

Feed and Feed Ingredient Manufacturing Committee Report/Minutes

Monday, August 3, 2015

1:30-3:00

2015 Annual Meeting

Denver, Colorado

Committee Recommendations to Board and Membership:

The committee has no recommendations needing membership authorization.

Committee Participants:

Members present: Ken Bowers, Bill Burkholder, Bob Church, Stan Cook, Mike Davidson, Tim Darden, Bob Geiger, Jamey Johnson, Ben Jones, Ali Kashani, Darlene Krieger, Doug Leuders, Dragan Momcilovic, Wayne Nelson, Shaness Thomas, Judy Thompson

Advisors present: David Ailor, Tomas Belloso, Bill Bookout, Lorri Chavez, David Dzanis, David Fairfield, Matt Frederking, David Meeker, Jessica Meisinger, Richard Sellers, Charles Neece

Committee Report/Minutes:

1. Meeting called to order by Judy Thompson at 1:30 pm MT. Members and advisors in the room and introduced themselves.
2. The minutes from the 2015 Mid-Year Feed and Feed Ingredient Manufacturing Committee Meeting held on January 14, 2015 were voted on and approved on April 2, 2015. These were posted to the website. No further action needed.
3. **Review of Action Items (See Attachment A for summary of updates)**
 - **Mineral Guidelines Working Group – Bill Burkholder**

Working Group has finalized 90% of their revision of the Mineral Guidelines in the current OP including the tables. The one remaining issue is being researched related to selenium in aquaculture. The Working Group is planning to submit their recommendation prior to the January 2016 meeting.
 - **Emergency Response Working Group – Darlene Krieger**

The working group has completed much of their charge including:

 - reviewing and revising the information on emergency response in the OP (completed)
 - developing a folder in the Feed Bin for States to place any table top exercise materials they may have for others states to use (completed)
 - developing a table top exercise (4 hours) which was conducted at the 2015 Feed Administrator’s Seminar in April 2015 in conjunction with training on ICS (completed). The intent is to use the input received to develop a larger exercise in conjunction with the 2017 Mid-Year Meeting.

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- **Feed Preventive Control Alliance Certificate Program Training Material – Mike Davidson**
 - No new developments to report at this meeting.

- **Education and Training Committee Liaison – Ken Bowers and Bob Geiger**
 - No new developments to report at this meeting.

- **AAFCO FSMA Implementation**
 - Working Groups formed to address the items assigned by the FSMA Implementation Task Force. Charge to the working group and deadlines are identified in the Action Item Table in Attachment A.
 1. Strategy for AAFCO GMPs – Ken Bowers (lead), Bob Church, Bob Geiger, Matt Frederiking, Richard Sellers. Charge to working group
 2. Model Feed Safety Program Plan in OP – Judy Thompson (lead), Linda Morrison, Bob Waltz
 3. Contaminant and Hazard Lab Strategy – Mike Davidson (lead), Srinu Chigulubadi (FDA) (will need additional working group members)
 4. Inspector Training for Ingredient Manufacturing Inspections – Judy Thompson (lead), Mike Davidson, Darlene Krieger, David Ailor, Matt Frederiking

4. US Federal Regulatory Update – Dr. Dan McChesney

FSMA

Nothing new that wasn't discussed this morning.

Veterinary Feed Directive

October 1, 2015

No changes for most drugs. The current VFD drugs (2-3) are required to meet the new requirements related to format, caution statement, etc.

January 1, 2017

Many other drugs (100 + as well as combinations) will be converting to VFD drugs. FDA is preparing a letter for drug sponsors and feed industry detailing the strategy to move forward to implementation including new labelling requirements. Labels to be approved on three days in December 2016 on three consecutive days: pioneer, generic, combinations. To facilitate uninterrupted trade, FDA is proposing that between now and June 30, 2016, that they will meet with all drugs sponsors individually to review new proposed labels that will meet the January 2017 requirements. After these meetings, a Memorandum of Conference will be issued that confirms that the label discussed is approved in principle. The expectation is that the drug sponsor will start the process to develop and print labels/bags for January 2017 and that they will manage inventory so products sold after January 1, 2017 will be in the marketplace with the new label. Drug premixes that are in the sponsor's warehouse on January 1, 2017 will be required to be modified (e.g., stickered) to bring them into compliance so that only properly labelled product will be sold after January 1, 2017.

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The animal pharmaceutical industry has requested permission to use transitional labelling and FDA will formally advise them of their concurrence in the near future. Transitional labels will contain a banner/box identifying the specific claims for that drug that will not be permitted on labels after January 1, 2017 and identifying the new required caution statement. The use of transitional labels will be permitted until the new labels are printed and available and will be permitted to remain in the marketplace after January 1, 2017.

Questions from the floor about:

- How veterinarians will be ready for October 15, 2015 and January 1, 2017. What are the approved sources of drugs and combinations? Information available in the Code of Federal Regulations, <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm>, Blue Bird Labels (June 30, 2016), www.medicatedfeed.com and Medicated Feed Compendium, all identify the drugs and the combinations approved.
- How to make sure that the drugs that are needed continue to be available. Possibly AVMA can be a driver for this? Currently number of veterinarians writing VFDs is very small. After the deadline of January 1, 2017 a lot more veterinarians will be required to write VFDs.

Next Steps

The FDA will also identify the labels for Type B and C medicated feeds that contain VFD drugs that will be permitted in the marketplace after January 1, 2017. Some ongoing questions, e.g., Part 11 (electronic signature) requirements (it is an old document (18 years) when computers were “new” so might not be necessary) and issues related to minor species use for some of the drugs (order will not permit extra-label use) still need to be addressed.

There are some sectors, e.g., bee keepers that have flown under the radar using what will in the future be VFD drugs that will need to be informed. Education of livestock producers will also be required.

FDA is currently doing outreach through the Producer Groups so the word will get out. Major species will be easier to reach than the smaller groups (bees). FDA has also developed materials for feed mills and livestock producers, practicing veterinarians, veterinary students and has posted them and a Q + A document along with Draft Guidance 120 on their web-site

(<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>). FDA is also developing a video on VFDs that should be available in 6-8 months.

There have also been a couple of webinars hosted by AFIA where FDA was involved. The transcripts of the webinars are available at <http://feedstuffs.com/vfd.aspx#vFeed>. Another source of information is <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>.

Feed industry has issues with label changes, etc. and concerns about regulator training requirements, whether there will be a grace period after January 1, 2017 and how long it will be. Concerns with the capacity of the limited number of bag manufacturers to get things printed fast enough. Poultry industry will also have issues as they don't currently use VFD drugs and many of the new VFD drugs are used in poultry production.

Plan to have a one-day training session on VFDs/Medicated feed labelling for regulators and industry at the AAFCO annual meeting in August 2016.

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6. Preventive Control Alliance (David Fairfield, NGFA, Pat Tovey, PFI, Sonya Lambkin, FDA)

Discussion this morning provided the full state of the work and no further update was required.

7. Canadian Regulatory Update - Judy Thompson

Judy provided the Membership with a regulatory update of the current and planned changes for the Canadian Food Inspection Agency (CFIA). (See Attachment B)

8. ISO/TC 34/SC 17 – Management Systems For Food Safety – Working Group 9 - Feed Production (David Fairfield).

Work was initiated to develop technical specifications for prerequisite programs for animal feeds to support management systems for those companies using ISO 22000. Animal food requirements will be applicable to animal feed for food producing animals as well as pet food. On paper, the Working Group includes representatives from 15 countries. Two meetings have been held so far with a total of nine countries participating. Working Group 9 met in Copenhagen September, 2014. At that meeting, the decision was made to use PAS 222 as a seed document. A second meeting was held in Washington, DC in February 2015. The output of this meeting was distributed to the entire ISO membership for review. The draft was approved by 39 countries (12 countries included comments that they would like considered) and one vote for disapproval (Panama). The third (and final?) meeting will be held in Paris October 13-15, 2015 to review and incorporate received. If the document is finalized at that meeting, the standard should be published in June 2016. American National Standards Institute (ANSI) is the organization representing the USA. The U.S. Technical Advisory Group includes Henry Turlington (AFIA), Pat Tovey (PFI) Dave Harlan (Cargill), Dave Fairfield (NGFA).

9. Report from the Joint FAO/WHO Expert Meeting on Hazards Associated with Animal Feed – Judy Thompson

Judy provided the Membership with a report on the recent Joint FAO/WHO Expert Meeting held in Rome in May 2015. (See Attachment C) A copy of the draft report is also included for your information (See Attachment D).

10. Meeting adjourned at 3:53 MST as there was no other business that required discussion.

Acceptance of Minutes

On September 9, 2015 Bob Church moved that the minutes be accepted. Motion seconded by Bob Geiger. Minutes were approved by Committee members on September 15, 2015 with twelve affirmative and no dissenting votes.

Attachment A - Action Item Table

Responsible	Item	Action	Timing / Status
Mineral Guidelines Working Group	Review and Revise Mineral Guidelines	<p>Working group to develop plan to review and revise Mineral Guidelines in the OP for discussion by the Committee</p> <p>Workgroup Members: Bill Burkholder (lead) Jon Nelson, Tim Costigan, Jennifer Kormos David Syverson, Bill Hall, Dave Dzanis, Roger Hoestenbach</p> <p>Update Working group is progressing well and it is expected that a report will be provided to the committee before the January 2016 Mid-Year meeting.</p>	Update at January 2016 Mid-Year Meeting
Darlene Krieger	Strategic Plan – Emergency Response	<p>Working Group to:</p> <ul style="list-style-type: none"> • review and revise the information on emergency response in the current OP (completed) • develop a folder in the Feed Bin for States to place any table top exercise materials they may have for others states to use (completed) • develop a table top exercise that could be used at an upcoming AAFCO meeting <ul style="list-style-type: none"> ○ Tabletop exercise at April 2015 Feed Administrator’s Seminar (completed) ○ Larger tabletop exercise to be held in conjunction with the 2017 Mid-Year Meeting <p>Workgroup Members: Darlene Krieger (lead), Glo Dunnavan, David Fairfield, Dragan Momcilovic, Tim Darden, Mark Glover, Stan Cook, Tim Lyons</p>	Update at January 2016 Mid-Year Meeting

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Responsible	Item	Action	Timing / Status
Judy Thompson	FSMA Implementation Task Force	<p>Items identified at April 27, 2015 meeting</p> <ol style="list-style-type: none"> 1. By January 2016, determine the path forward for: <ol style="list-style-type: none"> a. AAFCO GMPS (in consultation with MBRC and PFC) <ol style="list-style-type: none"> i. Develop a plan for states that have adopted AAFCO's model GMPs to make the transition to FSMA GMPs ii. Review the Model Bill and Regulations and propose changes to align with FSMA requirements. b. Model Feed Safety Program Plan (in consultation with Linda Morrison (OP Section) and Bob Waltz (Feed Safety Coordinator)) <p>Working Group#1 – Ken Bowers (lead), Bob Church, Bob Geiger, Matt Frederiking, Richard Sellers</p> <ol style="list-style-type: none"> b. Model Feed Safety Program Plan (in consultation with Linda Morrison (OP Section) and Bob Waltz (Feed Safety Coordinator)) <p>Working Group# 2 – Judy Thompson (lead), Linda Morrison, Bob Waltz</p> <ol style="list-style-type: none"> 2. After FSPCA/FDA conclude their work in this area, determine the contaminants, hazards, matrix and action levels and enforcement strategies to provide guidance to LMSC to inform method development priority setting. Integrate collaboratively into current LMSC priorities. (in consultation with FSPCA, EIC, ISC, IDC and LMSC) <p>Working Group# 3 – Mike Davidson (lead), Srinu Chigulubadi (FDA) ++</p> <ol style="list-style-type: none"> 3. After FSPCA/FDA conclude their work in this area, determine whether training material for feed ingredient manufacturing from the FSPCA will meet the needs of Inspectors for training (in consultation with ETC and ISC) <p>Working Group# 4 – Judy Thompson (lead), Mike Davidson, Darlene Krieger, David Ailor, Matt Frederiking</p>	Ongoing committee updates

Attachment B – Canadian Regulatory Update PPT



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Attachment C – Joint FAO/WHO Expert Meeting on Hazards Associated with Animal Feed PPT

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Attachment D – Executive Summary of the Report from the Joint FAQ/WHO Expert Meeting on Hazards Associated with Animal Feed (May 12-15, 2015/Rome, Italy)



Executive
Summary_FINAL.PDF