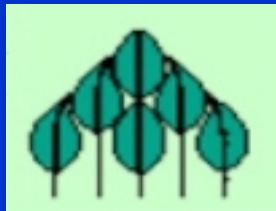


Feed Mill QA Programs and the European Market



**Dan King, Ph.D.
Florida Citrus Processors Association**

**Citrus Processing Short Course
Food Safety & HACCP
September, 2003**



**Productschap Diervoeder [PDV]
aka Product Board Animal Feed
or the Dutch Feed Board**

➤ **The Product Board Animal Feed -- regulatory industrial organization for businesses and for employees in the animal feed production chain in the Netherlands.**

Areas for special attention in common policy are:

- **Quality and product safety**
- **Social matters**
- **Research**
- **Market information**
- **Communication**
- **Market organization regulations**

History/Events leading to changes in Dutch requirements

- 1986 -- lead contamination in Holland (Netherlands)
- 1988/89 - aflatoxin in milk in Holland & Germany
- '90's -- BSE in UK, Ireland, & France
- 1998 -- dioxins in Brazilian citrus pulp, in EU
- 1999 -- dioxins in Belgian feeding fats in Belgium & Holland
- 1999/00 -- diesel oil contamination of palmoil

➤ Published in 1999, Dutch Quality Policy is based upon approach with three areas of ‘Risk Analysis’ --

➤ Risk Assessment, as by HACCP principles at both

➤ generic [the ‘chain’ level], and

➤ specific [individual company level],

(principles of hazard identification and risk characterization)

➤ Risk Management, also as by HACCP principles

(principles of control measures, monitoring, verification)

➤ Risk Communication, of results and program progress; includes trackability/traceability, and the EWS (Early Warning & Response System)

Key Elements for Quality Assurance Programs for compliance with PDV Standards

- Written Product Specifications
- Process Description, including generic flowchart of supply chain and verified flowchart of the production process
- Risk Analysis identifying Hazards and CCP's in Process
- Documented Control Measures for Critical Points
- Measuring Strategy
- Evaluation and Implementation Plan
- Periodical External audit

Food safety

“Feed for Food” -- PDV motto for special quality program

- Focuses - animal feed safety as component of overall food safety.
- Animal feed and food for human consumption can never be viewed in isolation from one another.

GMP + HACCP

- Pro-active quality assurance based on HACCP
 - HACCP risk management system + PDV’s Good Manufacturing/Managing Practice quality assurance standards (GMP).
- GMP + HACCP quality assurance system (known as GMP+)
 - Covers entire chain, from feed ingredients producer to transport company and livestock farmer.
 - Independent inspectors monitor compliance

Early Warning System

- Early Warning & Response System (EWS).
 - Identify/eliminate potential hazards for people and/or animals arising despite preventive quality assurance.

Tracking & Tracing System

- Irregularities in animal feed can be tracked down as quickly and as accurately as possible.
- Proper registration of ingredients and animal feeds makes recall possible when contamination occurs and identifies the source.

FCPA Member producers of Florida Citrus Pulp Pellet (CPP) responses ---

- 2000/01 - FCPA Members developed monitoring program for dioxins in finished CPP
- 2001 - FCPA Members developed Risk Analysis and HACCP principle-based “Quality Assurance Program for Citrus Pulp Pellets”
- Programs developed to meet December 31, 2001 PDV target for certification audits of foreign facilities

- **Generic Model** - quality program model based on
 - Risk assessment programs using Hazard Analysis and Critical Control Point (HACCP) Principles.
 - Identification of the risks, controls for the risk control points
 - Correction activities for risks deviating from control values
 - Proper documentation of the process and control measurements
 - Verification of the effectiveness of the program
 - Recall, tracking, and notification procedures
- Backed by cGMP's, SOP's, and SSOP's
(‘Pre-requisite Programs’)

Key Elements for Quality Assurance Programs for compliance with PDV Standards

- Written Product Specifications
- Process Description, including generic flowchart of supply chain and verified flowchart of the production process
- Risk Analysis identifying Hazards and CCP's in Process
- Documented Control Measures for Critical Points
- Measuring Strategy
- Evaluation and Implementation Plan
- Periodical External audit



**Quality Assurance Model Program
for Citrus Pulp Pellets**

June 6, 2001

PRODUCT DESCRIPTION

Process Category:	Citrus By-Products
Product:	(Dried) Citrus Pulp
Common Name:	Citrus Pulp Pellets (CPP) ; Feed
How To Be Used:	Animal Consumption
Type Of Package:	Bulk
Intended Use:	Livestock Feed
Distribution Control:	Must Meet Storage and Transportation Requirements

Feed Mill QA Programs



fcpa

(Fig. 1) QUALITY ASSURANCE PROGRAM FOR THE FEEDMILL PRODUCTION OF CITRUS PULP PELLETS (CPP)
GENERIC PROCESS FLOW DIAGRAM

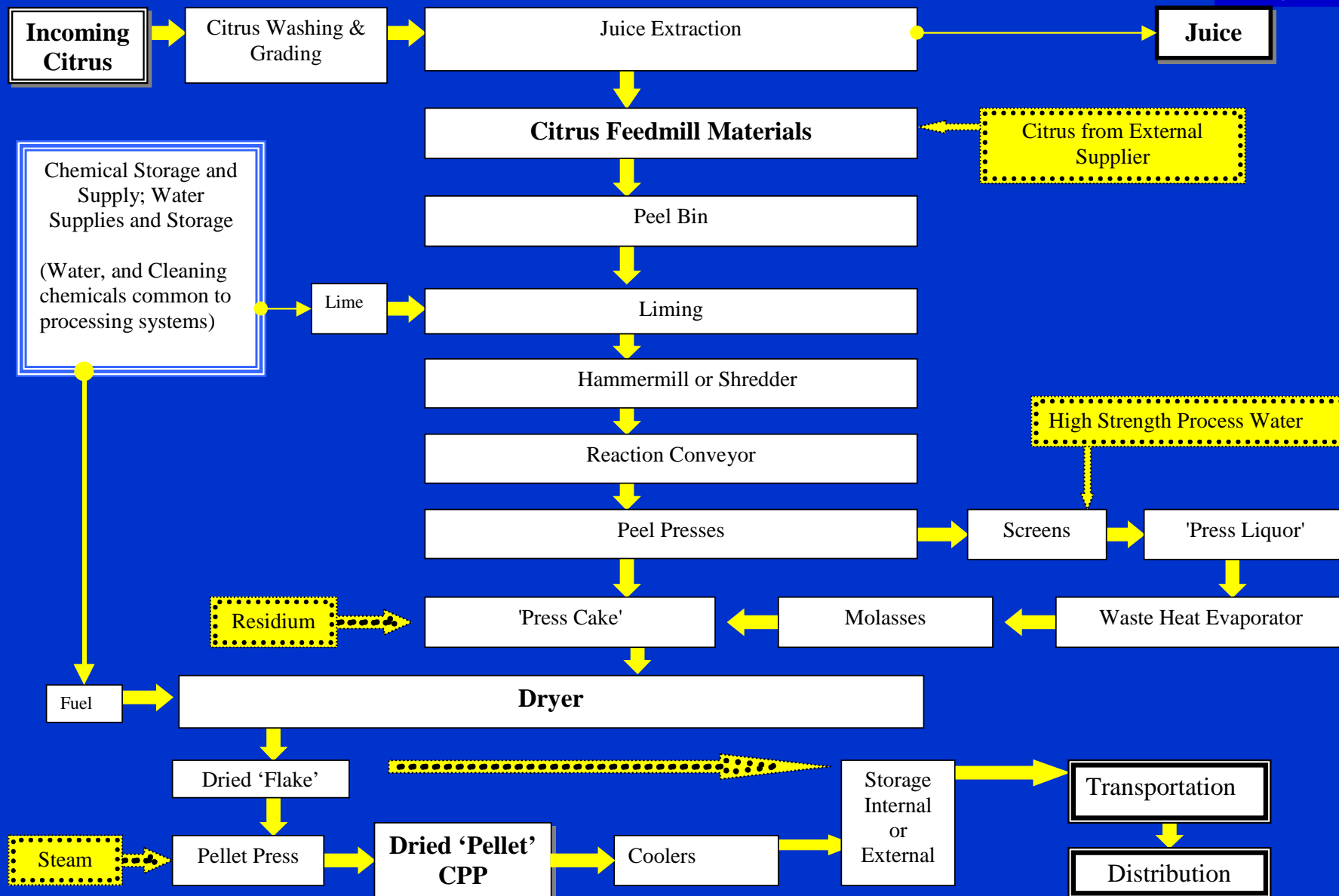


Table 1 -- RISK ASSESSMENT				
		Potential Source	Potential Source	Potential Source
Undesired Materials	RISK	1	2	3
Metal, stones, glass, plastic	Moderate	With incoming citrus	From equipment	From maintenance
Salmonella, E.coli ;'pathogens'	Moderate	With incoming citrus	Incidental handling	From animal re-contamination on site
Arsenic	Low	From citrus	From process water	From process chemicals
Cleansing Agents	Low	Caustics	Acidic and basic sanitation agents	
Dioxin	Low	From contaminated lime		
Fecal or urine residue	Low	With incoming citrus	Incidental handling	From facility wastewater
Fungal contamination; mycotoxins	Low	With incoming citrus	From recontamination during storage	From recontamination during transport
Lubricants;Mineral Oils	Low	Non-food grade lubricants	Mineral and petroleum machinery oils	
Non-citrus plant material	Low	With incoming citrus	From facility properties	
Other Pesticide residues	Low	From citrus	From process water	
Other toxic plant material	Low	With incoming citrus	From facility properties	
Packing Materials	Low	From facility operation waste		
Process Additives	Low	During feedmill process	During process	
Treated wood	Low	With incoming citrus	From facility properties	
Vermin, insects remains	Low	With incoming citrus	Inadequate pest controls	
Wastewater or sludge	Low	From facility properties	From municipal sewer system	

Pre-Requisite Programs

PRP 1	Facilities
PRP 2	Production Equipment, including Preventative Maintenance
PRP 3	Specifications
PRP 4	Supplier Control
PRP 5	Chemical Control
PRP 6	Receiving, Storage and Shipping
PRP 7	Cleaning Procedures
PRP 8	Standard Operating Procedures (SOP's)
PRP 9	Quality Assurance
PRP 10	Water quality
PRP 11	Recall
PRP 12	Personal Hygiene
PRP 13	Training
PRP 14	Pest Control.

Each of the pre-requisite programs (PRP) is described in the text portions of the Quality Assurance Program manual

Table 2-- Risk Analysis and Controls			PRP= Pre-Requisite Program; RCP = Risk Control Point		
Step	Point in Process Flow	Risk(s)	Risk Potential	Addressed by PRP # or RCP	Principle Risk Prevention/Verification
1	Incoming Citrus	Pesticide contamination	Low	3;4;6	FDACS, FDA Programs for testing for pesticide residues
2	Fruit Grading and Washing	Foreign materials	Moderate	RCP 1(P)	RCP 1P--Removal of foreign materials at grading step
2a	Water Addition	Contaminated rinse water	Low	2;8;9;10	Preventative maintenance on boilers; QA assessment of water
2b	Fruit Cleaning Chemicals	Improper chemical; improper strength	Low	2;3;4;5;6;8;10	QA verification of SOP's; review of Certifications of Analysis/MSDS; Preventive maintenance schedule
3	Juice Extraction	Lubricant or petrochemical contamination	Low	2;3;7;;8;13	QA verification of SOP's; use of 'food grade' lubricants only; review of Certifications of Analysis/MSDS; Preventive maintenance schedules
4	(External Citrus Source)	Non-citrus plant materials; pesticide residues; foreign materials	Low	3;4;6	Supplier is required to operate under similar product safety provisions as the feedmill facility
5	Peel Bins	Animal or microbial contamination	Low	2;7;8;14	QA review of SOP's for inspection and cleaning; pest control system review;

Table 2-- Risk Analysis and Controls (cont.)

PRP= Pre-Requisite Program; RCP = Risk Control Point

Step	Point in Process Flow	Risk(s)	Risk Potential	Addressed by PRP # or RCP	Principle Risk Prevention/Verification
6	Liming	Improper chemical; improper strength	Low	2;3;4;5;6;8;10	QA verification of SOP's; review of Certifications of Analysis/MSDS; Preventive maintenance schedules
6a	Lime supply	Dioxin contamination	Low	3;4	Certificate of analysis from supplier verifying dioxin free; FCPA Monitoring program results for dioxin contamination
7	Hammermill	Foreign materials (metal; lubricants)	Low	2;13	Preventive maintenance schedules; metal removal systems
8	Reaction Conveyor	Foreign materials (metal; lubricants)	Low	2;8;9;10;13	Preventive maintenance schedules; metal removal systems
9	Peel Presses	Foreign materials (metal; lubricants); contaminated process water	Low	2;13	Preventive maintenance schedules; metal removal systems; preventative maintenance on boilers; QA assessment of water
9a	High Strength Process water	Microbial or chemical contaminants	Low	5;7;8;10	Preventative maintenance on boilers; QA assessment of water; SOP's
10	Peel Screens	Foreign materials (metal; lubricants); contaminated process water	Low	2;8;9;10;13	Preventive maintenance schedules; metal removal systems
10a	(Addition of residium)	Animal or microbial contamination	Low	3;4;8	QA review of SOP's for inspection and cleaning; pest control system review;

Table 2-- Risk Analysis and Controls (cont.)			PRP= Pre-Requisite Program; RCP = Risk Control Point		
Step	Point in Process Flow	Risk(s)	Risk Potential	Addressed by PRP # or RCP	Principle Risk Prevention/Verification
11	Dryer	Survival of microorganisms	Moderate	RCP 2(B)	RCP 2B--Maintenance of dryer temperatures within control standards; monitoring of documentation on temperature and moisture controls
11a	Dryer Fuel Supply	Chemical contaminants	Low	2;3;4;5;6	Certificate of analysis or MSDS from supplier verifying fuel quality
12	Pellet Press	Foreign materials (metal; lubricants); contaminated process water	Low	2;8;9;10;13	Preventive maintenance and calibration schedules; metal removal systems
12a	Addition of steam	Steam contaminated by boiler chemical	Low	2;8;9;10	Preventative maintenance on boilers; QA assessment of water
13	Cooler(s)	Animal or microbial contamination of cooling air	Low	1;2;7;8;13;14	Preventive maintenance and schedules
14	Storage	Recontamination by biological organisms or water	Moderate	1;2;6;8;13;14	Facility design and SOP's to prevent post-production contamination; pest control programs; Preventative maintenance programs
15	Transportation	Recontamination by biological organisms or water; Foreign materials (metal; lubricants)	Low	1;2;6;7;8;13;14	Building design; SOP for appropriate environment maintenance; pest control programs; use of food grade lubricants

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Pre-Requisite Programs

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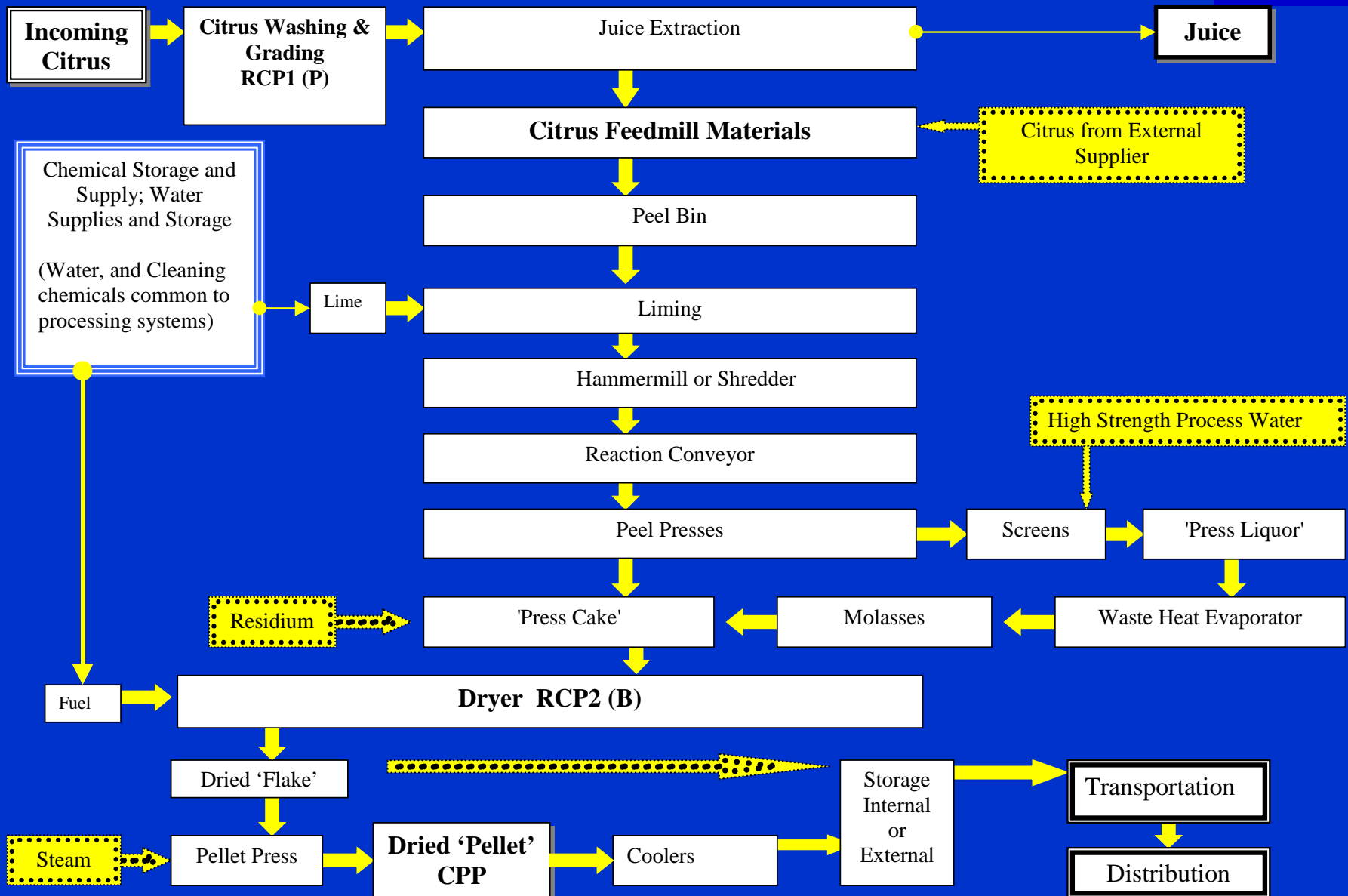
Specifications --(**PRP 3**) All incoming fruit is received under contract specifications. Included in these specifications are the requirements relative to proper licensing, pesticide use, and documentation. *All process chemicals must meet product safety requirements, as well as compatibility requirements with raw materials and other process chemicals.*

Supplier Control.-- **(PRP 4)** The facility assures that its fruit suppliers have in place effective trip ticket and pesticide application records. All fruit suppliers must comply with federal and Florida Department of Agriculture rules with respect to citrus grove management, including rules in regard to pesticide application.

The facility maintains vendor certification for any chemicals used in the processing of fruit, or the processing of peel. Equipment vendors are required to provide equipment designed to be maintained with the necessary design principles for safe production.

Feed Mill QA Programs

(Fig. 1) QUALITY ASSURANCE PROGRAM FOR THE FEEDMILL PRODUCTION OF CITRUS PULP PELLETS (CPP)
GENERIC PROCESS FLOW DIAGRAM



RECALL PROCEDURES

Recall Procedures for CPP developed and initiated by the Quality Assurance Risk Prevention (QARP) Team.

Procedural steps--

- Identification of a non-conforming product**
- Evaluation of the risk associated with the non-conforming product**
- Initiation of withdrawal/recall procedures**
- Notification of the distribution chain**
- Initiation of corrective risk assessment procedures**

December, 2001

- **FCPA Member feedmills audited and certified as approved suppliers of feedstuff to GMP+ certified buyers**
- **Certified/approved CPP facilities subject to ‘verification’ audits**
- **All Member facilities scheduled to be listed on PDV database of approved suppliers (in 2002)**
 - **‘QC-fi’ and ‘Status – Verified’**

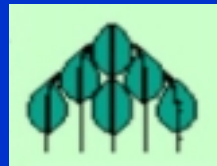
The current (2003) structure and requirements may be found on the PDV website, ---

PDV web site: <http://www.pdv.nl>.

- PDV documentation and guidance for compliance**
- 4/11/03 --- ‘new’ regulations published by PDV**
- All producers of feed materials, domestic or foreign, will now be required to meet ‘GMP Standards’**
- GMP Standards now extensively documented**
- Suppliers will be required to meet certification standards by
January 1, 2004**

GMP 13 Audits

Structure of Evaluation and Assessments of Non-conformities



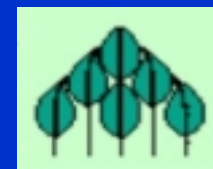
Initial audit -- Comprehensive assessment of the quality system and consists of:

1. Assessment of quality documentation --

Items required -- (for example organization structure, scope of QA program, Directors statement (see e.g., GMP23), management review of QC program, risk assessment, etc.)

2. On-site audit inspection --

Establish whether the practical implementation of the requirements of the GMP standards is taking place in the correct manner.

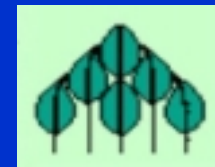


Later -- Supervision audit --

Assessment of compliance with applicable GMP standards during the period of validity of the certificate.

- 1. Incorporation of improvement measures and items on checklists (GMP32 & specific product).**
- 2. Supervision audits at least twice per year
One unannounced basis **, and one announced**

**** Unannounced audits may be forgone due to issues with bioterrorism and biosecurity; PDV to make decision on unannounced audits**

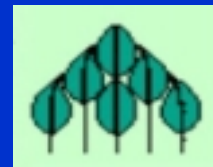


Later -- Supervision audit (cont.)

Announced supervision audit ---

- 1. Written documentation required by QA program is maintained .**
- 2. On-site audit inspection to determine that practical implementation of the requirements of the GMP standards is taking place in the correct manner.**

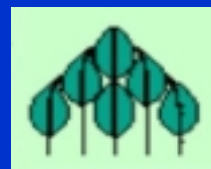
(Unannounced audits similar, depending upon reason for audit)



Extension audit

Extension audit occurs at the end of a certification period (expected to be three years), to assess whether the company continues to meet the conditions for GMP certification.

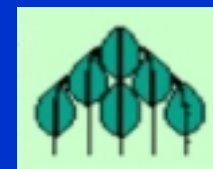
The extension audit is a comprehensive assessment of the quality system.



Audit Classifications GMP31: 11-04-2003 © PDV

Category 3 Nonconformities examples

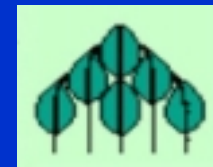
- Issue with slight risk to product meeting GMP standard
- Required element not properly or completely documented
- Previously described element not updated as a result of legislation change
- Quality records overlooked or > 2 months out of date
- Element not properly implemented, but with limited risk
- Uncorrected Cat. 3 nonconformity is re-classified Category 2
- Must be corrected in specified time



Audit Classifications GMP31: 11-04-2003 © PDV

Category 2 Nonconformities examples

- **Category 3 finding not adequately addressed**
- **Essential element of GMP standard not met, isolated incidence, and risk to next link of chain is absent**
- **Major backlog of out of date records**
- **Incorrect implementation of element critical to safety of the product**
- **Cat. 2 found during extension audit prevents certification from being extended**
- **Correction period a max. of 6 weeks**
- **Uncorrected Cat.2 reclassified Cat.1**



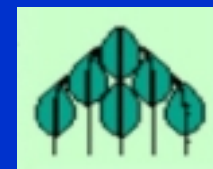
Audit Classifications GMP31: 11-04-2003 © PDV

Category 2 Nonconformities examples (cont.)

- **Cat. 2 related to purchasing or delivering non-conforming product ---- the product must be recalled**

Category 1 Nonconformities examples

- **Audit finding relating to essential GMP-elements, incidentally or structurally, allows direct or possible major hazard to safety of man, animal, or environment, and possible direct risks to next links in the food chain**
- **Previous Cat. 2 audit finding with late or inadequate correction factors implemented**

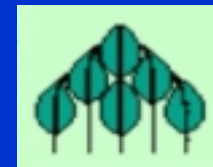


Audit Assessments and Conclusions

GMP31: 11-04-2003 © PDV

Nonconformity assessments and results ---

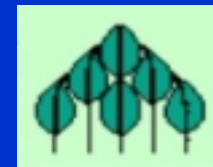
- **Less than ten Cat. 3 Nonconformities -- Facility in compliance with GMP standard**
- **Ten or more Cat. 3 - Not in compliance; facility must correct within specified period (max of 6 weeks)**
- **One or more Cat. 2 -- Not in compliance; facility must correct within specified period (max of 6 weeks), depending on nature of problem; facility must recall non-conforming product; in next 3 months, facility will be re-audited at least once, unannounced, depending upon seriousness**



Audit Assessments and Conclusions

GMP31: 11-04-2003 © PDV

- **One or more Cat. 1 audit findings -- facility not in compliance with two possible results , depending upon seriousness**
 - 1. Facility must immediately correct problem; next 12 months, will be audited at least 4 times, at least two unannounced;failure to correct, or finding of another Cat. 1 will result in suspension of certificate**
 - 2. GMP-certification suspended immediately for 3 months; after 3 months if corrections are adequate, the suspension will be removed; next 12months, will be audited at least 4 times, at least two unannounced; failure to correct will result in revocation of certificate**



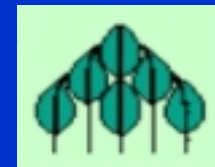
GMP 13 Audits

GMP32 ‘Checklist’ of Audits

(PDV will require auditors to utilize)

**Basic Requirements of Quality System and Areas of
Consideration for Conformance/Nonconformance to
the GMP Standard**

(§ Reference is to Section of GMP13)





Item	Description	§
	<u>Basic requirements for Producers</u>	Ref.
1	<i>Awareness of responsibility for the feed and food safety of feed materials</i>	4.1.1
1	<i>QC system implemented and documented & based upon HACCP principles</i>	4.1.2
1	<i>QC documentation</i>	4.1.3
2	Compile and maintain a manual with all required documents for operating system	4.1.3
2	Manual includes product specs, process specs, hazard identifications, risk evaluations and ID of CCP's , control measures, measurements points and checks, evaluation and communication	4.1.3
2	Manual up to date	4.1.3



Item	Description	§ Ref
	<u>Basic requirements for Producers (cont.)</u>	
1	<i>Independent verification</i>	4.1.4
1	<i>Management responsibility</i>	4.1.5
2	Formulation of the scope of the QC system	4.1.5
2	Description of tasks, responsibilities & authorities of employees	4.1.5
1	<i>Contracts</i>	4.1.6.1
2	All feed sold by contract (type, quantity, price and position of goods). All terms precise and unambiguous, preferably in accordance with recognised contractual terms	4.1.6.1
2	Supplier provides client with scope of QC system & other key information about the feed	4.1.6.1



Item	Description	§ Ref
	<u>Basic requirements for Producers (cont.)</u>	
1	<i>Order receipt and Processing</i>	4.1.6.2
2	Able to demonstrate appropriate methods for confirming and recording type, quantity and quality of orders received	4.1.6.2
1	<i>Packaging and delivery documents</i>	4.1.6.3
2	All relevant contractual and legal information on delivery documents (bulk – includes EU required Statutory Statements	4.1.6.3



Item	Description	§ Ref
	<u>Product Specification</u>	5.2
1	<i>Product specs include – name; description; intended use; transport, storage and usage rules; legal demands; sectoral agreement demands; other GMP requirements; client specifications</i>	5.2
	<u>Product Process Specification</u>	5.3
1	<i>Production process specifications describes all process steps and process conditions (process diagram and explanations</i>	5.3



Item	Description	§ Ref
	<u>Hazard Identification</u>	5.4
1	<i>Each step of the production process identified and evaluated for all possible hazards classifications (chemical, physical, and microbiological</i>	5.4
	<u>Risk Evaluation and Determination of CCP's</u>	5.5
1	<i>Risk level (identified and classified) for each hazard, including justification, has been determined to determine the CCP's and the type of control measure to be applied</i>	5.5
1	<i>Each CCP defined and documented</i>	5.5



Item	Description	§ Ref
	<u>Control measures for critical control points</u>	5.6
1	<i>Control measures are determined and documented (e.g. cultivation and harvesting procedures, storage directions, transport directions, cleaning protocols, pest control programs, and contamination prevention)</i>	5.6
	<u>Monitoring and verification</u>	5.7
1	<i>Monitoring and verification strategy, and corrective measures are documented</i>	5.7
2	CCP's in production process and products are inspected and sampled periodically on a published schedule. Results are documented.	5.7



Item	Description	§ Ref
	<u>Monitoring and verification (cont.)</u>	5.7
1	<i>Monitoring and verification strategy, and corrective measures are documented (cont.)</i>	5.7
2	Where inspection and sampling indicated insufficient control, corrective actions taken	5.7
2	Measurement protocols of product quality are based on internationally standardised laboratory methods used by qualified laboratories	5.7
2	Customers are informed of results	5.7

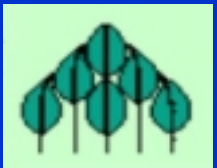


Item	Description	§ Ref
	<u>Evaluation, actualization, & communication</u>	5.8
1	<i>Manual must be actualised at least every 2 years and after modification in the production process</i>	5.8
2	Prior to actualization an evaluation takes place	5.8
2	Customers advised of modifications	5.8
2	Customers informed when feed material does not meet specifications	5.8

- **All FCPA Citrus Pulp Pellet producers are currently listed as ‘approved companies’ (from whom GMP+ certified companies may buy) on the PDV database, under the ‘GMP13 Standard’**
- **PDV has converted those facilities previously certified as ‘QC-fi’ , status ‘Certified’ to GMP13**
- **All foreign suppliers, previously certified under the QC Standard, will now be required to be certified under GMP13**
- **All FCPA Member facilities are in process to be ‘re-certified’ under GMP13 by a PDV-approved agency**

Feed Mill QA Programs and the European Market

Appreciation is expressed to the By-Products Committee of the FCPA for its efforts in developing the QC model, and to the Productschap Diervoeder for permission to use and adapt their documentation for use in this presentation.



The current structure and requirements for this program may be found on the PDV website, ---

PDV web site: <http://www.pdv.nl>.

[Under 'kwaliteit', click on 'ENG' for the English versions of]

<http://www.pdv.nl/english/kwaliteit/> -- the GMP+ program

http://www.pdv.nl/english/kwaliteit/copy_page475.php -- the list of currently certified companies and certification bodies

http://www.pdv.nl/english/kwaliteit/regeling_diervoedersector/ -- the GMP+ regulation

http://www.pdv.nl/english/kwaliteit/Risk_analysis/ -- the database of risk analysis for various feedstuff

<http://www.pdv.nl/english/kwaliteit/page940.php> - the 'EWS' and reporting of non-standard product

<http://www.pdv.nl/english/organisatie/page843.php> -- website that links to the PDV 'Newsletter', only available currently on the website

