



# *Regulating Medicated Feeds in Canada*

*Presentation to Banff Pork  
Seminar*

*January 2001*

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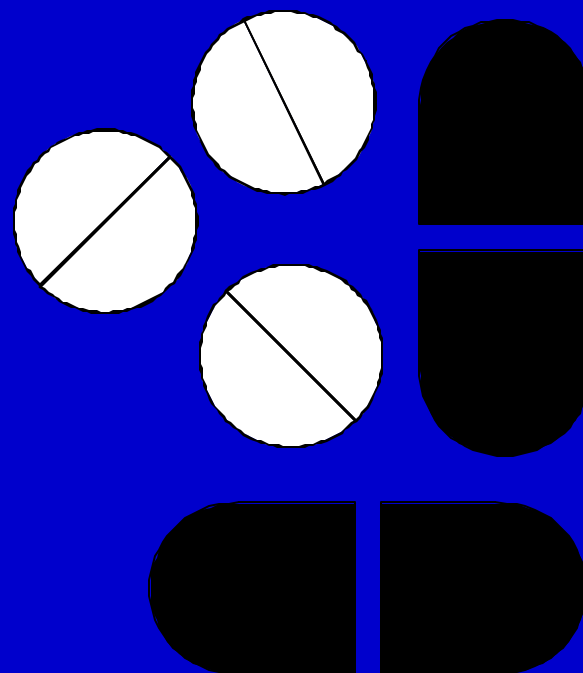
*Canadian Food Inspection Agency*

*Ottawa, Ontario*

# *Regulating Feed-additive Drugs in Canada - Current Situation*

*Health Canada (HC) / Food and Drug Act*  
*responsible for:*

- new veterinary drug and supplementary use approvals (DIN's)*
- manufacturing standards (GMPs) for approved veterinary drugs*



# *Regulating Feed-additive Drugs in Canada - Current Situation*

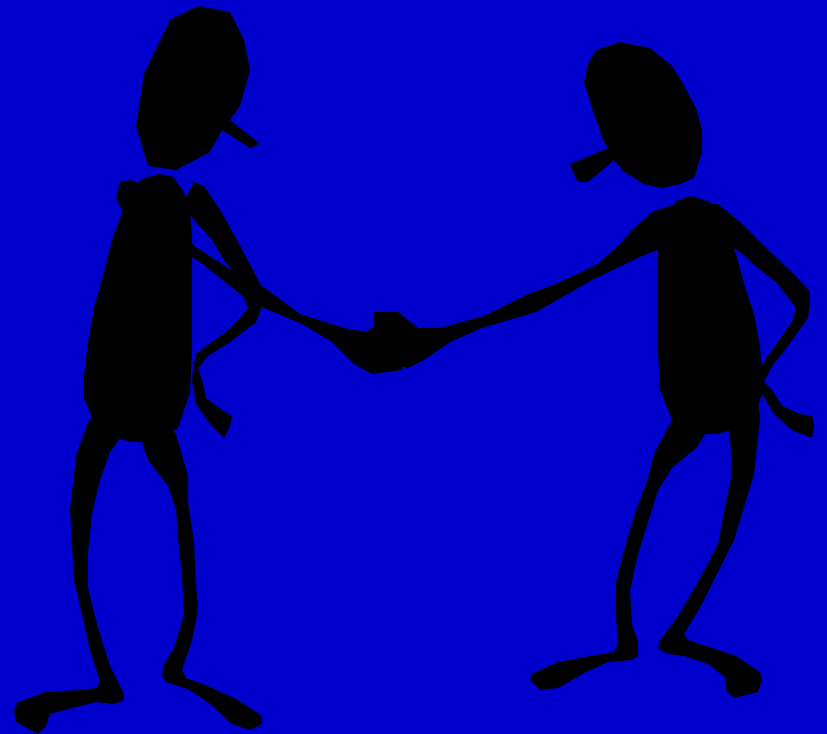
## *Canadian Food Inspection Agency (CFIA) / Feeds Act responsible for:*

- product-based verification and monitoring of drug use in feeds in accordance with approvals*
- verification and monitoring of “off-label” drug use (e.g. veterinary prescriptions for medicated feeds)*

# *Regulating Feed-additive Drugs in Canada - Current Situation*

*Shared  
(HC + CFIA)  
responsibilities:*

- enforcement action  
relative to drug use  
non-compliance*

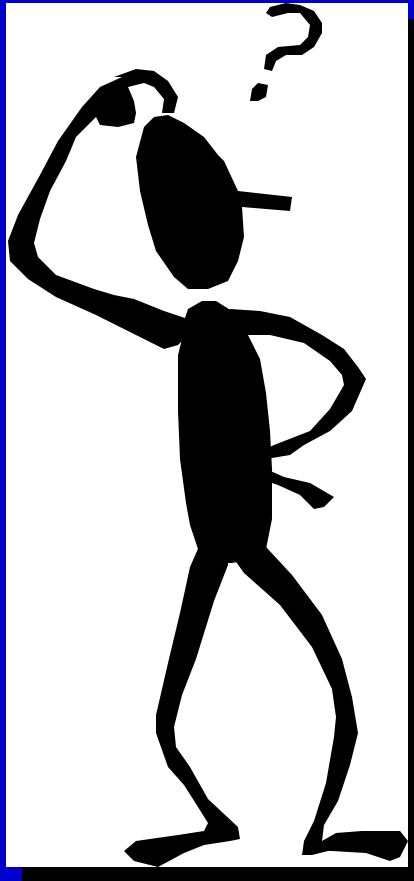


# *The Feeds Act and Regulations*

## ***Safety is a priority***

- ✘ livestock*
- ✘ consumers of foods of animal origin*
- ✘ bystander exposure*
- ✘ the environment*

# *Medicated Feed Manufacturing - Reasons for Concern?*



- ✍ Over- or under-medicated feeds may prove harmful or ineffective to livestock*

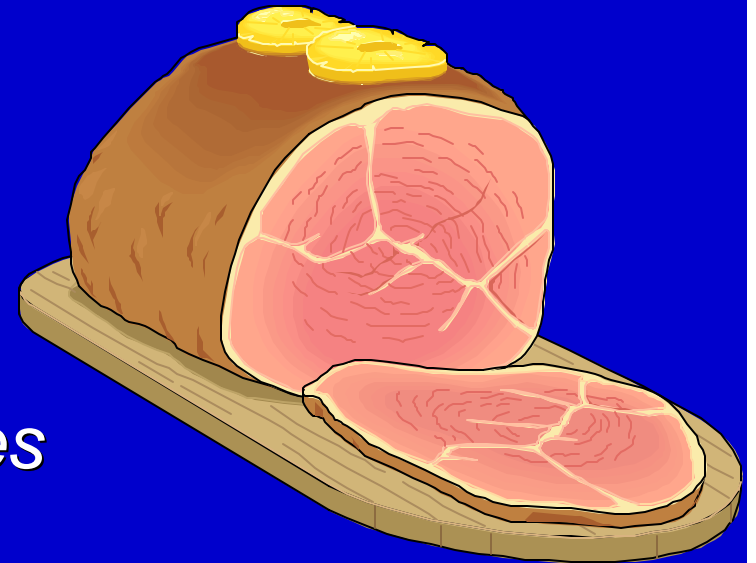
# *Medicated Feed Manufacturing - Reasons for Concern?*

- ✍ Small amounts of medicated feeds left in feed mixing systems can contaminate subsequent feed lots*
  - contaminated feeds may give rise to tissue residues in market animals or may prove harmful to other livestock species*

# *Medicated Feed Manufacturing - Reasons for Concern?*

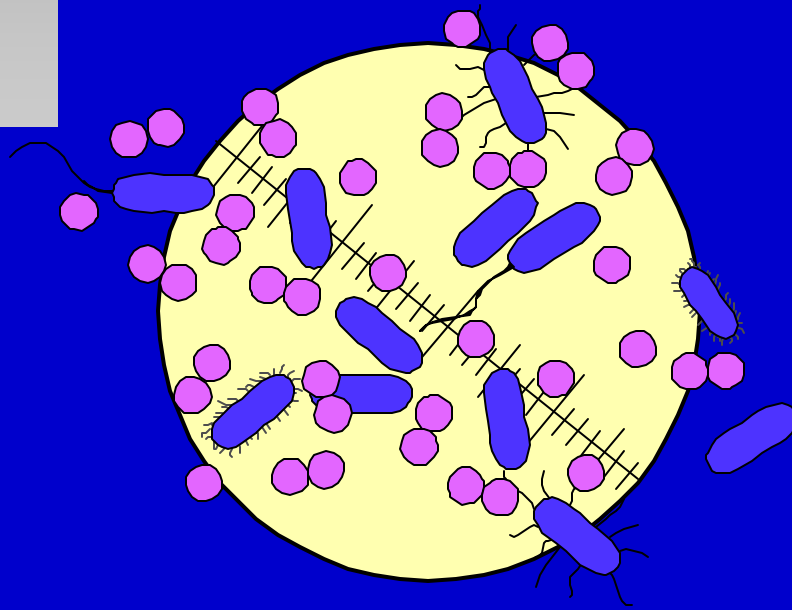
## *✂ Drug residues in animal tissues*

- consumers can suffer allergic reactions to residues*



# *Medicated Feed Manufacturing - Reasons for Concern?*

- ✍ Concerns about antibiotic resistance developing in pathogens from widespread drug use*



# *Consultation Process*

*Since 1993, CFIA has been consulting and negotiating with Canadian livestock producer groups and feed industry on the development of GMP regulations relating to medicated feed manufacturing on the farm and in commercial feed mills*



# *Medicated Feed*

## *Regulatory Framework*

### **Stakeholders**

- ✍ Feed industry*
- ✍ Livestock producers (pork, beef, dairy, chicken, turkey, aquaculture, sheep)*
- ✍ Animal health industry*
- ✍ Provincial governments*
- ✍ Health Canada, Fisheries and Oceans*

# *Proposed Regulations Respecting the Making of Medicated Feeds*

- ✍ Proposed Regulations developed after years of consultation and negotiation with stakeholders*
- ✍ Regulations to be promulgated under the Health of Animals Act*
- ✍ Set of minimum standards to be used in the manufacture of medicated feeds*

# *Proposed Regulations Respecting the Making of Medicated Feeds*

- ✍ On June 9, 1999, Agency arrived at consensus on regulations with Steering Committee of stakeholders*
- ✍ Agency prepublished regulations in Canada Gazette Part I on February 5, 2000*

# *Proposed Regulations Respecting the Making of Medicated Feeds*

- ✍ Regulations will require that all manufacturers of medicated feeds be licensed*
- ✍ Three year phase in period*
  - Year one - commercial feed mills*
  - Year two - farms using drug premixes (DIN)*
  - Year three - farms using medicated premixes and supplements*
- ✍ Sale of medicated products will be restricted*

# *Proposed Regulations Respecting the Making of Medicated Feed s*

*✍ Example GMPs contained in regulatory proposal:*

- feed mixers validated regularly*
- scales and meters verified regularly*
- drug inventory kept and reconciled with actual drug usage*
- documentation of procedures*
- records of manufacturing, distribution*
- random sampling/follow up*

# *Proposed Regulations Respecting the Making of Medicated Feed s*

## *Challenges*

- ✍ integration of regulations with producer-developed, voluntary HACCP-based production systems*
- ✍ implementation and oversight on '000's of farms*
- ✍ costs to food production system*

# *Resources*

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- ✍ No cost recovery for licences or inspections expected to apply as part of implementing the regulations*

## *Resources (con't)*

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*Third party delivery of on-farm inspections a possibility:*

- *Chicken Farmers of Canada & Canadian On-farm Food Safety Program considering delivery of inspections on their own*
- *provinces may want to deliver inspections as well*

## *Licences (s. 4)*

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*Operators of medicated feed manufacturing establishments will have to:*

- apply to CFIA for a licence*
- pass a pre-licencing compliance inspection*
- be issued a licence (3 year duration)*

# *Key Manufacturing Standards*

*Weigh scales / meters must be:*

- ✍ appropriate for the intended use*
- ✍ calibrated upon installation and as frequently as necessary (not less than 1x per year) (s. 13)*

## *Key Standards (con't)*

*Mixer performance must be verified:*

*✍ upon installation and as frequently as necessary (not less than 1x per year)  
(s. 14)*

*Operator must notify CFIA of any changes in scales, meters or mixers (s. 15)*

## *Key Standards (con't)*

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*Feeds must be made by sequential production unless equipment is cleaned or flushed between lots of feeds (s. 17)*

## *Key Standards (con't)*

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*Collected dust, rework, returns or recalls contaminated by drugs must be identified and used only in feeds containing the same drug or disposed of (s. 18)*

## *Key Standards (con't)*

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- ✍ Inventory must be kept and reconciled for medicating ingredients and medicated feeds used to make other feeds (s. 20)*
- ✍ All lots of feed for sale must be identified by a lot number or date of manufacture (s. 21)*

# *Discrepancies/Contamination*

*If an Operator discovers a discrepancy with medicating ingredients or suspects a contamination, the operator must:*

- ✎ stop selling/using the feed(s) in question*
- ✎ promptly investigate and take corrective measures (s. 22)*

# *Discrepancies/Contamination*

*In addition, the Operator may have to:*

- ✍ notify purchasers of suspect feed(s) or animals fed the suspect feed(s) and provide precautionary measures*
- ✍ recall suspect feeds*
- ✍ reuse or dispose of feeds in accordance with the regulations*

# *Records (s. 25)*

*Documentation must be kept for at least 3 years respecting:*

- ✍ reports of investigations for out-of-compliance sample results and discrepancies/contamination*
- ✍ drug inventories*
- ✍ test results*
- ✍ distribution records*

# *Proposed Regulations Respecting the Making of Medicated Feeds*

*Comment period (90days) response  
to Gazette 1 publication:*

*✍ over 200 letters & e-mails with  
written comments received by the  
Minister's Office & CFIA*

# *Proposed Regulations Respecting the Making of Medicated Feeds*

- ✍ Comments reviewed and next steps planned at meeting of Medicated Feeds Regulations Steering Committee June 23, 2000*
- ✍ CFIA asked to coordinate preparation of a “Manual of Procedures” (MoP) prior to implementing regulations*

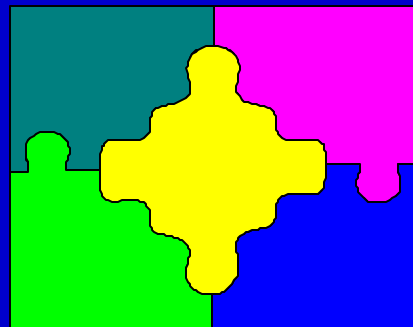
# *Proposed Regulations Respecting the Making of Medicated Feeds*

- ✍ CFIA met with Canadian Federation of Agriculture's on-farm HACCP Implementation team in September 2000 to organize MoP development*
- ✍ CFIA held workshop November 2-3, 2000 with producers & feed industry representatives to start development*

# *Manual of Procedures*

*Two Working Groups developing procedures/principles for:*

- ✍ Scale performance / drug use inventory*
- ✍ Mixer performance / equipment clean out procedures*



# *Manual of Procedures*

## ***Next Steps:***

- ✍ Draft procedures are with Working Groups for review & comment*
- ✍ Pilot projects to demonstrate procedures and investigate other approaches planned for early 2001*

# *Proposed Regulations Respecting the Making of Medicated Feeds*

## ***Next steps***

- ✍ Develop implementation plan*
  - Inspector training/certification*
  
- ✍ Gazette II*