

DTSC/CICC POLLUTION PREVENTION CHALLENGE PROGRAM

**DTSC GREEN CHEMISTRY SYMPOSIUM III
OCTOBER 30, 2007**

- Contract manufacturer of custom active pharmaceutical ingredients and registered intermediates located in Rancho Cordova
- Typical drugs have included Cancer, HIV, Influenza, Osteoporosis, and Epilepsy
- Regulated by the US Food and Drug Administration
- Held to stringent current Good Manufacturing Practices (cGMP)



AFC plant, California



Chemical Industry Pollution Prevention Challenge



The Department of Toxic Substances Control
California Environmental Protection Agency
and
The Chemical Industry Council of California

CICC

Recognize

Ampac Fine Chemicals LLC

Green Chemical Processing: A Vision for Success

For its industry leadership and commitment to pollution prevention through an interdisciplinary team approach to implement a sustainable chemical manufacturing process for the effective recovery of a solvent stream for reclamation and reuse.

Presented May 16, 2007

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How did we get there?

- A couple of years ago, AFC re-established the Waste Minimization Team

- The goals of the team are:
 - ◆ To identify waste management activities that can result in source reduction opportunities
 - ◆ Recycle wastes offsite that can not be recovered “as is”

- Meet bi-weekly to monitor status of existing projects and to evaluate new proposed projects

Waste Minimization Team

■ The team consists of representatives from all departments and areas of responsibilities, including:

- ◆ Research and Development
- ◆ Procurement
- ◆ Process Engineering
- ◆ Project Management
- ◆ Maintenance
- ◆ Quality
- ◆ Operations
- ◆ Finance
- ◆ EH&S

■ The team follows the SB14 principles, factors and approaches to evaluate each proposed source reduction project

| ACC Process | Potential Projects | Input - Raw Material | Operational Improvements | Product Formulations | Production Process | Administrative | Expected change in amount of waste generated | Technically Feasible | Financial Evaluation | Product Quality | Employee Health & Safety | Environmental Compliance | Releases and Discharges | Status |
|-------------|---|----------------------|--------------------------|----------------------|--------------------|----------------|--|---|---|---|--------------------------|--------------------------|-------------------------|---|
| 261/278 | Recycle 90% ethanol/10% heptane from 278 drying process | X | | | X | | Approximately 2500 gallons per batch and 45 batches per year for 5 years | Project requires 40K in modifications to the vacuum system and adding condenser | Potential annual cost avoidance of \$531K in raw materials and \$47-79K in waste | R&D and validation data demonstrated no effect on product | No change | No effect | No effect on SPCC plan | Complete. Program in place on 12/02/06 with Batch #199. |
| 321/323 | Recycle 90% ethanol/10% heptane from 323 drying process | X | | | X | | Approximately 4800 kg Ethanol and 500 kg Heptane per batch and 90 batches per year for 5 years | No modifications are necessary. | Potentially annual cost avoidance of \$1,063K in raw materials and \$95-158K in waste | R&D and validation data demonstrated no effect on product | No change | No effect | No effect on SPCC plan | Complete. Program in place starting with Batch #36 on 06/28/06. |

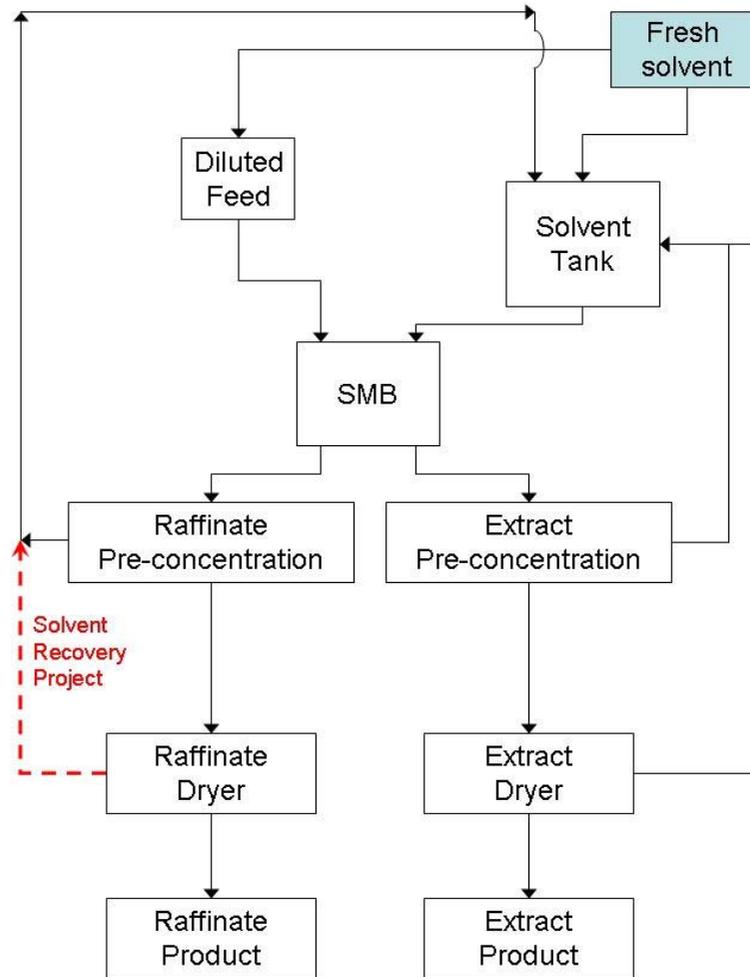
The Project:

To recycle the dryer solvent condensate from the raffinate portion back into the process

A brief lesson in chromatographic separations using simulated moving bed (SMB) technology



Raffinate Dryer Condensate Project

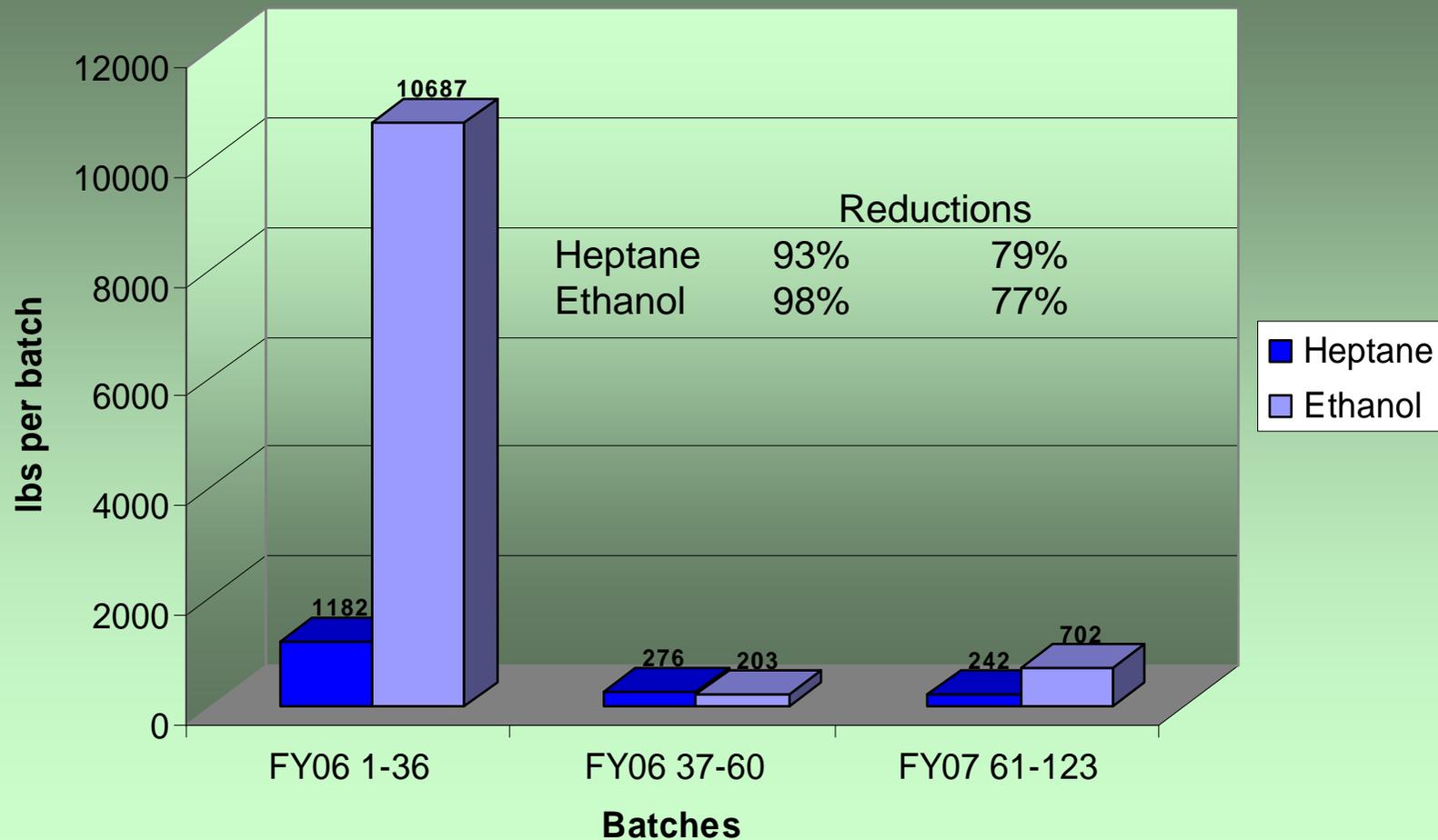


Challenges

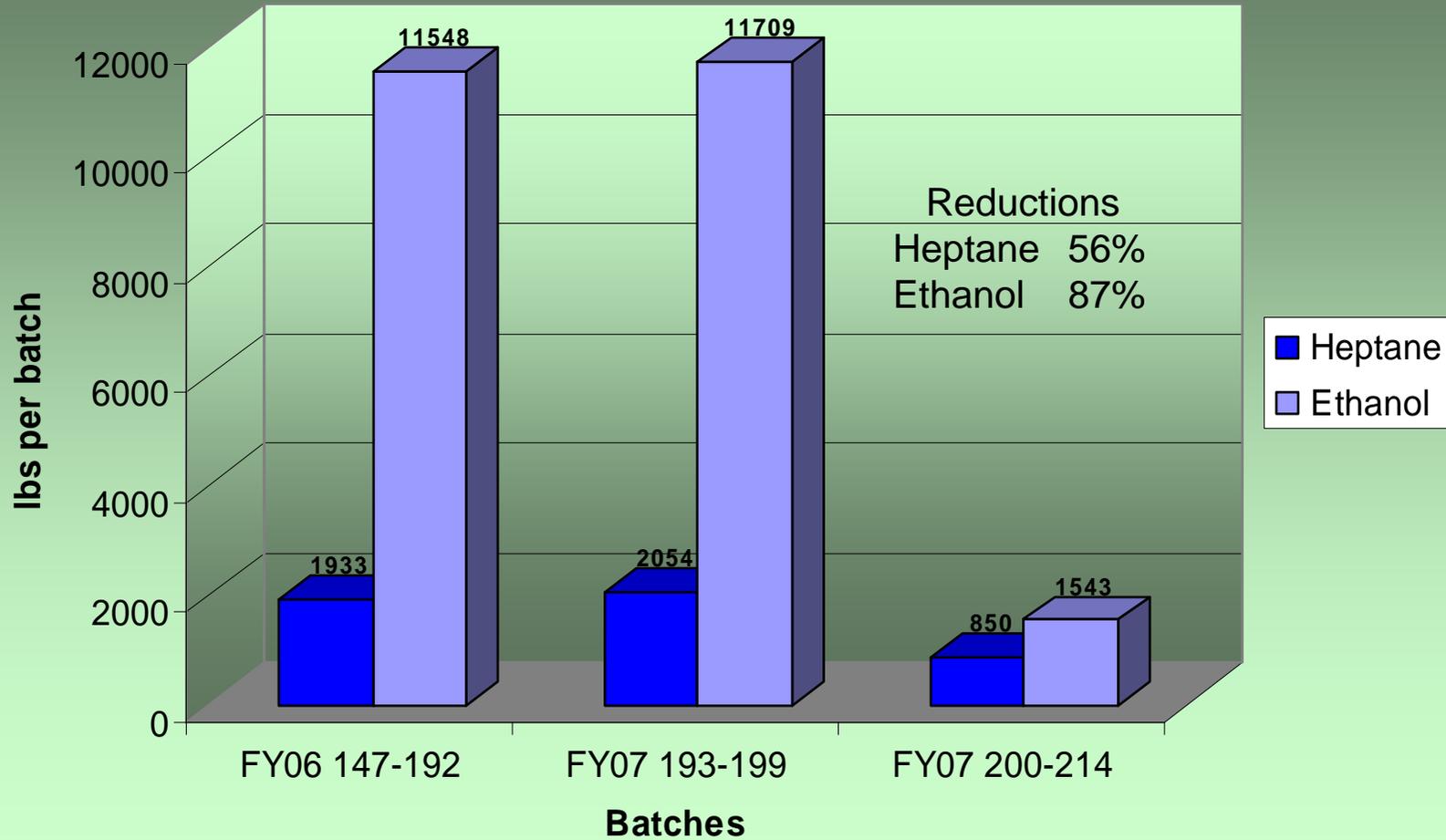
- Extensive R&D to demonstrate no adverse effects on product quality due to impurities introduced by the recycled stream
- Needed customer approval
- Raw material specifications
- Additional quality control testing
- Process equipment modifications
- Implement changes meeting FDA and cGMP criteria
- Re-validate the entire process
- The customer re-filed the process with FDA

The success of the project

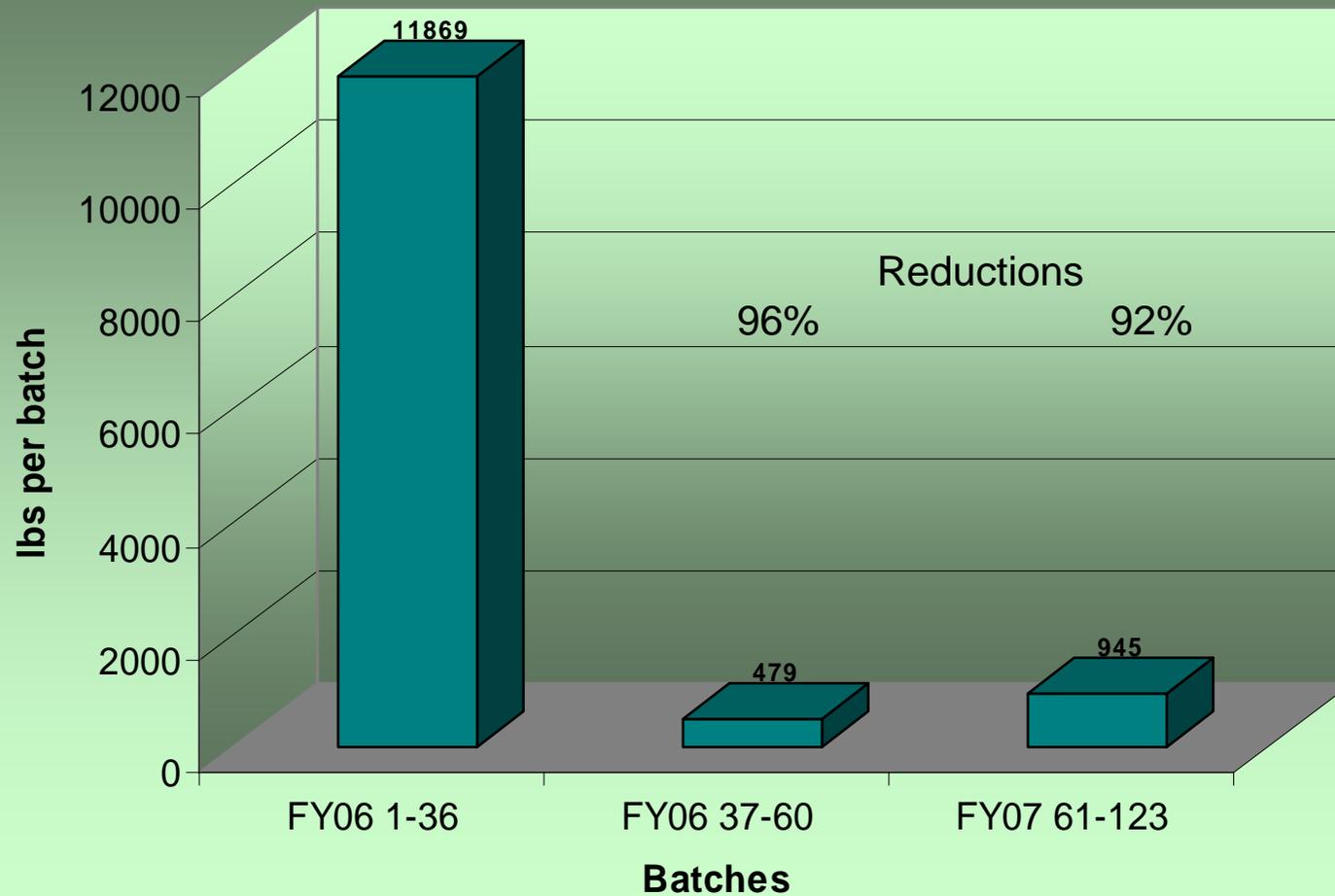
5-1000 Solvent Recovery Project Raw Material Usage



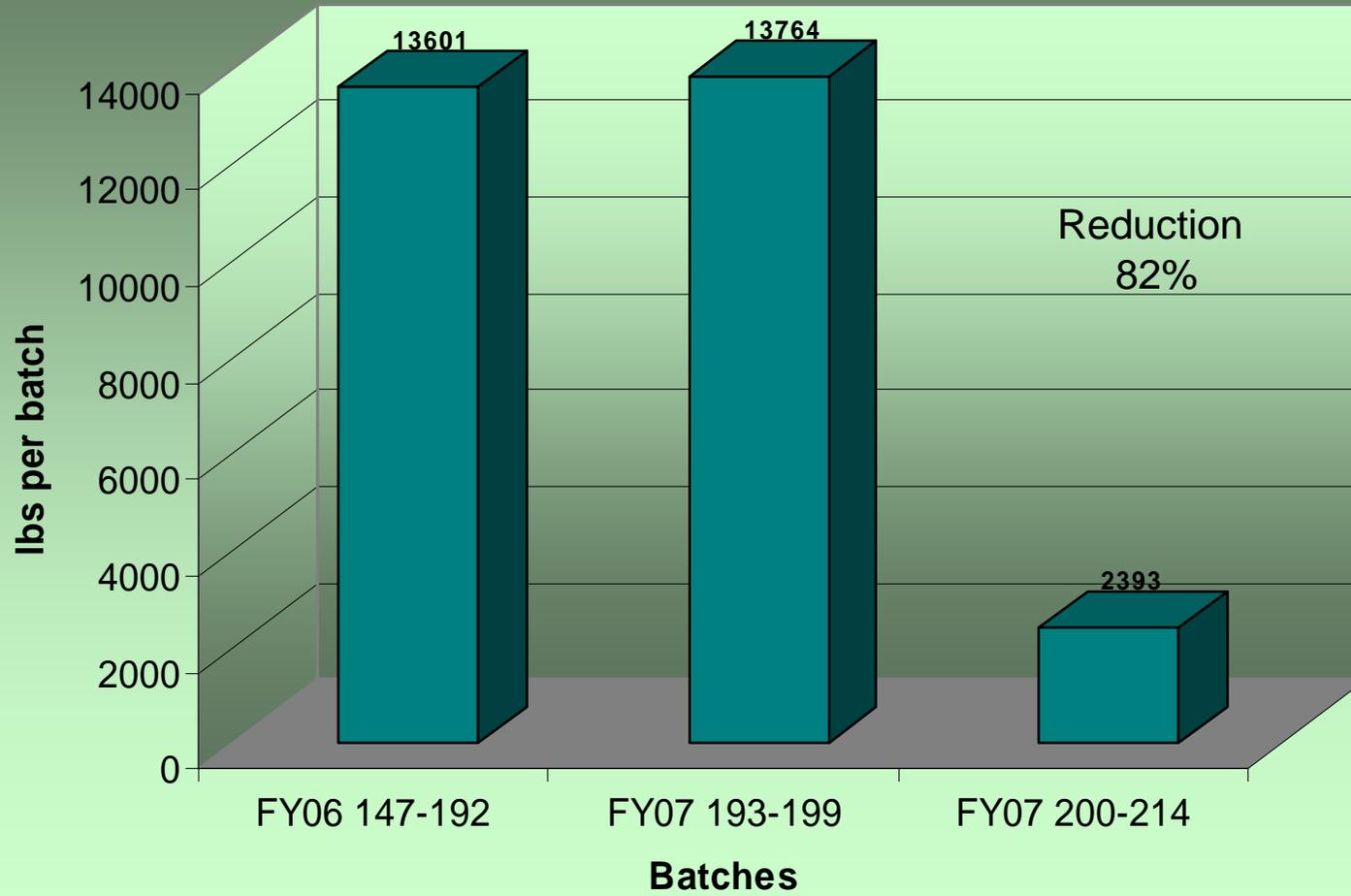
6-800 Solvent Recovery Project Raw Material Usage



5-1000 Solvent Recovery Project Waste Generation

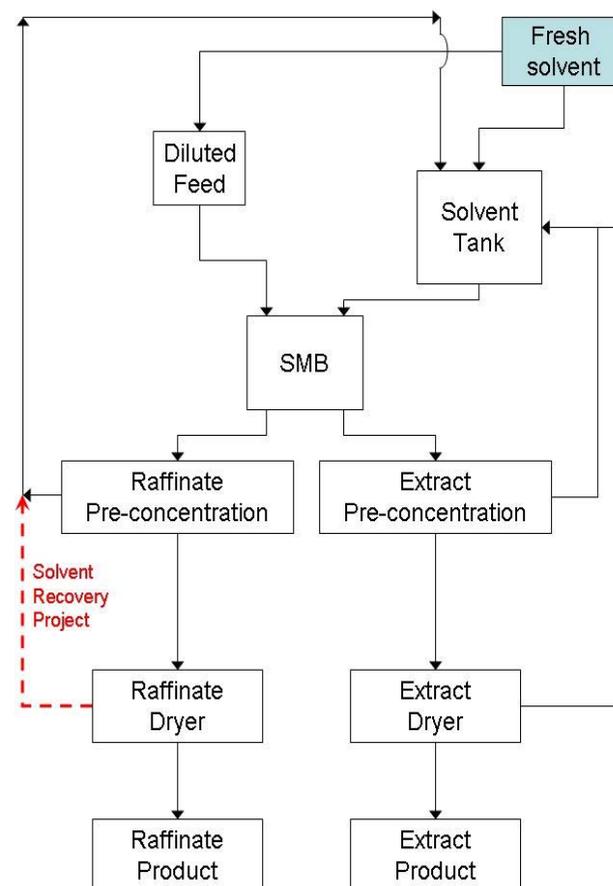


6-800 Solvent Recovery Project Waste Generation



Estimated Reductions...so far!

| Fiscal Year | Reduction in Ethanol Usage, lbs | Reduction in Heptane Usage, lbs | Reduction in Waste Generation, lbs |
|--------------|---------------------------------|---------------------------------|------------------------------------|
| 2006 | 252K | 22K | 273K |
| 2007 | 781K | 76K | 857K |
| Total | 1.033K | 97K | 1.130K |



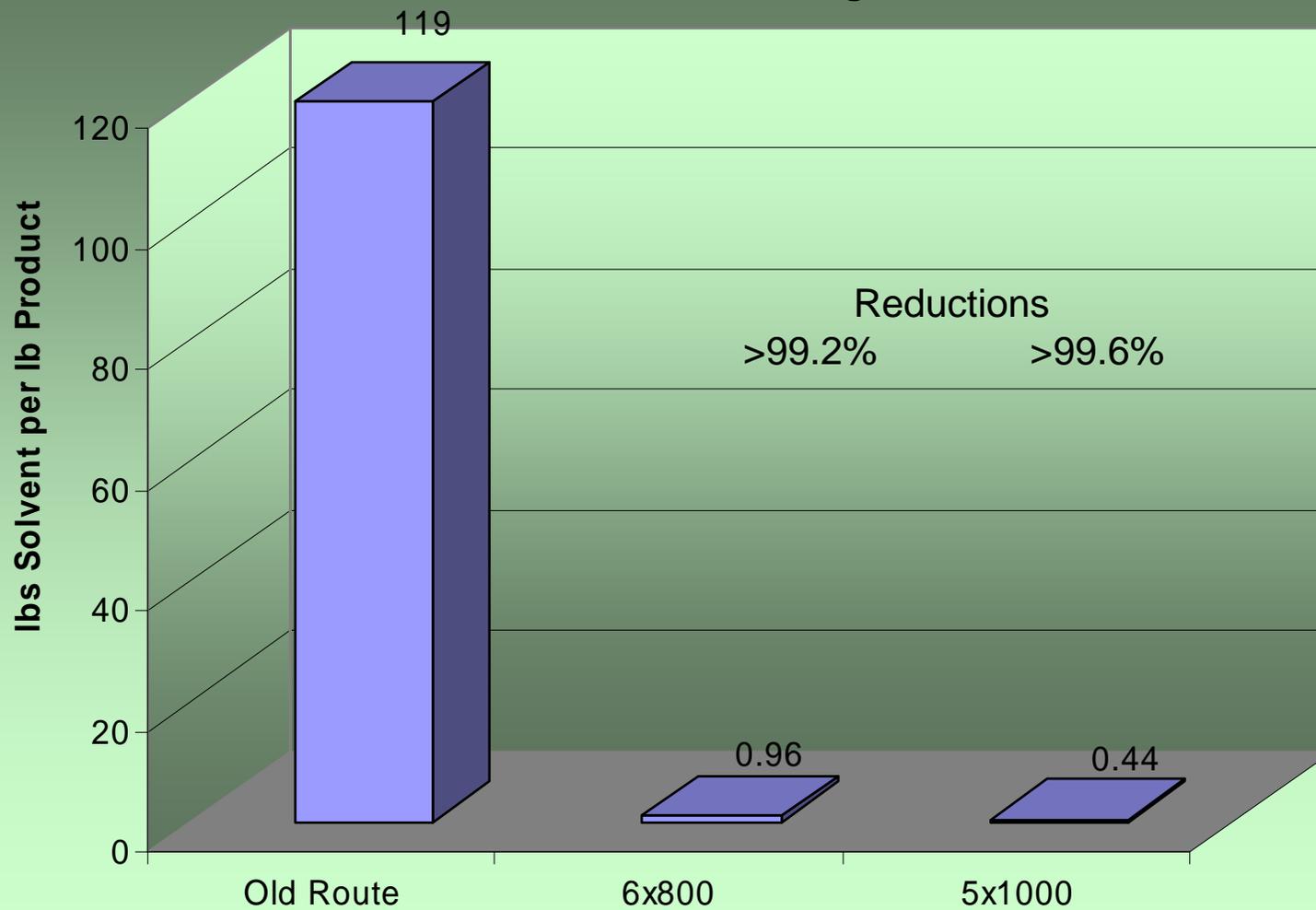
The Whole SMB Recycling Process

- Through the inherent design of the SMB as a continuous process :
 - ◆ 5x1000 SMB unit recycles 633K pounds solvent per batch
 - ◆ 6X800 SMB unit recycles 873K pounds solvent per batch
 - ◆ A estimated annual total of 111 M pounds solvent
- The raffinate portion is racemized back into a 50/50 mixture as feed for the SMB process
- SMB provided an innovative technology-based solution

But, that's only a small part of the story

- Prior to this raffinate dryer project, and even the use of SMB technology, this pharmaceutical manufacturing process utilized traditional chemical synthesis processes to manufacture the same final product
- The former chemical synthesis route
 - ◆ Demanded a large portion of the manufacturing facility for four (4) separate processes
 - ◆ Required a large work force
 - ◆ Utilized anhydrous ammonia and subjected the facility to the Federal Risk Management Program
 - ◆ Used excessively large quantities of raw materials

Chemical Synthesis vs SMB Solvent Usage



So, where do we go from here?

Green Chemistry Initiative

- There are additional opportunities to reclaim other process streams that may require refining (i.e. distillation, filtration) prior to re-use
- Industry needs to work with DTSC on implementing regulations to allow more flexibility for generators to reclaim streams onsite without a tiered or Part B Permit
- DTSC should recognize pollution prevention and continuous improvement projects as integral components to the Green Chemistry Initiative (GCI) to encourage companies to implement these activities
- These projects are typically good for the bottom line

Green Chemistry Initiative

- Ban specific chemicals based on use in a product **not** a raw material or substance outright
 - ◆ No lead in paint or toys, but allow lead as a raw material for other non-risk products, lead-acid battery

- The Pharmaceutical Industry should retain its exemption status from GCI
 - ◆ EU Reach program currently exempts pharmaceuticals
 - ◆ Pharmaceutical Industry is heavily regulated by FDA
 - ◆ Product quality concerns
 - ◆ Compounds and processing routes are filed with FDA