

MELAMINE UPDATE

FDA Science Board
December 3, 2007



JUNE 2007 BOARD MEETING

- Recall of pet food in March 2007
- Methods developed and disseminated for feed
- Food producing animals feed contaminated
- Safety/Risk assessment

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TODAY'S UPDATE

- Methods improvement/validation
- Safety/Risk assessment/prevention
- Next steps

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METHODS IMPROVEMENT/VALIDATION

- Methods improvement
 - ORA
 - NCTR – Labeled standards
 - CVM – Incurred residues and toxicity

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CVM -- FISH INCURRED RESIDUES

- Dose with both melamine and cyanuric acid and both
- 4 species/serial sacrifice
- Tissue residues/renal crystal formation
- Data analysis not complete
- Morphology and composition of cat crystals

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RISK ASSESSMENT

- Status
- Information needs
 - Mode of action
 - Species differences -- bioaccumulation in edible tissues

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PREVENTION

- Food protection plan applicability
 - Prevention – build safety in from the start
 - Intervention – risk based inspection and testing
 - Response – Rapid reaction, effective communication
- Food protection plan principles
 - Focus on risks over product life cycle
 - Target resources to optimize risk reduction
 - Address both unintentional and deliberate contamination
 - Use science and modern technology systems

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NEXT STEPS

- Continue methods refinement/validation
- Dose threshold for forming crystals
- Dosing sequence as pre-condition for eliciting renal toxicity
- Effects of ammeline and ammelide
- Biomarkers as precursor of renal crystal formation
- Elimination of residues and crystals upon termination of exposure
- Additional safety/risk assessment as appropriate

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