

Executive Summary - Part I
Auditor Judgment Summary
Cebro/White Oak Frozen Foods - April 1-2, 2004

Section Summary						
Category	Section	Auditor Judgment				
		Fully Meets	Substantially Meets	Does Not Meet	Critical Failure	Not Applicable/Auditable
1. Management Responsibility	1.1 Management Commitment and Review	✓				
2. Fundamentals	2.1 Infrastructure	✓				
	2.2 Sanitation		✓			
	2.3 Pest Control	✓				
	2.4 Chemical Control	✓				
	2.5 Personnel Practices	✓				
	2.6 Training & Education	✓				
	2.7 Handling, Storage & Delivery	✓				
	2.8 Vendor Approval		✓			
	2.9 Control of Materials	✓				
	2.10 Packaging Approval for Use	✓				
	2.11 Equipment Approval for Use	✓				
	2.12 Traceability and Recall Management	✓				
	2.13 Crisis Management	✓				
	2.14 Calibration, Measuring and Test Equipment	✓				
	2.15 Food Security		✓			
	2.16 Traffic Control	✓				
	2.17 Maintenance		✓			
3. Food Safety & HACCP Systems	3.1 HACCP Systems	✓				
	3.2 Microbiological Testing	✓				
	3.3 Analytical Testing	✓				
	3.4 Food Allergens & Chemical Sensitivities	✓				
	3.5 Foreign Material Control		✓			
4. Manufacturing Quality Systems	4.1 Conformance to Customer Specifications	✓				
	4.2 Process Control	✓				
	4.3 Inspection & Test	✓				
	4.4 Control of Nonconforming Materials	✓				
	4.5 Good Laboratory Practices	✓				
	4.6 Document Control and Record Keeping	✓				
	4.7 Corrective & Preventive Action		✓			
	4.8 Continuous Improvement	✓				
	4.9 Customer Service	✓				
	4.10 Internal Auditing	✓				
5. Regulatory Considerations	5.1 Labeling Approval	✓				
	5.2 Regulatory Compliance	✓				
	5.3 Management of the Regulatory Process	✓				

Audit Judgments used for Summarizing the 36 Sections of the Checklist

The audit is designed to qualitatively describe the facility's Food Safety and Quality Systems, which are described in five categories. The auditor shall assess the site's performance, relative to the checklist criteria.

The audit report is based on the objective evidence provided to the auditor and observations of how the items in the checklist are deployed on the facility's factory floor. The reader is able to interpret the results of each audit relative to their own expectations and methods for measurement.

Fully Meets	Meets or exceeds the intent of the checklist in design and execution.	Evidence indicates system is fully effective. An effective, well developed and executed system. All checklist criteria for the section have been addressed, as applicable to this facility's programs. Procedures are established, maintained and documented where so noted in the checklist, and can be corroborated by multiple parties and verified by objective evidence.
Substantially Meets	Minor elements from checklist missing, or inadequately designed, or not effectively executed.	Evidence indicates system is adequate but not fully effective. A good, functional system with minor opportunities for improvement. Most applicable checklist criteria have been addressed but some inconsistencies and non-critical deviations exist in documentation or implementation. Procedures appear to be adequately practiced, but cannot be corroborated by multiple parties or verified by objective evidence, or there are several examples of non-critical record-keeping errors, or in-plant observations indicate several, minor deviations from established procedures.
Does Not Meet	Key system elements of checklist missing and/or poorly designed and/or poorly executed.	Evidence indicates system is not effectively developed or implemented. System is poorly designed or not followed. Multiple applicable checklist criteria for the section are missing or not performed. Multiple or repetitive deviations observed in execution or key records.
Critical Failure	Clear evidence or direct observation of conditions that would allow adulterated product to be placed into commerce and/or a clear regulatory failure likely to result in product recall, facility closure or further regulatory action.	Critical violation of GMPs with practices or conditions leading to confirmed or highly probable adulteration of product, or significant deficiencies in required regulatory programs, likely to result in product recall or facility closure; and deficiencies likely would have gone undetected in the absence of the auditor.
Not Applicable/ Auditible	A system that is not needed , or major portions are not controlled at this facility.	Systems described in this section are not needed because of the nature of products or processes at this facility, or systems are controlled somewhere other than by the facility, e.g. corporate, and there is insufficient direct evidence for the auditor to verify actual practices of the key criteria in the section or judge their consistency or effectiveness.