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Food Aid Safety and Quality Management Scheme

With a Look at FDA's Preventive Controls for Human Food Rule

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Elements of Desired Food Manufacturing System

- **Pre-award assurance of existing supplier-owned quality system; Including Pre-award inspection/survey**
- **HACCP-based, with goal of FDA FSMA Preventive Control Rule compliance**
- **Must be preventive/ proactive**
- **In-line with industry supplier/customer practices**
- **Should comply with applicable international regulations**
- **Government is part of release/conformity compliance**



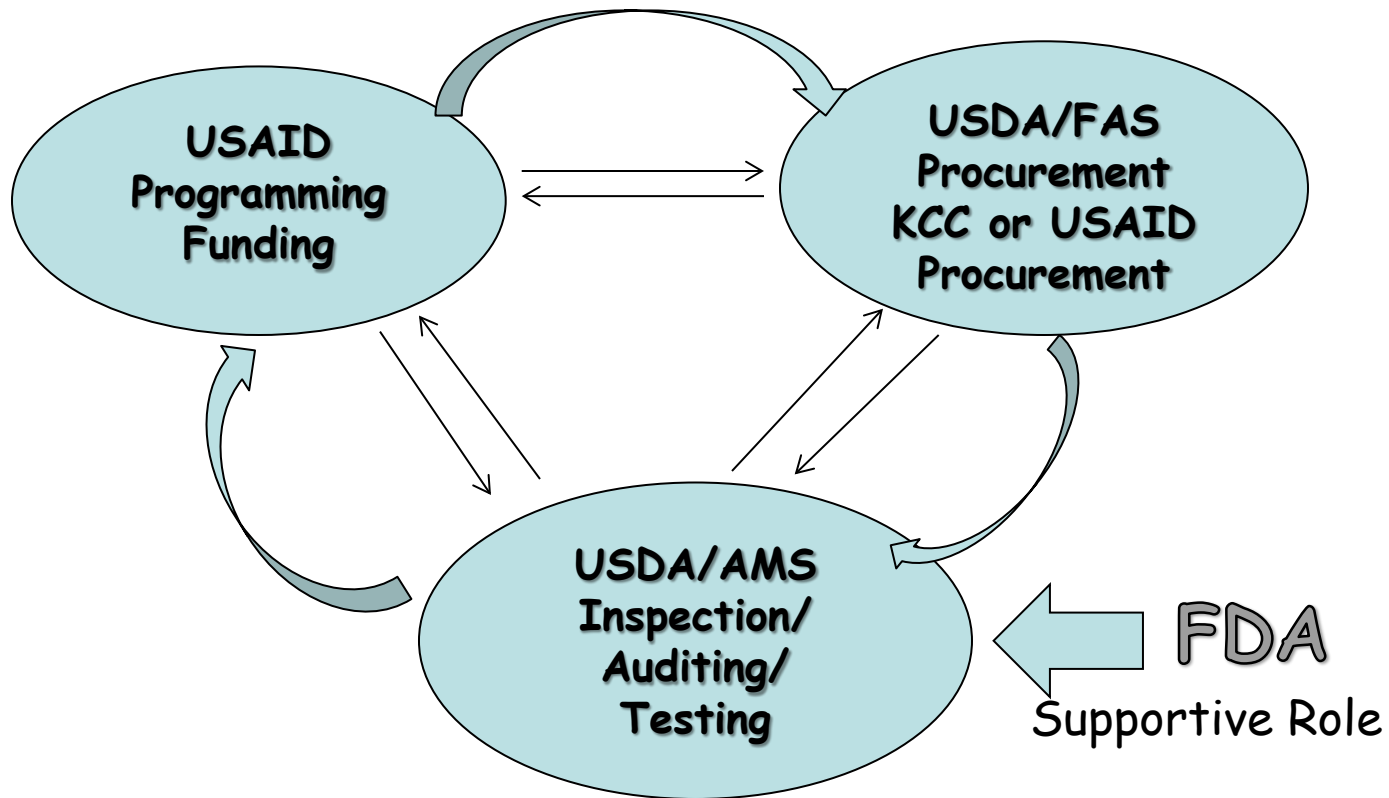
USG Humanitarian Food Aid Commodity Safety and Quality Management Scheme (Team: Ruffo Perez, Richard Boyd, Quentin Johnson, Andy Greenfield)

No.	Phases	Requirements
1	Qualification audit/ preliminary Survey	<ol style="list-style-type: none">1. A preliminary USG audit, before granting contract to potential suppliers, to include:<ul style="list-style-type: none">• Assess facility's HACCP and other food safety & quality systems• Review of written quality plan including commitment from top management• Review 3rd party audit reports covering current/potential suppliers
2	Start-up process	<ol style="list-style-type: none">1. Facility demonstrates capability2. Facility generates baseline data (production, environmental, finished product compliance)3. Initial USG monitoring; Validation of firm's sampling plans and quality systems; Transition from continuous monitoring by USG
3	Ongoing monitoring through indicative parameters	<ol style="list-style-type: none">1. Suppliers provide Certificates of Analysis and Conformance2. USG continues testing indicative parameters. Currently, for RUFs microbiology USG tests for EB and Salmonella, and for micronutrients Vitamin A and Iron
4	Periodic audits	<ol style="list-style-type: none">1. Will assess supplier performance and process capability2. At least annual frequency; (If it is a new contract, USG presence might be compulsory, at least for one production cycle)



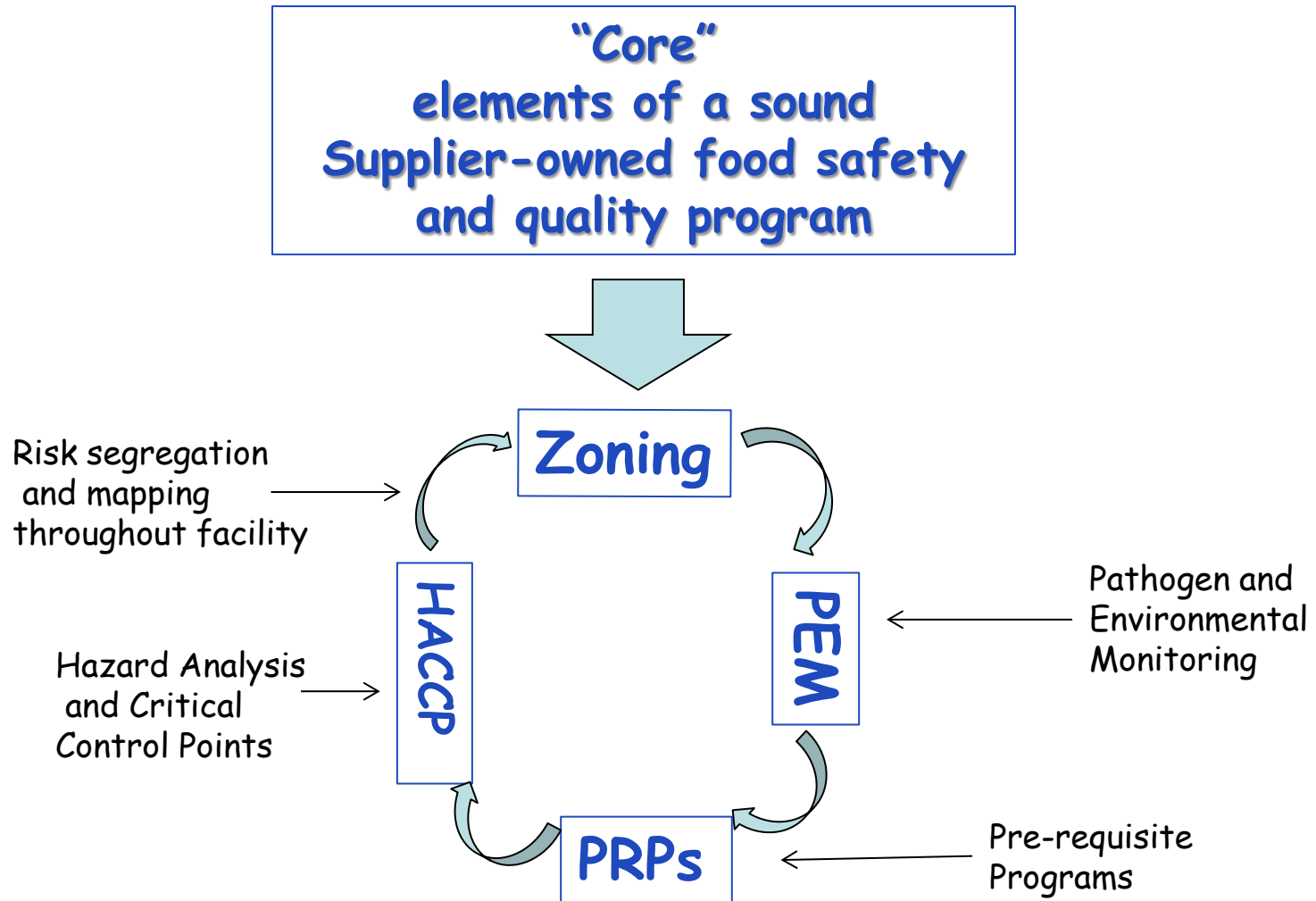
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USG Ready-to-Use Foods Purchasing System





The Culture of Food Safety - A Preventive Food Safety Approach







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FSMA Preventive Controls for Human Food Rule¹

- Applies to facilities regulated under FDA
- Revises current Good Manufacturing Practices
- Adds new preventive control requirements, including:
 - Written Food Safety Plan
 - Hazard Analysis
 - Preventive Controls
 - Monitoring
 - Corrective Actions
 - Verification
 - Supply-Chain Program
 - Recordkeeping
 - Recall Plan
 - Personnel Qualifications
- Staggered Phase-in for Compliance
 - Sept 2018 – Very small businesses (< \$1M yearly prod.)
 - Sept 2017 – Small businesses (< 500 employees)
 - Sept 2016 – All other businesses
 - Some exemptions apply

¹<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf>



FSMA Preventive Controls for Human Food Rule

- PC Rule training for industry and regulators is available through the Food Safety Preventive Control Alliance, see <http://www.iit.edu/ifsh/alliance/>. FSPCA is a joint effort between FDA and the Illinois Institute of Technology, Institute for Food Safety and Health.
- FDA is developing guidance documents to assist industry on:
 - Hazard Analysis & Preventive Controls
 - Environmental Monitoring
 - Food Allergen Controls
 - Validation of Process Controls
 - Small Entity Compliance Guide



USG Shared Goal around Food Aid Safety and Quality

Partnership for efficient humanitarian food aid manufacturing that:

- *Applies current best practices in food safety and quality;*
- *Is poised to meet upcoming food safety regulations;*
- *Successfully meets the needs of recipients.*