

“BRINGING NEW CHEMICALS TO MARKET”

Joint Meeting

AIChE/CHMM

Holiday Inn - Willow Brook IL

February 9, 2005

- Miriam Wiggins - Lewis, USEPA TSCA Div, HQ Washington DC
- Roger M. Masson, JD, Rundak & Suri
- Jeffery P. Perl, Ph.D., PE, CHMM

“Bringing New Chemicals To Market”

OVERVIEW

- What We Will Cover Tonight
- Why is This Important
- Who is Affected
- How to Do It

“Bringing New Chemicals To Market”

Roadmap-Checklist

- Develop a Chemical - Is it necessary?
- Patent - Or Trade Secret?
- Determine Market - How Much to Make
- Set Pricing - What will Market Bear
- Engineering Evaluation/ Cost Assessment
- Preliminary Design/Engineering
- EPA Interaction - Permitting
- CAS Interaction - Chemical Naming
- Toll Manufacturing or Design/Build
- SFP Status Today

“Bringing New Chemicals To Market”
Develop a Chemical - Is it necessary?

- Done by the Company and its Investors
- Specialty Fertilizer Company
- Fertilizer Enhancement Product
- 10-15% Crop Yield Improvement

“Bringing New Chemicals To Market”
Determine Market - How Much to Make

- SFP
- Set by Market Study

“Bringing New Chemicals To Market”
Set Pricing - What will Market Bear

- SFP
- Set by Market Study

“Bringing New Chemicals To Market”
Engineering Evaluation/ Cost Assessment
Preliminary Design/Engineering

- Determine Cost to Build Grass Roots Plant
- Compare with Outsourcing- AKA Toll Manufacturing

“Bringing New Chemicals To Market”

The EPA Program

- USEPA Statutes Set By Congress
- Regulations as Interpreted by USEPA
- Long Commenting Industry Period
- Federal Register
- Led to Present System
- Protect Health and Safety
- Protect Company Business Information
- Miriam Wiggins-Lewis will explain it best!

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USEPA

Miriam G. Wiggins-Lewis is Acting Chief of EPA’s New Chemicals Prenotice Branch, Chemical Control Division, where she has responsibilities for implementing guidance on Toxic Substances Control Act (TSCA) section 5 substantive issues. The branch is charged with providing direct response to inquiries which involve technical, regulatory and procedural issues relating to the premanufacture notification (PMN) requirements and related policies for new chemical substances under section 5 of TSCA.

Previously, Ms. Wiggins-Lewis served as Senior Prenotice Coordinator of the branch. She has been with the Agency since 1989. In addition, she has worked as a program manager in the New Chemicals Program.

Ms. Wiggins-Lewis holds a B.A. in Psychology and English from the University of Pittsburgh.

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USEPA

CCC

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“Bringing New Chemicals To Market”
USEPA - The Permitting Experience

- Appears Complex
- Easy if Approached in Pieces
 - CHMM Background Provides “Convergence”
- Positive Relations Between ACS and EPA
- Went from Confidential to Non-Confidential
- Up To Date Web Based Guidance
- Extremely Helpful EPA Telephone Staff Support
- System Functions Very Well

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CAS Interaction - Chemical Naming

- Chemical Abstract Service - CAS
- Uniform Chemical Naming System
- Generic - Confidential Business Information
- Specific - CAS Number Issued
- American Chemical Society
- Links Chemical Properties to CAS Number/Name
- USEPA Uses this to do Structure Toxicity Review (SAR)

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Patent - Or Trade Secret?

- Cost
- Control of Information
- Is it really Necessary
- Overcome Impediment to Investment
- Roger Masson will explain the rest!

“Bringing New Chemicals To Market” Patent - Or Trade Secret?

Roger Masson is a patent attorney with the firm of Ryndak & Suri. Before becoming an attorney, he practiced as a chemical engineer in chemical, petroleum, and environmental fields for over a decade.

“Bringing New Chemicals To Market”
Patent - Or Trade Secret?

“Bringing New Chemicals To Market”
Toll Manufacturing or Design/Build

- Toll Manufacturing Benefits
 - No Capital Investment
 - Shorten Concept to Production Time
- Toll Manufacturing Set Backs
 - Quality Control
 - Secrecy
 - Scheduling
 - Price Control

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Toll Manufacturing or Design/Build

- Challenges

- Analytical Protocols - QA/QC
- Manufacturing Protocols - Recipe
- ESOH Considerations
- Shipping and Handling - Location
- Raw Material Pricing
- Contract Negotiations
- Secrecy Agreements
- Site Visit
- Scheduling
- Price Control

“Bringing New Chemicals To Market”

SFP Status Today

- Toll Manufacturing Chosen
- Several Large Batches Already Made
- Established Strong Positive Link Between Toller and SFP
- Good Technical Relations Key to Success
- Regulatory Compliance Throughout