NCIMS Update

The Dairy Practices Council
40th Annual Conference
November 6, 2009

Holiday Inn Express & Suites
Latham, New York

John Beers, Chair NCIMS

32nd NCIMS Conference

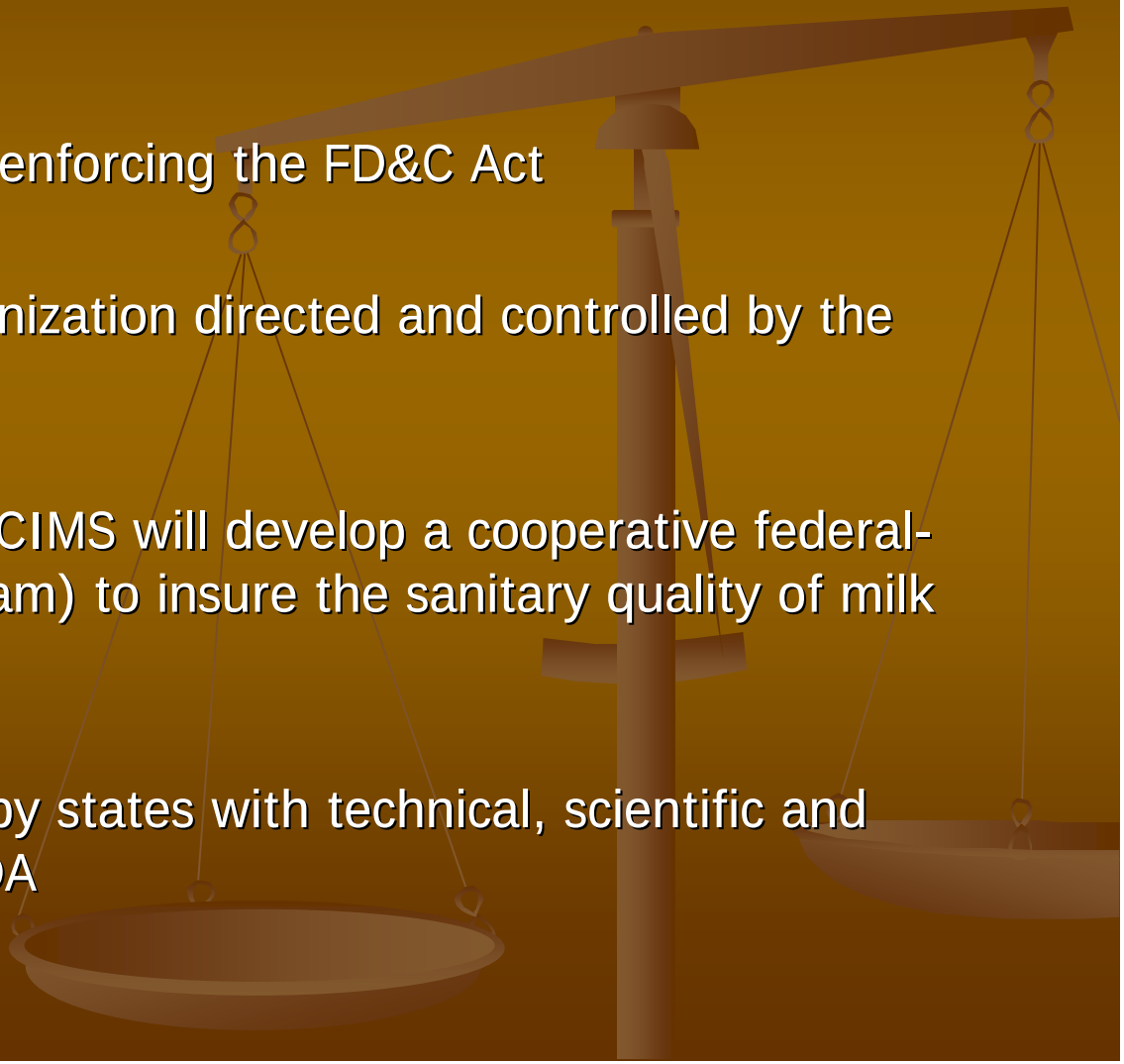
- April 17-22, 2009
- Caribe Royale Orlando
- Orlando, Florida

Overview of NCIMS

- The National Conference on Interstate Milk Shipments (NCIMS).
- We are a non-profit organization whose goal is "***To Assure the Safest Possible Milk Supply for All the People.***"
- The Conference is made up of persons involved in the dairy industry, from the dairy farmer, to processing plant personnel, the persons involved in inspecting the dairy farmer's operation and/or the processing plant, the persons who make the laws concerning the inspections, those who enforce the laws, the academic researcher and adviser, and the consumer of the dairy products.

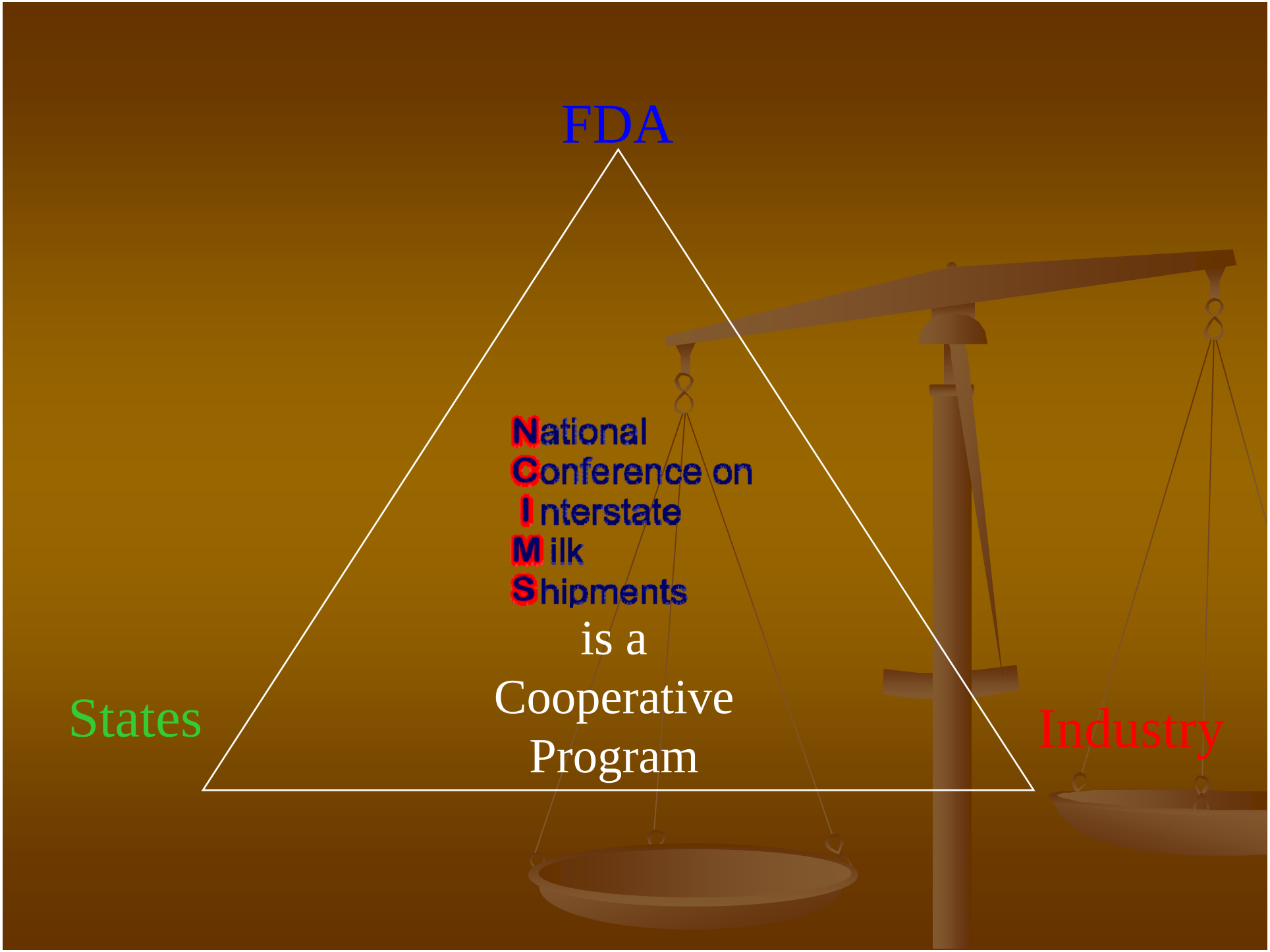
MOU

- Memorandum of Understanding Between FDA and the NCIMS (1977)
- FDA has responsibility for enforcing the FD&C Act
- NCIMS is a voluntary organization directed and controlled by the member states
- Collaboratively FDA and NCIMS will develop a cooperative federal-state program (IMS Program) to insure the sanitary quality of milk shipped interstate
- IMS program is operated by states with technical, scientific and oversight inspection by FDA



MOU

- IMS Program relies on the PMO and related technical documents to ensure safety and wholesomeness of milk
- FDA considers these standards and requirements adequate for the protection of public health
- Agreement with FDA and NCIMS to follow principles of the Procedures and execute the IMS program


FDA
National
Conference on
Interstate
Milk
Shipments
is a
Cooperative
Program
States
Industry

2009 NCIMS Conference

- NCIMS meets biennially in odd-numbered years to consider changes, additions, deletions and modifications to the IMS regulations.
  - The Conference had its first official meeting in 1950
- More information www.ncims.org
- Model Documents, Memos, IMS List:
  - PMO, Methods of Making Sanitation Rating on Milk Supplies, Procedures of NCIMS, Constitution & Bylaws
  - http://www.cfsan.fda.gov/~ear/prime.html

NCIMS Executive Board
27 Members Maximum

CHAIRMAN
(comes from
Board Members)

VICE CHAIRMAN
(comes from
Board Members)

Western States - 4 members + 1 at large	Central States - 4 members + 2 at large	Eastern States - 4 members + 1 at large
1 state rating	1 state rating	1 state rating
1 industry	1 industry	1 industry
1 state enforcement	1 state enforcement	1 state enforcement
1 local health department	1 local health department	1 local health department
1 U.S. Department of Agriculture	1 education	1 FDA
	1 laboratory	

OTHER MEMBERSHIPS:

U.S. Trust Territories, Non U.S. Countries or Political Subdivisions

Non-Voting Members:

Executive Secretary Treasurer	Immediate Past Chairman
Program Chairman	Chairman of NCIMS Liaison Committee
3 Council Chairman	Consumer Representative
IDFA	NMPF

Executive Board

- Elected Western States
  - Stephen Beam - California
  - George Blush - Kansas
  - Daniel Borer - Nebraska
- Industry – Jodeen, Meenderink
- USDA – Kenneth Vorgert

Executive Board

- Re-elected Chair:

  John Beers – Virginia Department of Agriculture & Consumer Services

- Re-elected Vice Chair:

  Don Breiner – Land O'Lakes, Pennsylvania

Proposal Process - Prior to Conference

Request for proposals - November

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Proposal submitted by deadline - February

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Program Committee assigns proposal to Council and, if appropriate, Committee - February

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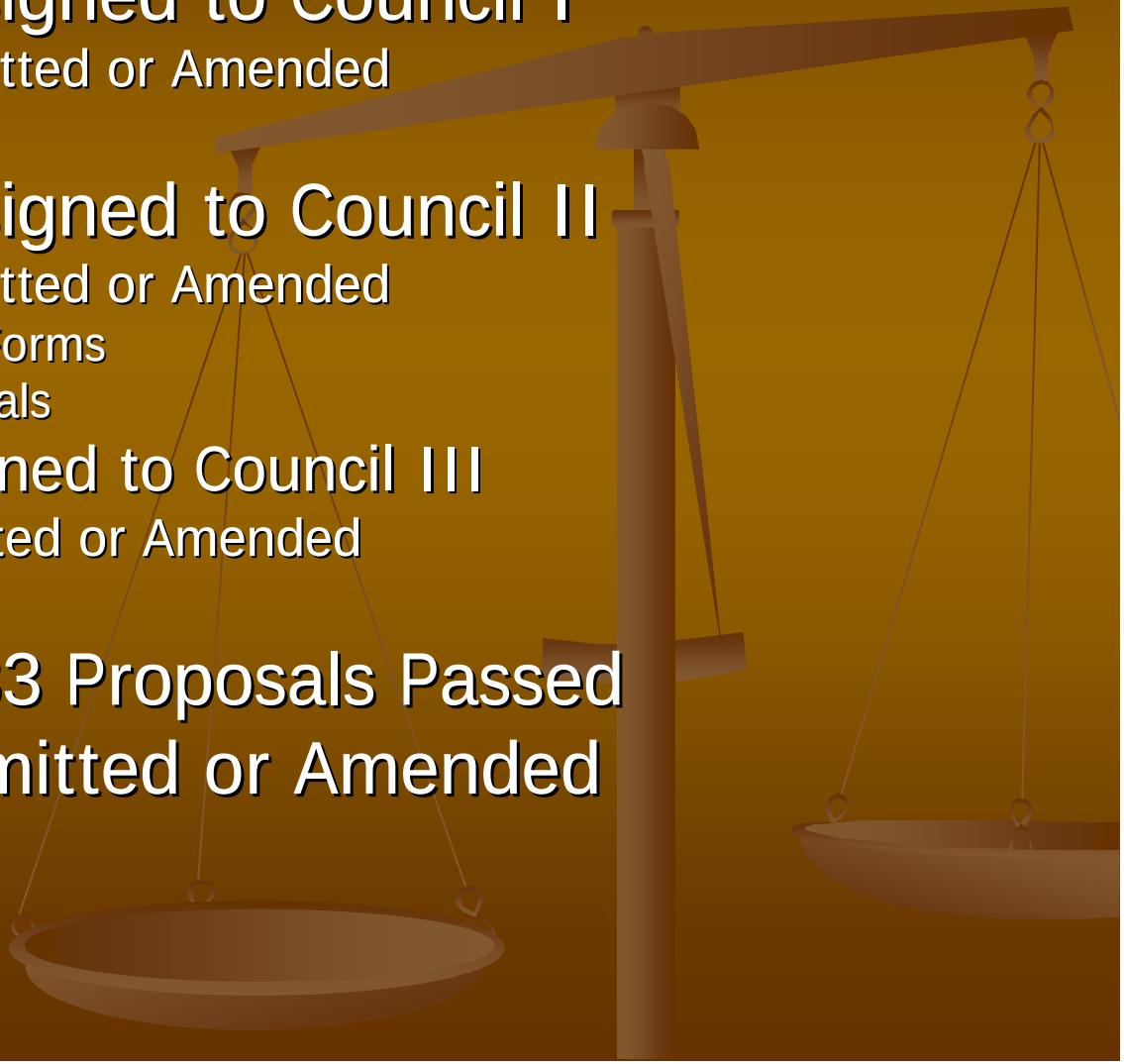
NCIMS Conference – April-May

Proposals to 2009

- 53 Proposals Assigned to Council I
  - 23 Passed as Submitted or Amended
- 64 Proposals Assigned to Council II
  - 39 Passed as Submitted or Amended
    - 23 - 2400 Series Forms
    - 16 – other proposals

  16 Proposals Assigned to Council III
  - 7 Passed as Submitted or Amended

69 of 133 Proposals Passed as Submitted or Amended



Proposal Assignments

COUNCIL	PROCEDURES	PMO (includes DMO)	OTHER
I	NONE	Sec. 7, 8, 9, 10, 12, 13, 14 App. A, C, D, H, I, J, M, O and Q	Technical Issues SSCC
II	NONE	Sec. 1, 2, 3, 4, 5, 6, 15, 16 App. B, E, F, G, L, N, P and R	MMSR EML
III	ALL PROCEDURES ITEMS	Sec. 11, 17, 18 App. K PMO Introduction	Resolutions Constitution/Bylaws Reciprocity Issues

Proposals are assigned to appropriate Committees (i.e., Laboratory, MMSR, SSCC, Hauling, HACCP, Scientific Advisory, Technical Review, etc.). Committee recommendations are then referred back to the appropriate Councils for further consideration.

Proposal Process - At Conference

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Committee decision and recommendation to Council (Fri-Sat)

Reports to Councils

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Council discussion and recommendation to Delegates (Sun-Mon)

(Pass, Amend and Pass, No Action)

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Voting Delegates deliberation and decision (Tue-Wed)

(Pass, Amend and Pass, No Action)

Note: all proposals that are sent as "no action" from Council are considered together and dispensed with, unless held over for consideration by state delegate

NCIMS Committees

- **Standing Committees**
  - Constitution & Bylaws –Lewis Jones
  - Documents Review – Mike Wiggs
  - HACCP Implementation – Jason Crafts
  - Laboratory – Frank Barcellos
  - Method of Making Sanitation Ratings (MMSR)- Mike Wiggs
  - NCIMS/FDA Liaison – Sue Esser
  - Other Species Milk - Lynn Hinckley
  - Program - Cary Frye
  - Hauling Procedures - Chris Thompson, Chair
  - Scientific Review – Dr. Stephen Beam, Chair
  - Single Service Container and Closure – Randy Chloupek, Chair
  - Technical Engineering Review – David Lattan, Chair

NCIMS Committees

- **Ad Hoc Committees**
  - Appendix N Modification Study – Roger Hooi
  - Aseptic Pilot Program Implementation - Susan Esser
  - Defining Grade "A" Dairy Products - Will Francis
  - International Certification Pilot Program - Claudia Coles & Gene Wright
  - Animal/Herd Shares Study Committee – Wayne Cook

Councils

Council I	Council II	Council III
Laws & Regulations	Responsibilities of Conference Participants	Application of Conference Agreements
Chairman & Vice Chairman (no vote)	Chairman & Vice Chairman (no vote)	Chairman & Vice Chairman (no vote)
20 Members	20 members	20 members
10 regulatory 10 industry	10 regulatory 10 industry	10 regulatory 10 industry
4 alternates	4 alternates	4 alternates

The Chairman appoints a consultant for each Council from the Board. The consultant has no voting rights but will offer advice when needed.

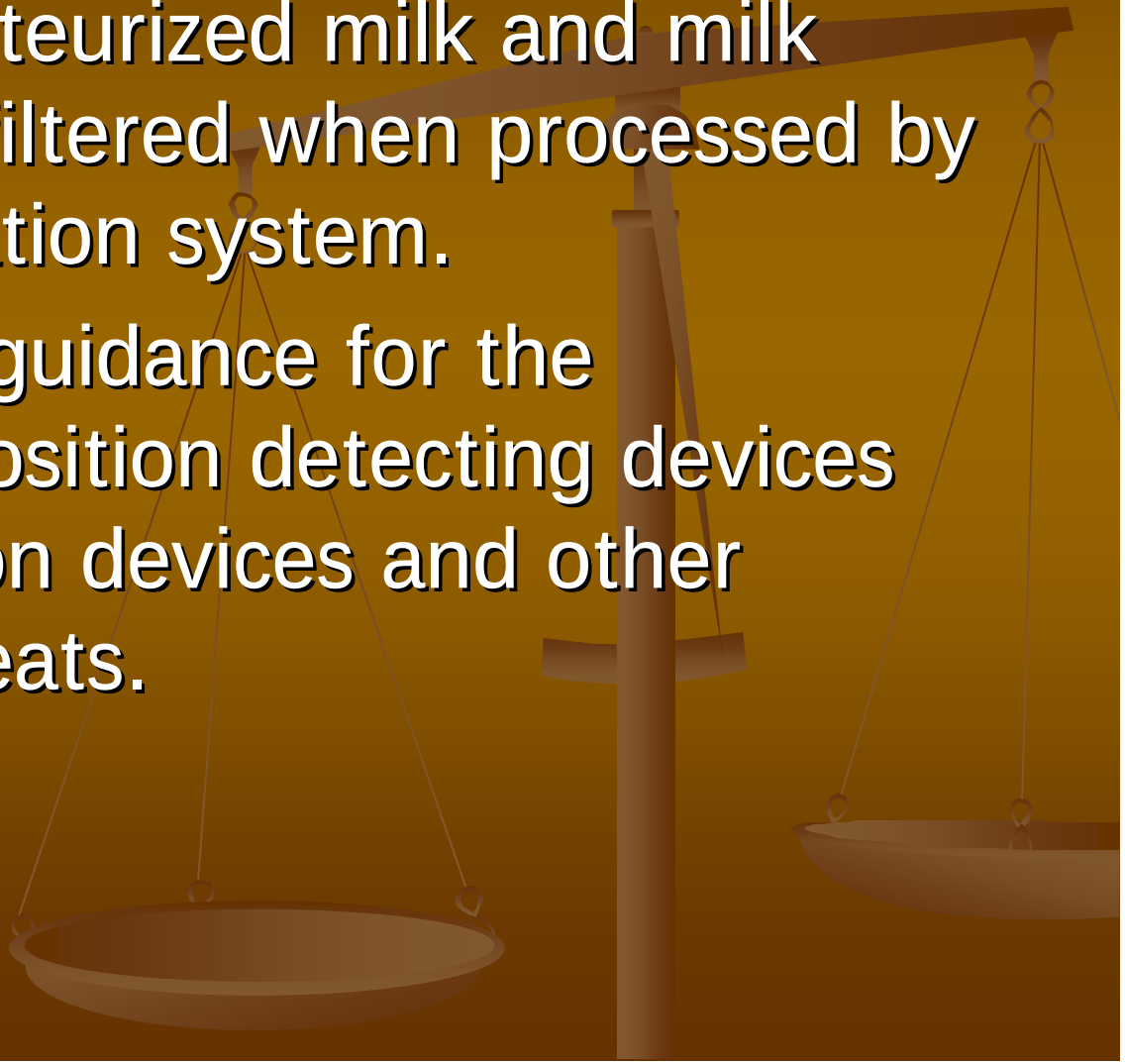
FDA also appoints a consultant for each Council.

Council I Proposals

- 102 – Raise SCC for goat milk to 1,500,000 from 1,000,000
- 104 – Allow study of carbon dioxide as a processing aid in addition to refrigeration in the transportation of raw milk
- 110 – Require recording charts on farm bulk tanks to identify the producer, date, tank ID and signature or initials of installer.

Council I Proposals

- 114 – Allow pasteurized milk and milk products to be filtered when processed by membrane filtration system.
- 115 – Provides guidance for the application of position detecting devices for flow-diversion devices and other process valve seats.



Council I Proposals

- 117 – Clarify the requirements related to water that is not separated from pasteurized milk and milk products.
- 119 – Establish requirements for use of UV Light disinfection as equivalent to pasteurized water for use in dairy plants.
- 122 – Eliminates the requirement to pasteurize condensed product 5 degrees Fahrenheit higher.

Council I Proposals

- 123 – Clarify the exemption for pasteurization prior to entering a RO or UF system
- 125 – Eliminates the use of the term “metering pump” when referring to a pump used to regulate the flow through a holding tube
- 126 Clarify the relationship between homogenizers and timing pumps when both are used in a pasteurization system

Council I Proposals

- 128 – Clarify brucellosis requirements and add 4th option (state brucellosis-free herd certification program)
- 129 – Changes equipment requirements under Appendix B. to refer to “single use sample containers” instead of “sterile bags, tubes or bottles and refers to “non-sterile sample containers” instead of “sterile sample containers” under Appendix J.
- 131 – Establishes requirements for UV Light disinfection for water supplies in the PMO

Council I Proposals

- 132 – Changes title of Appendix H – Pressure Relief Valves and new HTST Drawings
- 134 – Use of spring loaded vacuum breaker disallowed on HTST system
- 137 – Modifies HACCP CCP Model to address flow rates to verify minimum holding times

Council I Proposals

- 139 – Eliminates the requirements to test electronic recording thermometer in boiling water and ice.
- 141 – Clarify and edits equipment test
- 142 – Clarifies under what circumstances vacuum systems and their associated isolation valves need to be tested.

Council I Proposals

- 145 – Modifies test #14.1 to provide for the required calibration of a steam injector controller in the holding tube
- 148 – Eliminate the 90 day grace period for 1 year certification of Single Service facilities
- 150 – Provides for use of a fail-safe instrumented air-block system to separate product /CIP in an AMI installation

Council II Proposals

- 201 through 220, 223, 224 & 226 pertaining to 2400 series forms sent to Lab committee to report to Executive Board
- 227 – Add Easygel Aerobic Plate Count Media, Pectin Gel Method to the Milk Laboratory Evaluation Form

Council II Proposals

- 229 – Add Easygel Violet Red Bile Media, Pectin Gel Method, to the Milk Laboratory Evaluation Form

Council II Proposals
Definition of Grade “A” Milk Product

- 232 – Amend the definition of Grade “A” milk and milk product – For the first time have a clear line between Grade “A” and non Grade “A”
  - 1 - All milk products with standard of identity (21 CFR Part 131 with exception of Sweetened Condensed Milk
  - 2 - Cottage Cheese (21 CFR Part 133.128) and Dry curd cottage cheese (21 CFR Part 131.129)

Council II Proposals
Definition of Grade “A” Milk Product

3 - Whey and Whey products (21 CFR 184.1979, 184.1979a, 184.1979b, 184.1979c and Definition QQ of the PMO

4 - Modified versions of these foods listed in first and second bullet above pursuant to 21 CFR Part 130.10 related to nutrient content claims and a standardized term

5 - Milk and milk products as defined in items 1, 2, 3, and 4 above packaged in combination with foods not included in this definition that are appropriately labeled with a statement of identity to describe the foods in final package form (cottage cheese with pineapple)

Council II Proposals
Definition of Grade “A” Milk Product

6 - Products not included in Items 1 – 5 are Grade “A” products which have a minimum of 2.0% milk protein and a minimum of sixty-five percent (65%) by weight milk, milk product or a combination of milk products

- Safe and suitable as defined in 21CFR 130.3(d) non-grade “A” dairy ingredients can be utilized in the products defined in Items 1-6 above when added to a level needed for a functional or technical effect, and limited by Good Manufacturing Practices

Council II Proposals
Definition of Grade “A” Milk Product

- Note: When a non-grade “A” dairy ingredient is used to increase weight or volume of the product, or displace grade “A” dairy ingredients, this use is not a suitable functional or technical effect.
- DOES NOT INCLUDE:

1 – Milk or milk product in which the milkfat has been substituted in part or in whole by any other animal or vegetable fat

Council II Proposals
Definition of Grade "A" Milk Product

- DOES NOT INCLUDE:

2 – Coffee based products where coffee or water is the primary ingredient

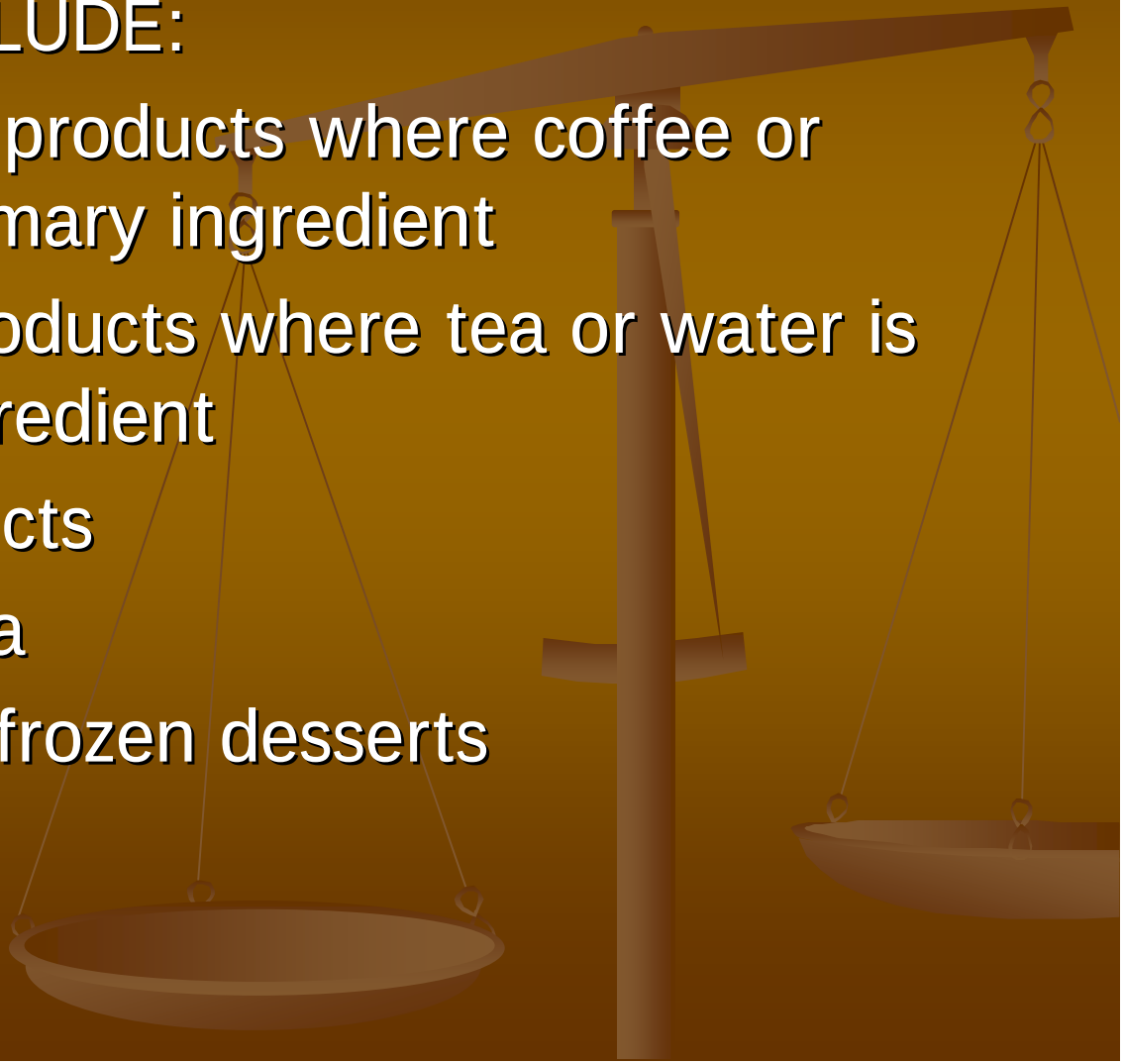
3 – Tea based products where tea or water is the primary ingredient

4 – Dietary products

5 – Infant formula

6 – Ice cream or frozen desserts

7 – Butter



Council II Proposals
Definition of Grade "A" Milk Product

- DOES NOT INCLUDE

8 – Cheese (standardized, except cottage cheese (21 CFR Part 133.128) and dry curd cottage cheese (21 CFR Part 133.129); or

9 – Puddings.

MAY BE INCLUDED

Milk and milk products which have been retort processed after packaging or which have been condensed or dried are only included if they are used as an ingredient to produce any milk or milk product defined above.

Council II Proposals
Definition of Grade “A” Milk Product

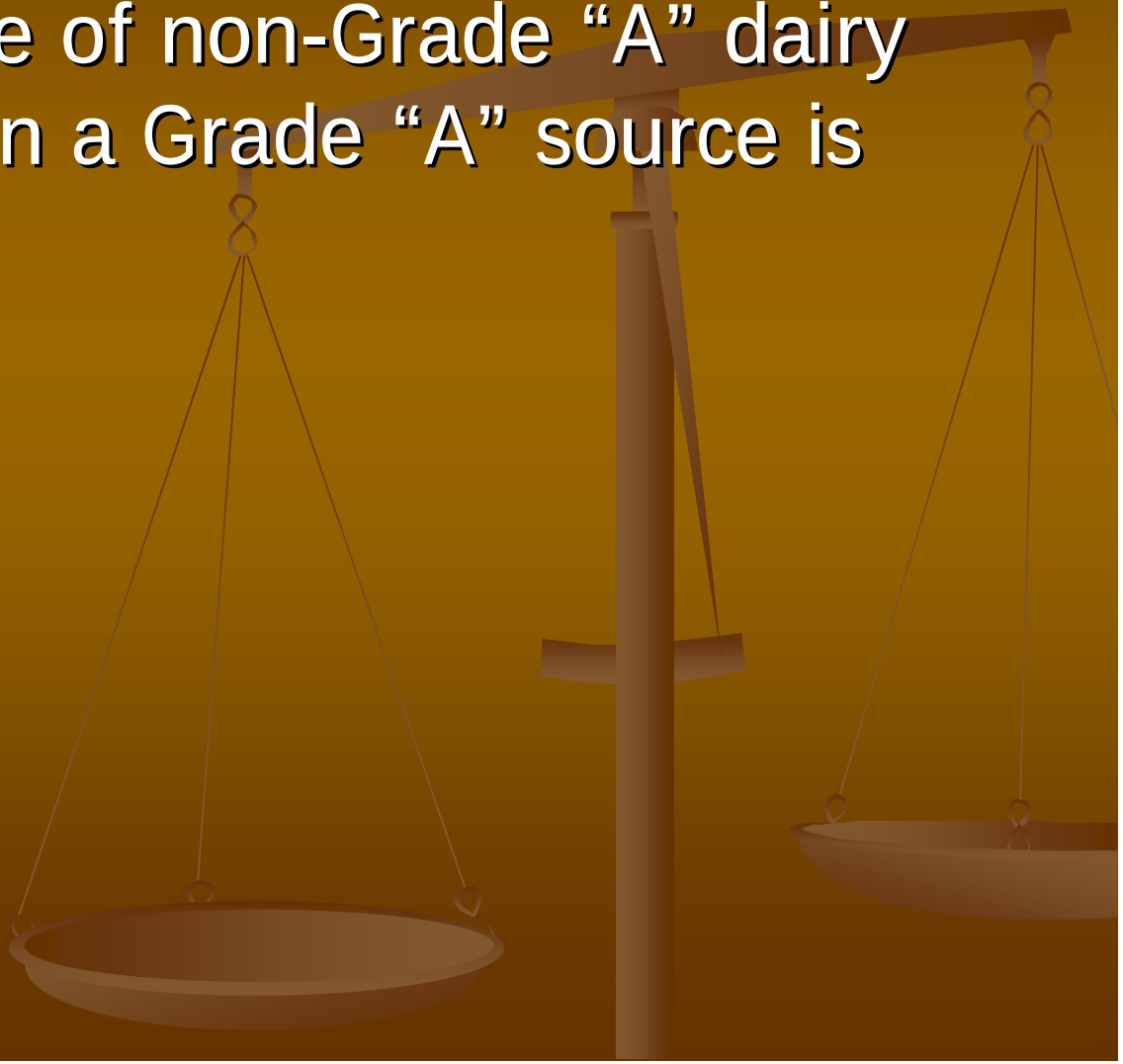
- MAY INCLUDE:

Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” milk and milk products, if they meet the requirements of this Ordinance.

Grade “A” powder blends must be made from Grade “A” powdered milk and milk products, except that small amounts (Max 5%) of functional ingredients which are not Grade “A” are allowed.

Council II Proposals

- 233 – Allows use of non-Grade “A” dairy ingredients when a Grade “A” source is not available



Council II Proposals

- 234 – Clarifies definition of Hooved Mammals to include species that may not have “true hooves”
- 236 – Clarifies when accelerated sampling must be used
- 242 – Changes requirements for re-certification of Certified Industry Inspection personnel

Council II Proposals

- 248 – Requires use of the Pyronine Y-Methyl Green Stain when performing Single Strip direct Microscopic Somatic Cell Counts on sheep milk
- 252 – Allows milk tank that makes multiple pickups to provide a copy of the wash tag to the processing plant
- 254 – Updates Appendix G. Chemical and Bacteriological Tests

Council II Proposals

- 255 – Accepts the Fast Alkaline Phosphatase test as an approved electronic Phosphatase method
- 256 – Amends Appendix L to include all applicable PMO CFR references
- 257 – Corrects an error to the reference to the FDA Commissioner omitted from Appendix N and placed in Section 6 of PMO

Council II Proposals

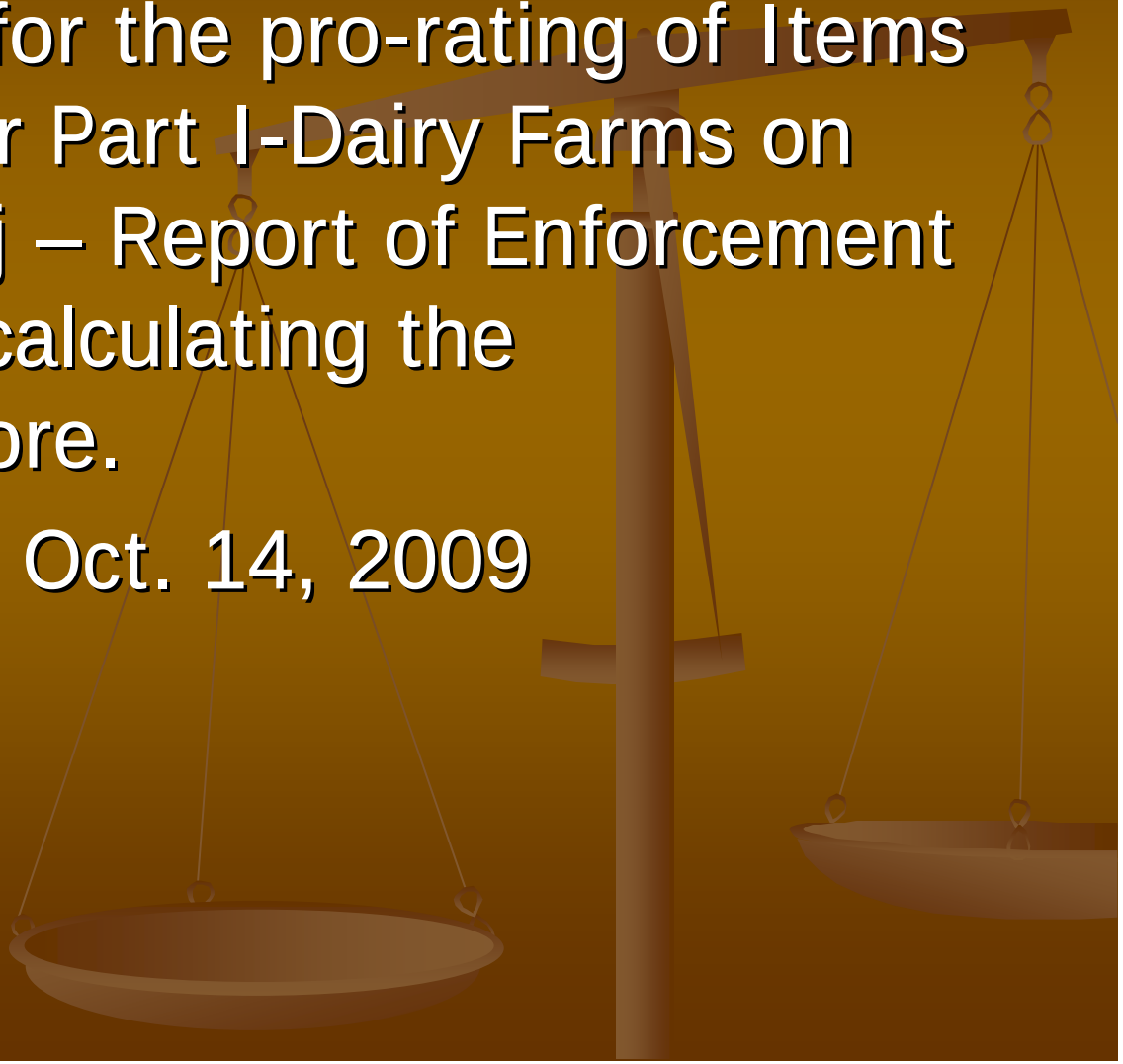
- 259 – FDA Risk Assessment Study and Appendix N Committee requested to include in their risk assessment whether to modify CVM data requirements for bata-lactam screening tests to require the detection of penicillin G, cephapirin, ceftiofur and one other of the six approved beta-lactam drugs. Current protocol requires 4 beta-lactams of 6, but does not specify specific drugs that must be detected.

- 260 – FDA Risk Assessment Study and Appendix N Committee requested to include in their risk assessment whether to modify CVM data requirements for milk screening tests to reflect current residue tolerances for the six beta-lactam drugs. Ceftiofur tolerance has changed from parent compound to total metabolite for example.

Council II Proposals

- 262 – Provides for the pro-rating of Items 10 and 11 under Part I-Dairy Farms on Form FDA 2359j – Report of Enforcement Methods when calculating the enforcement score.

  Effective Oct. 14, 2009



Council III Proposals

- 301 – Extends the Aseptic Pilot Program through December 31, 2011

  Effective October 14, 2009
- 302 – Modifies Form FDA 2359m, Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report to better reflect NCIMS HACCP requirements

Council III Proposals

- 303 – Updates Section 12 of the Form FDA 2359m, Milk Plant, Receiving Station or Transfer Station NCIMS HACCP System Audit Report.
- 304 – Extends the voluntary International Certification Pilot Program until December 31, 2011 – Effective October 14, 2009
- 307 – Allows Third Party Certifier to add two additional plants after their existing two are listed – Effective October 14, 2009

Council III Proposals

- 311 – Clarifies that a dairy farm can only be listed in one BTU at a time – Effective October 14, 2009
- 312 – Clarifies type of training required to maintain continuous certification as HACCP Listing Officer is dairy plant HACCP audit and IMS listing training

Proposal Process - Post Conference

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Transcript of Conference to FDA - within 45 days after conference (May 8, 2009)

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FDA concur/non-concur letter to Executive Board - within 90-days after receiving transcripts (August 8, 2009)

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Executive Board meeting (September 9 – 10, 2009)

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FDA concurs and mutually agreeable non-concurs published in IMS-a-47 dated October 14, 2009

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Implementation – One year after electronic publication of affected documents or notification to states by IMS-a

(FDA updates published documents, PMO, Procedures, MMSR, EML, etc)

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Unresolved business sent to next Conference

2011 NCIMS Conference
Sheraton Baltimore City Center
Baltimore, Maryland
April 28 – May 4, 2011

Thank you!

John Beers

Virginia Department of Agriculture and Consumer Services