

AIB International

GMP Inspection Results Report

Consolidated Standards for Inspection: Distribution Centers

Inspection Information:

Facility Name	Diamond State Warehousing & Distribution
Account #	19814
Facility Address	300 Pigeon Pt Rd New Castle, Delaware 19720 United States
Date(s) of Inspection	17 Sep 2012

Score

Category Score Range	180-195	160-175	140-155	<=135	
Categories	MI	IN	S	U	
Operational Methods and Personnel Practices	1	0	0	0	195
Maintenance for Food Safety	0	2	0	0	170
Cleaning Practices	1	0	0	0	195
Integrated Pest Management	1	1	0	0	175
Adequacy of Prerequisite and Food Safety Programs	1	3	0	0	160
				Total Score	895

Facility-Specific Questions

#	Question	Comments
1.9	Does the facility use bulk dry materials?	No
1.9.a	State the bulk dry materials received.	N/A
1.9.b	Provide the screen size of the sifter.	N/A
1.9.c	State the frequency of screen and tailings checks.	N/A
1.11	Does the facility use processing aids?	No
1.11.a	What are the processing aid(s)?	N/A
1.11.b	Are processing aids segregated from non-food materials?	N/A
1.11.c	Is food approval documentation provided?	N/A
1.14	Does the facility use bulk liquid materials?	No
1.14.a	State the bulk liquid materials received.	N/A
1.14.b	State where strainers are provided.	N/A
1.14.c	State the frequency of strainer inspections and if they are documented.	N/A
1.15	Are foreign material control devices used?	No
1.15.a	List the device(s) used.	N/A
1.15.b	Are they present on all lines?	N/A
1.15.c	Comment on device testing observed during the inspection.	N/A
1.22	Does the site have temperature controlled areas such as coolers and freezers?	Yes, several coolers were used for quality purposes.
1.22.a	State the temperatures noted at the time of the inspection.	Cooler #1 - 57, Cooler #2 - 57, Cooler #3 - 65, Cooler #4 - 44, Cooler #5 - 45
1.22.b	State the method of temperature monitoring (manual or continuous).	Temperatures were recorded several times per day and were recorded on the facility refrigerator log.
1.22.c	State if an alarm system is present.	Yes, an email would be generated to alert personnel if temperatures exceeded set parameters.

1.25	Are cans, bottles, or other rigid packaging materials used at this facility?	No
1.25.a	What is the rigid packaging? Cans, bottles, boxes?	N/A
1.25.b	State how they are cleaned prior to filling (water, air rinse, etc.).	N/A
1.25.c	State if the systems were functional.	N/A
1.25.d	State the maintenance frequency and records maintained for this equipment.	N/A
2.21	Does the site use potable water, ice, or steam for product or food contact?	No
2.21.a	State the source of the potable water supply (well, city, etc.).	Local water company
2.21.b	State the source of the records indicating potability.	Annual report issued for 2011 in June of 2012.
2.21.c	Is ice made in-house or purchased?	N/A
2.21.d	List the source of testing records for ice and if they indicated that it was potable.	Water company results were on file. Records indicated that water met USEPA drinking water standards.
2.21.e	Is food approval documentation provided for chemicals used for the generation of steam for food contact?	N/A
2.21.f	List the source of testing records for steam used for product contact.	N/A
2.21.g	State if the back flow prevention devices are checked for function and provide the last date of testing.	There were no backflow prevention devices.
3.2	Does the facility use sanitizers on food contact surfaces?	No
3.2.a	Is sanitizing followed by a potable water rinse?	N/A
3.2.b	Is the sanitizer concentration verified?	N/A
3.2.c	Are corrective actions documented when results are not in compliance with label directions?	N/A
4.4	Are IPM services provided by a contractor?	Yes
4.4.a	State the name of the service provider.	J.C Ehrlich Company
4.4.b	Is the business license current?	Yes, valid until 12/31/2012.
4.4.c	Are the PCO licenses current?	Yes, the PCO was licensed by the Delaware Department of Agriculture (expires 12/31/2012).

4.4.d	If licensing of PCO's is not required, were training records current?	The license was on file.
4.6	Were pesticides used at this site?	Yes
4.6.a	State the names of the pesticides reviewed during the inspection.	Records indicated that P.T. PI (499-444 and Generation Blue Max Mini Blocks (7173-288) had been used since the previous visit.
4.6.b	Were current labels provided?	Yes
4.6.c	Were current MSDS (Chemical Safety Data) sheets provided?	
5.2	Who was assigned responsibility for food safety at the facility?	
5.2.a	Does the facility have a current license to produce, manufacture, or store food products (local health department, state, or other agency)?	
5.2.b	For facilities producing in or exporting to the USA, has the facility had to report or have they received notice of receipt of a Reportable Food (Reportable Food Registry - RFR)? [INFORMATION ONLY - NOT SCORED]	
5.10	Does the site have a documented Microbiological Control Program in place?	
5.10.a	State if the testing is for sanitation, environmental, raw materials/finished products.	
5.10.b	State the microorganisms tested for.	
5.10.c	State if an in-house or outside lab is used.	
5.11	Does this country have allergen regulations or does the site ship to countries with allergen regulations?	
5.11.a	State the names of the allergens handled at this facility.	
5.16	Has the site been inspected by a regulatory agency in the past year?	
5.16.a	State the name of the agency and the date of inspection.	
5.16.b	State if the site addressed findings identified by the regulatory inspection.	
5.22	List the materials for which specifications were reviewed.	
5.23	List materials for which COA's or letters of guarantees were reviewed.	

5.24	Does the process contain a kill step?	
5.24.a	State the kill step.	
5.25	Is there a HACCP program in place?	
5.25.a	List the CCPs.	
5.25.b	State if the plan has been validated and who did the validation.	
5.25.c	State the date of the most recent reassessment.	
5.25.d	State the names of the products falling under regulatory HACCP produced or stored at this site.	

Findings with Risk

#	Risk	Standard	Requirement #	Location	Finding/Recommendation
1	Minor Issues Noted (MI)	Containers and Utensils	1.24.1.3	Facility Overview	<p><u>Finding:</u> Some improperly labeled and/or color-coded containers were noted during the inspection.</p> <p><u>Recommendation:</u> All secondary containers should be clearly marked as to content to avoid confusion and possible misuse.</p>
2	Improvement Needed (IN)	Pest Prevention	2.9.1.3	Receiving Area	<p><u>Finding:</u> One side cushion was missing on the exterior of dock door #6, the dock plate side seal was badly torn on overhead door #2 and the personnel door at the receiving dock had a damaged hinge and was ajar. These openings created possible entry points for pests. As a general statement, gaps of 1/4 inch (6 mm) or greater could allow pest entry.</p> <p><u>Recommendation:</u> The door and seals should be repaired or replaced as part of the pest exclusion efforts.</p>
3	Improvement Needed (IN)	Water Quality	2.21.1.6	Support Areas	<p><u>Finding:</u> Back siphonage devices were not provided and maintained to prevent backflow and back siphonage.</p> <p><u>Recommendation:</u> Backflow devices should be installed and monitored on a periodic basis. These devices protect the water supply.</p>
4	Minor Issues Noted (MI)	Water Quality	2.21.2.1	Facility Overview	<p><u>Finding:</u> Backflow and back siphonage devices were not included in the Preventive Maintenance Program.</p> <p><u>Recommendation:</u> When installed, the devices should be added to the program.</p>
5	Minor Issues Noted (MI)	Periodic (Deep) Cleaning	3.5.1.1	Production	<p><u>Finding:</u> Webbing and dust accumulations were pointed out along the perimeter was behind cooler #3.</p> <p><u>Recommendation:</u> This area should be deep cleaned. The activity should be added to the MCS.</p>
6	Minor Issues Noted (MI)	Interior Rodent Monitoring Devices	4.12.1.4	Production	<p><u>Finding:</u> A few of the interior traps contained webbing and debris.</p> <p><u>Recommendation:</u> The traps should be cleaned during their weekly service to help ensure functionality.</p>
7	Improvement Needed (IN)	Insect Light Traps	4.13.1.4	Production	<p><u>Finding:</u> Shatter-resistant bulbs were not used in ILT units and light tubes were not incorporated into the Glass, Brittle Plastics, and Ceramics Program.</p>

					<u>Recommendation:</u> It was suggested that shatter-resistant bulbs be used. This would limit the potential for glass dispersion in the event of accidental breakage.
8	Minor Issues Noted (MI)	Insect Light Traps	4.13.2.2	Production	<u>Finding:</u> ILT light tubes were changed annually (last done 10/26/2011) but the date for the change did not coincide with the beginning of the active season. <u>Recommendation:</u> The tubes should be changed on an annual basis at the beginning of the active season. This would help ensure maximum efficiency during peak insect season.
9		Written Policy	5.1.1.3	Facility Overview	<u>Finding:</u> There is no evidence of communication of the Policy Statement at this facility. <u>Recommendation:</u> The policy should be communicated. This is sometimes done by posting or formally covered during the structured employee training program.
10	Improvement Needed (IN)	Accountability	5.2.1.2	Facility Overview	<u>Finding:</u> A current and accurate organizational chart was provided. The responsibility for ensuring regulatory compliance was not defined. <u>Recommendation:</u> This responsibility should be clarified to help ensure that the facility had a designated person or persons that understands and complies with changes to regulatory laws and guidelines.
11	Improvement Needed (IN)	Training and Education	5.5.1.3	Facility Overview	<u>Finding:</u> The training program did not define requirements for ensuring comprehension of the information presented. <u>Recommendation:</u> The criteria should be developed and implemented. This frequently takes the form of a written test or quiz.
12	Improvement Needed (IN)	Written Procedure Audits	5.7.1.1	Facility Overview	<u>Finding:</u> A risk-based audit of procedures was not completed. <u>Recommendation:</u> The audits should be done. Audits should be conducted at least annually. The scope and frequency of the audit should be based on risk assessment or importance of activity. Competent auditors should be independent of the area of the operation being audited. Audit documentation would need to include identified observations, specific assignments, Corrective Actions, and actual accomplishments. Audit findings should be brought to the attention of the person responsible for the area or activity inspected. Timelines should be set for Corrective Action implementation. Results of Corrective Actions should be verified for completion.
13	Minor Issues Noted (MI)	Preventive Maintenance	5.14.1.1	Facility Overview	<u>Finding:</u> This small facility did not have a formal maintenance function. Small repairs were

		Program		<p>handled in-house and larger repairs were contracted on an "as needed" basis.</p> <p><u>Recommendation:</u> Future maintenance activities should focus on door seals and backflow device installation/ testing.</p>
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Additional Comments

#	Risk	Standard	Requirement #	Location	Finding/Recommendation
1		Rejection of Shipments	1.1.1.4		<u>Finding:</u> Temperature documentation appeared to be complete (if required by the customer).
2		Material Inventory	1.4.1.1		<u>Finding:</u> Ingredients and packaging materials were rotated per the customer in this public warehouse. Inventories were managed in the automated inventory management system.
3		Material Inventory	1.4.1.2		<u>Finding:</u> This facility had no insect-susceptible materials in storage longer than four weeks (produce distribution).
4		Temperature Measuring Devices	2.17.2.2		<u>Finding:</u> Temperature measuring devices used in processes not critical to food safety were calibrated to a defined standard (ice slurry method weekly).
5		Integrated Pest Management (IPM) Program	4.1.1.1		<u>Finding:</u> A written Integrated Pest Management (IPM) Program was in place for this facility. The "Integrated Pest Management Service Program" was reviewed during the inspection.
6		Facility Assessment	4.2.1.1		<u>Finding:</u> The annual facility assessment (9/13/2012) was documented and current.
7		Signed Contracts	4.4.1.1		<u>Finding:</u> A signed agreement was in place with J.C. Ehrlich Pest Control Company to provide IPM services. A copy of the service agreement included: materials, the facility name, facility contact person, frequency of services, description of services, term of contract, a current list of approved chemicals, emergency call procedures, service records to be maintained and notification requirements for changes in materials or services. The contract was signed and implemented in March 2009.
8		Credentials and Competencies	4.5.1.3		<u>Finding:</u> GMP training records for IPM service providers (1/23/2009) were on file.
9		Credentials and Competencies	4.5.1.6		<u>Finding:</u> A current certificate of insurance (expires 10/1/2012) was on file.
10		Written Policy	5.1.1.1		<u>Finding:</u> The facility had a documented "Quality Policy" (Policy #107-01) outlining its commitment to produce, store and distribute safe and legal products. The policy was included in the facility's "Quality Manual" and which was signed by the President on 3/10/2008.
11		Accountability	5.2.1.3		<u>Finding:</u> The facility had a designated process (trade group membership) for remaining current on changes in legislation, food safety issues, scientific, technical, and industry developments.

12		Written Procedures	5.4.1.1		<u>Finding:</u> Written procedures were established to define step-by-step processes to ensure product safety. Alternates/Deputies were noted on the job descriptions.
13		Self-Inspections	5.6.1.1		<u>Finding:</u> Self-inspections were conducted by the Food Safety Committee (five operations personnel).
14		Chemical Control Program	5.9.1.1		<u>Finding:</u> A written Chemical Control Program "Diamond State Warehouse Chemical Control Program" that addresses all chemicals used in the facility was established.
15		Allergen Control Program	5.11.1.1		<u>Finding:</u> The food distribution center did not handle or produce products containing allergens. However, an "Allergen Audit" was performed on September 13, 2011, as evidence that a risk assessment had been performed confirming that no allergens or chemical sensitive ingredients were handled or utilized in the facility.
16		Receiving Program	5.15.1.1		<u>Finding:</u> A written Receiving Program was in place for the facility. The "Shipping/Receiving Trailer Inspection" (Policy #102- 01) was reviewed during the survey.
17		Receiving Program	5.15.1.8		<u>Finding:</u> Records reviewed (load inquiry form) indicated that documentation for incoming material inspections met the Program requirements.
18		Regulatory Affairs and Inspection Program	5.16.2.1		<u>Finding:</u> A written Regulatory Affairs and Inspections Program was on file. The Program included a list of personnel delegated to accompany all inspectors along with the company policy regarding recording devices, cameras, records, and sample taking. The "Third Party Inspection" (Policy #104-02) was reviewed during the survey.
19		Food Defense Program	5.17.1.1		<u>Finding:</u> Evidence of registration under the FDA Bioterrorism Act was on file at the facility (9/30/2010).
20		Food Defense Program	5.17.1.2		<u>Finding:</u> The facility had conducted a Vulnerability Assessment (checklist dated 7/9/2012) to identify food defense risks.
21		Recall/Withdrawal Program	5.19.2.2		<u>Finding:</u> The mock recall exercise included the first level of distribution outside of the control of the facility (last done 4/24/2012).

Standards Not Applicable

Standard #	Standard Name
1.6	Designated Rework Areas
1.7	Release Procedures
1.10	Sampling Procedures
1.20	Single-Service Containers
2.8	Air Makeup Units
2.15	Temporary Repair Materials
2.16	Food Contact Surface Construction
3.7	Food Contact Surface Cleaning
4.14	Pheromone Monitoring Devices
5.25	HACCP Program