

HACCP Systems: Management of Medication Residues in Feed Manufacturing

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Floradale Feed Mill

- **located near Elmira, Ontario**
- **multi-species production**
 - poultry - 50%
 - dairy/ruminant - 25%
 - swine - 20%
 - other - 5%
- **150,000 tonnes annual production**
- **no prohibited material**
- **28 medications in-house**

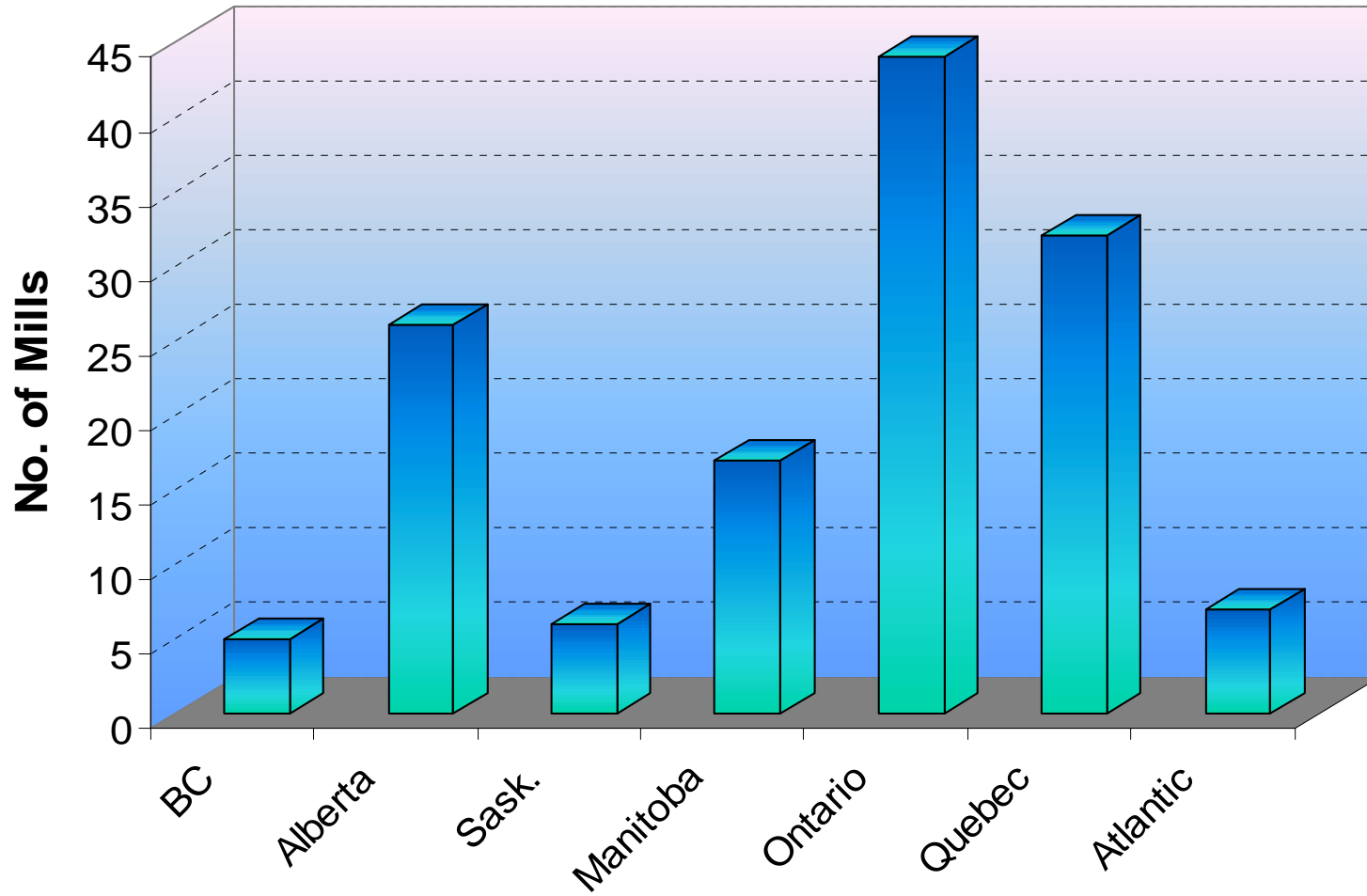
Presentation Outline:

1. Status of HACCP - Canadian mills
2. Guiding legislation - “contamination”
3. Practical realities of the manufacturing environment - process flow
4. Good manufacturing practices (GMPs) to minimize contamination
5. Evidence of animal product safety
6. To better understand

1. HACCP Status - Feed Mills

- 141 of 450-500 mills in Canada HACCP certified (Sept 03)
 - 30% of all mills
 - 60% of total production (estimated)
- Good Manufacturing Practices (GMPs) provide foundation
- drug management drives HACCP!

HACCP-Certified Mills in Canada (Sept 03)



2. Guiding Legislation

A. *Feeds Act and Regulations (CFIA) - Standards & General Requirements*

- **Section 14 - “A mixed feed shall not contain...**
 - (b) medicating ingredients other than as set out in the CMIB (brand, level, purpose, species) unless by vet prescription.”
- **Section 19 - “A feed shall not contain:**
 - (j) any material in quantities that could, when fed in proportions commonly used or as specified in the feeding directions, result in the production of an article of food that is prohibited from sale by virtue of Section 4 of the *Food and Drugs Act*”

2. Guiding Legis - cont'd

B. *Food & Drugs Act and Regulations*

(Health Canada) Section 4 - No person shall sell an article of food that:

- (a) has in or on it any poisonous or harmful substance ...
- (d) is adulterated

Division 15: “adulteration” by vet drug if
Maximum Residue Limits (MRLs) in
Table III are exceeded

2. Guiding Legis - cont'd

C. Regulations Respecting the Making of Medicated Feed (CFIA draft, 2000)

- “contamination” means:
 - in human food in excess of the MRL set out in Table III to Division 15 of the F & D Regulations for that ingredient; or
 - in animal food such that it is likely to result in human food having a residue of that ingredient in excess of the MRL for that ingredient

2. Guiding Legis - cont'd

- Dilemma - determining the regulatory definition of “contaminated” or “safe”!
 - carryover of drugs from one batch of feed to the next is a recognized reality. How much residue is safe?
 - some in CFIA propose to use the “detection” level as the standard, in the absence of safe residue-level information
 - precautionary principle?

Mill Equipment

- Major Scale
 - large volume ingredients (e.g., grain chop, protein meals)



Mill Equipment

- Micro-Bins/Scale
 - automated medicating ingredient weighing & delivery



Mill Equipment - cont'd

- Hand-Add Scale
 - manual medication weighing and delivery to mixer



Mill Equipment - cont'd

- Mixer (green) and mixer discharge



Mill Equipment - cont'd

- Pellet Mill
 - steam conditioning and pelleting



Mill Equipment - cont'd

- Air Cooler
 - pellet temperature and moisture removal

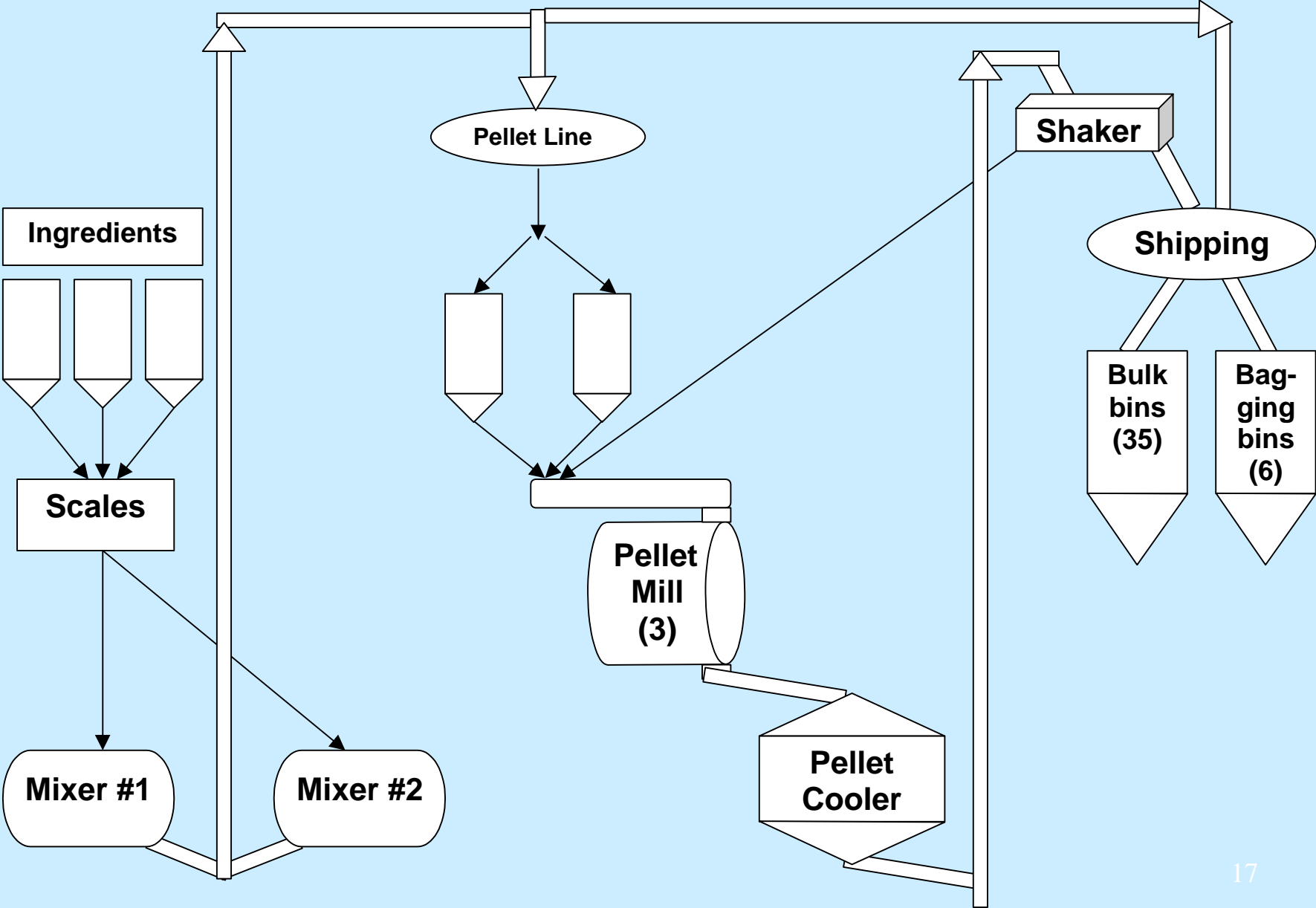


Mill Equipment - cont'd

- Bulk Shipping
 - conveyors,
turnheads, and bins



Process Flow - Feed Manufacturing



4. GMPs - risk minimization

- Receiving & storage
 - well labeled physical and active (hand-add boxes and micro-bins) inventory
 - deal with broken bags/spillage promptly
- Equipment
 - equipment purchase and maintenance
 - scale calibration and calibration checks
 - mixer validation (10% CV)

4. GMPs - risk minimization

- Manufacturing controls
 - daily medication inventory reconciliation
 - sequencing and equipment cleanout
 - group “like” animal species (compatible drugs)
 - high concentration/long withdrawal to low concentration/no withdrawal (not market ready)
 - flush mixers (10% of mixer capacity) and pellet mills where drugs/species are incompatible
- Shipping and labeling controls
- Personnel training & evaluation

RESIDUES IN FLUSH FEEDS

Drug/ Inclusion Rate	Flush Feed Volume (kg)	Residue in Flush (ppm)	MDL in Feed (ppm)	MRL - Health Canada (ppm)
salinomycin (60 ppm)	225	1.83 (mash)	0.5	0.35 (chicken, cattle, swine)
monensin (100 ppm)	2500	< 1.0 (mash) 2.7 (pellet)	1.0	0.05 (cattle, poultry)
tylosin (22 ppm)	1500	< 4.0 (mash) < 4.0 (pellet)	4.0	0.2 (cattle, swine, poultry)

System Flushing - yes, but ...

- high volume following feeds may well achieve same result (below MDL)
 - efficiency (save mixer down time)
 - what to do with flush material
 - bag it (labour, labeling, storing, risk of misuse, etc)
 - put back on to previous load (nutrition, medication dilution)
 - put to common bulk storage bin (in future, no!)
 - send to landfill
- => mill preference - use flush materials when shown to be justified (e.g., high risk drugs)

5. Evidence of Safe Food

- CFIA - “Canadian National Chemicals Residues Monitoring Program” (2002-2003)
 - 29 vet drug categ. (meat - all species n=73,000)
 - 100% of all samples in 18 of 29 categories compliant
 - 99% or more of all samples are compliant in 23 of 29 categories
 - 100% compliant samples in 6 of 6 vet drug categories for dairy commodities (n=3,600)
 - 100% compliant samples in 7 of 8 vet drug categories for eggs/egg products (n=1,500)

5. Safe Food - cont'd

- Where there are suspected violations in processing plants:

“Violations are almost always due to suspect animals bearing an injection mark, however, such animals do not enter the food distribution” - Eli Neidert, National Manager, NCRMP

“Generally, FDA finds other things than feed residues causing tissue residues” - Richard Sellers, VP Feed Control & Nutrition, American Feed Industry Association

5. Safe Food - cont'd

- Other sources of potential contamination (on-farm):
 - water soluble drugs (longer withdrawal for some)
 - vet prescriptions (withdrawal periods!)
 - feed/other source interactions
 - e.g. monensin (Controlled Release Capsule + feed)

➡ **farmer + feed company + vet - communicate!!**

➡ ***implement/monitor on-farm HACCP programs***

Penicillin sources - drug withdrawal periods

<u>Source</u>	<u>Days Withdrawal</u>
1. Feed - <u>broilers</u> (MIB - 2.2 ppm)	0
2. Feed - <u>swine</u> (vet script - 132 ppm)	10
3. Water treatment (Pot Pen G Potassium)	1 (swine, turkeys)
4. Injectable (Pen G Procaine)	10 (cattle, sheep) 8 (swine), 4 (milk)

6. To better understand...

Sulphamethazine - Health Canada MRL – *0.1 tissue, 0.01 milk*

Contaminating level <u>hog feed (ppm)</u>	Residue level – <u>kidney, liver (ppm)</u>	Residue level – <u>muscle (ppm)</u>
<2	<0.10	<0.035
2 – 8	0.1 – 0.35	0.035 – 0.1
>8	>0.35	>0.1

Source: U. of Kentucky, 1983

6. To better understand...(cont'd)

- Study currently underway (spring 2003):
“Safe Drug Carryover in Sequenced Feeds”

... a joint project of:

- Animal Nutrition Association of Canada (ANAC)
- Canadian Animal Health Institute
- CANTOX Health Sciences

6. To better understand...(cont'd)

- Objectives of ANAC study:

To determine drug carryover levels in feed which result in:

- safe food for humans

- MRLs (residues in approved species)

- tissue threshold levels (in non-target animals)

- safe feed for non-target animals

6. To better understand...(cont'd)

- Phase I
 - identify non-target species where tissue residue thresholds need to be determined
 - develop these thresholds (with HC, CFIA)
- Phase II
 - obtain drug carryover data from feed mills
 - develop safety factors for each drug: toxicological data; residue and depletion data; human “average daily intake”; non-target species toxicity. Then, work backward to a safe residue level in feed for non-target species

Conclusions

1. Ensure GMPs are enforced internally
 - equipment purchase, maintenance, calib.
 - daily medication reconciliation
 - personnel training & evaluation
2. Fine-tune your mill - feed hangups
 - conduct drug residue tests
3. Build respect for all drugs; employee sensitization to higher risk drugs

Conclusions - cont'd

4. Industry/gov't - actively encourage HACCP certification of all mills
5. Support continued research (ANAC study) into residue carryover impacts
6. For the public, highlight HACCP initiatives and the existing safety status of animal products in the marketplace