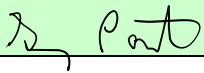
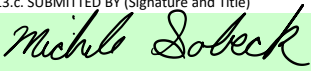


Wisconsin Department of Agriculture, Trade and Consumer Protection Division of Food and Recreational Safety Milk Certification Program		REPORT OF CERTIFICATION <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>		FOR FDA USE ONLY																									
				1	2	3	4	5																					
IDENTIFICATION																													
1. NAME OF SINGLE-SERVICE FABRICATING PLANT ProAmpac				2. CITY Neenah		3. STATE / COUNTRY Wisconsin / USA																							
4. STREET 1055 Winchester Rd				5. MFG. CODE NO 55- 4831			6. CODE PRODUCT CODE MATERIAL CODE																						
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION N/A				56 4	57 8	58 3	59 1	60 3																					
				61	62 3	PRODUCT CODE (60) 1. Containers 2. Closures 3. Other products 4. Containers and closures 5. Containers and other products 6. Closures and other products 7. Containers, closures and other products			MATERIAL CODE (62) 1. Metal 2. Paper (Includes laminates) 3. Plastic 4. Metal and paper 5. Metal and plastic 6. Paper and plastic 7. Metal, paper and plastic 8. Glass 9. Rubber 10. Paper, metal, plastic, and glass 11. Ceramic																				
7.a. RATING/ CERTIFICATION PERSONNEL <input type="checkbox"/> SHD <input type="checkbox"/> Other <input checked="" type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input type="checkbox"/> SSC		7.b. DATE OF PLANT CERTIFICATION 11/16/2023		7.d. EXPIRATION DATE* 11/15/24																									
		7.c. SANITATION COMPLIANCE RATING 81		MONTH 67	DAY 68	YEAR 69	YEAR 70	YEAR 72																					
				1	1	1	5	2																					
				4	2	4																							
*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. NOTE: Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.				8. SRO OR SSC Michele Sobeck																									
				9. CERTIFICATION RECOMMENDED <input checked="" type="radio"/> YES <input type="radio"/> NO			9a. LISTING TYPE <input type="radio"/> FULL <input checked="" type="radio"/> PARTIAL																						
LABORATORY CONTROL																													
10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY N/A goes on for further processing																													
11. INSPECTION RESULTS (Place an "X" under Items debited)																													
	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21	BACTI	COLI		
				X					X				X		X	X													
12. PERMISSION TO PUBLISH																													
Permission is hereby granted to release and publish the above-stated certification for use by Regulatory/Rating Agencies and prospective purchasers. It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant. This would include, but not be limited to: changes in processing lines/equipment involved in processing IMS materials or changes to product types or materials manufactured.																													
12.a. NAME OF PLANT ProAmpac																													
12.b. PLANT REPRESENTATIVE AUTHORIZING RELEASE (Signature) 						12.c. TITLE Greg Porter/Compliance Manager																							
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE																													
13.a. DATE OF REPORT 11/20/2023			13.b. RECOMMENDED CLASSIFICATION ACCEPTED <input checked="" type="radio"/> YES <input type="radio"/> NO			13.c. SUBMITTED BY (Signature and Title)  MSRO																							
FOR FDA USE ONLY																													
13. DATE RECEIVED			15. PUBLICATION OF RATING RECOMMENDED <input type="radio"/> YES <input type="radio"/> NO (If "NO", indicate why.)																										
16. DATE TRANSMITTED			17. SIGNATURE (FDA Regional Milk Specialist)																										

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		MANUFACTURING PLANT INSPECTION REPORT <i>(Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>		INSPECTING AGENCY/TPC/ CERTIFICATION AGENCY/SSC Wisconsin Department of Agriculture, Trade and Consumer Protection - Division of Food and Recreational Safety	
NAME AND LOCATION OF PLANT ProAmpac 1055 Winchester Rd Neenah, WI 54956					
1. FLOORS Smooth; impervious; in good repair..... (a) Joints between walls and floors tight; impervious..... (b) Floor drains properly trapped; sloped to drain..... (c)		10. LOCKERS AND LUNCHROOMS Separate from plant operation; self-closing doors..... (a) Eating/storage of food prohibited in fabrication and storage areas..... (b) Locker and lunchrooms clean..... (c) Cleanable trash containers provided; properly labeled, covered..... (d) Handwashing facilities convenient..... (e) Employee handwashing signs posted..... (f)		Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair..... (b) X Take-off tables and other container contact surfaces properly constructed; clean; in good repair..... (c) Grinders, shredders and similar equipment properly installed; protected from contamination..... (d) Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected..... (e)	
2. WALLS AND CEILINGS In fabrication areas—smooth; cleanable; light-colored..... (a) In fabrication and storage areas—good repair..... (b) Openings in walls and ceilings effectively sealed..... (c)		11. DISPOSAL OF WASTES Stored in covered, impervious, leak-proof containers; does not apply to production scrap..... (a) Waste containers properly identified..... (b) Storage of garbage/rubbish meets requirements..... (c)		16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND/OR CLOSURES Materials from approved source..... (a) Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated..... (b) Containers, closures or materials on floor not used..... (c)	
3. DOORS AND WINDOWS All outside openings protected against entrance of insects, rodents, dust, and airborne contamination..... (a) Outer doors tight, self-closing..... (b)		12. PERSONNEL - PRACTICES Hands washed as required..... (a) Clean outer garments; hair restraints..... (b) No person affected by disease in communicable form; while a carrier of such disease; or with inadequately protected wounds or lesions shall work in the fabrication areas..... (c) Tobacco use in authorized areas only..... (d) Unsecured jewelry not permitted in fabrication areas..... (e)		17. WAXES, ADHESIVES, SEALANTS, COATING AND INKS Handled and stored to prevent cross contamination with non-food-grade materials; storage areas clean and ventilated..... (a) Unused materials covered, labeled and properly stored..... (b) Nontoxic; imparts no flavor or odor; non-contaminating; complies with 21 CFR Parts 174-178..... (c) Transfer containers clean; covered, properly identified..... (d)	
4. LIGHTING AND VENTILATION Adequate light in all rooms..... (a) Ventilation sufficient..... (b) Pressure ventilation systems properly filtered..... (c) X		13. PROTECTION FROM CONTAMINATION Product contact surfaces protected; all materials in process properly protected..... (a) X Air under pressure directed at materials or product contact surfaces in compliance..... (b) Air directed at materials or product contact surfaces by fans or blowers in compliance..... (c) Pesticides approved; EPA registered..... (d) Pesticides used in accordance with directions; precludes contamination of containers/closures..... (e)		18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT Handling of container and closure surfaces minimized..... (a) Hands sanitized frequently or clean, single-use gloves worn; sanitizing dispensers convenient..... (b)	
5. SEPARATE ROOMS Fabrication areas separate from non-fabrication areas when required..... (a) Regrinding plastic and paper trim shredding, packaging and baling conducted in separate room(s) from fabrication areas or as Appendix J permits..... (b)		14. STORAGE OF MATERIALS AND FINISHED PRODUCT Away from any wall; soiled outer turns or edges discarded..... (a) X Stored in clean, dry place, protected from splash, insects, and dust..... (b) Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage..... (c) Containers for storage of resin, raw and reuse materials are covered, clean, impervious and properly identified..... (d) In-process storage bins that touch the product contact surface constructed of cleanable, nonabsorbent material; clean..... (e)		19. WRAPPING AND SHIPPING Single-service articles properly containerized prior to shipping..... (a) Packaged contents protected from contamination..... (b) Transportation vehicles clean; in good repair; not used for unapproved uses..... (c) Paperboard containers, wrappers and dividers not reused..... (d) Packaging materials in compliance..... (e)	
6. TOILET FACILITIES-SEWAGE DISPOSAL Disposal of sewage; other waste; in public sewage system or in compliance with Local and State Regulations..... (a) All plumbing complies with Local and State plumbing Regulations..... (b) Solid, tight-fitting, self-closing doors..... (c) Toilet rooms and fixtures clean; in good repair..... (d) Adequate light and ventilation; ducts vented to the outside..... (e) Proper handwashing facilities..... (f) Open windows effectively screened..... (g) Employee handwashing signs posted..... (h) Eating/food storage prohibited..... (i)		15. FABRICATING EQUIPMENT Contact surfaces clean; milk plant equipment utilized for preforming containers clean and sanitized prior to operation..... (a) X		20. IDENTIFICATION AND RECORDS Plant identification on outer wrapping as required..... (a) Glass containers properly labeled..... (b) Required bacteriological tests on file; maintained as required; and in compliance..... (c) Required bacteriological and chemical test records for all component parts used in final assembled product on file..... (d) Information on file from suppliers of raw materials, waxes, adhesives, sealants, coatings and inks indicating compliance..... (e) Information on file from suppliers of packaging materials indicating compliance..... (f) X	
7. WATER SUPPLY Safe; complies with bacteriological and construction requirements..... (a) No direct or indirect connection between safe and unsafe water..... (b) Sampled and examined as required..... (c) Recirculated cooling water used in water baths complies with bacteriological standards, tested semi-annually..... (d) Testing records maintained as required..... (e)		8. HANDWASHING FACILITIES Hot and cold and/or warm running water, soap, individual towels or air dryers convenient to fabrication areas; covered trash containers when required; hand sanitizers used as Appendix J permits..... (a) Handwashing facilities clean..... (b)		21. SURROUNDINGS Surroundings neat and clean and free of breeding areas, conditions attracting or harboring flies, insects or rodents..... (a) Driveways graded; no standing water..... (b)	
9. PLANT CLEANLINESS Floors, walls, ceilings, overhead beams, fixtures, pipes and ducts clean in rooms as required..... (a) X Plant free of evidence of insects, rodents and birds..... (b) Machines and appurtenances clean..... (c) X					
REMARKS (If additional space is required, please place information on the back of this Form or on a separate page.) See attached narrative report.					
DATE 11/16/2023		SANITARIAN/SRO/SSC/RMS Michele Soback			
NOTE: This Form has been developed for use with Appendix J of the <i>Grade "A" Pasteurized Milk Ordinance</i> .					

IMS SINGLE-SERVICE SURVEY

PLANT NAME: ProAmpac

PLANT #: 55-4831

DATE: November 16, 2023

A routine Interstate Milk Shippers (IMS) survey was conducted at this Single Service Manufacturing plant to determine compliance with the requirements of Appendix J of the Pasteurized Milk Ordinance (PMO). This survey was conducted by Michele Sobeck, WDATCP Milk Sanitation Rating Officer. Plant personnel accompanying this survey was Compliance Manager Greg Porter.

ProAmpac is a plastic film extrusion laminating and slitting facility with a Partial plant listing for IMS related products. Processing lines included in this plant's partial listing are: Extruder 1 and Winder 1.

The following violations were noted during the course of the survey.

A. DEBITED VIOLATIONS:

4c. Pressure ventilation systems properly filtered (2 points)

- The two small make-up air units that bring outside air into the air handling mezzanine adjacent to the main extrusion laminating processing room of the plant are not equipped with filters. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust shall be properly filtered.

9a&c. Plant Cleanliness (3 points)

- There is an accumulation of dirt, debris, and scrap material on the floor in multiple areas near and beneath Extruder 1.
- Accumulation of items and food containers (lost and found area) present in the corner of the lunch room.
- Piles of floor debris present near the shipping doors.

13a. Product contact surfaces protected; all materials in process properly protected (3 points)

- Several of the walkway cross-over platforms above the web path of Extrusion Laminator 1 have trap doors and open seams in them. The inside ledge of the trap doors and open seams in the deck plates are directly above the web path with no suitable protection in place whereby dirt and other contaminants will fall directly onto in-process materials below.

15a&b. Fabricating Equipment (5 points)

- Tape is wrapped over a number of the rollers in the web path for Winder 1 as well as being placed on the framework over the webpath. Makeshift devices such as tape shall not be used on fabricating equipment..
- The underside of the curing dryer of Extruder 1 has droplets of potential contaminants located directly over the webpath.
- Several of the support beams and framework of the winder and extruder are unclean.

20f. Identification and Records (3 points)

- There is no current documentation available within the past year indicating that the plastic bag materials used as overwrap for rolls of film stock at this plant comply with the bacteriological standards of PMO Appendix J, Section C. The most recent documentation are laboratory test reports dated 10/15/2020 for the plastic bags.

14a Storage of Materials and Finished Product (3 points)

- Several boxes of resin are stored directly against the wall which does not allow sufficient distance to facilitate inspection, cleaning and pest control activities.

B. NON-DEBITED VIOLATIONS:

17a. Waxes, Adhesives, Sealants, Coatings and Inks

- An accumulation of dried primer and other unclean conditions exists in the vicinity of the primer tank. Waxes, adhesives, sealants, coatings and inks used for containers and/or closures shall be handled and stored in a manner that shall prevent cross contamination with similar non-food-grade materials.

2b Walls

- Several areas of the warehouse ceiling are separating at the seams.
- Area of raw insulation present between dock doors 5 & 6.

C. NOTES:

The thin gauge flexible plastic film produced under this plant's IMS listing is a 3 layer laminated structure that is used as the product contact sealant layer in the further construction/processing of end cap closures utilized on single service canister type containers. The film produced here is packaged in roll-stock form and is utilized in further manufacturing operations at another IMS listed plant. The IMS specification is #1060107.

Sani-Wipes are used as the final cleaner/sanitizer on product contact surfaces of equipment. This product is an EPA registered sanitizer and is a no-rinse sanitizer only requiring air dry before next use on product contact surfaces.

Resin for the laminating process is received in Gaylord boxes. This resin forms the product contact layer on both sides of the 3 layer laminated film structure. The manufacturer's certification letter for this Marlex 1017 LDPE resin is maintained on file at this plant and states conformity to 21 CFR 177.1520(c)2.2.

The middle PET layer of the 3 layer laminated film structure does not make contact with product or the product contact surface of the film structure. This middle layer sourced from Kolon Industries of Korea, which is not an IMS listed plant. This plant maintains certification documentation on file from the manufacturer of the film that the materials utilized in the film complies with 21 CFR 177.1630(f),(g) dated 10/9/2020.

Regrind is not used in the manufacture of IMS single service products at this plant.

A PEI primer A131X is used as part of the extrusion laminating process. This primer does not meet the specifications of 21 CFR 174-178. Therefore, this plant commissioned a migration study on 7/29/2015 which indicates that none of the components of the primer migrated through the 1017 LDPE layer establishing that layer as a functional barrier. The migration study tested for any detectable components of the primer on the external surface of the film and was conducted using the same film structure specifications that are utilized for the IMS listed film processed at this plant: 1 mil 1017 LDPE extruded layer, primer, 4 mil PET layer, primer, 1 mil 1017 LDPE extruded layer.

Resin silos are not utilized for the storage of resins used in the manufacture of IMS related products at this plant.

Fan blown air (<15 PSI) in contact with in-process materials takes place at the turn bars in the Extrusion Laminator 1 processing line. The air intake for this fan blown air application is equipped with an air filter manufactured by Endustria Filter Manufacturers, Inc. which is rated 98% efficient at 10 microns. PMO Appendix H requirements for fan blown air specifies, "Intake air filter efficiency shall be at least 98% SAE J726, June 1987 using Air Cleaner (AC) coarse test dust" which correlates to the modern ISO 5011 standard of 20-120 micron test particles removed at a rate of 98%.

Compressed air (≥ 15 PSI) in contact with in-process materials take place at the curing sections of the Extrusion Laminator 1 processing line. A PCH High Efficiency Coalescing Filter is in place to remove moisture from the air supply piping downstream from the compressor. The final filter on the compressed air lines located near the point of application is rated to effectively remove particulates down to 0.01 of a micron. PMO Appendix H requirements for compressed air directed at in-process materials specifies, "Final filter efficiency shall be at least 99% as measured by the Dioctylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns)" which correlates to the modern HEPA standard of 99% efficiency for a 0.3 micron particle size.

No processing aids are used on product or product contact surfaces of fabricating equipment in conjunction with IMS listed manufacturing operations at this plant.

Bacteriological testing of the plastic film manufactured here is not required by PMO Appendix J as this plant is not the final producer of the single service container/closure.

The stretch wrap overwrap material used over rolls of work in progress product is obtained from Berry Plastics of Evansville, IN and has a letter of guarantee that the material complies with 21 CFR 174.5, 175.105, 175.300, 177.1340, 177.1430, 177.1520(c)2.1,2.2,3.1,3.2,3.1a,3.2a, 177.1640, 178.2010, and 178.3740. This material does not need to be tested since it does not come in direct contact with the product.

The Clear Pro HL-200 Star Seal IC bags used over rolls of finished product is obtained from BMSI of Monroe, GA and has a letter of guarantee that the material complies with 21 CFR 177.1520. There is no current documentation available indicating that this overwrap material complies with the bacteriological standards of PMO Appendix J, Section C as previously mentioned in this report. The last round of testing was conducted on 10/15/2020 by Summit Laboratories.

Food grade lubricants, which are NSF H1 listed, are used in applications where incidental contact with product or product contact surfaces may occur on the IMS listed processing lines at this plant. These lubricants are stored in cabinets and racking in the maintenance supply storage area of the plant.

Outside make-up air for production areas of the plant is supplied via air handling equipment located on the utility mezzanine adjacent to the extrusion laminating processing room of the plant. The two smaller make-up air handling units that bring outside air into this mezzanine area (which opens directly into the processing room) are not currently equipped with intake air filters as mentioned above in this survey report.

Water for the plant is supplied by the Town of Neenah municipal water supply system.

There are no direct water bath cooling water applications utilized in conjunction with IMS listed processing operations at this plant. Recirculated cooling water is only utilized in thick walled chill rolls as part of processing operations at this plant.

There are 4 RPZ cross-connection control device(s) in place on the water distribution system in the plant that are regulated by the State's water control authority (DSPS) and were last inspected on 7/05/2023.

In general this is an under-one-roof facility with the following primary rooms: processing room including IMS extrusion laminating line and other non-IMS processing equipment, a maintenance room, a receiving dock and warehouse, and a winder/slitter processing room which also includes warehousing areas and the shipping dock. The non-production areas were found to be adequately cleaned and maintained to production room standards. Separate rooms for the office and break room facilities also exist at this plant.

Pest control services are provided by Valley Pest Control with routine service on a weekly basis. Pest control service records are maintained on file at this plant.

There are no offsite storage facilities utilized in conjunction with products processed at this plant.

The label applied to the outer wrap and inside the core of roll stock film prior to shipment out of this plant is properly labeled including the plant name "ProAmpac", city "Neenah", and state "WI" along with other material and production information.

D. REQUIRED DOCUMENTATION:

The following documentation is required. It is recommended that documentation supporting these items be maintained as applicable in an IMS binder to facilitate future IMS surveys.

1. Only resin in compliance with applicable sections of 21 CFR, Parts 174 – 178 may be used to produce IMS single-service items. Component materials and component parts must be manufactured in an IMS listed facility. Documentation, in the form of letters of guarantee, must be available at the plant.
2. Line cleaning and / or sanitization procedures (written SOP) after maintenance, after cleaning with non-food grade cleaners or after producing non-IMS product.
3. Pest control records.
4. Annual Cross Connection Control Performance Tests for testable backflow protection devices.
5. Verification letters indicating that waxes, adhesives, sealants, coatings, and inks meet the applicable requirements of 21 CFR, Sections 174–178.
6. Verification that materials, which do not meet the applicable requirements of 21 CFR, Parts 174–178, are not applied to, come into contact with, or migrate to a product contact surface or incidental product contact surface of a finished product. Migration testing may be utilized to establish that a functional barrier is present or that there is no set-off of lacquer / coating components when in rollstock or nested-container form.
7. Documentation that wraps and liners meet the applicable sections of 21 CFR, Sections 174 – 178 and the bacteriological testing criteria listed in Appendix J, Section C (minimum annual test).
8. Bacteriological product testing results (refer to PMO Appendix J, Section C), performed in an IMS listed laboratory, when applicable.
9. Compressed and fan blown air filter efficiency documentation, when applicable (refer to PMO Appendix H, Section II – Air Under Pressure – Filter Performance).
10. Private well water supply and recirculated cooling water bath bacteriological test results, when applicable.
11. Documentation that glycol is food grade or USP, if used as a cooling medium in a thin-walled heat exchanger or in a recirculated water bath.
12. Air intake systems for production areas and resin silos must be filtered and inspected. If the plant has a safety policy that precludes access to these areas an alternate approach may be utilized. On the day of the survey, plant personnel may take photos of silo intake filters and final filter banks for

production area HVAC units. In addition, a HVAC filter change log which identifies the specific filters, the date(s) changed and the condition of the filter(s) should be maintained.

E. CONCLUSION:

Based upon a passing score of 81 it will be recommended that this plant continue to be included on the IMS List as a certified supplier of single service product(s). The findings of this survey were discussed with plant management at the conclusion of the plant visit. If you have questions or concerns pertaining to this survey, feel free to contact me at michele.sobeck@wisconsin.gov

U.S. Department of Health and Human Services
Food and Drug Administration
STATUS OF MANUFACTURING PLANTS
(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant ProAmpac
Number 55-4831
Date of Certification 11/16/2023

Sanitation Compliance Rating¹ 81

NAME OF PLANT		ITEMS OF SANITATION																								REMARKS			
		Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination		Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures		Waxes, Adhesives, Sealants, Coating and Inks		Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records			Surroundings	Bacterial Count*	Coliform Count*
	ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21			
	WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10	
ProAmpac					2					3				3		3	5							3					19
TOTALS					2					3				3		3	5							3					19

Footnotes:
¹Sanitation Compliance Rating = 100 – Total Debits
²Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)
^{*}Used only when not in compliance.