

**THE 48<sup>th</sup> ANNUAL DAIRY  
PRACTICES COUNCIL  
CONFERENCE  
BUFFALO, NEW YORK  
November 8-10, 2017**

Frank Flores

Office of Food Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration



# TOPICS

- CFSAN/MST and RMS Positions
- 2017 NCIMS
- Appendix N Pilot Program
- International Certification Program
- Single Service Consultants



# TOPICS

- Grade “A” Equivalency Determinations
- Non-Grade “A” Assignments
- FDA’s Food Safety Plan Builder Tool &  
Application



# CFSAN/Office of Food Safety

- Nega Beru, Ph.D. – Director
- John Sheehan – Director, Division of Dairy, Egg and Meat Products
- Monica Metz – Chief, Milk & Milk Products Branch



# Milk & Milk Products Branch

- Bob Hennes – Team Leader
- Dennis Gaalswyk (Part Time Grade “A”)
- Steve Sims
- Frank Flores
- Randy Elsberry
- Robert Altobelli



# NEW MILK SPECIALISTS

- Paul Klug
  - Lenexa, Kansas
- Amanda Zick
  - Albany, New York
- 3 Vacant Positions
  - Central
  - Northeast



# 2017 NCIMS CONFERENCE

- 98 Proposals Submitted and deliberated
- Council I – 38 Proposals
- Council II – 46 Proposals (8-Lab Procedures/Issues and 9-2400 Forms)
- Council III – 10 Proposals
- Joint Council – 4 Proposals



# 2017 NCIMS CONFERENCE ACTIONS JOINT COUNCIL

- 4 – Submitted
- 2 – Passed as Amended
- 2 – Tabled



# 2017 NCIMS CONFERENCE ACTIONS COUNCIL I

- 38 – Submitted
- 3 – Passed as Submitted
- 7 – Passed as Amended
- 28 – No Action



# 2017 NCIMS CONFERENCE ACTIONS COUNCIL II

- 46 – Submitted
- 3 – Passed as Submitted
- 17 – Passed as Amended
- 5 – 2400 Form
- 21 – No Action



# 2017 NCIMS CONFERENCE ACTIONS COUNCIL III

- 10 – Submitted
- 1 – Passed as Submitted
- 4 – Passed as Amended
- 5 – No Action



# 2017 NCIMS CONFERENCE ACTIONS STUDY COMMITTEES

- Proposal 118 – Review and Evaluate Text in Item 16p and Appendix H (Tech Engineering Review Committee)
- Proposal 213 – Comprehensive Review of Appendix B and FORM FDA 2399a (Hauling Procedures Committee)



# 2017 NCIMS CONFERENCE ACTIONS STUDY COMMITTEES

- Proposal 217 – Review Appendix N, Section VI (non-beta lactam testing with non-evaluated/accepted tests) (Appendix N Modification Study Committee)



# 2017 NCIMS CONFERENCE ACTIONS STUDY COMMITTEES

- Proposal 230 – MMSR Review (including an assessment of the appropriate point value for 15p-Animal Food Provisions) (MMSR and Aseptic Program Committees)
- Proposal 303 – Procedures Review (MMSR and Aseptic Program Committees)



# Appendix N Tetracycline Pilot Program

Latest Update



# APPENDIX N PILOT PROGRAM

- Raw Milk Testing Pilot for Non-Beta Lactam Drugs
- Implementation Date: July 1, 2017
- Tetracycline Class of Drugs:  
Oxytetracycline, Tetracycline, and  
Chlortetracycline
- Testing Frequency: No Less than 1  
Out of 15 Bulk Milk Tankers/quarter



# APPENDIX N PILOT PROGRAM

- Test Methods
- M-a-85 Approved Methods for Tetracyclines: (Charm II Competitive)
- Pilot Approved Methods for Tetracyclines: (Neogen BetaStar Advanced; Charm Rosa SL (Dilution Confirmation) and IDEXX – SNAP (Dilution Confirmation))



# APPENDIX N PILOT PROGRAM

- Pilot Program will continue until a minimum 18 months of data is generated



# INTERNATIONAL CERTIFICATION PROGRAM (ICP)

- **IMS LISTINGS** (SEPARATE SECTION FOR IMS LISTED SHIPPERS FROM FOREIGN COUNTRIES)

**5 - CANADA (HW&A/MRC)**

**– 4 Plants and 1 Goat BTU  
(Ontario and British Columbia)**



# INTERNATIONAL CERTIFICATION PROGRAM (ICP)

## **2 - COLOMBIA (HW&A)**

**– 1 PLANT and 1 BTU (8 dairy farms)**

## **2 – MEXICO (MRC)**

**– 1 PLANT (aseptic listing) and 1 BTU (7 dairy farms)**



# SINGLE-SERVICE CONSULTANTS

## FDA CERTIFIED SSCs

- **HAROLD WAINESS & ASSOCIATES**
  - Ken Anderson - President
  - Dan Erickson
  - Gabriel Pascual
  - Walter Brown – SRO



# SINGLE-SERVICE CONSULTANTS

## FDA CERTIFIED SSCs

- **MILK REGULATORY CONSULTANTS, LLC**
  - Lynn Young – Owner/SRO



# SINGLE-SERVICE CONSULTANTS

## FDA CERTIFIED SSCs

- **PACKAGING CONSULTANTS INTERNATIONAL , INC**
  - Patrick Frontale - Owner
  - Kathrene Dutrow
  - Tina Marler



# Equivalency Determinations

- **Grade “A” equivalency determinations that are currently being conducted at the request of several governments and one supra-national entity:**
  - **New Zealand work continues. Proposed Overseas Market Access Requirements (OMARS) which are in respond to the preliminary report have been provided to FDA. The Final Draft of the report/findings is being finalized.**



# Equivalency Determinations

- **Grade “A” equivalency determinations (cont.):**
  - **European Union: Site visits have been completed for Ireland, Netherlands and France. Preliminary reports have been drafted and are currently under review.**



# Equivalency Determinations

- **Grade “A” equivalency determinations (cont.):**
  - **Canada:** has been paused at Canada’s request as it works to implement national food safety legislation. Canada will notify FDA when it is ready to recommence the work.



# NON-GRADE “A” ASSIGNMENTS

- **FSMA Preventive Control Inspections**
  - 240 domestic and 60 international
  - Target large firms (500+ employees)
  - Grade “A” IMS listed firms are not to be inspected



# FDA'S FOOD SAFETY PLAN BUILDER TOOL & APPLICATION

[http://www.fda.gov/Food/GuidanceRegulation/  
FSMA/ucm539791.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm)





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## Food

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### Food Safety Modernization Act (FSMA)

[The Law, Rules & Guidance](#)

[Fact Sheets & Presentations](#)

[Frequently Asked Questions on FSMA](#)

[FDA Actions and Meetings](#)

[FSMA Training](#)

[FSMA Technical Assistance Network \(TAN\)](#)

# Food Safety Plan Builder

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The U.S. Food and Drug Administration's (FDA) [Food Safety Plan Builder \(FSPB\)](#) is a tool designed to assist owners/operators of food facilities with the development of food safety plans that are specific to their facilities and meet the requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR Part 117).

Use of this tool is *strictly optional* on the part of the user. FDA is not requiring use of this tool to develop a facility's food safety plan. Although the content of the Food Safety Plan Builder v. 1.0 is consistent with the FDA's existing guidance and regulations, use of the Food Safety Plan Builder by owners and operators of food facilities **does not mean** that their food safety plan, preventive controls, good manufacturing practices and other food safety procedures are approved by FDA or comply with FDA requirements.

The Food Safety Plan Builder guides the user through the following sections:

- Facility Information
- Preliminary Steps

### Food Safety Plan Builder

- [View the Training Videos](#)
- [Download the Food Safety Plan Builder Tool](#)

- Good Manufacturing Practices (GMP) & Prerequisite Programs
- Hazard Analysis & Preventive Controls Determination
- Process Preventive Controls
- Food Allergen Preventive Controls
- Sanitation Preventive Controls
- Supply-Chain Preventive Controls
- Recall Plan
- Reanalysis of Food Safety Plan
- Food Safety Plan Report
- Signature
- Recordkeeping Procedures
- Important Contacts
- Supporting Documents

- [Read the User Guide](#)
- [System Requirements](#)

### Have Questions?

If you have additional questions or need more information, please email

[FoodSafetyPlanBuilder@fda.hhs.gov](mailto:FoodSafetyPlanBuilder@fda.hhs.gov)

[System Requirements](#)



[Additional Resources](#)



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## Food Safety Plan Builder Download

- FDA Home
- Food
- Guidance & Regulation
- Food Safety Modernization Act (FSMA)
- Food Safety Plan Builder (FSPB)



# FOOD SAFETY PLAN BUILDER

Thank you for your interest in the FDA's Food Safety Plan Builder. If you would like to receive updates and news on FDA's Food Safety Plan Builder tool, please provide your contact information in the fields below. Providing your information is *not* required to download the tool. All fields below are optional.

Name:

Firm Name:

Country:

Address:

Shipping Tool

Address line 2:

City:

State/Province/Territory:

Zip:

Phone:

Fax:

Email:

Confirm Email:

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## System Requirements

User's computer configuration must meet the minimum requirements outlined in the table below in order for the Food Safety Plan Builder tool to operate correctly.

**QUESTIONS?**

**THANK YOU!**

