

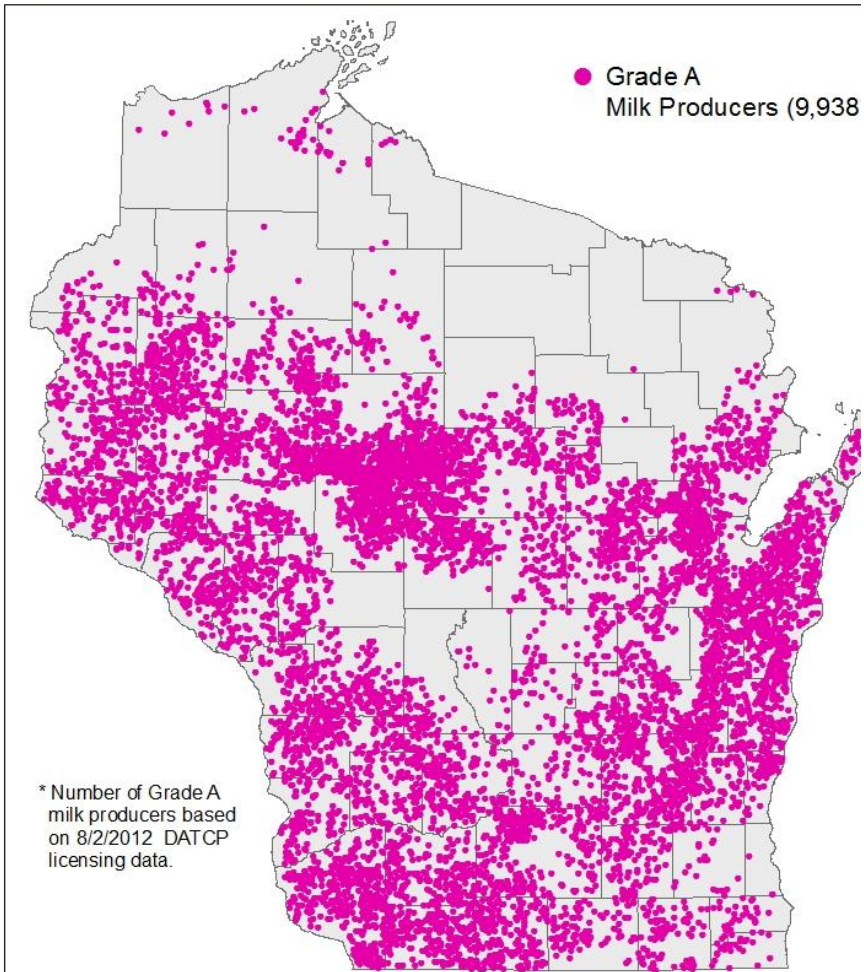
The State of the Wisconsin Dairy Producer

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Dairy Producers in Wisconsin (October 15, 2012)

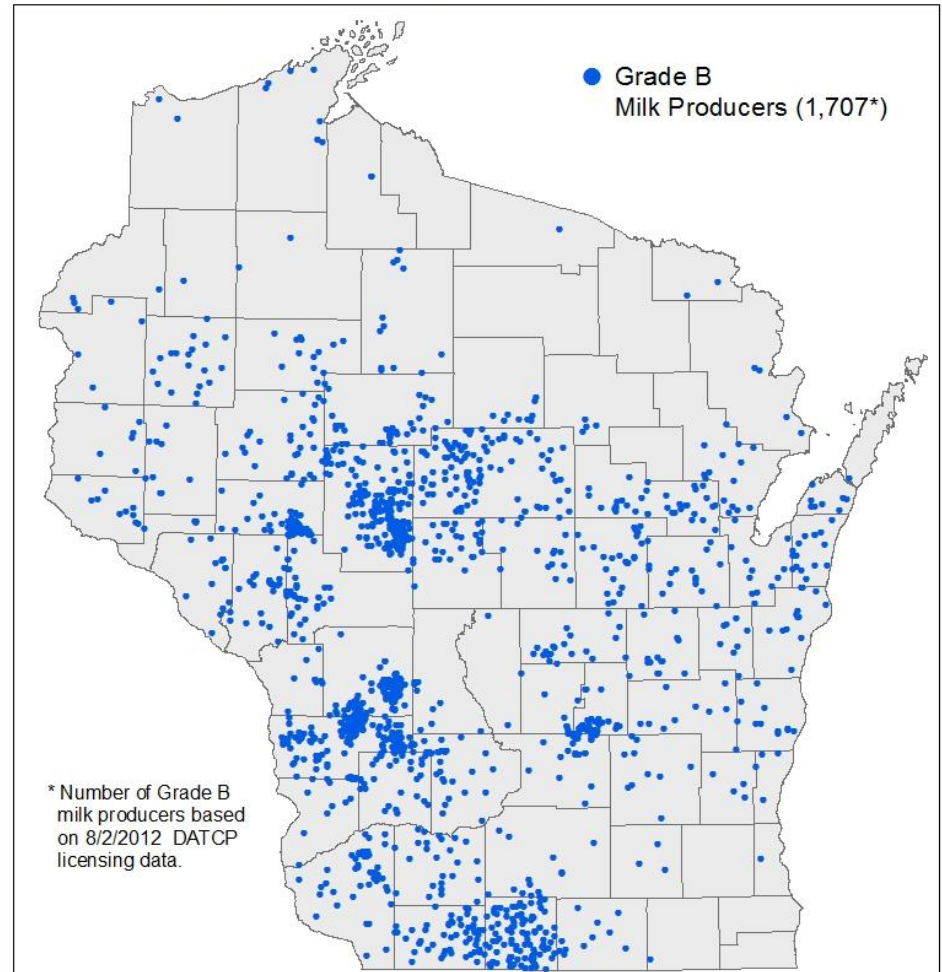
- 9787 Grade A
- 1667 Grade B – 14.5% of farms, 2% of milk
- Average Somatic Cell Count: ca. 255,000 per ml (2010 stats)

Wisconsin Milk Producers - Grade A



Map: Wisconsin Department of Agriculture, Trade and Consumer Protection 10/15

Wisconsin Milk Producers - Grade B



Map: Wisconsin Department of Agriculture, Trade and Consumer Protection 10/15/2012

Dairy Production Trends

- Decreasing number of farms
- Increasing number of cows per farm
 - average is over 100
 - roughly 1.2 million cows (2.6 million in 1946)
- Approx. 20,000 lbs. milk per cow per year
 - 5,100 lbs. in 1934
- 26 billion lbs. of milk (2010)
 - 18 billion lbs. in 1970

On-Site Dairy Farm Inspections

- Mandated in the Pasteurized Milk Ordinance (PMO) → allows WI to ship Grade A products interstate
 - Milk, cream, half-and-half, eggnog, NFDM
 - Cottage cheese
 - Whey and whey products
 - Yogurt and other Standard of Identity milk products (21 CFR 131)
- State Law (Chapter 97.24.3) requires our regulations to be in “reasonable accord” with the PMO
- Mandated surveys (Chapter 97.24.5) to make sure PMO requirements are met

What's involved in an on-site dairy farm inspection?

- Mainly observations to see if minimum standards are met
- Very little examination of records
- Paper and electronic records
 - 1 copy for producer
 - 1 copy filed and entered electronically

How well do inspection results relate to laboratory testing results?

- 2007 – 2008 Study
- *Journal of Dairy Science*, 2010. 93: 3957-3960
- Mandatory monthly reporting of SPC and SCC
 - Failure = at least 1 SCC > 750,000 OR at least 1 SPC > 100,000
- Drug-residue failures reported
 - Failure = (+) β -lactam result
- On-farm inspection results
 - Failure = at least 1:
 - mandated re-inspection OR
 - double-debit OR
 - grade permit suspension

SCC over 2 years	SPC over 2 years	Drug over 2 years	Inspection Failure rate
Pass	Pass	Pass	0.12
Pass	Pass	Fail	0.20
Fail	Pass	Pass	0.22
Pass	Fail	Pass	0.25
Fail	Pass	Fail	0.39
Fail	Fail	Pass	0.41
Pass	Fail	Fail	0.44
Fail	Fail	Fail	0.55

Probability of failing a farm inspection

SCC max. fail rate	SPC max. fail rate		
	0	0.1	0.2
0	0.12	0.25	0.21
0.1	0.21	0.35	0.48
0.2	0.21	0.45	0.51
0.3	0.21	0.48	0.51
0.4	0.19	0.54	0.53

How well do inspection results relate to laboratory testing results?

- Poorly: R values of ≤ 0.22
- Farm inspection is a “snapshot”
 - date may be different from lab result dates
 - date would only coincide with one day’s worth of drug residue test results
- Assuming milk will be pasteurized, what milk safety hazards can best be detected by an on-site farm inspection?
 - lack of cooling \rightarrow *S. aureus* growth and toxin production
 - misuse of drugs

Performance-Based Farm Inspection (PBFI) frequencies

- 1 – 4 inspections per year
 - Appendix P in PMO
 - ATCP 60.245
- Based on
 - Key inspection debits
 - Standard Plate Count = SPC
 - Somatic Cell Count = SCC
 - Drug-residues
 - Warning letters and other regulatory actions

A comment we wanted to investigate

- “I had one bad SCC result that month, but it happened to be the reported test result. Now I’ve been switched to higher inspection frequency.”
- If all other test and inspection results were unchanged, would reporting all SCC results lead to better or worse PBFi categorization?

What would happen to PBFI Frequency if all of the plant's SCC data were reported?

- 2007 – 2008 Study
- *Food Protection Trends*, 2011. 31: 28-32
- Assumed all other results were constant and all SCC data were reported
- All SCC results obtained from 2 plants
 - 5400 in 2007
 - 7193 in 2008
- PBFI categories at the end of 2007 and 2008

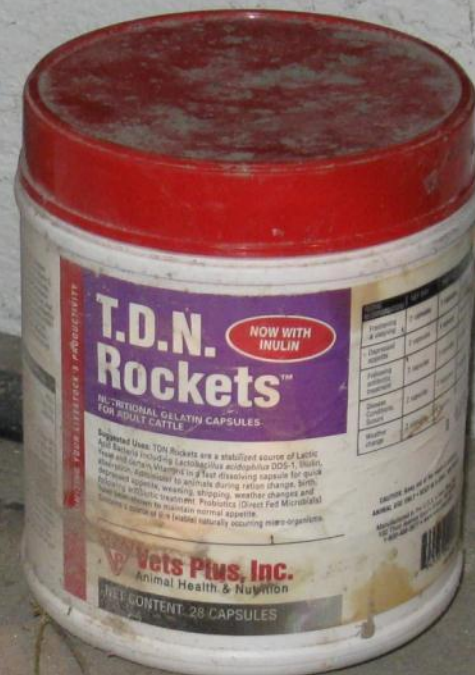
What would happen to PBFI frequency if all of the plant's SCC data were reported?

- Category 1 farms
 - → Category 1: 69%
 - → Category 2: 31%
- Category 2 farms
 - → Category 1: 30%
 - → Category 2: 68%
 - → Category 3 or 4: 2%
- Category 3 or 4 farms
 - → Category 1: 26%
 - → Category 2: 66%
 - → Category 3 or 4: 8%

Bottom Line

- Reporting all of the SCC results, and using these results in assigning PBFi frequency, would likely decrease the number of on-site farm inspections.
- Effect on efficiency is unclear.





What do we know already about drug residue test results?

- 28 million pounds of milk discarded in FFY 2011 for drug residues = 0.014% of total milk produced in US
- 98.7% of the drug tests conducted were for Beta Lactams
- Bob veal and dairy cattle accounted for 47.5% and 43.5% of FSIS-sampled animals with residue violations in 2010
- Top 3 violative residues were neomycin (25%), flunixin (14%), and penicillin (14%)

FDA Survey of Milk for Drug Residues

- Hypothesis: high incidence of (+) tissue results for dairy cattle at abattoirs is caused by poor drug use practices which could also lead to milk contamination.
- Farms from Repeat Violators list (900) vs. “control” farms (900)
- Farm identity hidden from analysts, FDA, regulators
- January – November, 2012
- “Non-regulatory” survey

Milk will be analyzed for:

Ampicillin	Sarafloxacin
Bacitracn	Sulfachloropyridazine
Cephaprin	Sulfadiazine
Chloramphenicol	Sulfadimethoxine
Chlortetracycline	Sulfamerazine
Ciprofloxacin	Sulfamethazine
Cloxacillin	Sulfaquinoxaline
Doxycycline	Sulfathiazole
Erythromycin	Tetracycline
Florfenicol	Thiabendazole
Flunixin	Tilmicosin
Gentamicin	Tripelennamine
Neomycin	Tylosin
Oxytetracycline	Tulathromycin
Penicillin G	Virginiamycin

The Bottom Line

- Establish a veterinarian – client – patient relationship
- Use only Rx drugs or FDA-approved OTC drugs with veterinarian's guidance
- Pay attention to dose and delivery – they matter
- Know and observe the withdrawal time
- Keep records
- Keep drugs for lactating animals separated from drugs for non-lactating animals

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Tilmicosin Injection, USP

300 mg tilmicosin, USP as
tilmicosin phosphate per mL

TM

**Do Not Use in Automatically
Powered Syringes.**

**No Administrar con Jeringas
Accionadas Automáticamente.**

Caution: Federal (USA) law restricts this
drug to use by or on the order of a
licensed veterinarian.

Description: Micotil[®] is a solution of the
antibiotic tilmicosin. Each mL contains
300 mg of tilmicosin, USP as tilmicosin
phosphate in 25% propylene glycol,
phosphoric acid as needed to adjust pH
and water for injection, Q.S. Tilmicosin,
USP is produced semi-synthetically and is
in the macrolide class of antibiotics.

NADA 140-929

Approved by FDA

UPC 7 27804 20213 2

100 mL



NDC 0856-1050-01

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CHLORHEXIDINE
Suspension
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For prevention and
treatment of metritis
and vaginitis in
mares caused
by pathogens
sensitive to
chlorhexidine
hydrochloride.

For Use in Horses Only
0.95 Fl Oz
(28 mL)

NADA 010-434, Approved by FDA

050315
MAR12

050315
Lot
Exp. Date

ADMINISTRATION:
Central mares:
uterine
removed
genitalia
and a
pipette
cervix
infused
Treatment
hours
Store at
15° to 30°
Keep out of

Unattached pla-
and any excess
should be
The external
carefully cleaned
inseminating the
Nolvasan Suspension
repeated in 48 to 72
room temperature
at children.
Not for use in
Animal Health
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OXYMYCIN 200

astitis in lactating dairy cattle

pharmacological Preparation

05/12/11

FTIOFUR HCl 125mg/tube

er.

5 doses.

stration.

Days

DAM, WI

RX EXP: 04/08/12 ISSUED: 5

PURCHASE SEAL
12-10 mL



Pfizer Company
NY, NY 10017

Pfizer

DESCRIPTION
Each 10 mL PLASTET® Disposable Syringe Contains:
Ceftiofur equivalents (as the hydrochloride salt):
Microcrystalline Wax
Labrafil M 1944 CS
Cotransed Oil
SPECTRAMAST® LC Sterile Suspension (ceftiofur hydrochloride) is
indicated for the treatment of clinical mastitis in lactating dairy cattle
associated with coagulase-negative staphylococci, Streptococcus
dysgalactiae, and Escherichia coli. Cows with systemic clinical signs
caused by mastitis should receive other appropriate therapy under the
direction of a licensed veterinarian.

INDICATIONS FOR USE

DISCARD MILK FOR 72 hrs AFTER LAST TREATMENT

READ RESIDUE WARNINGS

DO NOT SLAUGHTER COW FOR 2 days AFTER TREATMENT

125 mg
750 mg
500 mg
q.s.

Pfizer

Pharmaceuticals & Chemicals Division
Pfizer Inc., New York, NY 10017



PURCHASE SEAL
12-10 mL



Needle made of stainless steel;
hub of aluminum.

CAUTION:
Refer to applicable state laws
regarding use of needles and syringes
in animal health markets.

KEEP REFRIGERATED

LACTATING
COW
TREATMENT

Another comment we investigated

- “Small farms produce higher-quality milk than big farms.”
- Problems with the statement
 - What does “higher-quality” mean?
 - What do “small” and “big” mean?
 - Family farms (“good”) can be “big”

Journal of Dairy Science 2011; 94: 4237 - 4241

- All Grade A and B farms in WI during Feb. – Dec., 2008
 - Monthly reported SPC and SCC results
 - Farms categorized into CAFO (DNR database),
 $> 6,500$ lbs/day, or $\leq 6,500$ lbs/day
 - Assume average daily production of 55.2 lb per cow
 - 3 size categories: ≥ 714 , $119 - 713$, ≤ 118
- “Quality” defined by SPC and SCC

Let's do the numbers...

SPC	≤ 118 cows (12,866 farms)	119 – 713 cows (1,565 farms)	≥ 714 cows (160 farms)
Median	31,300 A	26,000 B	25,000 B
Mean	58,700 C	36,300 D	35,000 D
90 th percentile	100,100 E	46,800 F	40,500 F
Maximum	250,200 G	110,500 H	113,600 GH

Different letters within a ROW indicate a significant difference ($P < 0.05$)

Let's do the numbers...part 2

SCC	≤ 118 cows (12,866 farms)	119 – 713 cows (1,565 farms)	≥ 714 cows (160 farms)
Median	348,000	266,000	179,000
Mean	369,000	273,000	240,000
90 th percentile	511,000	344,000	288,000
Maximum	625,000	394,000	313,000

All values within a ROW are significantly different ($P < 0.05$)

The latest question: How easy will it be for WI dairy producers to meet EU standards for SCC?

- Monthly reported SCC result
- Rolling window for 3 months
- Geometric mean (example below)

$$\sqrt[3]{(\text{January Sample}) * (\text{February Sample}) * (\text{March Sample})}$$

$$\sqrt[3]{(250,000) * (200,000) * (450,000)} = 249,000$$

- Problems occur when
 - the geometric mean first exceeds 400,000 (notification and corrective actions)
 - the geometric mean first exceeds 400,000 in 3 consecutive months after notification (suspension, segregation, plant leaves EU program)

Wisconsin average SCC values

- 2007 – 2008 PBFi study (2 plants' producers, all SCC results available)
 - 27.3% of farms never exceeded 400,000
 - 58.7 % of farms exceeded 400,000 on no more than 20% of samples
 - 10.9 % of farms were at \leq 400,000 on less than 20% of samples
- 2008 SPC/SCC study (all producers)
 - Means and medians for all farm-size categories were less than 400,000
 - 90th percentile values for large and CAFO farms were less than 400,000

Wrapping it up

- WI dairy producers face a challenging environment
 - Economic pressures
 - Increasing expectations for safety and quality
 - Poised for success
- On-site farm inspections — due for an “extreme makeover”?