

Successful Abscission Agent Development & Commercialization in Florida Oranges

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Handling Systems of Fruits and Nuts

Presentation Agenda

- I. Abscission Agent History in Oranges
- II. Identifying Development Candidates
- III. Development & Registration
 - a) “Must have” requirements
 - b) Key hurdles to registration
 - c) Risk assessment
- IV. Commercialization
 - a) Manufacturing requirements
- V. Benefits & Summary

Mechanical Harvesting History in Florida Oranges

- First steps towards improving productivity of harvesting in Florida citrus began in 1950s
- Numerous mechanical harvester concepts evaluated from 1960s through 1970s
- Mechanical harvesting research dropped off in late 1970s and 80s
- Labor shortages and increasing costs prompted renewed research in 1990s
- Key issue identified was need to be able to harvest late season Valencia without impacting next crop
- Required an abscission agent that could selectively loosen mature fruit



First generation CREC slider crank limb shaker catchframe harvest system.



USDA 80-auger or spindle unit.



Removing the Impediment to Late Season Harvest

The problem:

- ~30% Valencia acreage remains to be harvested after May 1
 - processors: fruit delivered into June
- Mechanical harvesting past May 1st reduces yield the next season by as much as 50%



Abscission Agent “Must Have” Requirements

- Highly selective for mature fruit
- No phytotoxicity to tree, immature fruit, or blossoms or adverse impact on juice quality or yield
- Consistent performance
- No obvious barriers to EPA registration
- Attractive grower economics

Identifying Abscission Agent Candidates

- IFAS (Dr. Jackie Burns) led extensive screening effort of >500 compounds
- In 2004, CMNP (5-chloro-3-methyl-5-nitro-1H-pyrazole) was determined to be best candidate

CMNP - Attributes

- Reduces mature fruit detachment force (FDF) by 75% or greater within 3 to 4 days of application
- No leaf or blossom drop or FDF reduction observed in immature fruit
- No adverse effects on return yield from repeated annual applications
- Juice quality (% acid and Brix) were not impacted by CMNP

Development & Registration

- Efficacious abscission agent identified
- What about EPA registration?
 - Toxicology
 - Metabolism and residue
 - Environmental Fate
 - Ecotoxicology
 - Product chemistry
 - Risk assessment
- Over 120 studies required to complete the Section 3 submission

Development & Registration



has the licensed rights to

- develop,
- register,
- manufacture, and
- commercialize

CMNP as an abscission agent, globally.

Development & Registration

I: Make the Test Compound

- Two-fold Purpose:
 - 1) To confirm the manufacturing process, and
 - 2) Produce enough to support all EPA studies and continuing field work.

Development & Registration

2: Preliminary Studies

- Acute toxicology
- Develop analytical methodology
- Develop formulation
 - Ease of use
 - Stability under typical storage conditions
- Make ^{14}C labeled CMNP to support metabolism and environment fate studies.

Development & Registration

3: Crop Metabolism Studies

- Must determine fate of CMNP in crop.
- Identify key metabolites.
- Develop & validate analytical methodology.
- Conduct field residue studies to determine CMNP and metabolite residues in whole oranges and processed parts.



Development & Registration

4: Toxicology Studies

- Wide range of studies required to identify any potential risk from exposure to CMNP or metabolites.
- Long term feeding, reproductive, genetic toxicology, etc.
- Also, animal metabolism studies to elucidate the fate of CMNP and identify any significant metabolites.

Development & Registration

5: Environmental Fate Studies

- Wide range of studies designed to verify the fate of CMNP and metabolites in the environment.
- Includes requirement to develop & validate analytical methodology to monitor CMNP and metabolites in soil.
- Large scale field dissipation studies are conducted to verify soil metabolism and movement under real world conditions.

Development & Registration

6: Ecotoxicology Studies

- Includes wide range of tests designed to evaluate the risk that CMNP poses to non-target organisms.
- Includes aquatic, avian, insect and plant species.
- Both acute and long term testing.



Development & Registration

7: Risk Assessment

- Primary focus of EPA in assessing a new product for registration is risk assessment.
- EPA defines risk as the probability of harmful effects to human health or the environment resulting from the use of a product.
- EPA then uses risk assessment to determine the nature and magnitude of the risk.

Development & Registration

7: Risk Assessment (continued)

- EPA risk assessments fall into two broad categories
 - Human health
 - Dietary
 - Exposure
 - Environmental
 - Non-target plants and animals



Development & Registration

7: Risk Assessment (continued)

- A scientific process which is based upon:
 - How much of the chemical is present? Considers all sources.
 - What is the level of exposure to the population (or population subgroup)? Considers intensity, duration, and frequency.
 - What is the inherent toxicity of the compound? Based upon the toxicology studies conducted with substantial safety margin.

Development & Registration

7: Risk Assessment (continued)

- Risk assessments run at different levels – from most conservative Tier I to very highly refined models.
- If a chemical passes at Tier I – no further assessment. If it fails, refinements done.
- Registrant can adjust label and use of compound to mitigate risk, for example, reducing the number of applications or rate.

Development & Registration

Summary

- There are a huge number of hurdles that a new product seeking EPA approval must clear.
- Failure to pass any one of these hurdles can result in a product being denied registration or having substantial label and use restrictions required.
- Acceptable levels of biological efficacy in the field are only the first step.

Commercialization

Manufacturing

- Need to demonstrate manufacturing process for the technical material on commercial scale.
 - Safety
 - Product quality
 - Product yield
 - Cost of production



Commercialization

Manufacturing (continued)

- Formulation
 - Objective is easy to use formulation, cost effective, stable in storage and that performs consistently.
 - Inert ingredients used in formulation must have food crop tolerances.
 - Need to demonstrate production on a commercial scale.

Commercialization

Manufacturing (continued)

- Scale of production can have significant impact on cost.
- Many crop production chemicals are used broadly on multiple crops and geographies.
- CMNP is a narrowly focused product in both geography and crop.

Commercialization

Manufacturing (continued)

- Need to plan in advance to produce product in anticipation of EPA approval.
- But can't formulate and label product until the EPA issues final approval of label.

Commercialization

Summary

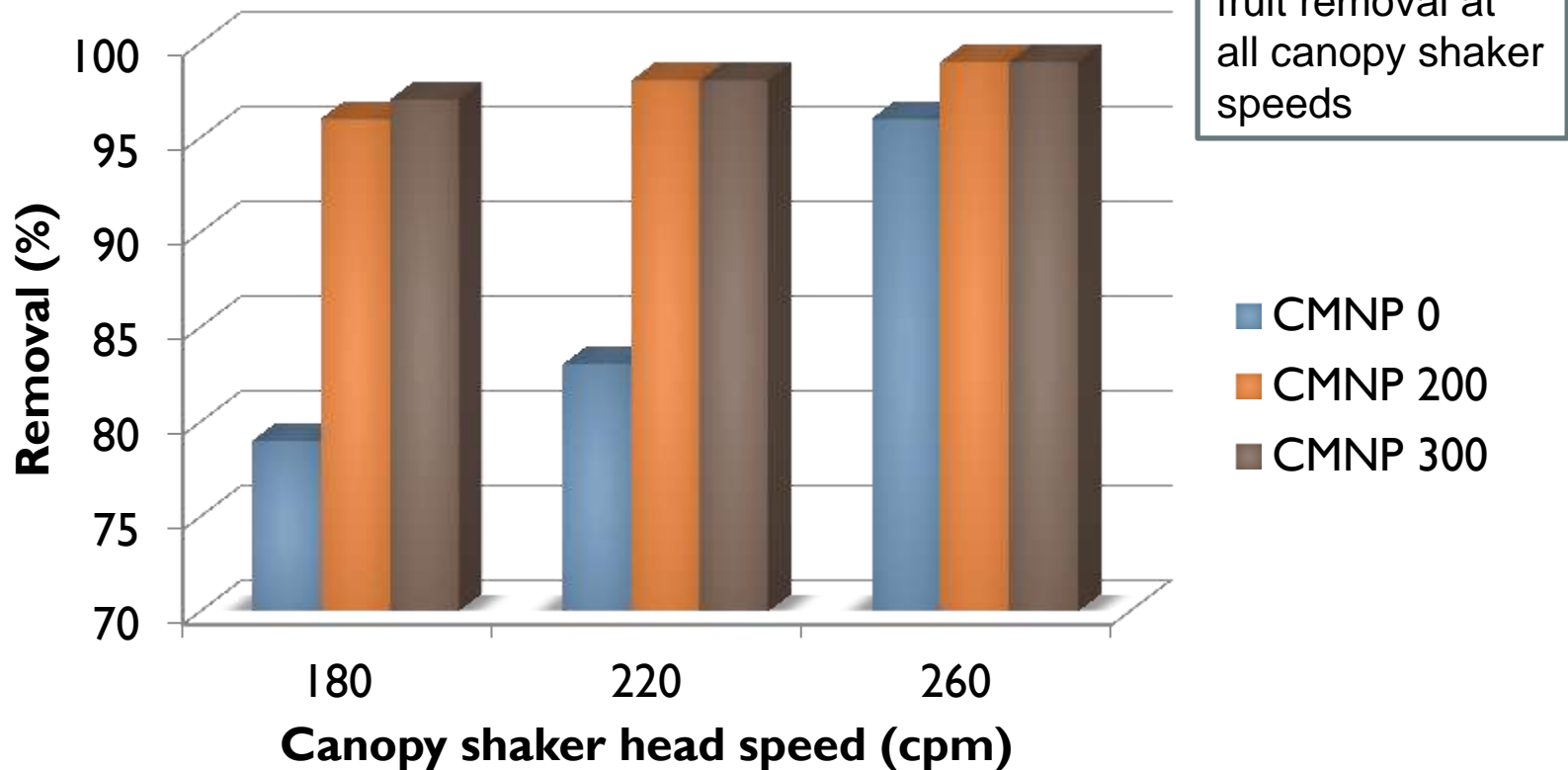
- Manufacturing and formulation scale up is critical final step in delivery of product to end user.
- Scale of use directly impacts manufacturing options and cost of production.
- Timing is critical to ensure product can be on market soon after EPA approval.

Abscission Agent Benefits

- Allow mechanical harvesting of late season Valencia
- Reduce harvesting costs
- Minimize tree and fruit damage
- Reduce debris
- Increase harvester efficiency

Grower & Harvester Benefits

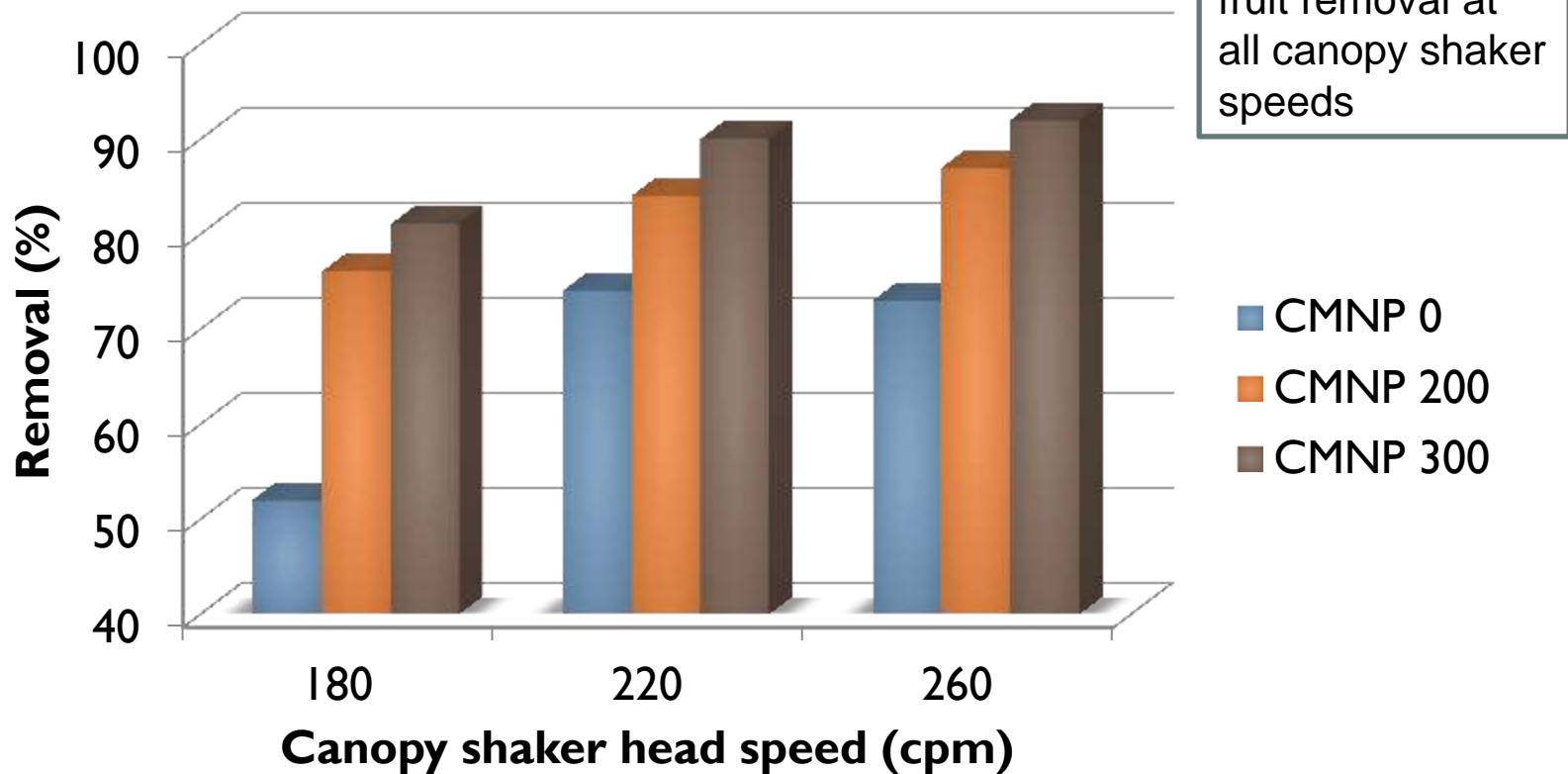
Hamlin - Jan 2009



*Source: Ebel, UF-IFAS

Grower & Harvester Benefits

Valencia - Apr 2009



*Source: Ebel, UF-IFAS

Grower & Harvester Benefits

Benefits of Abscission Technology to Mechanical Harvesting

- Solve the 'late season' problem
 - Remove mature *Valencias* without impacting new crop
- Lower fruit detachment force (FDF)
- Less energy (CPM) required
 - Minimize tree and fruit damage
 - Limit equipment damage and repair
 - Increase fruit recovery



Grower & Harvester Benefits

Benefits of Abscission Technology to Mechanical Harvesting (*continued*)

- Faster equipment ground speed
- Optimize equipment utilization

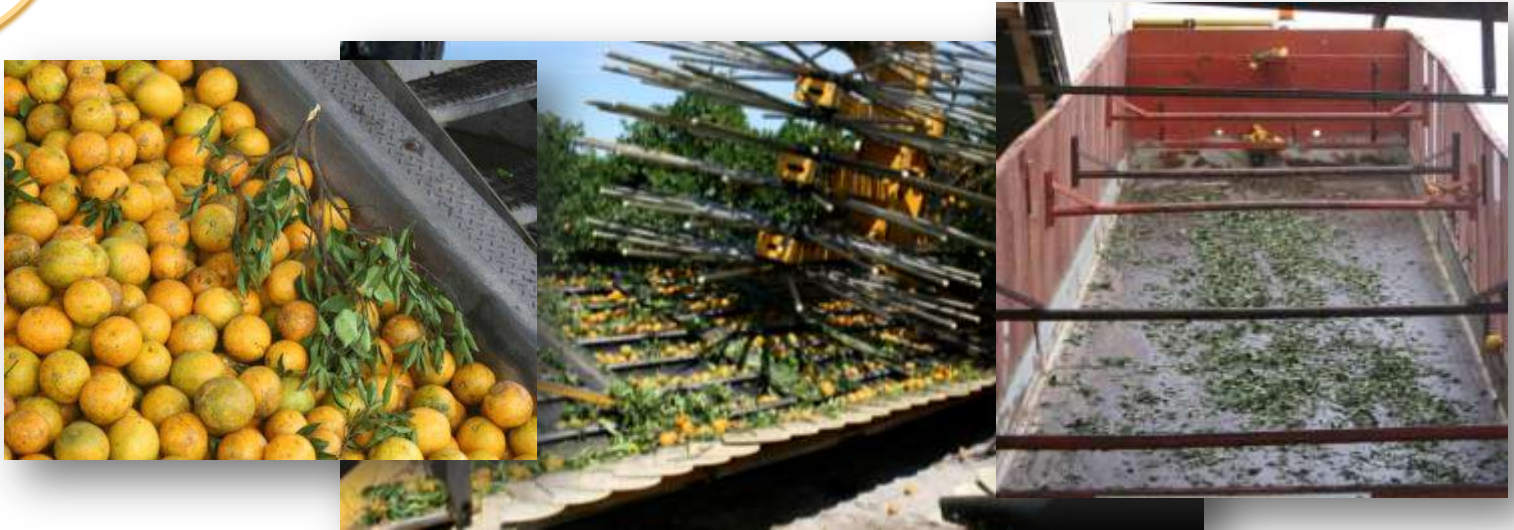
Economic Benefits

	MH without CMNP (70% recovery)	MH with CMNP (80% recovery)	MH with CMNP (85% recovery)	MH with CMNP (90% recovery)	MH with CMNP (95% recovery)
Harvest speed, Tree/hr:	300	375	375	375	375
Harvest cost without gleaning, \$/box:	\$1.80	\$1.04	\$0.98	\$0.92	\$0.88
Harvest cost with gleaning, \$/box:	\$2.16	\$1.40	\$1.28	\$1.13	\$0.98
Harvest cost with abscission, \$/box:	\$ -	\$1.70	\$1.55	\$1.40	\$1.25
Harvest cost savings, \$/box:	\$ -	\$0.46	\$0.61	\$0.76	\$0.91

- MH with CMNP assumes 25% increase in harvesting speed
- MH with CMNP includes CMNP & application cost

*Source: Roka, UF-IFAS, 2004, revised 2008

Harvester & Processor Benefits



- Based upon multiple IFAS trials from 2007 – 2009 on multiple varieties
 - Mechanical harvesting does increase debris by approximately 2X over hand harvesting.
 - Use of CMNP reduced debris found in mechanically harvested fruit to levels equivalent to or below hand harvesting.

*Source: Spann, UF-IFAS

Harvester & Processor Benefits

- Processors have raised concerns that mechanically harvested fruit loads have increased debris
- Increased costs from debris due to:
 - Additional staffing on line to remove debris.
 - Potential for damage to processing equipment from debris resulting in downtime.
 - Cost of hauling and disposing of increased debris in loads.
- CMNP is the solution to debris issue

CMNP Registrations Status

- Section 3 Registration and Tolerance
- Submitted January 2011
- EPA actively reviewing submission package



The screenshot shows the AgroSource website with the following content:

- AGRO SOURCE™** logo at the top left.
- Navigation menu: Home, Products, Crop Solutions, News, About Us.
- CMNP Registration** section header.
- A photograph of oranges on a tree with the caption: "Photo courtesy of UF IFAS Citrus Research and Education Center (CREC)".
- Text: "In 2004, AgroSource, in conjunction with the Florida Department of Citrus (FDOC), the Citrus Harvesting Research Advisory Council (CHRAC) and the University of Florida Institute of Food and Agricultural Sciences (UF-IFAS), began a formal program to achieve a citrus abscission agent product that facilitates mechanical harvesting for the Florida Citrus Industry."
- Text: "Through a careful screening of several compounds, CMNP was selected as the priority abscission agent candidate. Subsequently, AgroSource has conducted the product development and registration program for CMNP in Florida Oranges. CMNP has now been advised to the U.S. Environmental Protection Agency (EPA) registration review process."
- Current regulatory status for CMNP:**
 - ✓ Section 5: **Experimental Use Permit (EUP) & Temporary Tolerance (TT)**
 - Submitted to EPA December 2009
 - EPA Decision: Anticipated in July 2011
 - ✓ Section 3: **Federal Registration by the EPA**
 - Submitted to EPA January 2011
 - PRA Date to be determined
- Text: "Upon successful registration, AgroSource will commercialize and steward CMNP to the Florida Citrus Industry."
- Text: "Click Here To learn more about **AGRO SOURCE™**" with a link icon.

www.agrosource.net

Summary of Benefits

- CMNP can provide benefits to all segments of the citrus industry
 - Reduce harvesting costs
 - Address labor issues
 - Increase efficiency of both mechanical and manual harvesting
 - Allow for mechanical harvesting of late season Valencia
 - Reduce debris in harvested loads
 - Improve harvest management
 - Enhance fruit and juice quality

Thank You!



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