
Capacity 100kg / 0.05Kg
Serial No. 1145346

Calibrated 21.12.2023 to National standards Cert No.JH/10011/23

Accurate weigh Company Jadeva Scales Location production hall Model JIK8CSB

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Site No. of scales No.2 Capacity 30kg / 0.201Kg Serial No. 42105422803 Calibrated 21.12.2023 to National standards Cert No.JH/10012/23

5.6 Product inspection, testing and measuring

Quality checks are carried out and recorded for each step in the production process and recorded to verify that products meet specification quality parameters, and any critical technical &legal requirements. Quality inspections are based on risk and industry accepted practice, any specified additional customer requirements to be adhered to are also implemented as appropriate.

Offline Quality checks are undertaken and documented at the start of every run and every 10th box throughout the run by Production operatives. Checks are undertaken for acceptable hole perforations, dimensions, reel formation slit edges, slack edges creasing & contamination.

Samples used for checking are placed in job bag and retained by the site until next run

Hazard and risk principles have been used to determine the need for any in line product testing equipment for product safety, quality and legality are upheld.

The risk assessment concluded that no inline measuring equipment was required with the sites offline checks being carried out being suitable and sufficient for operations.

Offline quality checks are carried out and recorded every reel change as detailed in job bag works order with specification inspection details documented

There is no inline test equipment critical to product safety or quality in the process to divert NC product out of the process

Test methodology in place at site for offline testing of perforation patterns, it is validated to sites own test criteria and methodology

If finished product is identified as defective it is segregated and labelled with quarantine ticket awaiting disposition rework or destroy and recycle.

There is no automated inspection equipment – vision systems in use at site to check material features

External verification testing critical to product safety & legality is carried out Migration testing is undertaken by suppliers of raw material on a regular basis. Test facilities used are accredited to ISO:17025

The site has personnel who understand the test results as supplied by the raw material suppliers, if there were any issues the supplier would be contacted

Material SOC results are in compliance with EU10/2011 and amendments

Evidence

Site tour 22.1.2024

Checks are recorded on the Process control quality inspection record sheet Process Control Slitting – Punching procedure 5.4.1 Issue 4 dated 28.6.2021

Quality inspections viewed during site tour

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Inprocess inspection checks on Elite 2 slitting machine

Job No. 1300 slitting 70μm PET clear film reel 14255mm slit into 9 reels at 138mm wide x 1000metres

Master Reel No. S924661-3/4

Material batch GI No.14255. Material supplier JBF

Quality checks and line clearance by AG Verified by SW

Inprocess inspection checks on Eldec 2 punch -slitting machine

Job No. 115728 S/O No. 7100 Punching 3 lanes of 8mm holes

Master reel No. BDB1503958 25µm OPP

Quality checks and line clearance by MH Verified by JB

Inprocess inspection checks on Eldec 1 -perforating slitting machine

Job No. 14882 S/O No. 6675

Slitting from 1520mm to 2 x 750mm wide x 2400m reels, with P30 strip 100mm centre of slit reels

Master Reel No. BDK1502063

Quality checks and line clearance by MH Verified by JB

5.7 Control of non-conforming product

Procedure for Control of Non-conforming Product is in place at the site It is trained out to relevant personnel which includes identification and quarantining of any out of specification material so as the product disposition can be determined by senior site management

Any out of specification product identified during the manufacturing process is labelled and quarantined. The company ensures that out-of-specification product is clearly identified, labelled, and quarantined through documented operating procedures, work instructions and quality checks and is subject to review at the annual management meeting, monthly meetings and through internal audits

All instances of non-conforming product are recorded on the Quarantine Log and Disposition Record sheet

All N/C material is subject to inspection and scrap, re-work, concession, or positive release and is documented on the log, along with root cause analysis, corrective action and preventative action taken. In the event of root cause analysis being necessary for any failures identified the corrective and preventative measures implemented are reviewed for effectiveness {This is also a topic for discussion on the management review}

Evidence

Control of Non-Conforming product procedure 5.7 Issue 2 date 23.11.2020 Corrective Action - root Cause analysis procedure 3.6 issue 1 dated 1.9.2020 No non-conforming material was observed during the assessment. Quarantine Area Log and Disposition records Management review minutes 2.6.2023 Customer complaints

5.8 Incoming goods

There is a procedure for raw materials and intermediate product intake at the site Procedure requires matching of incoming goods to purchase order – product specification Materials are ordered by raising purchase orders on MIS system or customer supplied product on reciept documentation and customer PO No.

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Orders can only be raised against approved suppliers. Or customers supplying their own material Certificates of analysis, Certificates of conformance, along with statements of compliance as applicable.

Inwards goods inspection carried out to verify material integrity and checking details on the material delivery note match purchase order requirements.

There is a vehicle inspection procedure in place

All incoming goods are visually checked by warehouse personnel for taint, odour, pest infestation, contamination & damage.

There are bulk delivery areas at the site, reels of plastic on pallets via curtain sided or container vehicle trailers with security measures such as locks or metal traces on curtains to prevent any malicious intervention.

Reels are transferred into storage racking on pallets and transferred into slitting or perforation dept for conversion operations. Reels are identified with a batch No. that is recorded on the sites MIS system

If defective material is received an NCR report is completed and used to record root cause and corrective actions and preventative measures that have been applied.

No defect material reports have been raised since the last evaluation

Goods inwards checks carried out on incoming material to match PO. and any damage or contamination There is no testing of material conducted on goods inwards at the site.

FIFO is also implemented as sometimes orders are changed by customers or cancelled etc so as the prescribed shelf life is not compromised

Checks carried out on incoming material to match BOM on works order No. prior to issuing to production by warehouse.

Evidence

Purchasing and Goods Receipt Procedure 5.8.1 issue 3 dated 8.9.2020.

Incoming goods and purchasing were challenged during the evaluation

PO No. of materials 1819 dated 19.9.2023

Reciept of material 7.12.2023

Raw Material description BOPP Clear film 1210 x 20µm x 25650 metres {material in warehouse}

Qty 44 reels recieved Reel No. BDJ1502270

Material supplied by Nahar Poly Films Ltd

GRN Note No. 14081

Reciepted and inspected by CF

Details of incoming material matched sites PO details & was recorded on goods receipt document

5.9 Storage of all materials and intermediate and finished products

Procedure Storage procedures are risk based and covers product contamination

The risk-based procedure details the need for effective segregation and storage of materials to maintain product safety and product quality.

The procedures have details of storage and segregation requirements are inclusive of Details of packing finished products

Segregation of products to reduce potential of cross contamination from physical, microbiological, or allergenic items to prevent mixing or taint

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Products / raw materials are stored off the floor and away from walls

There are no requirements for specific handling or stacking of finished products to prevent product damages Raw materials and finished products were noted as adequately protected and were effectively segregated

There is no WIP at site, single process either slitting or pouch sealing as finished goods, then to warehouse and dispatch to customer

Finished products are on lined pallets poly bagged - wrapped and palletised to protect them from contamination

Raw materials are stored warehouse on pallets and wrapped - controlled so to prevent any potential product contamination, including taint or odour, or malicious intervention

Customer requirements are upheld at site with finished goods using FIFO principles to effectively rotate products; the site operations have no intermediate process stages.

There is no off- site storage used by the site {Rented warehouse adjacent to site}

Pallets are stored internally to ensure they are clean and uncontaminated; they are inspected for splinters or contamination prior to entering the premises and also before entering the slitting and pouch making depts.

Product contamination - segregation procedure 5.9.6 covers product contamination Raw materials if returned as part used to storage are wrapped; the site generally uses all the material as a lot of items are made from customer supplied materials or for generic stock products.

Finished palletised product from the production hall is poly bagged and wrapped to prevent contamination and is stored in loading bay area or in separate segregated warehouse

Hazardous chemicals such as lubricants are stored in the chemical cupboard so as to reduce the potential risk for contamination and compromising product safety, quality or legality.

Materials for recycling are stored externally in secure segregated area and covered to protect against any contamination hazards.

Evidence

Site Tour 22.1.2024

Product contamination - segregation procedure 5.9.6 issue dated 8.9.2020

5.10 Dispatch and transport

The site utilises 3rd party transport who operate under RHA terms and conditions 5.10 details the procedures in place for dispatch and transport of products. There is also a documented preload hygiene inspection check conducted by site FLT operatives.

The products may be loaded onto a vehicle with other goods as they are adequately protected with appropriate protective packaging

Other customer's goods will be loaded onto the vehicles at another pick up points, and it is not possible the site would know what they may be, and it is impossible for the site to police they are reliant on the RHA trading arrangements in place.

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Utilising a pallet network distribution operation following RHA guidelines for safeguarding and protecting customers goods whilst in transit and at drop off and pick up locations. Drivers as part of RHA guidance are required to park in secure locations.

Products are boxed with a liner or in reel format, palletised and wrapped as protection to protect the products from contamination, taint and odour or potential of malicious intervention

Products and materials are packed and labelled. Labels are produced for each job;

Main label – attached to each roll, Warehouse outer label – used when picking product.

New pallets are used for finished product.

Pallets are protected from the elements and inspected prior to use so as they are dry contamination free and not damaged

The site have none of their own vehicles and don't lease any for deliveries {consequently cleaning of the vehicles is managed by the transport providers}

The site has no transport of its own and utilises 3rd party transport

Delivery vehicles and shipping containers are subjected to documented hygiene inspection inclusive of taint and odour checking prior to being loaded with a Vehicle Hygiene Check Sheet in place

Transport services provider using RHA terms and conditions applicable

Drivers are not permitted access to manufacturing or warehouse areas with a Bell provided for attention of despatch personnel to attend.

Drivers may use the site facilities they are directed via designated walkways to facilities and do not enter production or storage areas

Evidence

Storage and Dispatch Procedure 5.8 Issue 3 dated 8.9.2020 Haulier Agreement Doc 5.8.1 issue 2 dated 16.9.2020

Transport services provider

M & S Transport

RHA terms and conditions applicable

Haulier agreement doc 5.8.1 issue 2 dated 16.9.2020 signed by M Kennedy for M & S Transport dated 11.1.2024

Goods out challenged as part of vertical audit

Customer Paragon Ltd

Customer NOT182485 dated 623.11.2023 (for delivery 4.12.2023)

Site Sales O/No. 6922

Description Rolls of 145mm x1500m X 50µm PET Clear

Product Item No. 50PET-ED7R1-KG

Qty ordered 5 rolls Job No. 15368

Qty delivered 5 rolls on 1.12.2023

Delivery Note No. 9799 Haulier MS Transport

Vehicle Hygiene checks carried out prior to loading by CF

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Non-applicable clauses

5.3 No printing at site

5.6.3 No inline test equipment to be specified

5.6.6 No inline test equipment in the process

5.6.9 There is no automated inspection equipment – vision systems in use at site

to check material features

5.6.10 No subcontracted migration testing carried out

5.10.4 No company owned or leased vehicles

6. Personnel

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

Staff Recruitment Training & Awareness; Induction

Training is provided for all personnel including any temporary workers and contractors prior to starting work at site and personnel are adequately supervised whist conducting their roles during working times at the site.

All personnel receive a site induction prior to starting work; this is followed up by job specific on the job training commensurate with the role for which they are employed.

There is an induction checklist used to ensure that all relevant topics are covered and includes the site hygiene rules - jewellery policy.

Training as applicable within operations covers;

Product inspection and testing

No printing at site

Packaging inspections

Process control specific points as required in the manufacturing process

Laboratory testing by 3rd party non at site

Product defence

The site has defined documented training programmes in place that incorporates requirements of communicating changes of operational practices and procedures; toolbox talk briefings are carried out by the Operations Manager and Quality Manager as applicable

Refresher training carried out by the site to review the competency of personnel and provide as necessary any additional training as appropriate. Operational Job mentoring and instruction, coaching, reviewing experience and current working methodologies, and as necessary external training provision.

The training details training date, duration of training, course content, trainer, or the external training provider, and name of person and attendance confirmation.

Records of training are retained and readily available.

Training is tracked by the matrix managed by the Operations manager in conjunction with Quality Manager. The operator is signed off to a procedure ensuring they understand the requirements for each step of the process including bag inspection and quality checks.

Personnel skills continually reviewed to meet business needs

Agencies are not used by the site for training

Any training needs are discussed at management meetings and the production manager will authorise as appropriate any identified new training requirements.

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Site reviews competencies of all staff annually to ensure that the correct training is available and that the training delivered has been effective.

Any person conducting training requires to be sufficiently qualified to do so and may be in the form of certificates as evidence or experience in the role

Personnel at site are all English speaking and can read English

All training media is in English language

Evidence

Training matrix for training needs viewed at evaluation with quality manager Logistics Team Leader CF

Logistics Incoming Goods storage & Dispatch operation update training trainer SW on 24.1.2022 duration 20 mins

FLT refresher training via BB Training 21.12.2020 Duration 1 day Cert No. BBG 1596 trainer WB Refresher food safety training including site security, product vulnerability, quality procedures pest control awareness and self-care laundry training, HARM, Non-conformance responsibilities and actions to take 19.10.2023 by SW 3hrs

Slitting Machine Operative training AG

Slitter machine operation update training in process control procedure Slitting – Punching, 5.4.1 Issue 4 dated 24.1.2023 trainer JB duration 3 months

Refresher food safety training including site security, product vulnerability, quality procedures pest control awareness and self-care laundry training, HARM, Non- conformance responsibilities and actions to take 19.10.2023 by SW 3hrs

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

Personnel Hygiene Policy is in place and conveyed to all personnel inclusive of employees, temporary employees' visitors and contractors at induction – or by company host to visitors.

Site Hygiene policy - rules are displayed on entry notice at reception & prior to site entry.

The hygiene rules are inclusive of: -

jewellery, watches wrist bands, fingernails, false nails, nail varnish nail polish, nail art, perfumes and aftershaves, personal possessions, mobile phones, eating and drinking, protective clothing, hand washing, infectious illness reporting & use of personal medicines in production areas.

Compliance with the site's hygiene rules is monitored on a daily basis by dept manager and also checked by quality & Compliance Manager as ref in the internal audit programme.

Entry to Production

Hand-wash basin, hot water, liquid non scented soaps, hand dryers, hand-wash signage & sanitizer gel Hand washing is required each time personnel enter the production hall to minimise the risk of product contamination

Operatives personal possessions and mobile phones are not permitted in production or storage areas at site. The only permitted mobile phones are management issued phones used by dept managers within the business for operational use requirements.

Blue nitrile gloves are available for protection for any visitors who cannot comply with the site fingernail policy, and insistence conveyed by host that they don't handle any site products whilst in production or storage areas. If any product is permitted to be handled as agreed by host for inspection purposes it has to be placed in bin for recycling afterwards and not returned into the process

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The sites jewellery policy states that the only jewellery permitted in production and warehouse areas is a plain band ring, medical alert jewellery without stones, wedding wrist bands and sleeper earrings of continuous loop type.

There were no violations noted of the site rules noted during site evaluation tour

6.2.3 Unauthorised personal mobile phone noted on work station in production slitting dept NC

All cuts and grazes are protected via site issued and monitored blue plasters

Blue finger stalls and blue nitrile disposable gloves are also available if required as an additional protection Evidence

Site tour 16.1.2023

Personal Hygiene Policy – Site hygiene rules 6.12 issue 3 dated 2.9.2020

Medication risk assessment part of HARA dated 2.6.2023

Plaster – dressing log and issues of blue plasters records 6.2.6 issue 1 dated 2.9.2020

6.3 Staff facilities

Suitable staff facilities on site, consisting of;

Personal lockers are accessed via designated walkway into production area

Personal lockers are provided for employee's lockers suitable & sufficient for segregation of personnel items and issued protective clothing

Coat hanging pegs for external clothing garments.

Eating or drinking is not permitted in locker rooms—changing area

Entry to Production

Hand-wash basins, hot water, liquid non scented soaps, paper towels, hand-wash signage & sanitizer gel Toilets do not open directly onto production or storage areas at site 2 door segregation in place; toilets are prior to entering into production areas.

Toilets have Hand-wash basins, hot water, liquid non scented soaps, towels, hand-wash signage.

Facilities for visitors are in place as instructed by host so as they can and do obey the site hygiene policysite rules.

No food is taken into production processing areas or storage areas of the site Canteen facilities.

Lined marked out walkways used to access canteen

Plastic chairs, table, lidded lined waste bin. Potable drinking water, fridge, no open food stuffs, sink with liquid soaps & paper towels.

There is potable drinking water in the canteen

Eating or drinking is not allowed in production or storage processing areas.

Designated external smoking area with waste provision & hand wash signage on production entry door. Electronic cigarettes are classed as general smoking and can only be used in designated smoking area. Smoking is illegal internal of premises in the UK inclusive of electronic cigarettes – vaping

Evidence

Site tour 22.1.2024

Personal Hygiene Policy – Site hygiene rules 6.12 issue 4 dated 5.1.2023

6.4 Medical screening

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There are procedures in place so as employees are made aware to inform their line managers of any infections or diseases, they could prevent them from working with direct contact food packaging.

Health questionnaire entry procedure to site requirement for visitors and contractors to confirm they are not suffering from a condition or symptoms of a condition that could put product safety at risk if entering production, packing or storage areas at the site.

Employees who are returning to work after illness have to undergo a return to work interview with General Manager covered in induction referenced in site hygiene rules & personal hygiene procedures. There are procedures in place so as contractors or visitors to site suffering from any infections or diseases that will prevent them from working with direct contact food packaging for as long as symptoms persist. There is no medical screening in place at the site with all Covid 19 requirements being removed by the government in England. There is however a Covid 19 risk assessment as part of HARA study; and any changes on government advise on medical screening will be implemented accordingly for site personnel & visitors to the site.

Evidence

Visitor Medical Questionnaire filled in by auditor on entry to premises as requested by host on both days Personal Hygiene Policy – Site hygiene rules 6.12 issue 4 dated 5.1.2023

Evidence

Site tour 22.1.2024

Personal Hygiene Policy – Site hygiene rules 6.12 issue 4 dated 5.1.2023

6.5 Protective clothing

The site has risk assessed workware as part of the HARA study

Hair nets, beard snoods and moustache snoods are in use at site as determined by risk assessment

Workwear is not permitted to be worn to and from the workplace, change on site Issued protective clothing is permitted to be worn in all depts at site

There is no requirement for personnel to remove workware prior to entering canteen, toilets or to go to outside to smoke. As determined by HARA risk assessment

Employees are provided with T-shirts, jumpers, Hi-Viz vests and trousers and is replaced as necessary, they effectively cover the upper torso areas of employees

There is no external upper torso pockets or buttons on the workware provided

The employees are provided with adequate sets of protective clothing for activities carried out, and replacements are readily available for damaged or worn items

Safety footwear is mandatory at the site as risk assessment determination

Lab style coats are provided for visitors.

There are selfcare home laundry laundering arrangements in place, with a plastic bag provided to take washed clothing from home to the site

Blue Nitrile disposable gloves are provided for production personnel and are readily available for replacement and do not pose a contamination risk to the products

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Used disposable visitor coats, are placed in designated bin at entry – exit area of production to prevent product contamination

Evidence

Site tour 22.1.2024

Personal Hygiene Policy – Site hygiene rules 6.12 issue 4 dated 5.1.2023

Self are guidance for home laundry issue 1 dated 2.9.2020

Protective clothing - hair covering risk assessment in HARA study issue 8 dated 2.6.2023

Non-applicable clauses

6.3.10 No drinking of water permitted in production or storage areas

Requirements for traded products

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

Not applicable Out of scope

7.2 Specifications

Not applicable Out of scope

7.3 Product inspection and laboratory testing

Not applicable Out of scope

7.4 Product legality

Not applicable Out of scope

7.5 Traceability

Not applicable Out of scope

Non-applicable clauses

Not applicable Out of scope

Additional Module: Plastic Pellet Loss Prevention

10.1.1 Senior management commitment and control improvement

Not applicable Out of scope

10.2.2 Hazard analysis and risk assessment

Not applicable Out of scope

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10.3.5 Internal audits Not applicable Out of scope 10.3.6 Corrective and preventive action Not applicable Out of scope 10.3.13 Management of incidents Not applicable Out of scope 10.4.2 Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas Not applicable Out of scope 10.4.4 Site security Not applicable Out of scope 10.4.5 Layout Not applicable Out of scope 10.4.8 Housekeeping and cleaning Not applicable Out of scope 10.4.10 Waste and waste disposal Not applicable Out of scope 10.5.8 Incoming goods Not applicable Out of scope 10.6.1 Personnel: training and competence

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Not applicable Out of scope

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Not applicable Out of scope

Non-applicable clauses