

CFSAN/DEB/MST UPDATE

THE DAIRY PRACTICES COUNCIL
ANNUAL CONFERENCE
MADISON, WISCONSIN
NOVEMBER 9, 2012

DENNIS GAALSWYK

Division of Plant and Dairy Food Safety

Office of Food Safety

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration



ADMINISTRATIVE UPDATE

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN) – OFFICE OF THE CENTER DIRECTOR

■ DIRECTOR

- Michael M. Landa, J.D.

■ SENIOR SCIENCE ADVISOR

- Donald Zink, Ph.D.

■ SENIOR ADVISOR

- Roberta Wagner



ADMINISTRATIVE UPDATE

- DEPUTY DIRECTOR FOR OPERATIONS
 - Linda Katz, Ph.D. (Acting)
- DEPUTY DIRECTOR FOR REGULATORY AFFAIRS
 - Ted Elkin, M.S., M.P.A. (Acting)
- DIRECTOR, OFFICE OF ANALYTICS AND OUTREACH (Formally Office of Food Defense, Communications and Emergency Response)
 - Kathy Gombas (Acting)
- DIRECTOR, OFFICE OF COMPLIANCE
 - Michael Roosevelt (Acting)

CFSAN ORGANIZATION

Reporting to the Deputy Director for Operations:

- OFFICE OF FOOD SAFETY (OFS)
 - Nega Beru, Ph.D.

5100 Paint Branch
College Park, MD 20740
Mail Code: HFS-300

Main Telephone: (240) 402-1700
Fax: (301) 436-2599



OFS ORGANIZATION CHART

■ DIRECTOR

- Nega Beru, Ph.D.

■ DEPUTY DIRECTOR

- William R. Jones, Ph.D (Acting)

■ DIVISION OF PLANT & DAIRY FOOD SAFETY

- John F. Sheehan, J.D.

■ DAIRY AND EGG BRANCH

- Monica Metz - Branch Chief

- Combines Grade “A” and Non-Grade “A” Dairy Programs
- Includes all Regulatory Programs for Foods Derived from Animals



DAIRY AND EGG BRANCH

(DEB)

- Microbiologists
- Food Scientists
- Regulation Writers
- Cheese Processing Experts
- Compliance Experts
- Filth Experts
- Chemists
- Egg Specialists
- Senior Milk Specialists

DAIRY AND EGG BRANCH (DEB)

GRADE “A” MILK SAFETY PROGRAM

- BOB HENNES-Team Leader
- STEVE SIMS
- DENNIS GAALSWYK

DAIRY AND EGG BRANCH (DEB)

NEW TELEPHONE NUMBERS:

BOB HENNES: (240) 402-2175

STEVE SIMS: (240) 402-2153

DENNIS GAALSWYK: (240) 402-2006



DAIRY AND EGG BRANCH

(DEB)

- **POSITION ANNOUNCEMENTS FOR TWO (2) NEW POSITIONS WITHIN THE MILK SAFETY TEAM**
- **POSITION ANNOUNCEMENT FOR RESEARCH FOOD TECHNOLOGIST AT FDA MOFFETT RESEARCH CENTER (due to Joe Schlessner's retirement)**

FDA FIELD PERSONNEL CHANGES

NEW REGIONAL MILK SPECIALISTS:

JOIE NAVARRETE - INDIANAPOLIS, IN

DAVID PEARCE - HARRISBURG, PA

FRANK HARRIS - DALLAS, TX

JONATHAN GARDNER – BALTIMORE, MD



FDA PERSONNEL CHANGES

- New LPET Evaluation Officer – Annemarie Buchholz, Ph.D.
- CVM Compliance Division – Amber McCoig, DVM

PROJECTS

GRADE “A” EQUIVALENCY DETERMINATIONS

- Canada
 - Last U.S. on-site visits to Canada were conducted in Quebec and Ontario in October 2010
 - Canada performed an on-site evaluation of Grade “A” Milk Safety Program’s Laboratory Program in Oregon in July 2011
 - U.S. visit to farms in Alberta and several face-to-face visits scheduled from October to December of 2011 postponed due to budgetary issues and have not been rescheduled



GRADE “A” EQUIVALENCY DETERMINATIONS

➤ New Zealand

- In November 2010, 4 U.S. teams visited 12 plants, 22 farms and 4 laboratories in New Zealand
- Main emphasis was to accompany a Recognized Verifier or an Assessor from a Recognized Agency while they were conducting an audit of the plant or farm Risk Management Program
- Possible additional visit to New Zealand during 2013 depending on personnel and budgetary resources

GRADE “A” EQUIVALENCY DETERMINATIONS

➤ EU

- Individual member state equivalency determination issue still has not been addressed by the EU
- The EC still has not identified a technical team to work with the U.S. technical team
- FDA has informed the EU that we do not have the personnel to conduct this equivalency determination at this time and will not be able to do this until either Canada or New Zealand has been resolved

EU AUDIT OF U.S. DAIRY PROGRAM

- In June 2012, a team from the EU visited a plant, a dairy farm and a laboratory in Wisconsin; and two plants and a dairy farm in California
- Preliminary results expressed at the exit interview with FDA and USDA were very positive

RAW MILK FIELD SAMPLING

ASSIGNMENT FOR EU

- 153 of 320 samples have been collected to date. Remaining samples will be collected in November 2012 and February 2013.
- Samples are being collected by permitted industry samplers. All samples are being collected as investigational samples (INV).
- Samples are being tested utilizing three (3) separate FDA laboratories (mycotoxins, chemicals and metals).
- Results obtained will be used to address observations from the 2010 EU audit of the entire U.S. dairy program (FDA, State and USDA).



CVM RAW MILK SAMPLING

ASSIGNMENT

- Issued February 2012 for completion in FY 2012; extended into FY 2013 (Oct – Nov 2012)
- 1800 samples from dairy farms (900 targeted and 900 random)
- To date, approximately 93% of total samples have been received at the lab
- To date, approximately 88% of total samples have been analyzed

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

- Originally issued in April 2010, received several extensions, final sampling completed mid-2011, results summarized late 2011
- Firms in 27 States were inspected/sampled
- Approximately 20% occurrence of *Listeria* on all the cheese firms inspected
- Approximately 20% occurrence of *Listeria* on the artisanal cheese firms inspected

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

Environmental Sampling: Location

High
Risk



Low
Risk

Zone 1 – Product contact surfaces: conveyors, tables, racks, vats, tanks, pumps, slicers, packaging machines, etc.

Zone 2 – Non-product contact surfaces in close proximity to product: equipment exterior, refrigeration units, floors, etc.

Zone 3 – Telephones, forklifts, walls, drains

Zone 4 – Locker rooms, cafeteria, hallways

ENVIRONMENTAL SAMPLING FOR *LISTERIA* AT SOFT CHEESE FIRMS

- Zone 1 – Approximately 3% positive samples
- Zone 2 – Approximately 6% positive samples
- Zone 3 – Approximately 3% positive samples
- Zone 4 – No positives
- Finished product samples taken at 8 artisanal cheese firms were tested for *E. coli*, all samples were negative

ENVIRONMENTAL SAMPLING FOR *SALMONELLA* AT DRIED MILK FIRMS

- 11 firms inspected in FY 2012
- Approximately 80% of the firms had at least 1 (one) environmental positive
- Approximately 4% of the swabs were positive
- Zone 1 – No positives
- Zone 2 – Approximately 2% positive samples
- Zone 3 – Approximately 3% positive samples
- Zone 4 – No positives

DRUG RESIDUE RISK ASSESSMENT

- Drug Residues in Milk Assessment (Proposal 243 from the 2005 NCIMS)
 - NCIMS Drug Residue Committee requested an FDA Risk Analysis
 - 25 member team with CFSAN and CVM representatives
 - Drug Risk Assessment Model consists of four modules (On-farm, Processing, Consumer Exposure, and Hazard Characterization)
- Work groups meet monthly



DRUG RESIDUE RISK ASSESSMENT

- Risk Assessment will evaluate:
 - Likelihood and magnitude of drug use in cattle and drug presence in raw milk
 - Likelihood and magnitude of drug survival in milk and milk products after processing
 - Magnitude of human exposure to a drug via consumption of milk and milk products
 - Consequence of human exposure (acute or chronic)
- Final Result – A risk estimation score for a drug based on likelihood and severity of potential health effects

NATIONAL MILK DRUG RESIDUE DATA BASE

- Milk samples with animal drug residues slightly lower in FY 2011
 - 0.028% or 1,079 of the 3,787,251 milk samples analyzed tested positive for a drug residue.
 - A total of 3,796,684 tests were reported on the samples for 8 different families of individual drugs.
 - 26 testing methods were used to analyze the samples for residues.

Drug Residue Positive Tests

Published in NMDRD

<u>Fiscal Year</u>	<u>Percent Positive</u>
1995	0.144
2006	0.054
2007	0.042
2008	0.040
2009	0.035
2010	0.032
2011	0.028

INFORMATION FROM THE DAIRY and EGG BRANCH (DEB)

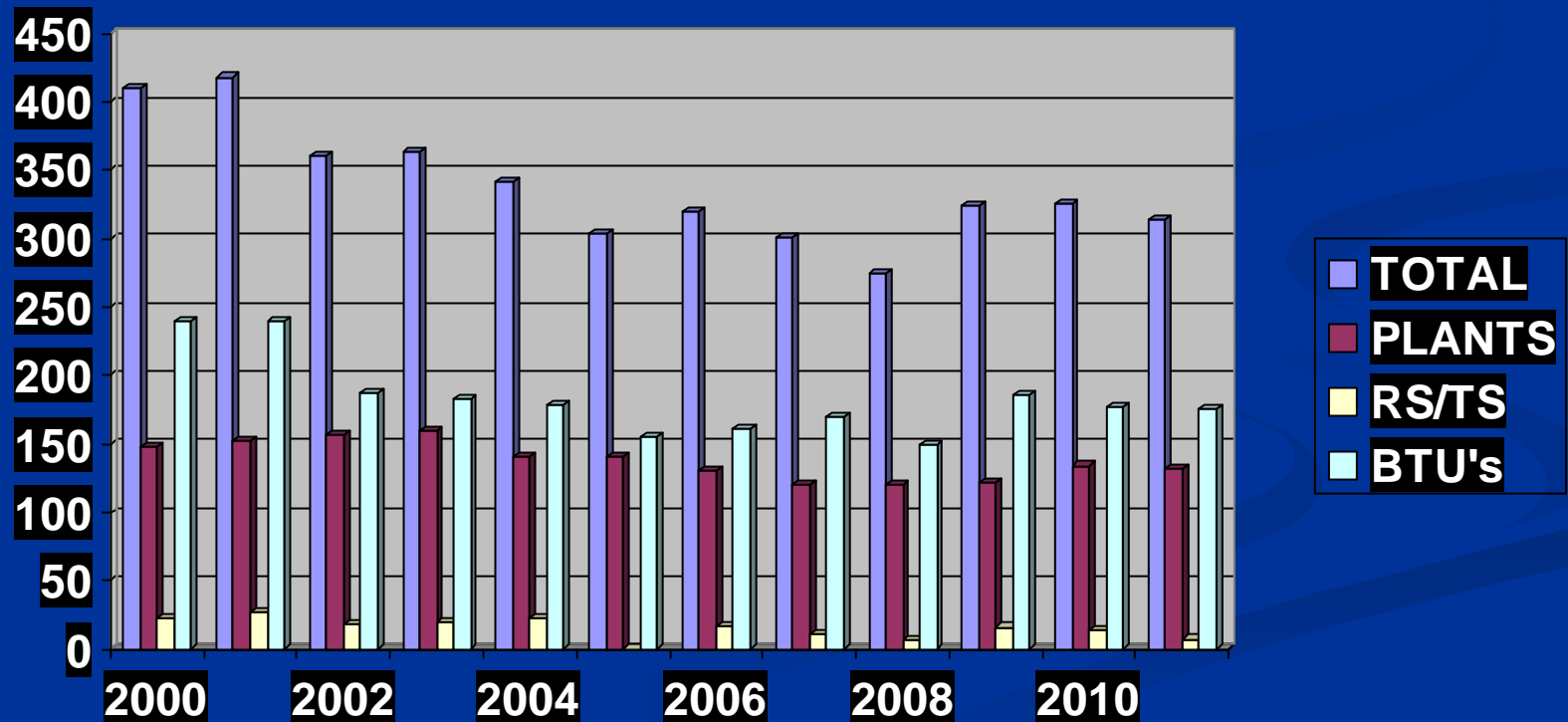


CHECK RATINGS

PLANTS, RS/TS AND BTU's

2000-2011

■ Average FY Total Number = 338



Grade “A” CHECK RATINGS FY’11

<u>REGION</u>	<u>BTU’s</u>	<u>PLANTS</u>	<u>RS/TS</u>	<u>TOTAL</u>	<u>Single Service</u>
NE	25	17	1	43	7
CEN	53	37	1	91	14
SE	25	16	0	41	17
SW	42	20	5	67	10
PAC	30	42	0	72	11
TOTALS	175	132	7	314	59

AVERAGE ADVERSE ACTION RATES (%) -CHECK RATINGS (2000-2011)

PLANTS	8.3%
RS/TS	6.9%
BTU's	15.1%
OVERALL	12.1%

TOTAL ADVERSE ACTION RATES (%) -CHECK RATINGS

FY	PLANTS	RS/TS	BTU's	ALL
2011	6.8%	0.0%	17.7%	12.7%
2010	6.7%	7.1%	9.6%	8.3%
2009	5.7%	6.3%	15.1%	11.1%
2008	8.3%	0.0%	16.8%	12.7%
2007	7.5%	18.2%	14.1%	11.6%
2006	8.5%	23.5%	16.8%	13.6%
2005	8.6%	0.0%	18.7%	13.5%
2004	13.5%	8.7%	15.7%	14.3%
2003	10.0%	10.0%	13.1%	11.6%
2002	5.1%	5.6%	15.5%	10.5%
2001	9.2%	3.7%	12.6%	10.8%

AVERAGE WITHDRAWAL RATES (%) -CHECK RATINGS (2000-2011)

PLANTS	2.1%
REC/TR	3.1%
BTU's	4.3%
OVERALL	3.2%

TOTAL WITHDRAWAL RATES (%) -CHECK RATINGS

FY	PLANTS	RS/TS	BTU's	ALL
2011	1.5%	0.0%	6.9%	4.5%
2010	1.5%	0.0%	2.8%	2.2%
2009	3.3%	6.3%	4.8%	4.3%
2008	1.6%	0.0%	6.7%	4.4%
2007	4.2%	9.1%	2.4%	3.3%
2006	2.3%	11.8%	5.6%	4.5%
2005	1.4%	0.0%	3.9%	2.6%
2004	4.3%	4.3%	5.1%	4.7%
2003	1.3%	0.0%	5.5%	3.3%
2002	0.6%	5.6%	5.3%	3.3%
2001	2.6%	0.0%	1.7%	1.9%

RECENTLY ISSUED CODED MEMORANDA

IMS-a-48

*ACTIONS FROM THE 2011 NCIMS
CONFERENCE*

Issued 11/7/2011

Implementation Date of 11/7/2012 for
States that can legal enforce the new
regulations based on the issuance of
IMS-a-48



RECENTLY ISSUED CODED MEMORANDA

- **M-I-11-5** (*2011 REVISION OF THE PROCEDURES*) - 10/28/2011
- **M-I-11-6** (*2011 REVISION OF THE METHODS*) - 11/30/2011
- **M-I-11-7** (*2011 REVISION OF THE PROCEDURES ON FDA's WEB SITE*) - 12/20/2011

RECENTLY ISSUED CODED MEMORANDA

- M-I-12-1 (*2011 REVISIONS OF THE INDEXES OF CODED MEMORANDA*)-
1/4/2012
- M-I-12-2 (*2011 REVISION OF THE PMO*) -
1/19/2012
- M-I-12-3 (*CHARM SCIENCES, INC. CHARM FLUNIXIN AND BETA-LACTAM TEST*) - 2/3/2012

RECENTLY ISSUED CODED MEMORANDA

- **M-I-12-4** (*APPLICATION AND STANDARD OPERATING PROCEDURES (SOP) FOR THE INSTALLATION AND USE OF AN ACCEPTABEL **ASEPTIC SAMPLER** FOR THE COLLECTION OF “**UNIVERSAL**” DAIRY FARM MILK SAMPLES FROM FARM BULK MILK TANKS AND/OR SILOS FOR ACCEPTANCE UNDER SECTION 6 OF THE PMO*)- **2/7/2012**
- **M-I-12-5** (*2011 REVISION OF THE **EML***)- **2/16/2012**



RECENTLY ISSUED CODED MEMORANDA

- **M-I-12-6** (*2011 REVISION OF THE PMO ON FDA's WEB SITE*) - 3/21/2012
- **M-I-12-7** (*2011 REVISION OF THE METHODS ON FDA's WEB SITE*) - 3/21/2012
- **M-I-12-8** (*2011 REVISION OF THE EML ON FDA's WEB SITE*) - 3/21/2012
- **M-I-12-9** (*QUESTIONS AND ANSWERS RECEIVED FROM THE FIELD; REGIONAL MILK SEMINARS; AND FDA TRAINING COURSES HELD DURING FYs 2010 AND 2011*) - 3/30/2012



RECENTLY ISSUED CODED MEMORANDA

- **M-I-12-10** (*TEAT PREPARATION PROTOCOL
INSENTEC B.V. GALAXY ASTREA 20.20 USA
AUTOMATIC MILKING SYSTEM*) - 5/14/2012
- **M-I-12-11** (*ADDITIONAL INFORMATION
RELATED TO THE STORAGE OF DRUGS
UNDER ITEM 15r OF THE GRADE A
PASTEURIZED MILK ORDINANCE (PMO)*) -
8/31/2011
- **M-I-12-12** (*CEPHALOSPORIN – ORDER OF
PROHIBITION*) - 9/27/2011

RECENTLY ISSUED CODED MEMORANDA

- **M-I-12-13** (ADDITION OF A CLAIM FOR CAMEL MILK TO THE IDEXX LABORATORIES, INC. NEW SNAP BETA-LACTAM TEST KIT) - 10/9/2012
- **M-I-96-10** (REVISION #8) (*DRUG RESIDUE TEST METHODS FOR CONFIRMATION OF PRESUMPTIVE POSITIVE RESULTS AND INITIAL PRODUCER TRACE BACK*) - 3/22/2012
- **M-a-85** (REVISION #14) (*BETA LACTAM TEST METHODS FOR USE UNDER APPENDIX N AND SECTION 6 OF THE PMO*) - 3/22/2012

CODED MEMORANDA BEING WORKED ON

*M-a-98 (??) (OFFICIAL REGULATORY TESTS
FOR GRADE “A” MILK AND MILK PRODUCTS)
– Under final review by NCIMS Laboratory
Committee, LPET and MST*

*M-I-12 (??) (QUESTION FROM NATIONAL
FIELD EXERCISE SEPTEMBER 27 – 29, 2011;
REGARDING TIME CRITERIA FOR THE
REGULATORY AGENCY RE-SEALING OF MILK
AND MILK PRODUCT PASTEURIZATION
CONTROLS)*



CODED MEMORANDA BEING WORKING ON

M-I-12-? (INDUSTRY AND REGULATORY AGENCY OBLIGATIONS UNDER THE PMO RELATED TO THE SCREENING OF BULK MILK PICKUP TANKERS FOR DRUG RESIDUES THAT ARE CONDUCTED IN ADDITION TO THE REQUIRED BETA LACTAM TESTING)

M-I-12-? (QUESTIONS AND ANSWERS RECEIVED FROM THE FIELD; REGIONAL MILK SEMINARS; AND FDA TRAINING COURSES HELD DURING FY 2012)



INTERNATIONAL CERTIFICATION PILOT PROGRAM

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

4 - CANADA

- *3 PLANTS AND 1 BTU (ONTARIO)*

2 - COLOMBIA

- *1 PLANT AND 1 BTU*

2 - GERMANY

- *1 PLANT AND 1 BTU*



INTERNATIONAL CERTIFICATION PILOT PROGRAM

■ IMS LISTINGS

2 - SPAIN

■ *1 PLANT AND 1 BTU*

3 - MEXICO

■ *2 PLANTS (same plant has both aseptic and PMO listings) AND 1 BTU*

INTERNATIONAL CERTIFICATION PILOT PROGRAM

■ IMS LISTINGS

1 - GREECE

■ *1 PLANT*

**1 ADDITIONAL PLANT AND 1 BTU
REGULATED BY THE STATE OF NEW
YORK**

2 - ROMANIA

■ *1 PLANT AND 1 BTU*



INTERNATIONAL CERTIFICATION PILOT PROGRAM

CHECK RATINGS CONDUCTED

3 PLANTS AND 1 BTU IN CANADA
(ONTARIO)

NOTE: 1 PLANT AND 1 BTU HAVE BEEN DONE TWICE.
ADVERSE ACTION - 1 PLANT REINSPECTION

1 PLANT AND 1 BTU IN SPAIN

1 PLANT AND 1 BTU IN MEXICO

1 PLANT AND 1 BTU IN GREECE



INTERNATIONAL CERTIFICATION PILOT PROGRAM

CHECK RATINGS PLANNED IN FISCAL *YEAR 2013*

1 PLANT AND 1 BTU IN SPAIN

1 PLANT AND 1 BTU IN COLOMBIA

1 PLANT AND 1 BTU IN ROMANIA

1 PLANT AND 1 BTU IN GERMANY



INTERNATIONAL CERTIFICATION PILOT PROGRAM

THIRD PARTY CERTIFIERS (TPCs)

**KEN ANDERSON (HAROLD WAINESS &
ASSOCIATES):**

**2 PLANTS AND 1 BTU IN CANADA
(ONTARIO)**

1 PLANT AND 1 BTU IN COLUMBIA

1 PLANT AND 1 BTU IN SPAIN

1 PLANT AND 1 BTU IN GERMANY

INTERNATIONAL CERTIFICATION PILOT PROGRAM

THIRD PARTY CERTIFIERS (TPCs)

LYNN YOUNG (MILK REGULATORY
CONSULTANTS):

1 PLANT IN CANADA (ONTARIO)

1 PLANT IN GREECE

1 PLANT (2 LISTINGS) AND 1 BTU IN
MEXICO

1 PLANT AND BTU IN ROMANIA



INTERNATIONAL CERTIFICATION PILOT PROGRAM

THIRD PARTY CERTIFIERS (TPCs)

JOE SMUCKER (SMUCKER &
ASSOCIATES):

NO LONGER A PART OF THE PILOT
PROGRAM



FDA MILK SAFETY COURSES

- ❖ *Milk Pasteurization Controls and Tests*
 - ❖ *December 3 – 7, 2012 in Arlington, TX*
 - ❖ *February 11 – 15, 2013 in Birmingham, AL*
 - ❖ *March 25 – 29, 2013 in Louisville, KY*
- ❖ *Milk Plant Sanitation & Inspection*
 - ❖ *March 18 – 22, 2013 in Atlanta, GA*
 - ❖ *April 8– 12, 2013 in Harrisburg, PA*
- ❖ *NCIMS HACCP*
 - ❖ *January 15 – 18, 2013 in Harrisburg, PA*



FDA MILK SAFETY COURSES

- ❖ *Dairy Farm Sanitation & Inspection*
 - ❖ *March 4 – 8, 2013 in Hagerstown, MD*
 - ❖ *June 24 – 28, 2013 in Ithaca, NY*
- ❖ *Special Problems in Milk Processing*
 - ❖ *June 3 – 7, 2013 in Fresno, CA*
 - ❖ *September 16 – 20, 2013 in Wichita, KS*

FDA REGIONAL MILK SEMINARS

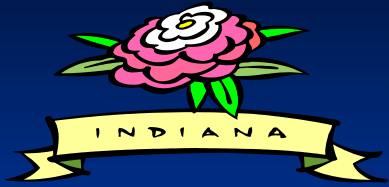
- ❖ *Southeast (SE) Region*

- ❖ *4th Quarter (July-September) of FY 2013 in Louisiana*

- ❖ *Northeast (NE) Region*

- ❖ *September 17 – 19, 2013 in Syracuse, NY*

2013 NCIMS CONFERENCE



INDIANAPOLIS



MARRIOTT DOWNTOWN

INDIANAPOLIS, IN

April 18-25, 2013



FDA POTENTIAL PROPOSALS

- Appendix I rewrite
- ???

Questions



THANK YOU!!!

