Endemic and Epidemic Lineages of *Escherichia coli* that Cause Urinary Tract Infections

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Women with urinary tract infections (UTIs) in California, USA (1999–2001), were infected with closely related or indistinguishable strains of *Escherichia coli* (clonal groups), which suggests point source dissemination. We compared strains of UTI-causing *E. coli* in California with strains causing such infections in Montréal, Québec, Canada. Urine specimens from women with community-acquired UTIs in Montréal (2006) were cultured for *E. coli*. Isolates that caused 256 consecutive episodes of UTI were characterized by antimicrobial drug susceptibility profile, enterobacterial repetitive intergenic consensus 2 PCR, serotyping, *Xba*I and *Not*I pulsed-field gel electrophoresis, multilocus sequence typing, and phylogenetic typing. We confirmed the presence of drug-resistant, genetically related, and temporally clustered *E. coli* clonal groups that caused community-acquired UTIs in unrelated women in 2 locations and 2 different times. Two clonal groups were identified in both locations. Epidemic transmission followed by endemic transmission of UTI-causing clonal groups may explain these clusters of UTI cases.

Community-acquired extraintestinal infections with *Escherichia coli* range in frequency from 6 to 8 million cases of uncomplicated cystitis per year to 127,500 cases of sepsis per year in the United States (*1*). Urinary tract infections (UTIs) caused by *E. coli* are one of the most common extraintestinal infections in women and, because of their high incidence, are the focus of most epidemiologic studies. The source of *E. coli* for these infections is a person's intestinal tract; however, how these *E. coli* are acquired by the gut is unclear. Risk factors that lead to intestinal colonization with extraintestinal *E. coli* differ from factors associated with development of infection.

Young, otherwise healthy, sexually active women have the highest risk for community-acquired UTIs. The main risk factors for UTI are recent and frequent sexual intercourse, contraceptive use, and a history of UTIs (*2,3*). Treatment for UTIs usually involves a short course of an antimicrobial drug, such as trimethoprim-sulfamethoxazole (TMP-SMZ). Over the past decade, the prevalence of drug resistance in *E. coli* has increased dramatically, complicating management of these infections. Across the United States and Canada, urinary tract isolates of *E. coli* from outpatient clinics showed increased resistance to TMP-SMZ and ampicillin (*4*). A more serious concern has been the gradual increase in fluoroquinolone (e.g., ciprofloxacin) resistance among UTI isolates (*5*).

There is increasing evidence that the *E. coli* that cause UTIs and other extraintestinal infections may be responsible for community-wide epidemics. In 1986–1987, *E. coli* O15:K52:H1 caused an outbreak of community-acquired UTIs and septicemia in South London, England (*6*). The distinctive drug resistance profile of this clonal group contributed to its recognition in London and other areas of Europe and the United States (*7,8*). Other outbreaks of UTI caused by *E. coli* have been described and include a cluster of UTI cases in Copenhagen, Denmark, caused by *E. coli* O78:H10 and a larger outbreak in Calgary, Alberta, Canada, caused by extended-spectrum β-lactamase (ESBL)–producing *E. coli* (*9,10*).

In 2001, we reported that a multidrug-resistant *E. coli* clonal group designated clonal group A (CgA), defined by an enterobacterial repetitive intergenic consensus 2 (ERIC2) PCR and characterized by O11, O77, O17, and O73:K52:H18 serotypes, caused 11% of all *E. coli* UTIs and 49% of all TMP-SMZ–resistant *E. coli* UTIs in 1

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California, USA, community over a 4-month period (*11*). Members of this clonal group were responsible for drug-resistant UTIs in university communities in Michigan and Minnesota and a community in Colorado (*12*), and for pyelonephritis in several states (*13*). We also identified additional clonal groups in a second cross-sectional study in Berkeley, California (*14*).

Identification of outbreak strains of *E. coli* that cause extraintestinal infections suggests that point sources, possibly contaminated food, may be responsible for local spread of genetically related *E. coli* strains in the United Kingdom. Recent work in the United Kingdom has focused on a possible link between the increase in ESBL-producing *E. coli* and food animal production. An estimated 30,000 cases of human infection with ESBL-producing *E. coli* occur each year in the United Kingdom, and studies have found epidemic strains of ESBL-producing *E. coli* in the United Kingdom and throughout the world (*15–17*). The Health Protection Agency has suggested that imported chicken may be a route for introduction of ESBL-producing *E. coli* into the United Kingdom. Recent research by this agency did not identify a direct link between ESBL-positive strains of *E. coli* and chickens and humans (*18*), but other investigators found evidence for a link between drug resistance and specific genotypes of extratintestinal *E. coli* in animal food products and human infections in Minnesota and Washington, DC (*19–21*).

To further investigate the molecular epidemiology of disseminated *E. coli* clonal groups that cause UTIs, we conducted a cross-sectional study in a population of university women from Montréal, Québec, Canada, with UTI caused by *E. coli* and compared these organisms with those isolated from women with UTI in California. We sought to identify women in similar risk groups, but at different times and in different locations, to determine whether unrelated women with UTIs caused by indistinguishable strains of *E. coli* could be identified, and to determine whether the distribution was identical of clonal groups that were causing UTIs in these 2 communities.

Methods

Study Design

We conducted a cross-sectional study in collaboration with the Student Health Services at McGill University in Montréal in 2006. Eligible women 18–45 years of age who came to the health center with a suspected UTI were enrolled in the study. A UTI was clinically defined as ≥2 symptoms suggestive of this infection and included dysuria, increased urinary frequency or urgency, pyuria, hematuria, and $>10^2$ CFUs of *E. coli*/mL of clean-catch urine. If a woman had ≥1 UTIs during the study period, only data concerning the first UTI was eligible for inclusion in the analyses. Details of studies in California have been reported (*11*,*14*). The study protocol was reviewed and approved by the McGill University, Institutional Review Board (A01-M04–05A).

Isolation of *E. coli*

Urine samples were immediately cultured on Uricult (Orion Diagnostica, Espoo, Finland) MacConkey/cysteine lactose electrolyte–deficient agar dip slides. One arbitrarily selected colony (or multiple if morphologically different colonies were present) was selected from the MacConkey side. Lactose- and indole-positive colonies were presumptively identified as *E. coli* (*22*). Those isolates that were either lactose or indole negative were cultured on CHROMagar orientation plates (Becton Dickinson BBL Diagnostics, Sparks, MD, USA) and tested for lysine and ornithine decarboxylases (Moeller decarboxylase tests; PML Microbiologicals, Mississauga, Ontario, Canada). The reference strains used for carboxylase testing included *Klebsiella pneumoniae* (American Type Culture Collection [ATCC] no. 13883) and *Enterobacter cloacae* (ATCC no. 13047). Those isolates that were classified as *E. coli* on the CHROMagar plates and positive for lysine and ornithine decarboxylases were presumptively identified as *E. coli*. One *E. coli* isolate from each urine culture was arbitrarily selected for further analysis.

Antimicrobial Drug Susceptibility

Isolates were screened for susceptibility to TMP-SMZ, ciprofloxacin, cephalothin, nitrofurantoin, ampicillin, chloramphenicol, streptomycin, and tetracycline by the disk diffusion assay (Becton Dickinson BBL Diagnostics). *E. coli* strain ATCC 25922 was used as the reference strain. Isolates were defined as resistant, intermediate, or susceptible to each antimicrobial drug according to Clinical and Laboratory Standards Institute interpretive criteria (*23*). Isolates with intermediate resistance were defined as susceptible.

ERIC2 PCR Fingerprinting

All *E. coli* isolates were screened by using the ERIC2 PCR fingerprinting assay (*24*). Images of electrophoretic patterns were scanned into a software program (GelCompar II version 3.5; Applied Maths Inc., Austin, TX, USA) for analysis. Dendrograms based on ERIC2 PCR patterns were inferred from the Dice similarity coefficient matrix generated by GelCompar by the unweighted pair group method with arithmetic averages. Isolates with fingerprints that were indistinguishable on visual inspection or by GelCompar II version 3.5 (Applied Maths Inc.) analysis were grouped and selected for further typing.

Pulsed-Field Gel Electrophoresis

*Xba*I and *Not*I pulsed-field gel electrophoresis (PFGE) was conducted on all putative clonal isolates, as defined

by ERIC2 PCR (*25*). Isolates showing <6 band differences in their patterns were considered to be possibly related according to the criteria of Tenover et al. (*26*). Images of patterns were scanned into GelCompar II version 3.5 and analyzed as for ERIC2 PCR.

Serotypes

Serotyping was performed for Montréal *E. coli* isolates that were indistinguishable by ERIC2 PCR. O and H serotyping was performed by the Enteric Diseases Program at the National Microbiology Laboratory, Winnipeg, Manitoba, Canada, by using established protocols. Isolates from California were evaluated for serogroup only at the *E. coli* Reference Center (Pennsylvania State University, University Park, PA, USA). Isolates that were motile but non reactive with O or H antiserum were classified as nontypeable (OUNTYPE) and those that were nonmotile were denoted (HNM).

Multilocus Sequence Typing and Determination of Phylogenetic Group

Multilocus sequence typing (MLST) was performed as described (*27*). Gene amplification and sequencing were performed by using the primers specified at the *E. coli* MLST website (http://web.mpiib-berlin.mpg.de/mlst/dbs/Ecoli). Allelic profile and sequence type (ST) determinations were assigned according to the *E. coli* MLST website scheme. The major *E. coli* phylogenetic group (A, B1, B2, and D) was determined by using a multiplex PCR (*28*).

Clonal Group

A clonal group was defined as ≥2 *E. coli* isolates showing indistinguishable patterns by ERIC2 PCR. These groups were given letter designations, such as CgA. Clonal group designations assigned for the California study isolates were retained (CgA to CgG), and clonal groups identified in Montréal were assigned new letter designation beginning with CgH. To support categorization of these clonal groups, isolates showing indistinguishable ERIC2 PCR patterns were also evaluated by PFGE, serotyping, drug susceptibility testing, MLST, and phylogenetic typing.

Statistical Analyses

All analyses were conducted by using Stata version 9.0 (Stata Corporation, College Station, TX, USA). Proportions and 95% confidence intervals (CIs) were estimated. Differences in proportions were assessed by χ^2 tests. Statistical significance was defined by $p<0.05$.

Results

Study Participants

From January 2006 to January 2007, 656 urine samples were submitted. *E. coli* was isolated from 300 urine samples obtained from 256 women in Montréal. Only samples from the first UTI were included in the analyses. A total of 311 (47%) samples yielded no bacteria, and 45 (7%) contained an organism other than *E. coli*. Results for the *E. coli* isolated from these 256 women with UTIs were compared with results for *E. coli* isolated from 434 women with UTIs in California (1999–2001).

Antimicrobial Drug Susceptibility

Antimicrobial drug resistance for the Montréal and California isolates is summarized in Table 1. For the drugs tested, isolates from Montréal showed comparable resistance levels to those from California, although resistance to TMP-SMZ was higher in isolates from California (20% in California vs. 14% in Montréal; $p = 0.07$) and ciprofloxacin resistance was slightly higher in isolates from Montréal (2% in California vs. 4% in Montréal; $p = 0.06$). Resistance to nitrofurantoin was not detected in isolates from either location.

ERIC2 PCR Fingerprinting

ERIC2 PCR fingerprinting identified 4 clonal groups (CgA, CgC, CgH, and CgI) among Montréal isolates (data not shown). The prevalence of these clonal groups in Montréal in 2006 was 13 CgA (5%, 95% CI 0.03–0.09), 10 CgC (4%, 95% CI 0.02–0.07), 7 CgI (3%, 95% CI 0.01–0.06), and 5 CgH (2%, 95% CI 0.01–0.04). CgA and CgC were identified from both study sites. In the California studies, 32 CgA isolates (7%, 95% CI 0.05–0.10) and 12 CgC isolates (3%, 95% CI 0.01–0.05) were identified. Clonal groupings were confirmed by PCR reamplification, and these groupings also included representatives of clonal groups identified in the California studies (*11,14*).

CgH was uniformly resistant to ampicillin and streptomycin and susceptible to all other drugs tested. CgC was susceptible to all drugs tested (except for 1 isolate that was resistant to ampicillin). CgA was primarily resistant to TMP-

Table 1. Antimicrobial drug resistance of *Escherichia coli**

Characteristic	Berkeley, California, USA†	Montréal, Québec, Canada‡	p value§
Total primary *E. coli*	434	256	
Drug	No. (%) resistant		
Trimethoprim-sulfamethoxazole	85 (20)	36 (14)	0.07
Cephalothin	11 (3)	7 (3)	0.90
Ciprofloxacin	8 (2)	11 (4)	0.06
Nitrofurantoin	0	0	
Ampicillin	ND	83 (32)	ND
Tetracycline	ND	40 (16)	ND
Chloramphenicol	ND	7 (3)	ND
Streptomycin	ND	48 (19)	ND

*ND, not done.
†October 1999–January 2000 and October 2000– January 2001.
‡January 2006–January 2007
§By χ^2 test.

SMZ and ampicillin; resistance to the other drugs varied. CgI showed the most extensive resistance. This group was resistant to ciprofloxacin and TMP-SMZ, and 2 members of CgI were resistant to 5 drugs. Drug-resistance profiles for each clonal group member from both study sites are shown in Table 2 and the online Appendix Table (available from www.cdc.gov/EID/content/14/10/1575-appT.htm).

Pulsed-Field Gel Electrophoresis

PFGE confirmed the presence of 4 clonal groups among the Montréal isolates. CgH was found only in Montréal and showed indistinguishable *Xba*I and *Not*I PFGE patterns (Figure 1). CgI was also found only in Montréal and could be considered possibly related by the criteria of Tenover et al. (*26*) (Figure 2). Patterns of CgC isolates (Figure 3) identified in California and Montréal differed by <6 bands, regardless of restriction enzyme used. The PFGE results for CgA varied the most among all clonal groups from Montréal; in some cases, the PFGE patterns showed >6 band differences (Figure 4).

Table 2. Characteristics of clonal isolates of *Escherichia coli* from women with urinary tract infections, Montréal, Québec, Canada, 2006

Isolate no.	Genotype*	Serotype	MLST†	Phy‡	Date of infection	Antimicrobial drug resistance profile§							
						CIP	CEP	NIT	TMP-SMZ	AMP	CAM	STR	TET
362	C	O1:H7	ST95	B2	2006 Jan 23	0	0	0	0	0	0	0	0
363	C	O1:H7			2006 Jan 23	0	0	0	0	0	0	0	0
413	C	O18:H7	ST95	B2	2006 Feb 13	0	0	0	0	0	0	0	0
414	C	O1:H7			2006 Feb 13	0	0	0	0	0	0	0	0
439	C	O1:H7			2006 Feb 28	0	0	0	0	0	0	0	0
762	C	O1:K1:H7	ST95	B2	2006 Sep 28	0	0	0	0	0	0	0	0
767	C	O1:K1:H7			2006 Sep 29	0	0	0	0	1	0	0	0
782	C	O2:K1:H7	ST95	B2	2006 Oct 10	0	0	0	0	0	0	0	0
957	C	O1:H7			2007 Jan 1	0	0	0	0	0	0	0	0
958	C	O1:H7	ST95	B2	2007 Jan 5	0	0	0	0	0	0	0	0
412	H	O6:H1	ST73	B2	2006 Feb 13	0	0	0	0	1	0	1	0
415	H	O6:H1			2006 Feb 13	0	0	0	0	1	0	1	0
422	H	O6:H1			2006 Feb 16	0	0	0	0	1	0	1	0
459	H	O6:H1			2006 Mar 10	0	0	0	0	1	0	1	0
471	H	O6:H1			2006 Mar 16	0	0	0	0	1	0	1	0
385	A	OR:H18	ST69	D	2006 Jan 30	0	0	0	0	1	0	1	0
434	A	O73:H18	ST69	D	2006 Feb 27	0	0	0	0	0	0	0	0
498	A	O77/17:H18	ST69	D	2006 Mar 24	0	0	0	1	1	0	1	0
713	A	OUNTYPE: HNM	ST69	D	2006 Sep 11	0	0	0	1	1	0	1	0
724	A	O15:H18	ST69	D	2006 Sep 13	0	0	0	0	0	0	0	0
799	A	OUNTYPE: H18	ST69	D	2006 Oct 16	0	0	0	1	1	0	1	0
839	A	O17:H18	ST69	D	2006 Nov 2	0	0	0	1	0	0	0	0
860	A	O25:H18	ST69	D	2006 Nov 11	0	0	0	0	0	1	0	1
868	A	OUNTYPE: H18	ST69	D	2006 Nov 15	0	0	0	0	0	0	0	0
908	A	O17:H18	ST69	D	2006 Nov 30	0	0	0	1	1	0	0	1
912	A	O17:H18	ST69	D	2006 Nov 30	0	0	0	1	1	0	1	0
913	A	O17:HNM	ST69	D	2006 Dec 1	0	0	0	0	0	0	0	1
956	A	OUNTYPE: H18	ST69	D	2007 Jan 3	0	0	0	0	0	1	1	1
375	I	O25:H4	ST131	B2	2006 Jan 25	1	0	0	0	1	0	0	0
452	I	O25:H4	ST131	B2	2006 Mar 8	1	0	0	1	1	0	0	1
544	I	O25:H4			2006 Apr 19	1	0	0	0	0	0	0	0
550	I	O25:HNM	ST131	B2	2006 Apr 20	1	0	0	1	1	0	1	1
760	I	O25:H4			2006 Sep 28	1	0	0	1	1	0	0	1
783	I	O25:H4			2006 Oct 11	1	0	0	0	1	0	0	0
841	I	O25:H4	ST131	B2	2006 Nov 3	1	0	0	1	1	0	1	1

*Determined by ERIC2 PCR (*24*).
†MLST, multilocus sequence typing, according to Tartof et al. (*27*); ST, sequence type.
‡Phy, phylogenetic group, determined by multiplex PCR (*28*).
§0, sensitive; 1, resistant, according to Clinical and Laboratory Standards Institute interpretative criteria (*23*). CIP, ciprofloxacin; CEP, cephalothin; NIT, nitrofurantoin; TMP-SMZ, trimethoprim-sulfamethoxazole; AMP, ampicillin; CAM, chloramphenicol; STR, streptomycin; TET, tetracycline.

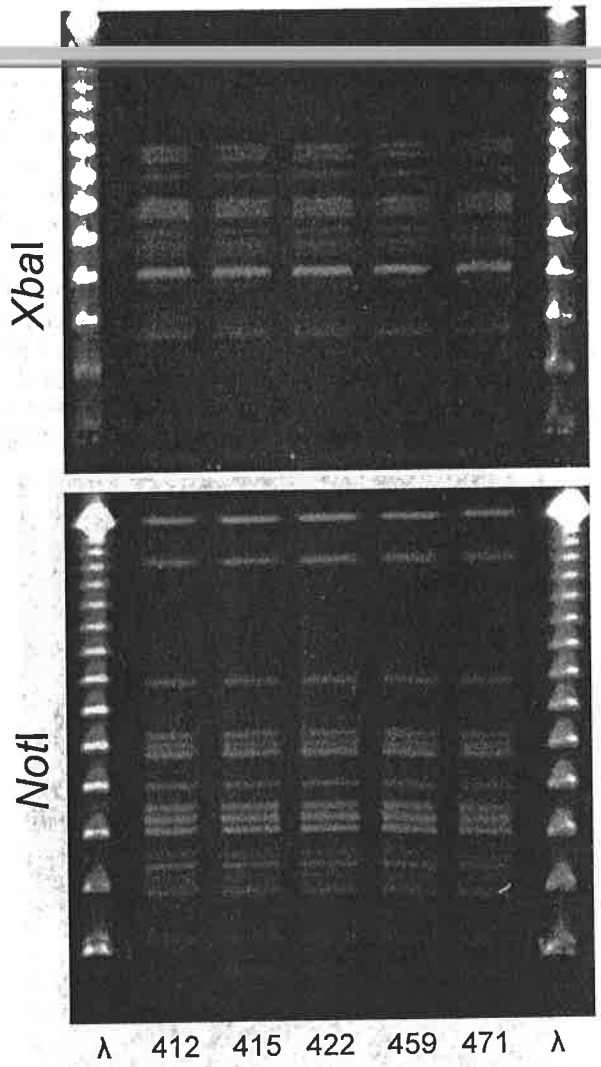

Figure 1. *Xba*I and *Not*I pulsed-field gel electrophoresis patterns for clonal group H *Escherichia coli* isolated from women with urinary tract infections in Montréal, Québec, Canada, 2006. The 5 isolates shown were serogroup O6:H1. First and last lanes, bacteriophage λ.

Serotypes

Serotype results for all clonal *E. coli* isolates identified in California and Montréal are shown in Table 2 and the Appendix Table. Serotyping was consistent within each clonal group, except for CgA, which showed 6 serogroups (O11, O77, O17, O73, O25, and O15) although O25 and O15 occurred only once. The complete serotype for CgA was O11/O17/O77/O73:K52:H18. CgC from both study locations showed the same serotype (O1/O18/O2:K1:H7).

MLST

Sequence types for selected members of each clonal group from the California and Montréal studies were determined (Table 2; Appendix Table). All sequence types were internally consistent within the clonal group. CgC and CgA isolates from both study sites showed the same sequence types (ST95 and ST69, respectively). CgH, CgB, and CgD showed the same sequence type (ST73). These 3 clonal groups also showed similar serogroups and phylogenetic groups but showed variable ERIC2 PCR and PFGE patterns; thus, they were not placed in the same clonal grouping.

Phylogenetic Group

Phylogenetic group was determined for selected members of each clonal group (Table 2 and Appendix Table). All phylogenetic group assignments were internally consistent within the clonal group and classified as either phylogenetic group B2 or D; both are typically associated with extraintestinal *E. coli*.

Time Cluster Analyses

In considering the hypothesis of endemic versus epidemic transmission of these clonal groups, temporal clus-

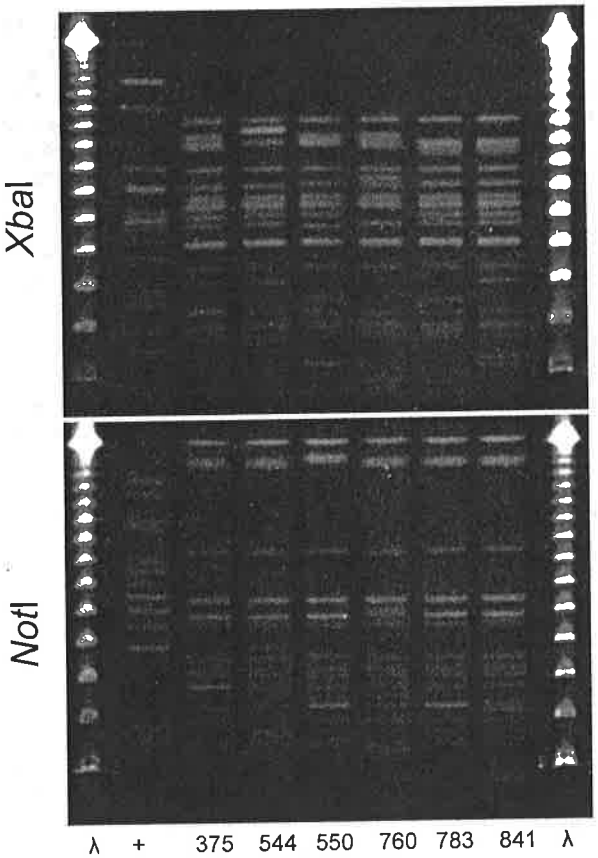

Figure 2. *Xba*I and *Not*I pulsed-field gel electrophoresis patterns for clonal group I *Escherichia coli* isolated from women with urinary tract infections in Montréal, Québec, Canada, 2006. The 6 isolates shown were resistant to ciprofloxacin and in serogroup O25:H4. First and last lanes, bacteriophage λ; lane +, positive control.

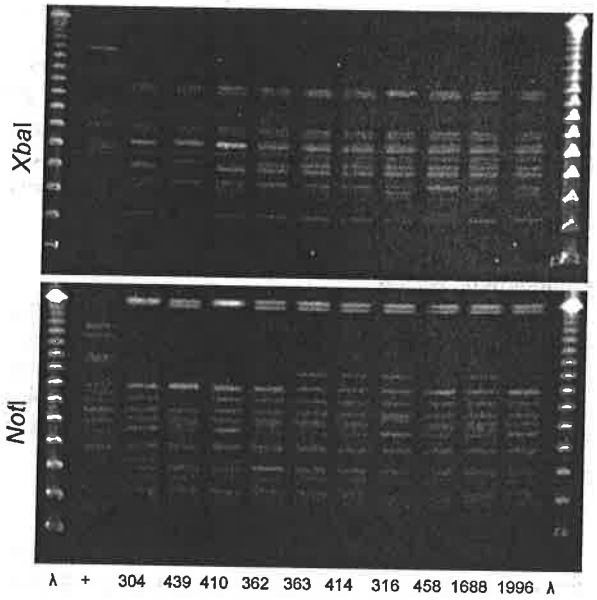

Figure 3. *Xba*I and *Not*I pulsed-field gel electrophoresis patterns for clonal group C *Escherichia coli* isolated from women with urinary tract infections in Montréal, Québec, Canada, 2006 (lanes 304, 439, 362, 363, and 414) and Berkeley, California, USA, 1999–2001 (lanes 410, 316, 458, 1688, and 1996). The 10 isolates shown were susceptible to all antimicrobial drugs tested and included serogroups O1, O2, or O18. First and last lanes, bacteriophage λ; lane +, positive control.

tering is a useful factor. Figure 5 shows the temporal pattern by week of UTI cases for all clonal groups in Montréal (Figure 5, panel A) and in California (Figure 5, panel B). Fluctuation in the number of *E. coli* UTIs over time corresponds closely to observation of clonal group–associated UTI cases. These results show clustering of some clonal groups, e.g., 3 of the 5 UTIs caused by CgH occurred in Montréal during week 7, and CgH did not appear again in Montréal after week 11. In California, CgA was present more frequently between October 1999 and February 2000 and dropped by 39% between the 2 sampling periods (*14*). CgB and CgD occurred exclusively in the second phase of the California study (Figure 5, panel B). Other clonal groups appeared throughout the year, although they often clustered by week. CgC was present during both data collection periods in California and caused UTIs throughout 2006 in Montréal. No clonal group members were identified during the summer in Montréal. However, this period corresponded to a decrease in the number of UTI cases at the student health services because of lower summer university enrollment (see total *E. coli* UTI by week, Figure 5).

Discussion

This study confirms the presence of drug-resistant, genetically related, and, in some cases, temporally clustered *E. coli* clonal groups (CgH, CgI, CgC, and CgA) that caused community-acquired UTIs in unrelated women in 2 locations and at different times. Drug resistance did not differ considerably between the 2 study sites, nor did the overall percentage of UTI caused by clonal groups: 4% (95% CI 0.10–0.18) in Montréal and 16% (95% CI 0.13–0.20) in California. Two clonal groups (CgA and CgC) were identified in both study locations, indicating widespread dissemination. These clonal groups shared common serogroups, PFGE patterns, drug-susceptibility profiles, MLST patterns, and phylogenetic groups. CgA isolates identified in Montréal did not show the same degree of genetic homogeneity as CgA isolates identified in the original California studies (*11,14*). CgA has also been

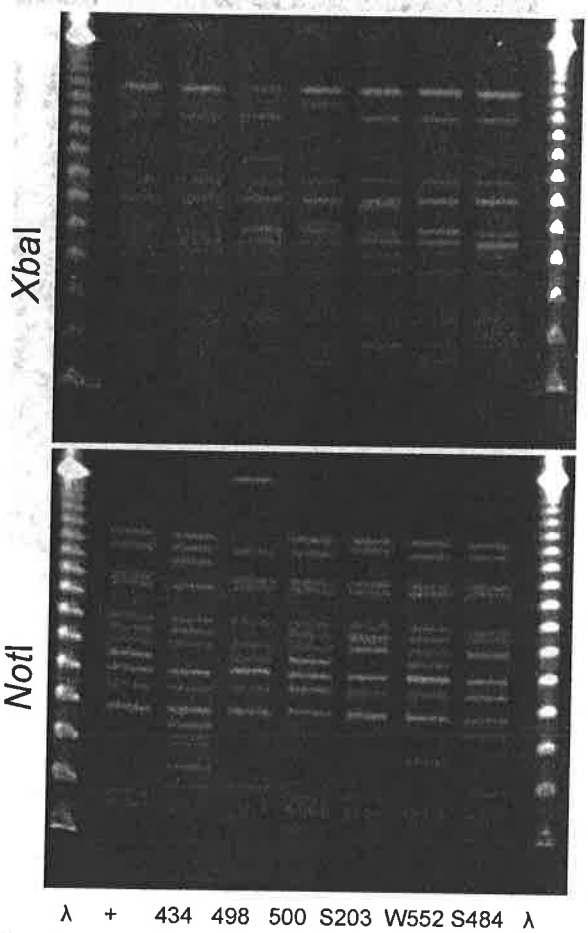

Figure 4. *Xba*I and *Not*I pulsed-field gel electrophoresis patterns for clonal group A *Escherichia coli* isolated from women with urinary tract infections in Montréal, Québec, Canada, 2006 (lanes 434 and 498) and Berkeley, California, USA, 1999–2001 (lanes 500, S203, W552, and S484). Antimicrobial drug resistance phenotypes and serogroups (O11, O17, O77, and O73) varied within and between the 2 study locations. First and last lanes, bacteriophage λ; lane +, positive control.

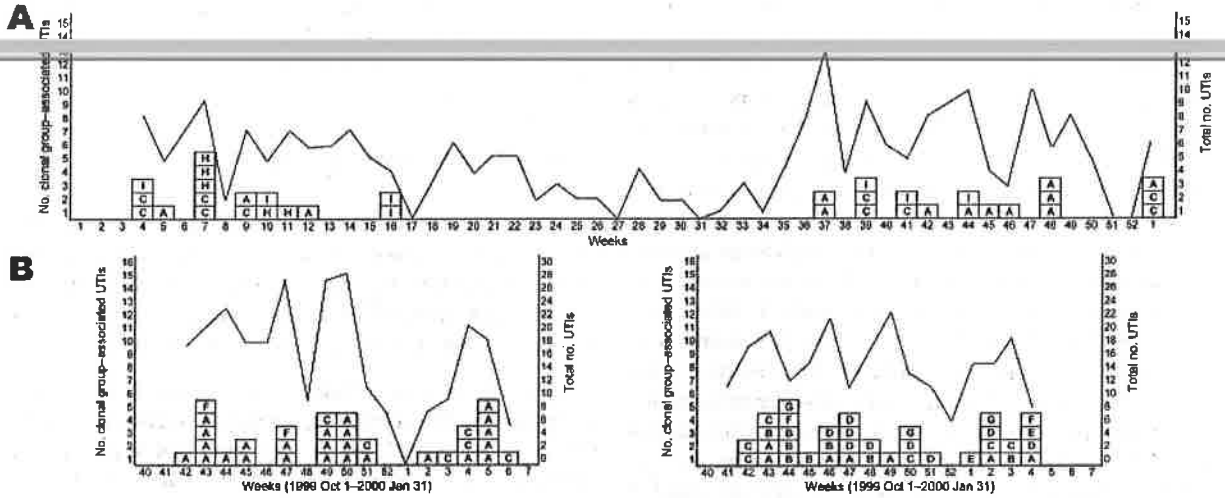

Figure 5. Temporal patterns of cases of urinary tract infections (UTIs) with *Escherichia coli* clonal groups by week in Montréal, Québec, Canada, 2006 (A), and Berkeley, California, USA, 1999–2001 (B). Clonal groups are identified by letters in boxes. Lines indicate the total number of UTIs with *E. coli* in each week for each study site. Samples were not analyzed during February–October 2000 in Berkeley.

recognized in many other locations and may represent a lineage that has been spreading over a longer period than other more genetically homogenous clonal groups identified (*6,11,14,29*). CgC members isolated from both study locations showed similar PFGE patterns, as well as common serotypes, MLST patterns, and phylogenetic groups, which suggest that these isolates are likely related. The fully susceptible nature of the CgC group and the similar drug resistance levels at the 2 study sites suggest that drug resistance or pressure may not have contributed to its selection and dissemination.

Of the 4 clonal groups, 3 showed resistance to ≥1 antimicrobial drugs. Most worrisome was CgI, which was resistant to ciprofloxacin and TMP-SMZ, drugs commonly used to treat patients with UTIs. Two members of CgI were resistant to 5 drugs. Identification of CgI serotype O25:H4 is also important because this serogroup and its drug resistance profile have been identified in a recent report on an emerging CTX-M type ESBL-producing *E. coli* (serotype O25:H4 and ST131) found worldwide (*30*). A possible link between the O25:H4 *E. coli* clonal group identified in Montréal and this emerging ESBL-producing *E. coli* clonal group should be investigated.

Temporal clustering (Figure 5) of these clonal groups from the 2 study sites was observed. Clonal groups tended to be identified in women on the same day and week or in adjacent weeks; CgH in Montréal and CgA in California followed this pattern. However, many of the clusters caused by these clonal groups did occur sporadically across the entire study period. The observed correlation between increased incidence of total *E. coli* UTIs and increased incidence of clonal group–associated UTIs may be a function of having sufficient numbers of UTIs to be able to detect these clonal groups of *E. coli*. However, underlying fluctuations in community-wide dynamics of these *E. coli* clonal groups (in a human or environmental reservoir) may influence the overall number of clinical infections.

One strength of our study is the ability to directly estimate the proportion of UTIs caused by each clonal group in the study communities. Because the study included all consecutive UTI specimens from a defined population and all *E. coli* were cultured and analyzed, it was possible to produce unbiased estimates of these proportions. Laboratory-based studies may overestimate prevalence of drug resistance, which in turn may bias the estimated proportion of clonal groups detected when specimens from recurrent, relapse, or complicated UTIs are disproportionately represented in the study samples.

One limitation of our study is the lack of epidemiologic data on possible *E. coli* transmission routes. Lack of epidemiologic information makes it impossible to determine what specific risk factors led groups of women to become infected with indistinguishable strains of *E. coli*. Therefore, detection of a specific transmission route (e.g., foodborne) could not be directly addressed in this study. However, an earlier study, on the basis of epidemiologic data, has implicated frequent consumption of chicken and pork in the development of drug-resistant UTIs (*31*). Also, limited reproducibility of the ERIC2 PCR may have contributed to an underestimation of the number of clonal groups, particularly those clonal groups with only a few members (*32*). However, additional genotypic and phenotypic analyses applied to these isolates contributed to the valid classification of these clonal groups.

Genetic homogeneity of the clonal groups identified in this study (CgH, CgC, and CgI), in addition to similar observations from other reports (*6,10,17*), suggests that these clonal groups are circulating in humans, most probably as part of the intestinal reservoir, and that they contribute to a sizable fraction of UTIs in the community. However, the degree of relatedness within each clonal group varied. For example, certain clonal groups (notably CgH) were highly clustered in time and showed indistinguishable genetic and other characteristics, which suggests local and recent transmission. Other clonal groups showed more diversity (e.g., CgA), possibly reflecting long-term, endemic transmission.

These results suggest 3 competing or coincident questions. First, do local, punctuated epidemics of specific strains or clonal groups occur as observed in this and earlier studies (*6,10,33*)? Second, do these clonal groups belong to a set of fairly conserved endemic clonal groups that are adapted for persistent and predominant colonization of the intestinal tract, and which have spread widely in human communities over varying periods of time (*6,10–14,29,33,34*)? Third, a combination of the first and second questions, are there periodic (epidemic) introductions of *E. coli* clonal groups in a community by an external source followed by endemic transmission? Already some evidence has indicated that animal-based foods or retail meats may contribute to the spread of these clonal groups (*19–21*). The number of infections, timing, and diverse locations in which these clonal groups are found argues against the possibility that person-to-person or household transmission contributes to our findings. However, limited local spread by these routes by certain clonal groups cannot be ruled out (*35–38*).

Positive and negative implications are associated with our results. One positive implication is that identification of lineages or clonal groups of *E. coli* that cause a sizeable fraction of community-acquired UTIs or extraintestinal infections may contribute to rational development of therapies and prevention strategies targeted toward these lineages. One negative implication is that tracing transmission routes and understanding the dynamics of these *E. coli* in external reservoirs and in human populations will be difficult and may impede possible control efforts, although ongoing attempts are under way to screen retail meats as a potential reservoir.

Annual incidence of UTIs and other community-acquired extraintestinal infections is high, in the millions, worldwide. Although each clonal group may account for a small fraction of all UTIs in a community, the high incidence of these infections implies that these clonal groups may contribute substantially to the overall extent of extraintestinal infections caused by *E. coli*. Furthermore, these clonal groups contribute, not only to uncomplicated infections such as cystitis, but also to severe infections such as pyelonephritis and septicemia (*13,39,40*). At a minimum, 10%–20% of these infections may be caused by 1 of a small set of extraintestinal pathogenic *E. coli* clonal groups, which are commonly resistant to ≥1 drugs. These facts point to the public health importance of understanding these *E. coli* lineages and their dynamics in the community and possible environmental reservoirs.

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MAJOR ARTICLE

Temporal Changes in the Prevalence of Community-Acquired Antimicrobial-Resistant Urinary Tract Infection Affected by *Escherichia coli* Clonal Group Composition

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Background. The changing prevalence of drug-resistant community-acquired urinary tract infection (UTI) is often attributed to local antimicrobial drug use or prescribing practices. However, recent molecular epidemiologic studies of community-acquired UTI suggest that other factors may play a greater role.

Methods. We conducted a multiyear, cross-sectional study to characterize temporal changes in the prevalence of drug-resistant community-acquired UTI at a university community in California. During four 3.5-month sampling periods, urine samples from patients consecutively presenting to the university health service with symptoms of UTI were cultured for *Escherichia coli.* Antimicrobial susceptibility and genotyping tests of the *E. coli* isolates were performed.

Results. We recovered 780 *E. coli* isolates from 1667 patients with UTI. The prevalence of trimethoprim-sulfamethoxazole, ciprofloxacin, and nitrofurantoin resistance showed no trend over the 4 periods. The prevalence of ampicillin resistance decreased significantly over the last 2 study periods. A single clonal group accounted for 75% of this decrease. Enterobacterial repetitive intergenic consensus 2 PCR–based genotyping revealed that only 4 large clonal groups accounted for 52% of the UTIs resistant to trimethoprim-sulfamethoxazole, ciprofloxacin, or nitrofurantoin. No initially pansusceptible clonal groups gained resistance over time.

Conclusions. This study revealed no obvious trend in the prevalence of drug-resistant community-acquired UTI in a single community. Prevalence at any time was influenced by a small number of *E. coli* clonal groups. This observation suggests that the introduction of strains that are drug resistant into a community plays a greater role in changing the prevalence of drug-resistant UTI than does the drug use or prescribing habits in that community.

Escherichia coli urinary tract infection (UTI) is one of the most common community-acquired (CA) infections in women. UTI resistance to empirically prescribed antimicrobial agents complicates the management of this disease [1–3]. In addition, reports of community outbreaks of multidrug-resistant (MDR) UTI caused by unique clonal groups of uropathogenic *E.coli* [4–6] raise some questions. Do undetected outbreaks contribute to temporal fluctuations in the prevalence of antimicrobial resistance in a specific community? Are changes in the prevalence of drug-resistant UTI in a community more dependent on the transient introduction or disappearance of genetically similar groups of drug-resistant *E.coli* than on the antimicrobial drug use or prescribing practice in that community?

The conventional approach to understanding antimicrobial resistance, which relies on tracking temporal changes in resistance among pathogens isolated from routinely submitted culture samples, provides a limited assessment of the prevalence of antimicrobial resistance in a community. Because urine samples from women with uncomplicated UTI are not routinely cultured in most settings, samples used to generate antimicrobial susceptibility data may not be representative of uropathogens from such patients with CA UTI, and these convenience samples may limit the usefulness of the

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Table 1. Study population and *Escherichia coli* antibiotic resistance.

Variable	Period 1[a]	Period 2[b]	Period 3	Period 4
No. of urine specimens	505	468	532	415
No. of unique patients	434	414	456	363
Age, median years (range)	22 (17–68)	22 (13–48)	22 (18–60)	23 (18–68)
E. coli drug resistance, proportion (%) of specimens				
Pansusceptible	NA[c]	NA	108/230 (47)	61/116 (53)
MDR	NA	NA	84/230 (36)	33/116 (24)
TMP-SMX resistant	47/228 (21)	38/206 (18)	37/230 (16)	19/116 (16)
Ciprofloxacin resistant	2/228 (1)	6/206 (3)	2/230 (1)	3/116 (3)
Nitrofurantoin resistant	4/228 (2)	1/206 (1)	2/230 (1)	2/116 (2)
Cephalothin resistant	NA	NA	79/230 (34)	33/116 (28)
Ampicillin resistant	NA	NA	80/230 (35)	28/116 (24)[d]

NOTE. Period 1 was from 11 October 1999 through 31 January 2000, period 2 was from 11 October 2000 through 31 January 2001, period 3 was from 11 October 2003 through 31 January 2004, and period 4 was from 11 October 2004 through 31 January 2005. MDR, multidrug resistant (defined as nonsusceptible to ≥2 of the 11 classes of drugs tested); NA, not available; TMP-SMX, trimethoprim-sulfamethoxazole.

[a] Results previously published in Manges et al. [4].
[b] Results previously published in Manges et al. [8].
[c] Three antibiotics were tested in periods 1 and 2, and 29 antibiotics were tested in periods 3 and 4.
[d] Statistically significant change in prevalence between periods 3 and 4 ($P \leq .05$).

resistance prevalence data to guide empirical treatment decisions for these patients.

Systematic sampling of urine specimens from patients with CA UTI can eliminate this sampling bias. In addition, genotype analysis of *E. coli* UTI isolates can augment susceptibility testing by delineating the temporal contributions of unique and genetically related strains. A more comprehensive picture of the dynamics of CA drug resistance can inform empirical treatment decisions and may facilitate the development of rational intervention strategies.

Here, we report the results of a serial cross-sectional study conducted from 1999 through 2005 in a California university community to test the hypotheses that the resistance of uropathogenic *E. coli* to empirically prescribed antimicrobial agents is increasing and to investigate whether the prevalence of drug-resistant CA UTI is dependent more on the introduction of clonal groups of *E. coli* into the community than on the antibiotic drug use or prescribing practices.

METHODS

Study design and sampling strategy. From October 1999 through January 2005, we conducted a series of cross-sectional studies at a California university health care service that included the following four 3.5-month sampling periods: period 1, 11 October 1999–31 January 2000; period 2, 11 October 2000–31 January 2001; period 3, 11 October 2003–31 January 31 2004; and period 4, 11 October 2004–31 January 2005. The collection of period 1 and 2 samples was nested within a separate 2-year study that examined changes in the prevalence of a major drug-resistant clonal group of uropathogenic *E. coli* in this student population [4, 7]. Period 3 and 4 samples were collected within a second 2-year prospective study initiated in October 2003 that examined the dietary habits of students with UTI [8]. Details of the 2 studies are provided in the respective publications [4, 7, 8].

During each period, urine specimens were obtained from patients consecutively presenting to the clinic with symptoms suggestive of UTI. A patient with *E. coli* UTI was defined as a patient who received a diagnosis of UTI (as stated on the laboratory referral documents) and had a urine culture yielding $\geq 10^2$ colonies per mL of urine with presumptively identified *E. coli*. If multiple urine specimens from the same patient were obtained, only the first specimen yielding an *E. coli* isolate (primary *E. coli* isolate) was included in the analysis. Study protocols were approved by the Committee for Protection of Human Subjects at the University of California at Berkeley.

Urine specimen collection and microbiological methods. All urine specimens obtained from clinic patients were picked up daily, preserved in 15% glycerol, and stored at −80°C until testing. Urine specimens were cultured by standard methods of the American Society for Microbiology [9]. Colonies isolated at concentrations of $\geq 10^2$ colonies per mL of urine with presumptively identified *E. coli* [7, 10] were selected for additional testing.

Antimicrobial susceptibility testing for trimethoprim-sulfamethoxazole (TMP-SMX), ciprofloxacin, and nitrofurantoin was performed during periods 1 and 2 by Etest strip (AB Biodisk). During periods 3 and 4, as part of a new study design protocol [8], susceptibility testing for 29 antimicrobial agents representing 11 drug classes was performed by the broth microdilution method (Microscan Dade-Behring). All susceptibility testing was interpreted according to Clinical and Labo-

ratory Standards Institute standards. Isolates exhibiting intermediate resistance were interpreted as resistant during analysis. An isolate was considered to be MDR if it was resistant to ≥2 separate classes of antimicrobial agents.

Genotype analyses. All TMP-SMX–resistant *E. coli* isolates and either a randomly selected subset (period 1, 49 isolates [27%]; period 2, 104 isolates [62%]) or 100% (periods 3 and 4, 290 isolates) of TMP-SMX–susceptible isolates were genotyped by enterobacterial repetitive intergenic consensus 2 (ERIC2) PCR, as described elsewhere [4, 11]. Groups of ≥2 isolates with ERIC2 electrophoretic banding patterns that were indistinguishable by visual inspection were designated to belong to ERIC2 clonal groups. Prototype uropathogenic strains CgA (ATCC BA-457) and CFT073 were included as reference strains for the ERIC PCR tests.

Statistical analysis. Comparisons of proportions were tested by Fisher's 2-tailed exact test. Cuzick's test for trend was performed to detect trends in resistance prevalence of the antimicrobial agents tested over the 4 periods of the study.

A test of negative binomial regression versus Poisson regression was used to examine the hypothesis that ERIC patterns displayed the same underlying prevalence of TMP-SMX resistance, pansusceptibility, or MDR. The basis of this test is that the negative binomial distribution can be thought of as an extension of the Poisson distribution that allows for variation in the underlying rates of antimicrobial resistance between the ERIC PCR patterns. A comparison of the relative fit of the Poisson and the negative binomial distributions via the log-likelihoods provides for a pseudolikelihood ratio statistic.

Temporal clustering of the major clonal groups, defined as the ERIC groups with ≥20 isolates per group, identified over the 4 sampling periods was investigated with Pearson χ^2 analysis. Poisson and negative binomial regression tests were used to examine the hypothesis that the rate of occurrence of these ERIC clonal groups was constant throughout the study period. All statistical analyses were performed using Stata, version 9.0 (StataCorp).

RESULTS

Study population and bacterial isolates. During the 4 sampling periods from 1999 through 2005, 1667 patients (age, 13–68 years) presented to the university health clinic (University of California, Berkeley) with clinical suspicion of UTI. Of these patients, 780 (47%) had primary *E. coli* isolates recovered at concentrations of $\geq 10^2$ colonies per mL of urine (table 1). *E. coli* accounted for 81% of the uropathogens isolated.

Antimicrobial resistance. Among the 780 *E. coli* isolates, the prevalence of resistance to TMP-SMX, ciprofloxacin, and nitrofurantoin was 18%, 2%, and 1%, respectively. No trends in the prevalence of resistance to TMP-SMX, ciprofloxacin, or nitrofurantoin were detected over the 4 periods (table 1).

Eleven (8%) of the 141 TMP-SMX–resistant isolates were also resistant to ciprofloxacin, and 2 (1.4%) were also resistant to nitrofurantoin. Isolates that were resistant to ciprofloxacin or nitrofurantoin were uncommon. Thirteen ciprofloxacin-resistant *E. coli* isolates were identified; 12 (92%) of these were MDR, 11 (85%) were resistant to TMP-SMX, and 1 was resistant to both TMP-SMX and nitrofurantoin. All 9 nitrofurantoin-resistant isolates were MDR, and those from period 3 and 4 were resistant to 5–8 classes of antimicrobial agents, including ampicillin and cephalothin.

During periods 3 and 4 (when 29 antimicrobial agents were tested), 169 (49%) of 346 isolates from these periods were susceptible to all 29 drugs tested (pansusceptible), 60 (17%) were resistant to a single agent, and 117 (34%) were resistant to ≥2 classes of drugs (MDR). Fourteen (12%) of the 117 MDR isolates were resistant to ≥6 of the 11 classes of drugs tested.

Among 346 *E. coli* isolates from periods 3 and 4, the prevalence of cephalothin and ampicillin resistance was 32% and 31%, respectively. The prevalence of resistance to ampicillin decreased from 35% in period 3 to 24% in period 4 ($P < .05$).

ERIC2 PCR genotyping results. Among 584 *E. coli* isolates tested by ERIC2 PCR, 35 distinct clonal groups, defined as those comprising ≥2 isolates per group displaying visually indistinguishable electrophoretic banding patterns, were identified. The number of clonal groups identified and the proportion of isolates belonging to these groups increased with the increasing percentage of isolates typed by ERIC2 PCR during each period (table 2).

During period 1, genotyping of 47 TMP-SMX–resistant isolates (100%) and 49 randomly selected TMP-SMX–susceptible isolates (27%) identified 3 clonal groups. Three additional clonal groups were identified during period 2, when 38 TMP-SMX–resistant isolates (100%) and 104 (62%) of 168 TMP-SMX–susceptible isolates were typed [4, 7].

Concurrent genotyping of the 346 *E. coli* isolates during periods 3 and 4 revealed 118 unique ERIC2 patterns. Two hundred sixty-four isolates (75%) were identified as belonging to 33 distinct clonal groups. Of the 26 clonal groups first identified among period 3 isolates, 9 (35%) were no longer circulating during period 4. Of the 24 clonal groups infecting patients during period 4, three had not previously been identified.

The 4 major clonal groups, CgC (49 isolates), CgA (40), CgH (33), and Cg3 (20), accounted for 41% of all the *E. coli* isolates and 54% of the clonally grouped *E. coli* isolates during periods 3 and 4. CgC (72 isolates) and CgA (61) were present during all 4 sampling periods, CgH (50) was isolated during each of the last 3 periods, and Cg3 was recovered only during periods 3 and 4 (table 2).

ERIC2 clonal groups and antimicrobial resistance. The association of ERIC2 clonal groups with the prevalence of drug

Table 2. Enterobacterial repetitive intergenic consensus 2 PCR groups and antimicrobial resistance.

Variable	Period 1	Period 2	Period 3	Period 4
No. of *Escherichia coli* isolates				
Total	228	206	230	116
TMP-SMX resistant	47	38	37	19
Typed	96[a]	142[a]	230	116
No. of clonal groups				
Total	3	6	30	24
With TMP-SMX–resistant isolates	2	5	7	8
Typed *E.coli* isolates				
Nonclonal group	63 (66)	105 (74)	55 (24)	30 (26)
Clonal group	33 (34)	37 (26)	175 (76)	86 (74)
Major clonal group				
CgA	25 (26)	7 (5)	30 (13)	10 (9)
CgC	6 (7)	6 (3)	31 (13)	18 (16)
CgH	0 (0)	17 (12)	24 (10)	9 (8)
Cg3	NA	NA	15 (7)	5 (4)
TMP-SMX resistant isolates				
Nonclonal group	22 (47)	26 (68)	9 (24)	6 (32)
Clonal group	25 (25)	12 (32)	28 (76)	13 (68)
Major clonal group				
CgA	23 (49)	4 (11)	15 (41)	4 (21)
CgC	0 (0)	0 (0)	5 (14)	0 (0)
CgH	0 (0)	3 (8)	2 (5)	1 (5)
Cg3	NA	NA	0 (0)	0 (0)

NOTE. Data are no. (%) of isolates, unless otherwise indicated. Period 1 was from 11 October 1999 through 31 January 2000, period 2 was from 11 October 2000 through 31 January 2001, period 3 was from 11 October 2003 through 31 January 2004, and period 4 was from 11 October 2004 through 31 January 2005. NA, not available; TMP-SMX, trimethoprim-sulfamethoxazole.

[a] All TMP-SMX isolates and a randomly selected subset of TMP-SMX–susceptible isolates were typed.

resistance was assessed. We found no statistically significant differences in the prevalence of TPM-SMX–resistant ($P = .74$), MDR ($P = .36$), or pansusceptible isolates ($P = .54$) between clonal and nonclonal group isolates during periods 3 and 4. However, antimicrobial drug susceptibility pattern was significantly associated with specific clonal groups, as assessed by the test of negative binomial versus Poisson regression (table 2).

Seventy-eight (55%) of 141 TMP-SMX–resistant *E. coli* isolates belonged to 11 clonal groups. During periods 3 and 4, these 11 clonal groups accounted for 41 (73%) of 56 TMP-SMX–resistant UTIs and only 159 (46%) of all 346 UTIs ($P < .001$). Four of these clonal groups (10 isolates) were entirely composed of TMP-SMX–resistant, MDR isolates and contributed 10 (18%) of 56 TMP-SMX–resistant UTIs ($P < .001$) and 10 (8.6%) of 117 MDR UTIs ($P < .001$), compared with 10 (2.9%) of all 346 UTIs, during periods 3 and 4.

The association of the major clonal groups (CgA, CgC, CgH, and Cg3) with antimicrobial resistance was examined further. These major clonal groups accounted for 203 (35%) of all of the 584 genotyped isolates in this study. A single clonal group, CgA, was responsible for 40 (12%) of all 346 UTIs during periods 3 and 4. However, during these periods, this clonal group accounted for 3 (60%) of 5 ciprofloxacin-resistant UTIs ($P < .05$), 19 (34%) of 56 TMP-SMX–resistant UTIs ($P \leq .001$), 22 (20%) of 108 ampicillin-resistant UTIs ($P \leq .001$), and 24 (21%) of 117 MDR UTIs ($P < .001$) (table 2).

None of the 61 CgC isolates found over the course of the study were resistant to ciprofloxacin or nitrofurantoin. Only 5 (8%; all isolated during period 3) were resistant to TMP-SMX. Although accounting for only 31 (13%) of the 230 UTIs during period 3, CgC was responsible for 17 (21%) of 80 ampicillin-resistant isolates ($P < .05$), 17 (20%) of 84 MDR isolates ($P < .05$), 5 (14%) of 37 TMP-SMX–resistant isolates ($P = 1$), and 11 (10%) of 108 pansusceptible isolates ($P = .18$) during period 3. However, during period 4, CgC accounted for 18 (16%) of the 116 UTIs and 13 (21%) of 61 pansusceptible infections ($P = .08$) but only 1 (3.6%) of 28 ampicillin-resistant UTIs ($P = .07$), 1 (3%) of 33 MDR UTIs ($P < .05$), and none of the 19 TMP-SMX–resistant UTIs ($P < .05$).

During periods 3 and 4, CgH was responsible for 33 (9.5%)

of all 346 UTIs, 3 (5.4%) of 56 TMP-SMX–resistant UTIs ($P = .32$), and 2 (50%) of 4 nitrofurantoin-resistant UTIs ($P < .05$). Cg3 infected 20 women during periods 3 and 4, accounting for 20 (5.8%) of 346 UTIs and 18 (11%) of 169 pansusceptible infections ($P < .001$). Eighteen (90%) of the Cg3 isolates were pansusceptible, and 2 (10%) showed intermediate susceptibility to cephalothin.

Temporal clustering of clonal groups. Temporal clustering, defined as the isolation of the same clonal group strain from ≥2 women on the same day, was observed during all periods of our study. There were 33 instances (1.7% of all clinic visits) in which ≥2 unrelated patients infected with the same ERIC2 clonal group presented to the clinic on the same day. Six clonal groups, including CgA and CgC, were responsible for these clusters (table 3). Although no significant temporal clustering was detected by χ^2 or negative binomial regression analysis, notable clusters of pansusceptible Cg3 isolates and TMP-SMX–resistant, MDR CgC isolates were observed during period 3.

DISCUSSION

Large surveillance networks [2, 3] continue to report both increasing trends and marked geographic variation in the prevalence of antimicrobial resistance of uropathogenic *E. coli* strains; such data are often used to guide empirical treatment choices [12, 13]. However, reliance on UTI management strategies based on a limited number of routine urine cultures of specimens from patients with uncomplicated CA UTI may result in antimicrobial susceptibility data that are unrepresentative of these patients. To assess whether such biases exist in the estimation of prevalence of drug-resistant CA UTI, we conducted a population-based study in a single community over 4 different periods spanning 6 years. In each period, we assessed drug susceptibility of all consecutively collected *E. coli* isolates from women with CA UTI.

Contrary to expectation, we found no evidence of increasing or decreasing prevalence of drug resistance in our community, except for 1 instance of a decrease in ampicillin resistance between periods 3 and 4. Notably, 75% of this decrease in the prevalence of ampicillin resistance could be attributed to a single *E. coli* clonal group (CgC).

Our results are consistent with those from a study performed with a similar sampling strategy at the Stoneybrook University health service (Stoneybrook, NY). After comparing results from a 7-month study period in 2003 with those from a similar period in 1993, Ansbach et al. [14] found no significant increase in the prevalence of drug resistance. Interestingly, the 14% prevalence of TMP-SMX resistance among *E. coli* isolates recorded by Ansbach et al. [14] was observed in a community where TMP-SMX remained the most commonly prescribed empirical therapy for UTI, although in our community, with an 18% prevalence of TMP-SMX resistance, the health service had switched (in early 1999) from prescribing TMP-SMX to treating UTI with nitrofurantoin or ciprofloxacin. The prevalence of nitrofurantoin and ciprofloxacin resistance remained similar in both communities over the different study periods.

Our genotyping results support the growing body of evidence that most drug-resistant CA UTIs are associated with a limited number of strains of *E. coli* that belong to distinct phylogenic groups [15, 16] and are sometimes associated with community outbreaks [4–6]. Our study documents that the majority (75%) of all CA *E. coli* UTIs in our community were associated with ERIC2 clonal group membership. Earlier studies based on the typing of selectively or randomly sampled collections of isolates did not reveal this level of clonality [7, 17, 18].

Table 3. Temporal clustering of enterobacterial repetitive intergenic consensus (ERIC) clonal group.

Variable	No. of *E.coli* isolates[a]	No. of clusters (no. of patients)			
		Period 1	Period 2	Period 3	Period 4
Same-day clusters[b]	584	5 (11)	3 (7)	20 (43)	5 (11)
Clonal group					
CgA	72	5 (11)	ND	6 (13)	0 (0)
CgC	61	ND	1 (2)	6 (13)	3 (7)
CgH	50	ND	2 (5)	3 (6)	1 (2)
Cg1	12	ND	ND	0 (0)	1 (2)
Cg3	20	ND	ND	4 (9)	0 (0)
Cg5	12	ND	ND	1 (2)	0 (0)

NOTE. Data are for 96 (42%) of 228 ERIC2 typed isolates in period 1, 142 (69%) of 206 isolates in period 2, 230 (100%) of 230 isolates in period 3, and 116 (100%) of 116 isolates in period 4. ND, none detected (<100% of isolates typed).

[a] The total number of typed isolates in each clonal group over all study periods.

[b] The occurrence of ≥2 patients presenting to the clinic on the same day who are infected with the same ERIC2 clonal group.

Although clonal group *E. coli* isolates were no more likely to be antibiotic resistant than nonclonal group isolates, antibiotic resistance was concentrated within a small number of specific clonal groups. Furthermore, the 6-year comparison in the same community provided us with an opportunity to determine if pansusceptible clonal group strains became resistant over this period. Interestingly, there was little evidence that the acquisition of resistance by these initially pansusceptible strains contributed substantially to the prevalence of drug-resistant UTIs during any of the sampling periods.

During the first sampling period, investigators identified a previously unrecognized MDR genetically related group of *E. coli*, CgA. This single group was responsible for 11% of all *E. coli* isolates and 49% of TMP-SMX–resistant *E. coli* isolates from patients with CA UTI at the university health service during period 1 [4]. Subsequent studies have revealed that CgA is responsible for cystitis, pyelonephritis, and septicemia in the United States and Europe [17, 19–21]. Many CgA isolates exhibit similar MDR antimicrobial susceptibility patterns, PFGE profiles, and multilocus sequence type membership, and many carry a class 1 integron with a single arrangement of class 1 drug resistance gene cassettes *(dfrA17-aadA5)* [22, 23]. The isolation of *E. coli* strains indistinguishable by ERIC2 PCR that belonged to CgA from animals and retail poultry meat products [24, 25] suggests that contaminated food products could be a source of human drug-resistant CA UTI. Over the 6 years of our study, CgA accounted for 12% of all typed isolates and 30% of isolates resistant to TMP-SMX, ciprofloxacin, or nitrofurantoin ($P < .001$).

Our study demonstrates that the prevalence of drug-resistant *E. coli* UTI at any 1 time is greatly affected by the prevalence of a small number of circulating clonal groups of uropathogenic *E. coli* that are sampled during the study period. The probability that different women with no obvious common exposure would be infected with such drug-resistant clonal groups is highly unlikely. The resistant clonal *E. coli* groups that we detected are more likely to have already been resistant when introduced into this university community. These observations suggest that fluctuations in the prevalence of drug-resistant UTI in a community cannot be solely explained by local drug prescribing practices, regardless of what these prescribing practices may be. If the prevalence of resistant UTI in this community was a result of the human antibiotic prescribing or use practices, the selective pressures of the drugs should have yielded many more genetically distinct drug-resistant *E. coli* isolates. Thus, the usual recommendation to restrict human antibiotic use at the community level may not have the expected impact on diseases such as drug-resistant UTI. Strategies developed to maintain the usefulness of CA UTI empirical treatment options may need to include interventions that target sources of drug-resistant *E. coli*.

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Food Reservoir for *Escherichia coli* Causing Urinary Tract Infections

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Closely related strains of *Escherichia coli* have been shown to cause extraintestinal infections in unrelated persons. This study tests whether a food reservoir may exist for these *E. coli*. Isolates from 3 sources over the same time period (2005–2007) and geographic area were compared. The sources comprised prospectively collected *E. coli* isolates from women with urinary tract infection (UTI) (n = 353); retail meat (n = 417); and restaurant/ready-to-eat foods (n = 74). *E. coli* were evaluated for antimicrobial drug susceptibility and O:H serotype and compared by using 4 different genotyping methods. We identified 17 clonal groups that contained *E. coli* isolates (n = 72) from >1 source. *E. coli* from retail chicken (O25:H4-ST131 and O114:H4-ST117) and honeydew melon (O2:H7-ST95) were indistinguishable from or closely related to *E. coli* from human UTIs. This study provides strong support for the role of food reservoirs or foodborne transmission in the dissemination of *E. coli* causing common community-acquired UTIs.

Extraintestinal infections caused by *Escherichia coli* cause serious illness and death. Every year, 6–8 million cases of uncomplicated urinary tract infections (UTI) occur in the United States and 130–175 million cases occur globally; >80% are associated with *E. coli* (*1,2*). The urinary tract is the most common source for *E. coli* causing bloodstream infections, which cause 40,000 deaths from sepsis each year in the United States (*1*). Uncomplicated UTIs alone are responsible for an estimated $1–$2 billion of direct healthcare costs in the United States annually (*1,2*). Antimicrobial drug resistance among extraintestinal *E. coli* is further adding to the cost of treating these infections (*3*). Drug-resistant infections often require more complicated treatment regimens and result in more treatment failures.

The immediate reservoir of *E. coli* that causes extraintestinal infections is the intestinal tract of the person. Although extraintestinal infections caused by *E. coli* are not usually associated with outbreaks, mounting evidence shows that extraintestinal *E. coli* may be responsible for community-wide epidemics. For instance, in 2001, we reported the discovery of *E. coli* O11/O77/O17/O73:K52:H18-ST69. This clonal group caused 11% of all *E. coli* UTIs and 49% of all trimethoprim/sulfamethoxazole-resistant *E. coli* UTIs in 1 California community over a 4-month period (*4*). It caused antimicrobial drug–resistant UTIs in Michigan, Minnesota, and Colorado (*5*), and pyelonephritis in several states (*6*). Other outbreaks of UTIs caused by *E. coli* have been described, including a large *E. coli* O15:K52:H1 outbreak in South London (*7*), clusters of cases in Copenhagen, Denmark, caused by *E. coli* O78:H10 (*8*), and cases in Calgary, Alberta, Canada, caused by an extended-spectrum β-lactamase-producing *E. coli* (*9*).

Identification of these outbreak strains has suggested that environmental sources, possibly contaminated meat and other foods, may play a role in the local spread of closely related *E. coli* strains. If there is a food animal reservoir for extraintestinal *E. coli*, then the use of antimicrobial agents in food animal production may select for antimicrobial drug–resistant forms of extraintestinal *E. coli* (*10,11*). Links between antimicrobial resistance and specific strains of extraintestinal *E. coli* in animal food products, specifically chicken meat, and human infections have been observed (*12–16*). In a previous study, we noted an increase

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in antimicrobial drug–resistant UTIs among women who report frequent chicken and pork consumption (*17*).

Evidence showing that food can be a reservoir for extraintestinal *E. coli* includes 1) community-based outbreaks of extraintestinal infections caused by epidemic strains of *E. coli* causing uncomplicated UTIs (*4,18*) and other severe infections (*6,19,20*); 2) the determination that these epidemic strains share antimicrobial drug susceptibility patterns and genotypes with isolates from retail meat (*12–15*); and 3) the epidemiologic association between retail meat consumption and intestinal acquisition of antimicrobial drug–resistant *E. coli* causing UTIs (*17*). On the basis of these observations, we hypothesize that retail chicken is the main reservoir for *E. coli* causing human extraintestinal infections.

Methods

Study Design

E. coli isolates from human clinical samples, restaurant/ready-to-eat foods, and retail meat were systematically sampled over the same period. Human clinical isolates and restaurant/ready-to-eat isolates were obtained from Montréal, Québec, Canada. Retail meat isolates from Québec and Ontario were included because women with infections were primarily from these regions. We hoped to maximize the probability that matching genotypes between *E. coli* from these 3 sources could be identified. *E. coli* isolates from each source were cultured and processed separately to prevent cross-contamination. The study protocol was approved by the McGill University Institutional Review Board (A01-M04-05A).

Sampling of *E. coli* Causing Human UTIs

E. coli isolates from women with UTIs in Montréal from June 1, 2005, to May 30, 2007, were included. Women 18–45 years of age with a suspected UTI were enrolled. UTI was defined as the presence ≥2 relevant symptoms including dysuria, increased urinary frequency or urgency, pyuria, and hematuria and $>10^2$ colony-forming units of *E. coli* per milliliter of clean-catch urine (*21*). A total of 1,395 consecutive UTI samples were obtained. Details about specimen culture and bacterial identification of *E. coli* are provided in Manges et al. (*18*). One *E. coli* isolate from each urine culture was arbitrarily selected for further analysis. If a woman had had recurrent UTIs, only the isolate from the first infection was included. The study sample (n = 353) of *E. coli* isolates was assembled in the following manner. All cephalothin-resistant *E. coli* (n = 19) were included. Isolates known to be members of a clonal group (n = 46) found to be closely related to or indistinguishable from other *E. coli* causing UTI in unrelated women were included (*4,18,22*) because we hypothesized that these *E. coli* would be more likely to be associated with food sources. A random sample of *E. coli* isolates resistant to ≥1 antimicrobial agents was assembled (n = 172). We chose to oversample resistant *E. coli*, as antimicrobial resistance has been associated with possible outbreaks of extraintestinal *E. coli* infections. A random sample of fully susceptible *E. coli* isolates (n = 116) was selected.

Sampling of *E. coli* from Retail Meat

A total of 417 *E. coli* isolates from fresh, raw retail chicken, beef, and pork products were selected from the collection of the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), which monitors antimicrobial resistance in bacteria from meat obtained from grocery and other retail stores in several provinces in Canada (*23*). Isolates collected by the CIPARS in Montréal, areas of Québec outside Montréal, and parts of Ontario from January 1, 2005, to July 31, 2007, were included as follows. All CIPARS isolates from Montréal were included because all cases of UTI occurred in Montréal (n = 197). All CIPARS nalidixic acid–resistant *E. coli* from all regions of Canada were included (n = 24); these isolates have been associated with reduced susceptibility to fluoroquinolones. Randomly selected susceptible and resistant isolates from outside Montréal, including other regions of Québec and Ontario, were selected to better represent the possible sources of retail meat exposure for the UTI cases. The overall sampling fraction for retail chicken meat-associated isolates was ≈60%, given that our primary hypothesis focused on retail chicken meat. The sampling fraction for retail beef was 20% and for retail pork 20%. A strong association between extraintestinal *E. coli* clonal groups and antimicrobial resistance has been reported (*4,7,9,18*). Our targeted sampling fraction for antimicrobial resistance was 60% for each retail meat category; however, only 25% of retail beef isolates were resistant.

Sampling of *E. coli* from Restaurant/ Ready-to-Eat Food Sources

We included all 74 *E. coli* isolates from restaurant and ready-to-eat food sources for Montréal collected from January 1, 2005, to December 31, 2007, by the Division de l'Inspection des Aliments (*24,25*). These isolates were recovered from a range of prepared and ready-to-eat foods, including meat, fruit, vegetables, and other items. Isolates were collected as part of routine surveillance activities and from complaint-related inspections of restaurants and establishments offering ready-to-eat foods.

Antimicrobial Drug Susceptibility

We determined the minimum inhibitory concentration values for 15 antimicrobial agents for all *E. coli* isolates by the broth microdilution method (*26*), using the Sensititre

Automated Microbiology System (Trek Diagnostic Systems Ltd., Cleveland, OH, USA). National Antimicrobial Resistance Monitoring System (NARMS) susceptibility panel CMV1AGNF was used for *E. coli* testing. Human clinical and restaurant/ready-to-eat isolates were also evaluated for resistance to cephalothin and nitrofurantoin by a standard disk diffusion method (*27*). Isolates were defined as resistant, intermediate, or susceptible according to Clinical and Laboratory Standards Institute and NARMS guidelines (*23*). Isolates exhibiting intermediate resistance were interpreted as susceptible.

Multilocus Variable Number Tandem Repeat Analysis

We performed multilocus variable number tandem repeat analysis (MLVA) on all isolates using capillary electrophoresis methods as described previously in Manges et al. (*28*). Essentially, 8 loci were amplified in separate PCRs by using fluorescent primers. Raw fragment lengths for each locus were binned manually using a minimum threshold of ± 3 bp to distinguish alleles. *E. coli* CFT073, K12, and O157:H7 were used as positive controls. The set of 8 alleles for each isolate was defined as the MLVA profile.

Enterobacterial Repetitive Intergenic Consensus Sequence 2 PCR Fingerprinting

E. coli isolates exhibiting indistinguishable MLVA profiles were compared by enterobacterial repetitive intergenic consensus sequence 2 PCR (ERIC2 PCR) fingerprinting (*29*). Isolates with fingerprints that were indistinguishable on visual inspection were grouped and selected for further typing.

Clonal Group Definition

A clonal group was defined as ≥2 *E. coli* isolates exhibiting indistinguishable MLVA and ERIC2 PCR patterns. We focused only on groups identified by MLVA and ERIC2 PCR that contained members from >1 source. Groups containing isolates from retail meat and restaurant/ready-to-eat food sources were included to determine whether related extraintestinal *E. coli* from retail meat isolates could be identified in prepared food. These groups were given a designation that included the serogroup and multilocus sequence type (MLST), as in serogroup O25:H4 and ST131 (O25:H4-ST131). Selected isolates representing each clonal group were chosen and evaluated by pulsed-field gel electrophoresis (PFGE), serotyping, MLST, and phylogenetic typing to confirm the identities of these clonal groups and to define their within-group variability.

Pulsed-Field Gel Electrophoresis

The standard Centers for Disease Control and Prevention protocol for molecular subtyping of *E. coli* O157:H7 by PFGE was used (*30*). PFGE of *Xba*I- and *Not*I-digested DNA was performed on selected isolates belonging to each clonal group. Isolates exhibiting identical PFGE patterns were considered genetically indistinguishable, those exhibiting 1–3 band differences were considered closely related, and those exhibiting 4–6 band differences were considered possibly related (*31*).

Serotyping

The Public Health Agency of Canada Laboratory for Foodborne Zoonoses performed O- and H-serotyping using established protocols. Isolates that did not react with O antiserum were classified as nontypeable (ONT), and those that were nonmotile were denoted NM.

MLST and Phylotyping

MLST on selected *E. coli* isolates was performed as previously described (*32*). Gene amplification and sequencing were performed by using the primers specified at the *E. coli* MLST website (http://mlst.ucc.ie/mlst/dbs/Ecoli). Allelic profile and sequence type determinations were assigned according to this website's scheme. Determination of the major *E. coli* phylogenetic groups (A, B1, B2, and D) was performed by multiplex PCR (*33*).

Statistical Analyses

Proportions and 95% confidence intervals for proportions were estimated. Differences in proportions were assessed by χ^2 tests; statistical significance was defined as a p value <0.05. All analyses were conducted using Stata version 9.0 (StataCorp LP, College Station, TX, USA).

Results

Final Sample Assembly

We analyzed 844 *E. coli* isolates obtained from human UTIs (n = 353), retail meat (n = 417), and restaurant/ready-to-eat foods (n = 74). Table 1 contains details regarding the year of isolation, geographic location, and specific meat or food source.

Clonal Group Identification and Characterization

Seventeen clonal groups were identified (containing a total of 72 isolates). Eleven groups contained isolates from human infections and retail meat sources; 5 groups contained isolates from retail meat and restaurant/ready-to-eat food sources; and 1 group contained isolates from restaurant/ready-to-eat food and human infections. Fifty-seven representative isolates were selected for evaluation by PFGE, MLST, serotyping, and phylotyping (Table 2).

On the basis of PFGE patterns, we identified 2 clonal groups (group 1 and group 2) that contained genetically indistinguishable isolates and 1 clonal group (group 3)

Table 1. Sources of 844 *Escherichia coli* isolates collected and analyzed in Canada, by year and location, 2005–2007*

Source	Total no. (%) isolates	Year, no. (%) isolates			Location, no. (%) isolates		
		2005	2006	2007	Quebec	Ontario	Other†
Clinical							
UTI	353 (42)	103 (29)	175 (50)	75 (21)	353 (100)	0	0
Retail meat							
All	417 (49)	178 (43)	158 (38)	81(19)	264 (63)	139 (33)	14 (3)
Chicken	253 (61)	107 (42)	101 (40)	45 (18)	141 (56)	99 (39)	13 (5)
Beef	82 (20)	37 (45)	26 (32)	19 (23)	81 (99)	1 (1)	0
Pork	82 (20)	34 (41)	31 (38)	17 (21)	42 (51)	39 (48)	1 (1)
Restaurant/ready-to-eat foods							
All	74 (9)	19 (26)	33 (45)	22 (30)	74 (100)	0	0
Chicken	21 (28)	7 (33)	6 (29)	8 (38)	21 (100)	0	0
Beef	13 (18)	3 (23)	6 (46)	4 (31)	13 (100)	0	0
Pork	5 (7)	0	4 (80)	1 (20)	5 (100)	0	0
Fish/seafood	6 (8)	2 (33)	2 (33)	2 (33)	6 (100)	0	0
Other meat‡	9 (12)	1 (11)	7 (78)	1 (11)	9 (100)	0	0
Other food§	20 (27)	6 (30)	8 (40)	6 (30)	20 (100)	0	0
Total	844 (100)	300 (36)	366 (43)	178 (21)	691 (82)	139 (16)	14 (2)

*UTI, urinary tract infection.
†British Columbia (n = 4) and Saskatchewan (n = 10).
‡Bison, lamb, duck, and snail.
§Fruits (honeydew melon), vegetables, cheese, rice, couscous, and pasta.

that contained closely related isolates from food sources and human UTIs. Group 1 contained *E. coli* characterized as O25:H4-ST131, which was identified in 1 sample of retail chicken meat and in 2 cases of human infection. The *Xba*I PFGE patterns of the human isolate (MSHS 161) and the retail chicken isolate (EC01DT06-1737-01) were indistinguishable, and the second human isolate (MSHS 1134A) differed by 1 band from the other 2 patterns (Figure 1, panel A). The *Not*I PFGE patterns of the 2 human isolates, which were indistinguishable, differed from the retail chicken isolate by a single band (Figure 1, panel B). The retail meat isolate from this group was susceptible to all antimicrobial agents tested, while 1 of the 2 isolates from human infections was resistant to cephalothin and the second was resistant to ampicillin, streptomycin, sulfisoxazole, and tetracycline.

Group 2 contained *E. coli* characterized as O2:H7-ST95; one isolate was from a restaurant/ready-to-eat food source (a honeydew melon) and 8 isolates were from cases of human infection. The *Xba*I PFGE patterns were indistinguishable for 3 of the human infection isolates (MSHS 100, 186, and 811) and the restaurant/ready-to-eat food isolate (68616.01); the other 5 O2:H7-ST95 isolates differed by 1 band (MSHS 1229), two bands (MSHS 95 and MSHS 1062), and 4 bands (MSHS 782 and MSHS 819) from the food source isolate, respectively (Figure 1, panel A). The *Not*I PFGE patterns for MSHS 100 and MSHS 186 were indistinguishable from the restaurant/ready-to-eat isolate, and the other human infection isolates differed by 1 to 7 bands (Figure 1, panel B). The *E. coli* isolate from the food source was fully susceptible, as were most isolates from the human infections, except for 2 (one was resistant to ampicillin, and the second to ampicillin, sulfisoxazole, and trimethoprim/sulfamethoxazole).

Group 3 contained *E. coli* characterized as O114:H4-ST117; one isolate was from retail chicken meat and the second was from a human UTI. The *Xba*I PFGE patterns of the human infection isolate (MSHS 1014A) and retail meat isolate (EC01DT05-0789-01) differed by 5 bands (Figure 2). The *Not*I PFGE patterns differed by >6 bands (Figure 2). Both isolates were fully susceptible. In addition to shared PFGE patterns, these 3 groups of *E. coli* shared the same MLSTs, serotypes, and phylotypes.

The clonal group characterized as *E. coli* O17/O73/O77:H18-ST69, also known as clonal group A (*4*), was identified in human and retail meat samples, although closely related PFGE patterns were not observed (group 4, Table 2). Three other groups (groups 5–7, Table 2), characterized as *E. coli* O4:H5-ST493, O36:NM-ST401, and O172:H16-ST295, exhibited shared MLSTs, serotypes, and phylotypes, but the PFGE patterns were not related.

Discussion

We report the identification of *E. coli* isolates from retail chicken and other food sources that are indistinguishable from or closely related to isolates from human UTIs. Our a priori hypothesis, based on results from previous studies, suggests that retail meat, specifically retail chicken meat, could be a reservoir for *E. coli* causing human extraintestinal infections. This study provides strong support for this hypothesis on the basis of genetic similarities between food and human clinical isolates.

Johnson et al. have proposed that antimicrobial drug–resistant *E. coli* from human feces (and human bloodstream

infections) tend to be more similar to antimicrobial-resistant and -susceptible *E. coli* from retail poultry meat sources (*14,15*). These observations indicate that the selection of resistant *E. coli* is more likely to occur in the animal food reservoir than in humans. In this study, we observed that genetically related *E. coli* from food sources and human infections tended to be susceptible, suggesting that both resistant and susceptible isolates causing UTIs in women may be transmitted through the food supply. Our study also identified members of the O2:H7-ST95 group, previously associated with extraintestinal disease in both humans and avian hosts (*34*). The O2:H7-ST95 food source isolate from this study was from a honeydew melon. Potential origins of this *E. coli* contamination could include human or food animal sources.

The *E. coli* O25:H4-ST131 clonal group, also identified in this study, has been associated with extended spectrum β-lactamase production and fluoroquinolone resistance and has been found across Europe and in Canada (*18,35–37*). The *E. coli* O25:H4-ST131 isolates identified in this study are susceptible; however, because this clonal group may be found in a food animal reservoir and transmitted by

Table 2. Characteristics of *Escherichia coli* clonal groups identified within isolates from 3 types of samples, Canada, 2005–2007*†

Group and strain	Type of sample	Isolate source	Location‡	Year	Genotype			MLST	Serotype
					MLVA	ERIC2	*Xba*I PFGE	ST	
1									
EC01DT06-1737-01	Retail meat	Chicken	Montreal	2006	1.033	33.01	33A.0	131	O25:H4
MSHS 161	Clinical	Human	Montreal	2005	1.033	33.01	33A.0	131	O25:H4
MSHS 1134A	Clinical	Human	Montreal	2007	1.033	33.01	33A.1	131	O25:H4
2									
68616.01	RTE	Honeydew	Montreal	2005	1.018	18.01	18A.0	95	O2:H7
MSHS 100	Clinical	Human	Montreal	2005	1.018	18.01	18A.0	95	O2:H7
MSHS 186	Clinical	Human	Montreal	2005	1.018	18.01	18A.0	95	O2:H7
MSHS 811	Clinical	Human	Montreal	2006	1.018	18.01	18A.0	95	O2:H7
MSHS 1229	Clinical	Human	Montreal	2007	1.018	18.01	18A.1	95	O2:H7
MSHS 95	Clinical	Human	Montreal	2005	1.018	18.01	18A.2	95	O2:H7
MSHS 1062	Clinical	Human	Montreal	2007	1.018	18.01	18A.2	95	O2:NM
MSHS 782	Clinical	Human	Montreal	2006	1.018	18.01	18A.4	95	O2:H7
MSHS 819	Clinical	Human	Montreal	2006	1.018	18.01	18A.4	95	O2:H7
3									
EC01DT05-0789-01	Retail meat	Chicken	Ontario	2005	1.023	23.01	23A.0	117	O114:H4
MSHS 1014A	Clinical	Human	Montreal	2007	1.023	23.01	23A.5	117	O114:H4
EC01DT05-0224-01	Retail meat	Chicken	Ontario	2005	1.023	23.01	23B	117	ONT:NM
EC01DT06-1887-01	Retail meat	Chicken	Montreal	2006	1.023	23.01	23C	117	O143:H4
EC01DT07-0956-01	Retail meat	Chicken	Other	2007	1.023	23.01	23D	117	O53:H4
EC01DT05-1700-01	Retail meat	Chicken	Quebec	2005	1.023	23.01	NT	117	O160:H4
EC01DT07-1050-01	Retail meat	Chicken	Ontario	2007	1.023	23.01	NT	117	O45:H4
EC01DT07-1090-01	Retail meat	Chicken	Montreal	2007	1.023	23.01	NT	117	O24:H4
MSHS 133	Clinical	Human	Montreal	2005	1.023	23.01	NT	117	O24:NM
4									
EC01DT06-0649-01	Retail meat	Pork	Montreal	2006	1.116	116.01	116A	69	O17/73/106:H18
MSHS 719	Clinical	Human	Montreal	2006	1.116	116.01	116C	69	O44:H18
MSHS 956	Clinical	Human	Montreal	2007	1.116	116.01	116D	69	ONT:H18
5									
EC01DT05-1012-01	Retail meat	Pork	Ontario	2005	1.102	102.01	102A	493	O4:H5
MSHS 769	Clinical	Human	Montreal	2006	1.102	102.01	102B	493	O4:H5
6									
EC01DT06-1265-01	Retail meat	Beef	Montreal	2006	2.107	107.01	107A	401	O36:NM
76083.08	RTE	Chicken	Montreal	2007	2.107	107.01	107B	401	O36:NM
7									
EC01DT06-0274-01	Retail meat	Chicken	Quebec	2006	2.097	97.01	97A	295	O172:H16
79287	RTE	Chicken	Montreal	2007	2.097	97.01	97B	295	O172:H16

*MLST, multilocus sequence typing; MLVA, multilocus variable number tandem repeat analysis; ERIC2, enterobacterial repetitive intergenic consensus sequence 2; PFGE, pulsed-field gel electrophoresis; ST, sequence type; RTE, restaurant/ready-to-eat foods; NT, nontypeable; ONT, serogroup nontypeable; NM, non-motile; UNK, unknown. An expanded version of Table 2 containing all isolates is available online at www.cdc.gov/EID/content/16/1/88-T2.htm.

†All isolates in groups 1, 2, and 5 were phylotype B2; all isolates in groups 3, 4, and 8 were phylotype D; all isolates in groups 6, 9, 10, and 11, as well as isolate MSHS 689 in group 17, were phylotype A; all isolates in groups 7, 12, 13, 14, 15, and 16, as well as isolate EC01DT05-0469-01 from group 17, were phylotype B1.

‡Other locations were Saskatchewan or British Columbia.

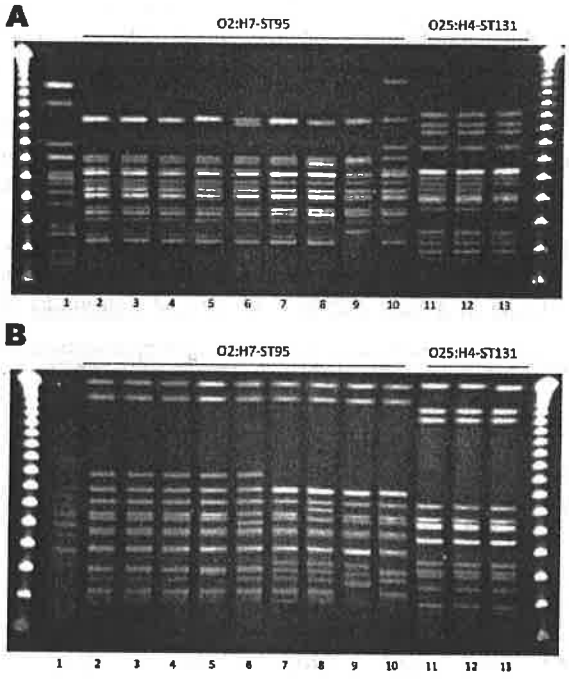

Figure 1. Pulsed-field gel electrophoresis patterns for *Escherichia coli* O2:H7-ST95 and *E. coli* O25:H4-ST131. A) *Xba*I; B) *Not*I. Lane 1 is the positive control *E. coli* O11:H18-ST69 (SEQ102); lane 2 is an *E. coli* O2:H7-ST95 isolate from a restaurant sample of honeydew melon (68616.01); lanes 3–10 are isolates from human urinary tract infection cases (UTIs; lane 3, MSHS 100; lane 4, MSHS 186; lane 5, MSHS 811; lane 6, MSHS 1229; lane 7, MSHS 95; lane 8, MSHS 1062; lane 9, MSHS 782; lane 10, MSHS 819); lane 11 is an *E. coli* O25:H4-ST131 isolate from a retail chicken sample (EC01DT06-1737-01); and lanes 12 and 13 are *E. coli* isolates from human UTIs (lane 12, MSHS 161; lane 13, MSHS 1134A). Outer lanes are pulsed-field molecular weight markers.

food, amplification and transmission of these highly resistant organisms could be possible. Extended spectrum β-lactamase-producing *E. coli* have not yet been identified by CIPARS (*23,38,39*).

This study was ecologic in design and presents several limitations. Epidemiologic information on the UTI cases was not available. Information on travel, history of antimicrobial drug use, dietary information, and other factors would have been useful to describe the study population and to assess the significance of other possible transmission routes that might explain our results. The study also oversampled retail chicken meat and consequently undersampled isolates from retail pork and beef. It is possible that closely related clonal groups could be identified that contain isolates from both human infections and pork or beef samples. Because of insufficient power in our sampling strategy we could not exclude the existence of these groups; additional sampling of isolates from retail pork and beef are underway to address this question. Despite oversampling isolates from retail chicken meat, we observed that 82% (a greater fraction than the 60% sampling fraction) of *E. coli* belonging to the 17 clonal groups were associated with retail chicken meat. We also oversampled antimicrobial drug-resistant isolates; however, most (53%) isolates that belonged to a clonal group were fully susceptible. Even though the size and scope of this study was limited, we were able to detect several instances of groups containing closely related isolates from human and food sources. It is therefore probable that a food reservoir exists and that food-borne transmission of extraintestinal *E. coli* is common.

The identification of 2 clonal groups containing isolates from retail chicken meat and human infections supports our a priori hypothesis. We cannot exclude the possibility that food source isolates were present because of human contamination during food production, processing or handling, even though it is very unlikely. Subsequent research will help determine whether these *E. coli* occur in a food animal reservoir or whether transfer of these *E. coli* results from contamination during food processing or preparation and reflects human-to-human transmission by food.

This study demonstrates that some *E. coli* from retail chicken meat and other food sources are closely related to *E. coli* causing human UTIs. Since a food animal reservoir apparently exists for *E. coli* that cause urinary tract and other extraintestinal infections, this further reinforces the need for responsible antimicrobial drug stewardship in

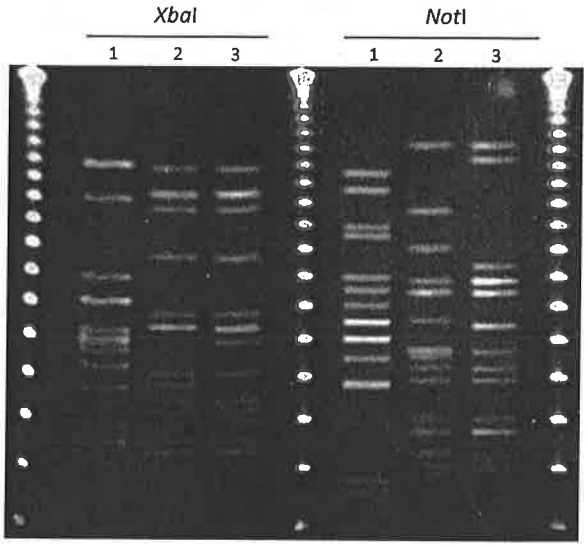

Figure 2. *Xba*I and *Not*I pulsed-field gel electrophoresis patterns for *Escherichia coli* O114:H4-ST117 (lanes 2 and 3). Lane 1 is the positive control *E. coli* O11:H18-ST69 (SEQ102), lane 2 is an *E. coli* O25:H4-ST131 isolate from a retail chicken sample (EC01DT06-1737-01), and lane 3 is an *E. coli* isolate from a human urinary tract infection case (MSHS 1014A). Outer and center lanes are pulsed-field molecular weight markers.

veterinary medicine and food animal production as well as in human medicine.

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Escherichia coli Isolates from Broiler Chicken Meat, Broiler Chickens, Pork, and Pigs Share Phylogroups and Antimicrobial Resistance with Community-Dwelling Humans and Patients with Urinary Tract Infection

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Abstract

Escherichia coli is the most common cause of urinary tract infection (UTI). Phylogroup B2 and D isolates are associated with UTI. It has been proposed that *E. coli* causing UTI could have an animal origin. The objective of this study was to investigate the phylogroups and antimicrobial resistance, and their possible associations in *E. coli* isolates from patients with UTI, community-dwelling humans, broiler chicken meat, broiler chickens, pork, and pigs in Denmark. A total of 964 geographically and temporally matched *E. coli* isolates from UTI patients ($n = 102$), community-dwelling humans ($n = 109$), Danish ($n = 197$) and imported broiler chicken meat ($n = 86$), Danish broiler chickens ($n = 138$), Danish ($n = 177$) and imported pork ($n = 10$), and Danish pigs ($n = 145$) were tested for phylogroups (A, B1, B2, D, and nontypeable [NT] isolates) and antimicrobial susceptibility. Phylogroup A, B1, B2, D, and NT isolates were detected among all groups of isolates except for imported pork isolates. Antimicrobial resistance to three (for B2 isolates) or five antimicrobial agents (for A, B1, D, and NT isolates) was shared among isolates regardless of origin. Using cluster analysis to investigate antimicrobial resistance data, we found that UTI isolates always grouped with isolates from meat and/or animals. We detected B2 and D isolates, that are associated to UTI, among isolates from broiler chicken meat, broiler chickens, pork, and pigs. Although B2 isolates were found in low prevalences in animals and meat, these sources could still pose a risk for acquiring uropathogenic *E. coli*. Further, *E. coli* from animals and meat were very similar to UTI isolates with respect to their antimicrobial resistance phenotype. Thus, our study provides support for the hypothesis that a food animal and meat reservoir might exist for UTI-causing *E. coli*.

Introduction

URINARY TRACT INFECTIONS (UTI) are one of the most common bacterial infections. In the United States, one third of women have at least one physician-diagnosed UTI followed by antimicrobial therapy by the age of 24 (Foxman, 2002). The financial costs, including doctor visits, antimicrobial therapy, hospitalization, and sick days, amount to $1.6 billion for community-acquired UTI in the United States alone (Foxman, 2002). The origin of uropathogenic bacteria has never been investigated in detail despite the impact of UTI on public health and health-care costs (Johnson *et al.*, 2007).

UTI is most often caused by *Escherichia coli* belonging to phylogroup B2, and to a lesser extent phylogroup D (Picard

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et al., 1999; Escobar-Paramo *et al.*, 2004a; Johnson *et al.*, 2005d; Moreno *et al.*, 2008). UTI is generally believed to be caused by bacteria—often the dominant isolate—from the host's own fecal flora (Gruneberg, 1969; Yamamoto *et al.*, 1997; Moreno *et al.*, 2006; Moreno *et al.*, 2008). The origin of these fecal isolates with uropathogenic potential in the human intestine is so far unknown. One hypothesis is that the uropathogenic *E. coli* may originate from contaminated food sources (Ramchandani *et al.*, 2005; Johnson *et al.*, 2005a). Because of the use of antimicrobials in food animals, meat is frequently contaminated with antimicrobial-resistant *E. coli*. In a recent American study, the investigators demonstrated a close resemblance between foodborne *E. coli* and *E. coli* causing UTI and urosepsis (Johnson *et al.*, 2005b). This suggests a possible transmission of *E. coli* via food products. If contaminated meat transmits *E. coli* that can colonize and infect humans, this may have substantial public-health and medical significance. Yet, only a few studies have been performed to evaluate this hypothesis. To our knowledge, most studies have investigated retail meat isolates only and/or human isolates (Ramchandani *et al.*, 2005; Johnson *et al.*, 2005a, 2005b, 2007), or had small sample sizes and little or no epidemiologic data were available (Johnson *et al.*, 2003, 2004, 2006a). Further, geographic and climate factors seem to influence the population structure of *E. coli*, and to our knowledge studies of large strain collections from animals, meat, and humans in Northern Europe are missing (Duriez *et al.*, 2001; Escobar-Paramo *et al.*, 2004b; Escobar-Paramo *et al.*, 2006).

Strains of *E. coli* from animals, meat, community-dwelling humans, and UTI patients were collected in Denmark. The number of isolates, the sampling scheme, and the epidemiological information make this strain collection unique. Using this material it was possible to test the hypothesis of an association between *E. coli* from animals and UTIs in humans. In 2004 up to 80,389 tons of broiler chicken meat and 148,649 tons of pork was consumed in Denmark (population: 5.5 million) (DANMAP, 2004; DANMAP, 2006). The chicken broiler meat and pork constituted the majority of the meat consumption, making this the focus of our study.

In this study, our objective was to investigate the phylogenetic background and antimicrobial resistance profile, and their possible associations in *E. coli* isolates from patients with UTI, community-dwelling humans, broiler chicken meat, broiler chickens, pork, and pigs in Denmark.

Materials and Methods

Source of strains and sampling schemes

The 102 *E. coli* urine isolates were collected from November 2005 to April 2006 in a general practitioner clinic (not associated to any hospital) from patients with community-acquired uncomplicated or complicated UTI. The clinic, which was based south of Copenhagen, consisted of 10 general practitioners serving approximately 10,800 inhabitants. Patients with UTI were included in the study only if they showed typical symptoms of UTI and delivered a midstream urinary sample taken after washing the external urethral meatus with sterile saline, and the urine sample was positive for leucocytes by the dipstick test and revealed at least $\geq 10^3$ CFU/mL of a typical urinary pathogen (Sobel and Kaye, 2005).

In 2004, about 109 fecal *E. coli* isolates were collected from humans in the community (community-dwelling humans) selected through the Danish Civil Registration system (a continuously updated register of all residents in Denmark) (scientific ethics committee approval (KF) 01-006/02) (DANMAP, 2004). Participants invited for the study were chosen by a selection algorithm so that they represented the age and sex distribution of the total Danish population taking the differential participation rates of various demographic groups into account. A total of 988 individuals were invited for the study and 125 confirmed their participation by returning the signed consent form. A total of 109 fecal *E. coli* isolates and questionnaire information on any antibiotics taken were obtained from 109 community-dwelling humans. The questionnaire information was used for interpreting the resistance data on community-dwelling human isolates. All *E. coli* isolates from community-dwelling humans, meat, and animals were collected in 2004 as part of the Danish Integrated Antimicrobial Resistance Monitoring and Research Program (DANMAP, 2004). Meat samples were collected throughout the year at randomly chosen wholesale and retail outlets in all regions of Denmark by the Regional Veterinary and Food Control Authorities, and represented the meat products sold in Denmark in 2004. One isolate was taken from each meat sample. In total, 197 *E. coli* isolates from Danish broiler chicken meat, 86 isolates from imported broiler chicken meat, 177 isolates from Danish pork, and 10 isolates from imported pork were included in the study. Fecal samples from Danish broiler chickens and Danish pigs were collected at slaughter in 2004 according to a stratified random sampling scheme by company staff or the Danish meat inspection staff. The number of samples taken at each slaughter house was proportional to the number of animals slaughtered each year at that slaughter house. The slaughter houses included processed 95% of the broiler chickens and 95% of the pigs slaughtered in Denmark. Samples from broiler chickens were collected weekly and samples from pigs were collected monthly. Only one animal per herd or flock was sampled. One isolate was taken from each sample. A total of 138 and 145 *E. coli* fecal isolates were obtained from broiler chickens and pigs, respectively. The meat from the slaughter houses was distributed nationwide.

Only one isolate per patient, community-dwelling human, meat sample, or food animal was included in this study. The community-dwelling human isolates were identified as *E. coli* using API20E (Biomérieux, France) and the UTI, meat, and animal isolates by indole, citrate, methyl red, and Voges–Proskauer reaction (DANMAP, 2004). The UTI isolates were deliberately sampled later than the community-dwelling human, animal, and food isolates to allow time for consumption of the meat and possible colonization and invasiveness of the *E. coli* isolates.

Determination of phylogroups

The phylogenetic background (A, B1, B2, and D) of all isolates was determined by triplex polymerase chain reaction using three DNA markers (Clermont *et al.*, 2000). Results obtained allowed classification of the isolates into the four major *E. coli* phylogenetic lineages or nontypeable (NT) isolates according to Gordon *et al.*, (A: *yjaA* positive; B1: TSPE4.C2 positive; B2: *chuA* and *yjaA* positive or *chuA*, *yjA*, and TSPE4.C2 positive; D: *chuA* positive or *chuA* and TSPE4.C2 positive; NT: *yjaA*, *chuA*, and TSPE4.C2 negative) (Gordon *et al.*, 2008). *E. coli* strains ECOR 20 (*yjaA*), ECOR 48 (*chuA*),

TABLE 1. ANTIMICROBIAL RESISTANCE FREQUENCIES (%) IN *ESCHERICHIA COLI* ISOLATES FROM URINARY TRACT INFECTION PATIENTS, COMMUNITY-DWELLING HUMANS, BROILER CHICKEN MEAT, BROILER CHICKENS, PORK, AND PIGS

			Broiler chicken meat			Pork		
Compound[a]	*UTI (%)*	*Humans (%)*	*(%)*	*(%)*	*chickens (%)*	*(%)*	*(%)*	*(%)*
Ampicillin	36	24	15	40	17	15	10	27
Chloramphenicol	7	4	1	8	0	2	0	4
Ciprofloxacin	5	1	7	22	12	2	0	1
Streptomycin	33	22	7	33	8	28	30	48
Sulfamethoxazole	33	22	15	45	18	18	40	33
Tetracycline	25	17	8	58	12	27	10	32
Trimethoprim	25	14	3	30	5	10	30	15
Number of isolates	102	109	197	86	138	177	10	145

[a]Gentamicin resistance was not included in the table as only one UTI patient isolate was resistant. All isolates were susceptible to ceftiofur. Some isolates were resistant to more than one antimicrobial.

ECOR 58 (*tspe4.c2*), ECOR 62 (*chuA*, *yjaA*, and *tspe4.c2*) were used as positive controls.

Antimicrobial susceptibility

Susceptibility to ampicillin (1–32 mg/L), ceftiofur (0.5–8 mg/L), chloramphenicol (2–64 mg/L), ciprofloxacin (0.03–4 mg/L), gentamicin (1–32 mg/L), streptomycin (4–64 mg/L), sulfamethoxazole (64–1024 mg/L), tetracycline (2–32 mg/L), and trimethoprim (4–32 mg/L) was determined for all isolates by a micro broth dilution method (Trek Diagnostics Systems, East Grinstead, United Kingdom). The antimicrobial agents tested were chosen because of their use in human antimicrobial therapy of *E. coli* infections. Tetracycline is used mostly in veterinary therapy and was therefore included as a potential marker of antimicrobial resistance from animals. Ceftiufur is used for animals only. However, it was included as a representative for third-generation cephalosporins and could be used to detect possible extended-spectrum beta-lactamase positive isolates. *E. coli* ATCC 25922 was used for quality control. Results were interpreted according to the Clinical Laboratory Standards Institute except for ciprofloxacin data, which were interpreted according to The Danish Reference Group for Antibiotic Susceptibility Testing (NCCLS, 2003; DSKM, 2004). Multiresistant isolates were defined as isolates resistant to three or more of the tested antimicrobial agents.

Statistical analysis

The individual isolate was the unit of statistical analysis. Possible associations between phylogroups and antimicrobial resistance, and the distribution of phylogroups between isolate origins were investigated by comparing proportions using Fisher's exact test (two-tailed) with a significance level of $p \leq 0.05$ (GraphPad Prism 5; GraphPad Software, San Diego, CA).

We analyzed how the *E. coli* isolates clustered within their phylogenetic group (A, B1, B2, D, and NT) according to their antimicrobial resistance phenotype using PROC CLUSTER in SAS 9.2, (SAS Institute, Cary, NC). In the cluster analysis, we used Jaccard's coefficient matching resistance with resistance. Hence, fully susceptible isolates were noninformative and excluded from the analysis. Ward's minimum variance clustering method was used and the number of clusters was based on maximizing the number of resistances shared by all isolates in a cluster. The results were observed in a dendrogram (PROC TREE in SAS 9.2).

Results

Antimicrobial resistance

Ampicillin, chloramphenicol, ciprofloxacin, streptomycin, sulfamethoxazole, tetracycline, and trimethoprim resistance was observed in isolates from all origins except for the isolates from broiler chicken (chloramphenicol susceptible) and imported pork (chloramphenicol and ciprofloxacin susceptible) (Table 1). Gentamicin resistance was only observed in one UTI isolate. Ceftiofur resistance was not detected in any isolates from food animals, meat, community-dwelling humans, or UTI patients. The resistance frequencies toward the tested antimicrobials varied among the different origins (0–58%) (Table 1). Among isolates from patients, community-dwelling humans, Danish and imported broiler chicken meat, Danish and imported pork, and pigs, antimicrobial resistance frequencies were highest for ampicillin, streptomycin, sulfamethoxazole, and tetracycline (Table 1). Among isolates from broiler chickens, antimicrobial resistance frequencies were highest toward ampicillin, sulfamethoxazole, tetracycline, and ciprofloxacin (Table 1). Ciprofloxacin resistance was most frequently observed in isolates from Danish (7%, $n = 13$) and imported broiler chicken meat (22%, $n = 19$) and broiler chickens (12%, $n = 17$) (Table 1). Of note, antimicrobial resistance to all of the antimicrobials tested and multiresistance were detected more frequently in isolates from imported broiler chicken meat compared with Danish broiler chicken meat ($p \leq 0.0004$) (Table 1 and Fig. 1A). Low to moderate frequencies of multiresistance were also observed in isolates from other origins (Fig. 1A). A total of 22% of the imported broiler chicken meat isolates were susceptible to all eight investigated antimicrobial agents. In contrast, 46–66% of the other isolates were fully susceptible (Fig. 1A). Of the 109 community-dwelling humans, two reported having taken antibiotics within 1 month before the sampling, two humans with multiresistant isolates had been in contact with broiler chickens and none with pigs, and most humans reported consuming broiler chicken meat and/or pork several times a week.

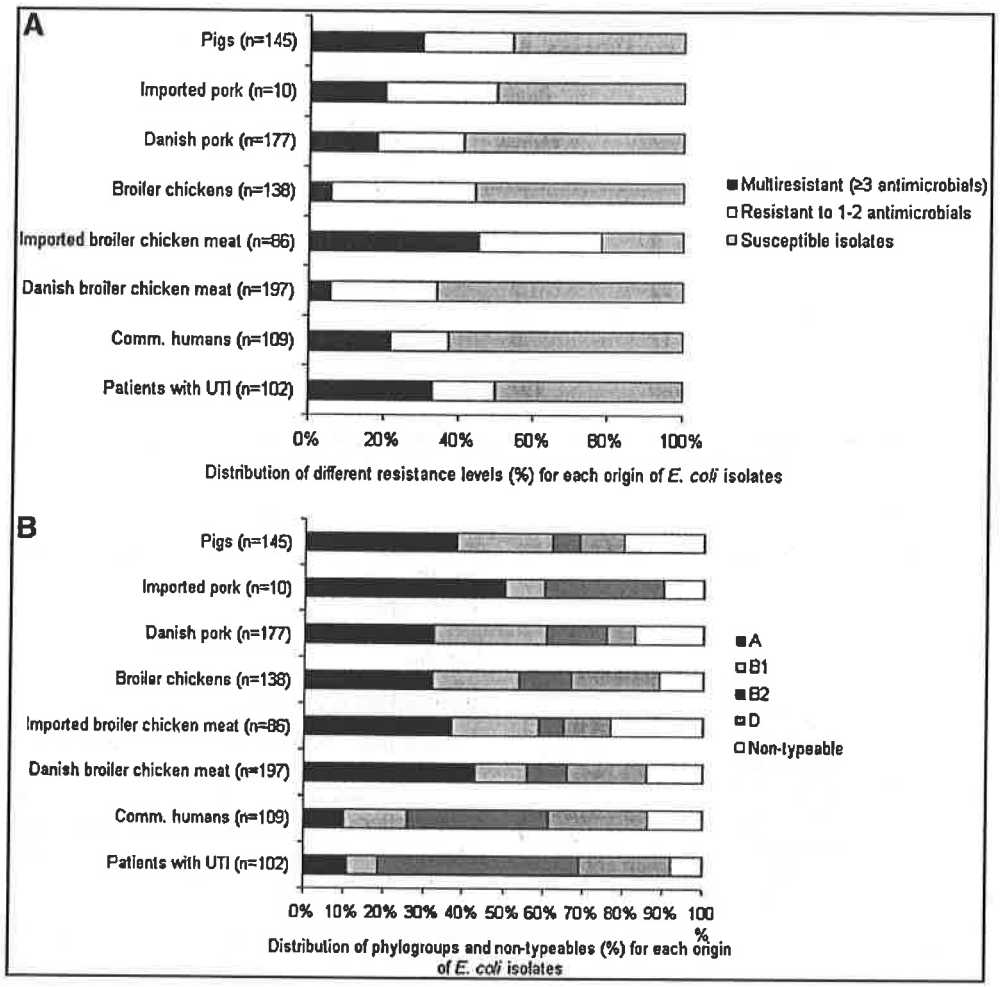


FIG. 1. (**A**) The percentage of fully susceptible *Escherichia coli* isolates, isolates resistant to 1–2 antimicrobials, and multiresistant (≥3 antimicrobials) isolates from each origin of isolates from UTI patients, community-dwelling humans (comm. humans), Danish and imported broiler chicken meat, broiler chickens, Danish and imported pork, and pigs are shown in stacked columns. (**B**) The distribution of phylogroups in all *E. coli* isolates from UTI patients, community-dwelling humans (comm. humans), broiler chicken meat, broiler chickens, pork, and pigs. UTI, urinary tract infection.

Phylogenetic distribution

Isolates belonging to all four major phylogenetic lineages and NTs were found among isolates from all origins except for imported pork isolates, where D isolates were absent among the 10 isolates (Fig. 1B). B2 isolates were the predominant phylogroup among isolates from UTI patients and community-dwelling humans (Fig. 1B). Phylogroup A was the dominant phylogroup among isolates from Danish and imported broiler chicken meat, broiler chickens, Danish and imported pork, and pigs (Fig. 1B). Using Fisher's exact test to analyze proportions, we found that the phylogroups were distributed similarly among isolates from UTI patients and community-dwelling humans ($p = 0.144$). Isolates from Danish and imported broiler chicken meat, and broiler chickens ($p = 0.053$), and isolates from Danish and imported pork, and pigs ($p = 0.055$), respectively, were different in their phylogroup distributions.

Antimicrobial resistance and phylogroups

Disregarding the imported pork isolates due to the low number ($n = 10$), isolates representing phylogroups A, B1, D, and NT isolates from all origins were resistant to one or more of the same five antimicrobial agents (ampicillin, streptomycin, sulfamethoxazole, tetracycline, and trimethoprim) (Fig. 2A, B, D, E). Isolates representing phylogroup B2 were resistant toward one or more of ampicillin, streptomycin, and sulfamethoxazole regardless of origin (Fig. 2C). The antimicrobial resistance patterns observed for the different origins varied from phylogroup to phylogroup or NT group (Fig. 2A–E). Statistical associations between specific phylogroups and specific antimicrobial resistance were investigated using Fisher's exact test. We found significant associations between antimicrobial resistance and phylogroups among isolates from different origins (UTI patients, broiler chickens, Danish and imported pork, and pigs) (Table 2).

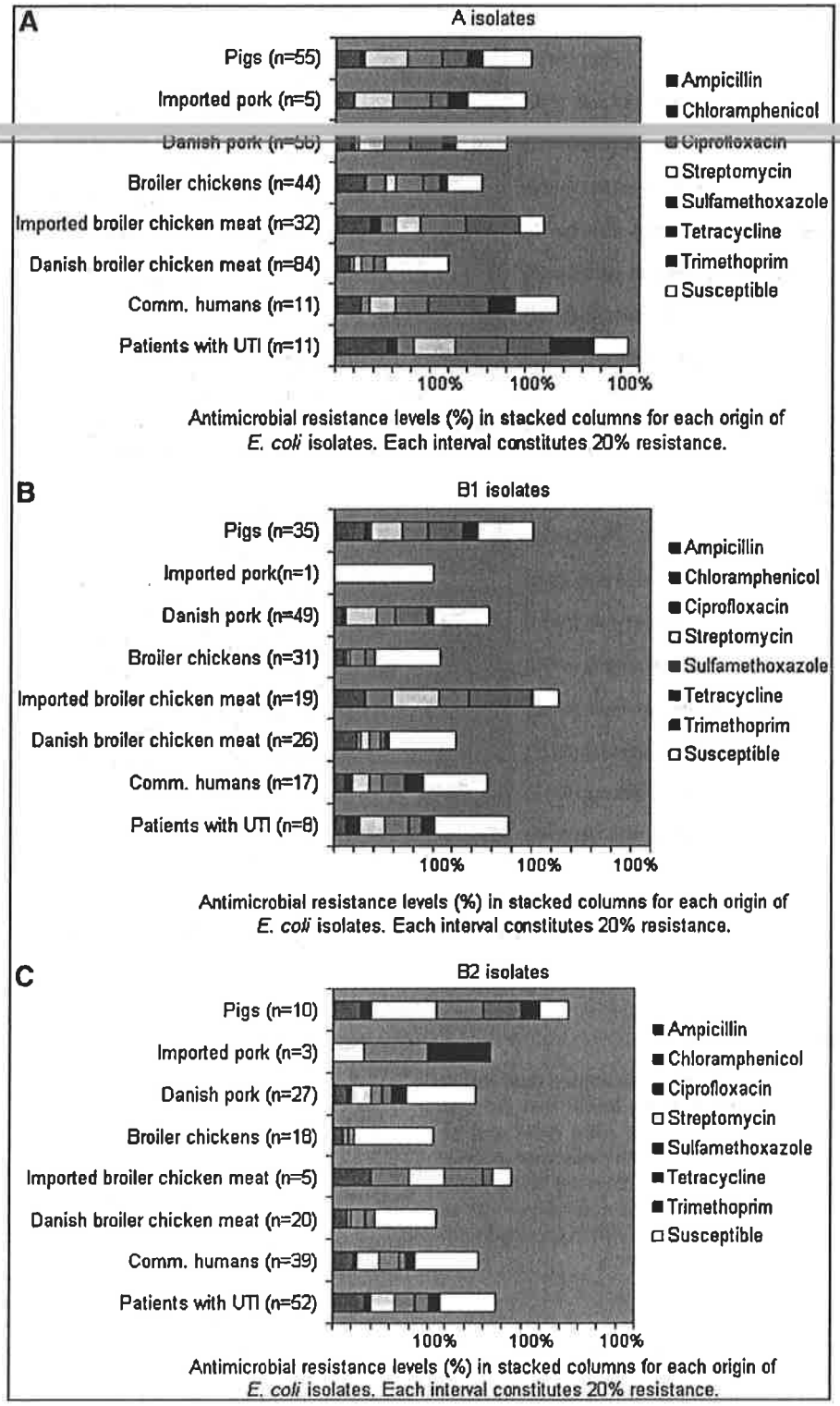


FIG. 2. Antimicrobial resistance frequencies (%) in (A) A, (B) B1, (C) B2, (D) D, and (E) nontypeable (NT) *E. coli* isolates from UTI patients, community-dwelling humans (comm. humans), broiler chicken meat, broiler chickens, pork, and pigs. The resistance frequencies of the seven of nine investigated antimicrobials are stacked in columns, which allows for comparison of resistance frequencies and patterns between the different isolate origins. Gentamicin resistance was not included in the figure as only one UTI patient isolate was resistant. Some isolates were resistant to more than one antimicrobial.

(*Figure continues* →)

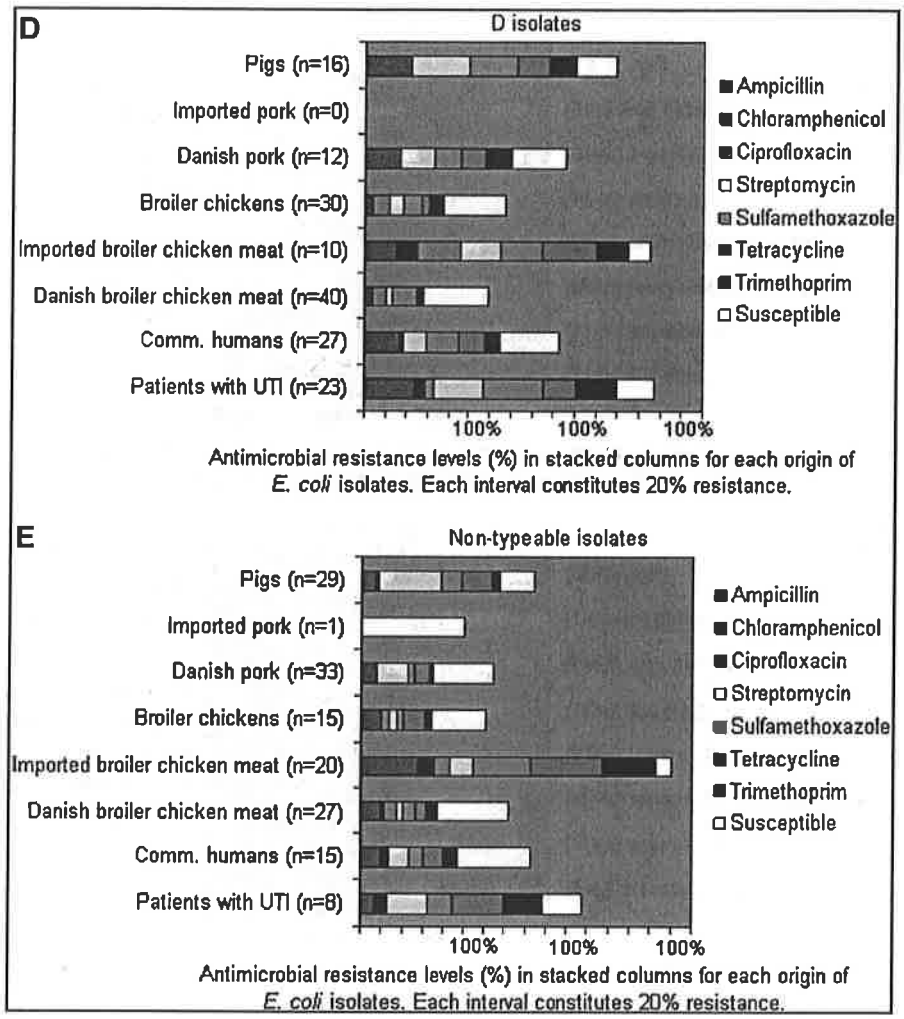


FIG. 2. (*Continued*)

Clustering of isolates

When analyzing the antimicrobial resistance data using Ward's minimum-variance method, we found that the UTI isolates clustered together with isolates from meat and/or animals, indicating similar antimicrobial resistance phenotypes across the reservoirs (Fig. 3A–E). Often the UTI isolates clustered with both broiler chicken/broiler chicken meat as well as pork/pig isolates. UTI isolates also often grouped with isolates from community-dwelling humans.

Discussion

This is the first study to present data on antimicrobial resistance phenotypes and phylogroups of a large collection of animal, meat, community-dwelling human, and human urinary tract *E. coli* isolates obtained from the same geographical region and in the same time period using carefully designed sampling schemes to ensure epidemiological representativeness.

The presence of B2 and D isolates (the phylogroups that are related to UTI) of animal origin in our study with similar resistance patterns to UTI isolates suggests that food animals and meat might be a source of such isolates to humans. Consistent with previous findings, B2 isolates predominated among isolates from patients and community-dwelling humans (Zhang *et al.*, 2002; Johnson *et al.*, 2005c).

Although B2 isolates were present only in low frequencies in food animals and meat (6–15%), B2 isolates are much more successful in colonizing the human intestine than A and or B1 isolates probably due to the virulence genes present in B2 isolates (Picard *et al.*, 1999). It is usually the host's dominant fecal isolate that causes UTI (Gruneberg, 1969; Yamamoto *et al.*, 1997; Moreno *et al.*, 2006; Moreno *et al.*, 2008). Animals and meat may pose a risk for intestinally acquiring *E. coli* of uropathogenic potential. Thus, even low prevalence of B2 isolates (7–30%) among the *E. coli* from broiler chicken meat, broiler chickens, pork, and pigs may pose a risk for acquiring *E. coli*.

It has been suggested that B2 *E. coli* isolates are less resistant to antimicrobial agents than non-B2 isolates (Johnson *et al.*, 2003). We could confirm this for our UTI isolates, Danish and imported pork, and broiler chicken isolates. We could not find any other significant associations for any of the other isolate origins, possibly due to low frequencies of antimicrobial resistance.

TABLE 2. STATISTICAL ASSOCIATIONS BETWEEN ISOLATES BELONGING TO ONE PHYLOGROUP IN RELATION TO *ESCHERICHIA COLI* ISOLATES FROM ALL THE OTHER PHYLOGROUPS

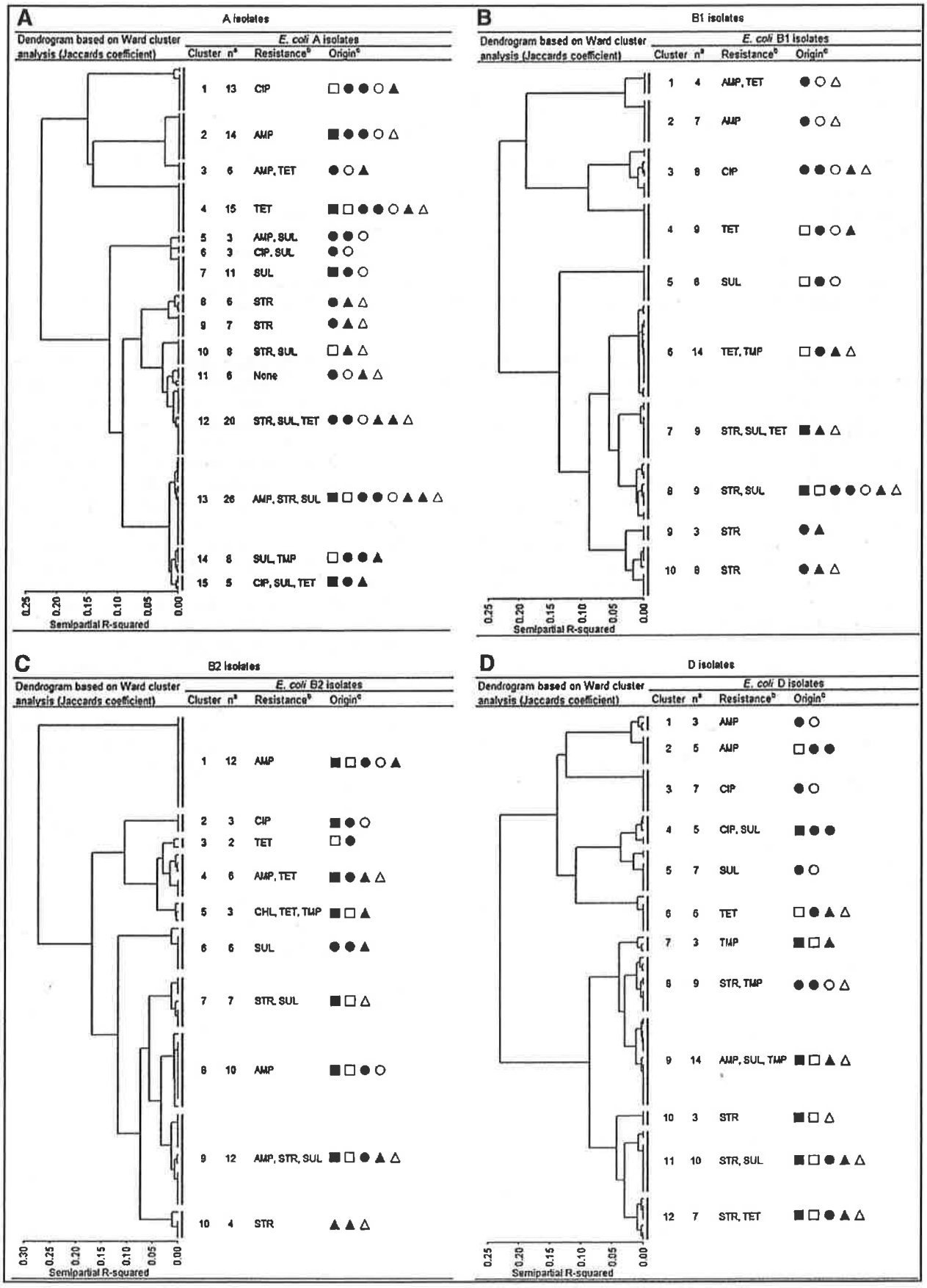
Origin[a]	*Phylogroup*	*Association*[b]
	[illegible]	[illegible]
	B2	SUL^S ($p=0.005$), TRI^S ($p=0.015$), resistance to <3 antimicrobials ($p=0.050$)
	D	SUL^R ($p=0.012$), multiresistance to ≥3 antimicrobials ($p=0.045$)
Broiler chickens	A	AMP^R ($p=0.002$), resistance to ≥1 antimicrobials ($p=0.001$)
	B2	Full antimicrobial susceptibility ($p=0.019$)
Danish pork	B2	TET^S ($p=0.033$)
Imported pork	B2	Full antimicrobial susceptibility ($p=0.048$)
Pigs	B1	Full antimicrobial susceptibility ($p=0.047$)
	D	Multiresistance to ≥3 antimicrobials ($p=0.040$)

[a]Only isolates of the same origin belonging to A, B1, B2, or D were compared. Fisher's exact test was used.
[b]AMP, ampicillin; SUL, sulfamethoxazole; TET, tetracycline; TRI, trimethoprim; R, resistant; S, susceptible.

A minor proportion of the *E. coli* isolates from patients and community-dwelling humans belonged to group A (10–11%) and group B1 (8–16%). Spread of clinical *E. coli* clones belonging to phylogroup A (e.g., ST10 and ST23) and B1 (e.g., ST359 and ST155) have been reported (Oteo *et al.*, 2009). The broiler chicken meat and pork were dominated by A and B1 isolates (56–60%). Consuming broiler chicken meat and pork may therefore more often expose the human intestine to A and B1 isolates than B2 and D isolates, and although A and B1 isolates may be less successful colonizers compared with B2 isolates, A and B1 isolates may predominate the fecal *E. coli* population in community-dwelling humans transiently from time to time (Picard *et al.*, 1999). If we accept the theory of the dominant fecal isolate causing the UTI, then these A and B1 isolates from meat may cause UTI (Gruneberg, 1969; Yamamoto *et al.*, 1997; Moreno *et al.*, 2006, 2008).

Through cluster analysis of the antimicrobial resistance phenotypes of all isolates within the individual phylogroups and the NT isolates, we found that antimicrobial-resistant UTI isolates appeared very similar to resistant meat and animal isolates. This indicates that broiler chicken meat, broiler chickens, pork, or pigs contaminated with antimicrobial-resistant *E. coli* could be a source of resistant isolates in community-dwelling humans and UTI patients. Antimicrobial resistance in *E. coli* from community-dwelling humans was similar to resistance frequencies in Danish broiler chicken meat, broiler chickens, and Danish and imported pork isolates. The antimicrobial resistance in community-dwelling humans was most likely not antimicrobial consumption driven because—to our knowledge—only 2 of 109 community-dwelling humans had received antimicrobial treatment within 1 month before sampling. One of these persons yielded a fully susceptible isolate. A recent case–control study identified frequent chicken and pork consumption as a risk for community-acquired UTI caused by antimicrobial-resistant *E. coli* (Manges *et al.*, 2007), and Corpet concluded that diet was very important for tetracycline-resistant *E. coli* in healthy humans (Corpet, 1988). Most of the community-dwelling humans in this study reported consuming broiler chicken meat and/or pork several times a week. No information on the dietary habits of the UTI patients was available. None of the community-dwelling humans with multiresistant *E. coli* isolates reported being in contact with pigs. Two out of 22 community-dwelling humans yielding multiresistant isolates had been in contact with broiler chickens. Therefore, we assume that if food and food animals were a source of resistant *E. coli* recovered from community-dwelling humans in this study, direct contact accounted for only a small fraction of the transmission. We do not know if the UTI patients had been in contact with animals. Horizontal transfer of antimicrobial resistance between *E. coli* of animal, meat, and human origin was not directly investigated in this study. However, ampicillin, streptomycin, sulfamethoxazole, tetracycline, tetracycline, chloramphenicol and the recently reported plasmid-mediated ciprofloxacin resistances are all shown to transfer horizontally (Johnson *et al.*, 2006b; Kikuvi *et al.*, 2007; Jakobsen *et al.*, 2008; Hawkey and Jones, 2009). Therefore, this mode of transmission is possible.

Our study had some limitations. The UTI patient isolates were limited to one region in Denmark. Further, only one isolate obtained per community-dwelling human, meat sample, and animals was investigated (Lautenbach *et al.*, 2008). The participant rate of community-dwelling humans was lower than expected. The UTI isolates were deliberately sampled later than animal, food, and community-dwelling human isolates. However, since there is limited knowledge on the period from ingestion to a possible episode of UTI, this may influence the relevance of any sampling period for UTI isolates. The cluster analysis was limited to antimicrobial resistance phenotypes only and thus excluded fully susceptible isolates. Further, isolates with similar phenotypic resistance profile may have different genotypic profiles. However, in lack of high trough-put affordable genotyping methods the phenotypes do still provide valuable information. The strengths of this study included the stratified random sampling scheme for food animal, meat, and community-dwelling human isolates, making the distribution of phylogroups and occurrence of antimicrobial resistance representative of the distribution and occurrence in the populations. The sampling of all isolates was carried out during the same time period, with a lag period for the UTI isolates, and across the same geographical area. This approach offers a representative sample of isolates for comparison. This study also included a large sample of isolates across a wider ranger of food animal, meat, and human sources in contrast to previous studies (Johnson *et al.*, 2003, 2004, 2005a, 2005b, 2006a, 2007; Ramchandani *et al.*, 2005).


A
A isolates
Dendrogram based on Ward cluster analysis (Jaccards coefficient)
E. coli A isolates
Cluster n[a] Resistance[b] Origin[c]
1 13 CIP
2 14 AMP
3 6 AMP, TET
4 15 TET
5 3 AMP, SUL
6 3 CIP, SUL
7 11 SUL
8 6 STR
9 7 STR
10 8 STR, SUL
11 6 None
12 20 STR, SUL, TET
13 26 AMP, STR, SUL
14 6 SUL, TMP
15 5 CIP, SUL, TET
0.25 0.20 0.15 0.10 0.05 0.00
Semipartial R-squared
B
B1 isolates
Dendrogram based on Ward cluster analysis (Jaccards coefficient)
E. coli B1 isolates
Cluster n[a] Resistance[b] Origin[c]
1 4 AMP, TET
2 7 AMP
3 8 CIP
4 9 TET
5 6 SUL
6 14 TET, TMP
7 9 STR, SUL, TET
8 9 STR, SUL
9 3 STR
10 8 STR
0.25 0.20 0.15 0.10 0.05 0.00
Semipartial R-squared
C
B2 isolates
Dendrogram based on Ward cluster analysis (Jaccards coefficient)
E. coli B2 isolates
Cluster n[a] Resistance[b] Origin[c]
1 12 AMP
2 3 CIP
3 2 TET
4 6 AMP, TET
5 3 CHL, TET, TMP
6 6 SUL
7 7 STR, SUL
8 10 AMP
9 12 AMP, STR, SUL
10 4 STR
0.30 0.25 0.20 0.15 0.10 0.05 0.00
Semipartial R-squared
D
D isolates
Dendrogram based on Ward cluster analysis (Jaccards coefficient)
E. coli D isolates
Cluster n[a] Resistance[b] Origin[c]
1 3 AMP
2 5 AMP
3 7 CIP
4 5 CIP, SUL
5 7 SUL
6 6 TET
7 3 TMP
8 9 STR, TMP
9 14 AMP, SUL, TMP
10 3 STR
11 10 STR, SUL
12 7 STR, TET
0.25 0.20 0.15 0.10 0.05 0.00
Semipartial R-squared

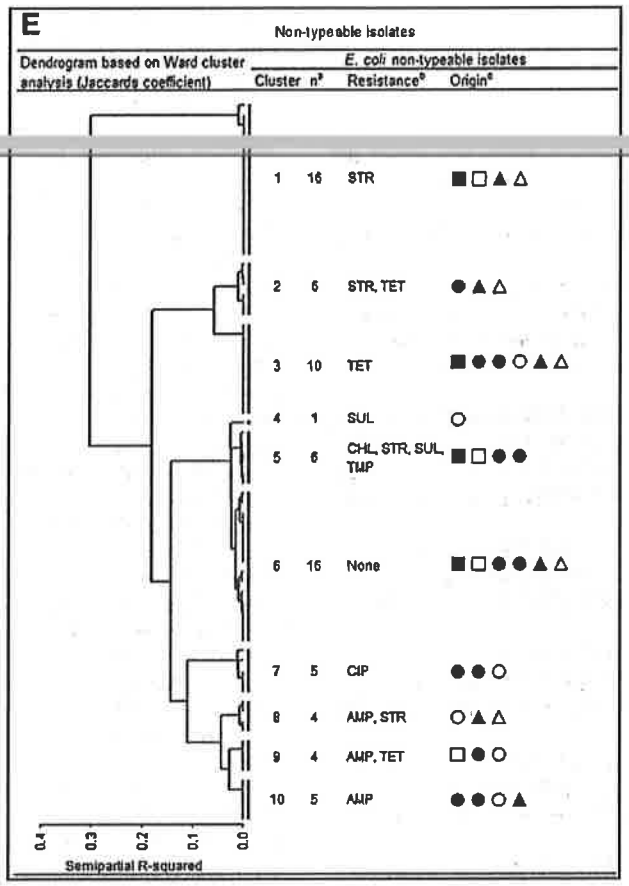


FIG. 3. (*Continued*)

Conclusion

The main finding of this study was detecting B2 and D isolates—the phylogroups that are related to UTI—among isolates from broiler chicken meat, broiler chickens, pork, and pigs that were similar in antimicrobial resistance phenotype to *E. coli* from UTI patients. The cluster analysis proved resemblance of animal and food isolates to UTI isolates. This provides support for the hypothesis that a food animal and meat reservoir might exist for UTI-causing *E. coli* (Ramchandani *et al.*, 2005; Manges *et al.*, 2007; Johnson *et al.*, 2008, 2009a, 2009b; Hannah *et al.*, 2009). Due to the good colonizing abilities of B2, even a low prevalence of such phylogroup isolates in meat and food animals could pose a risk for acquiring uropathogenic *E. coli* gastrointestinally. More studies are needed to confirm that uropathogenic *E. coli* originate from contaminated food and animals and possibly other sources as well (Skyberg *et al.*, 2006; Johnson *et al.*, 2007).

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FIG. 3. Dendrogram (Ward's Minimum-Variance method using Jaccards coefficient) of *E. coli* isolates belonging to the four phylogroups ((**A**) A, (**B**) B1, (**C**) B2, and (**D**) D) and the (**E**) NT isolates from UTI patients, community-dwelling humans, Danish and imported broiler chicken meat, broiler chickens, Danish and imported pork, and pigs showing their relatedness based on their antimicrobial resistance. Fully susceptible isolates were not included in the analysis (a total of 147 A isolates, 109 B1 isolates, 109 B2 isolates, 79 D isolates, and 75 NT isolates were excluded). If all isolates were resistant toward one or more antimicrobials, the resistance was given in the column Resistance. Individual isolates could be resistant to more antimicrobials besides those shared by all isolates in one cluster. Finally, the origin of isolates belonging to the specific clusters was shown. [a]n, number of isolates (fully susceptible isolates were not included in the analysis). [b]AMP, ampicillin; CHL, chloramphenicol; CIP, ciprofloxacin; STR, streptomycin; SUL, sulfamethoxazole; TET, tetracycline; TMP, trimethoprim. [c]Black square, UTI patients; white square, community-dwelling humans; black circle, Danish broiler chicken meat; gray circle, imported broiler chicken meat; white circle, broiler chickens; black triangle, Danish pork; gray triangle, imported pork; white triangle, pigs.

Disclosure Statement

No competing financial interests exist.

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ConsumerReports®

meat on drugs

The overuse of antibiotics in food animals & what supermarkets and consumers can do to stop it

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About Consumer Reports

Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, Auto Test Center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has more than 8 million subscribers to its magazine, website, and other publications. Its advocacy division, Consumers Union, works for health-care reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., in the states, and in the marketplace.

About This Report

This report represents the work of several divisions of Consumer Reports. The nationally representative survey was written and conducted by the Survey Research department, led by Mark Kotkin, Ph.D. CR's "secret shoppers" went into stores across the nation to see whether meat raised without antibiotics was available to consumers with the guidance of Julie Levine, associate director of Product Intelligence. Price and availability data were analyzed by our Statistics Department, led by Michael Saccucci, Ph.D. Labeling research was overseen by Urvashi Rangan, Ph.D., director of the Consumer Safety and Sustainability Group.

The report was researched and written by Meagen Bohne and Jean Halloran. Ms. Bohne is the Campaign Organizer for Consumers Union on food and product safety issues. Jean Halloran, director of Food Policy Initiatives for Consumers Union, has served on the FDA Food Advisory Committee and the National Research Council (NRC) Board on Agriculture and Natural Resources. She served as a member of the NRC Committee on Drug Use in Food Animals that produced the 1999 NRC report "The Use of Drugs in Food Animals: Benefits and Risks."

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meat on drugs
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not USDA-approved, is not helpful because the animal still could have been given antibiotics on a daily basis to prevent disease (just not for growth promotion).

"Grassfed" labels, usually found on beef, can also be useful, but require close scrutiny. If they are coupled with the "organic" label, consumers can be sure the cow was raised without antibiotics. If "grassfed" appears alone, however, antibiotics might have been given. "American Grassfed" and "Food Alliance Grassfed" labels also indicate that in addition to having been raised on grass, the animal in question received no antibiotics, but those products are available in very few stores.

Consumers Union recommends that all supermarkets move toward offering only meat and poultry raised without antibiotics, to be a part of solving a major national health crisis. We also urge consumers to buy these products wherever they can find them.

Background

Antibiotic resistance has become a major health crisis in the United States. "Superbugs"—bacteria that are immune to one or more antibiotics—are on the increase. According to the national Centers for Disease Control and Prevention, some 99,000 people died in 2002, the most recent year for which data are available, from hospital-acquired infections.[1] According to the Infectious Diseases Society of America, the vast majority of these infections were due to antibiotic-resistant pathogens.[2] In 2005, more than 18,000 deaths were attributed to a superbug called Methicillin-Resistant *Staphylococcus aureus* (MRSA).[3] Fifty years ago, such infections were easily treated with antibiotics.[4]

A primary cause of the increase in resistance is the misuse and overuse of antibiotics in both human medicine and livestock production.[5] However, according to an analysis of FDA data by the Center for Science in the Public Interest, 80 percent of all antibiotics sold in the United States are used on animals.[6] Farmers regularly administer low dosages of antibiotics to accelerate growth or to prevent animals from getting sick due to unsanitary and crowded living conditions on factory farms. Because antibiotics are so widely present on the farm, eventually most of the bugs that are vulnerable to the antibiotics are killed off, and only a very small handful of superbugs, ones immune to one or more antibiotics, remain. The superbugs then flourish and spread. The problem of antibiotics resistance cannot be overcome without addressing the huge quantities of antibiotics used on livestock. The superbugs that are immune to antibiotics on the farm exchange genetic material with bacteria elsewhere, leading to antibiotic resistance in hospitals and communities.[7]

Antibiotic resistance is not just a general public health problem. It can affect the individual consumer who gets sick from food. Foodborne illness sickens an estimated 48 million people in the U.S. each year, causing 128,000 hospitalizations and 3,000 deaths, according to the CDC[8]. If a person is sickened by preparing or eating raw or undercooked chicken contaminated with a disease-causing bug such as salmonella, that salmonella is likely to be a superbug, able to withstand one or more antibiotics. When Consumer Reports tested chicken for a January 2010 report, we found that two-thirds of our chicken samples were contaminated with salmonella or campylobacter, another bug that can make people sick, or both, and that more than 60 percent of those organisms were resistant to one or more antibiotics.[9]

Information on how many people actually get sick from superbugs in food is hard to come by since it is not systematically collected by any agency. But the Center for Science in the Public Interest has searched the scientific literature and documented 38 outbreaks between 1973 and 2011 that involved resistant bacteria. Almost half of those (17 of the 38) occurred since 2000.[10]

One of the largest recalls ever involving meat contaminated with an antibiotic-resistant bug occurred in 2011, when Cargill announced that it was recalling 36 million pounds of ground turkey, all produced at a plant in Springdale, Ark.[11] CDC, which was tracking the illnesses for months, eventually linked 136 cases, including one death, to the ground turkey, which carried Salmonella resistant to ampicillin, streptomycin, tetracycline, and gentamicin.[12]

The problem of antibiotic resistance is not new. Alexander Fleming, who discovered penicillin and received the Nobel Prize for that accomplishment, warned in 1945 that misuse of penicillin could result in resistant bacteria.[13] By 1977 the problem was sufficiently well documented that the FDA proposed withdrawing approval for use of penicillin and tetracyclines in animal feed.[14]

However, before the FDA could act, Congress required the FDA to conduct further studies. The agency contracted with the National Academy of Sciences (NAS) to complete a study. Then, in 1980, when the NAS study was done, Congress required more study.[15]

Since then, the combined political power of the factory farming and pharmaceutical industries has effectively thwarted any legislative or regulatory action, and this stranglehold shows no sign of breaking. Despite this, several members of Congress are continuing to push for federal action. In 2007, Representative Louise Slaughter, a microbiologist by training, introduced the Preservation of Antibiotics for Medical Treatment Act (PAMTA) into the House, a bill that would prohibit the use of medically important antibiotics in livestock production.[16] Senator Dianne Feinstein introduced a similar bill last year in the Senate.[17] But as of mid-2012 neither had passed.[18]

In 2010, the FDA said, "In light of the risk that antimicrobial resistance poses to public health, FDA believes that the use of medically important antimicrobial drugs in food producing animals for production purposes ... represents an injudicious use of these important drugs" and promised further action.[19] However, by the spring of 2012, the FDA had not done much more than call on drug companies to voluntarily stop selling antibiotics for growth-promotion purposes in animals.[20] Whether companies will comply remains to be seen.

It is therefore somewhat surprising that the cost of ending the use of antibiotics for growth promotion and disease prevention in livestock would be relatively small in terms of consumer prices. We already have farming systems that do not use antibiotics. All USDA Organic meat and poultry must be produced without use of antibiotics at any point in the animal's lifetime. Antibiotic use for growth promotion was banned in animal feed in Sweden in the 1980s,[21] in Denmark in the 1990s,[22] and in the rest of the European Union in 2006.[23] In the U.S., Perdue states that all its chickens are produced without antibiotics for growth-promotion purposes although the company does not rule out antibiotic use "as directed by our company's team of veterinarians."[24]

One can therefore compare the cost of producing meat in systems that do not use growth promoters with the cost of conventional meat production in the United States.

A 2001 study funded in part by the National Pork Producers Council found that based on the Swedish experience, if antibiotics were no longer added to feed for hogs in the U.S., the cost of producing a 250-pound hog would most likely rise by $5.24.[25] The increased cost to the consumer would be around 5 cents per pound. Given average pork consumption, that amounts to $2.75 per person per year. Subsequent studies came to similar conclusions.[26]

The consumer-price impact of raising chicken without antibiotics in feed or water (though allowing for use to treat individual sick chickens) is even smaller. In fact, a 2010 USDA study found that 44 percent of U.S. chicken producers had, by 2006, already phased out use of antibiotics for growth promotion and disease prevention.[27] A chicken grower gets a very modest 5 cents a pound for the chicken he or she produces. Those who did not use antibiotics as of 2006 were paid a fraction of a cent more than those who used the drugs (5.11 cents versus 4.89 cents). A 2007 study that compared data from 1998 to 2001 on some Perdue chicken facilities that did and did not use antibiotics in feed found that the antibiotic users actually had higher costs, by almost a penny per chicken, than those who did not use antibiotics.[28] Based on those studies, the cost to the consumer of eliminating antibiotics for disease prevention and growth promotion in chicken should be negligible.

According to those studies, there are also benefits to the animals in reducing antibiotic use, because to keep the animals healthy without a continuous supply of drugs, producers need to take proactive steps. For example, they will probably need to delay weaning of piglets by a week and switch to "all in all out" production

systems that allow them to clean a facility thoroughly after a batch of animals is raised to a certain weight.[29]

Small as these costs are to consumers, this is still a big profit center for the pharmaceutical industry. Sales of animal health products to agricultural operations were estimated to total $3.3 billion a year in 1995.[30] That might help explain why drug companies have opposed any ban on use of antibiotics in livestock.

Some livestock producers also oppose a ban. Some may find it much easier to control the spread of disease in dense growing facilities by giving low doses of antibiotics at all times, rather than engaging in frequent clean-outs and the other extra efforts needed to keep animals healthy without drugs. The livestock industry also argues that antibiotic use in animals does no harm. The pork industry recently took out an ad in Roll Call, a newspaper whose main audience is members of Congress and their staffs, that stated since antibiotics have been used in livestock for about 50 years, "if there was going to be an epidemic of resistance related to antibiotic use in agriculture, it would have occurred by now." [31]

However, significant studies of the issue, including a 1988 Institute of Medicine study, "Human Health Risks with the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed,"[32] and the 1999 National Research Council study "The Use of Drugs in Food Animals: Benefits and Risks,"[33] have concluded that there is a connection between antibiotic use in animals and the loss of effectiveness of these drugs in human medicine. The pork industry even argues that antibiotic use helps make food safe.[34] But new studies that have found superbugs in food—MRSA in pork[35] as well as the recent outbreak of salmonella resistant to four different antibiotics, found in ground turkey, which sent more than 100 people to the hospital and caused one death[36]—argue otherwise.

Consumers, and the supermarket chains that sell us our meat and poultry, have a choice. As of 2010, the average American bought and ate about 200 pounds of meat and poultry a year.[37] If supermarkets no longer stocked meat and poultry grown with antibiotics, antibiotic use in livestock production would drop drastically.

At least one large chain, Whole Foods, has already taken this important step. Consumers can shop there confident that any meat or poultry that they buy was raised without antibiotics. In most other stores, consumers can find at least some no-antibiotics meat. Consumers, and the supermarkets they shop at, can fight superbugs and be part of the solution. Together, they can help solve the problem of antibiotic resistance that has eluded government regulators for more than four decades.

Consumer Opinion

To gauge consumer perspective on this issue, the Consumer Reports National Research Center designed a telephone survey to assess consumer concerns and behaviors regarding antibiotics in animal feed. In March 2012, the survey was administered to a nationally representative sample of 1,000 U.S. residents demographically and geographically representative of the U.S. population. Half of the respondents were female, and the median age was 46.

Key findings of the survey included:

- A majority of respondents (86%) agreed that customers should be able to buy meat and poultry raised without antibiotics at their local supermarkets.
- Fifty-seven percent of respondents reported that meat raised without antibiotics is available in the meat section where they usually shop. Of those who do not have it in their local meat section, 82% said they would buy it if it were available.
- More than 60% of respondents stated that they would be willing to pay at least five cents a pound more for meat raised without antibiotics. Over a third (37%) would pay a dollar or more extra per pound.
- The majority of respondents (see table) were extremely or very concerned about issues related to the use of antibiotics in animal feed, including the potential creation of "superbugs" due to overuse of antibiotics, unsanitary and crowded conditions for livestock, human consumption of antibiotic residue, and environmental effects due to agricultural runoff containing antibiotics.
- Respondents were less concerned that limits on the use of antibiotics could cause price increases. Only 44% of all respondents were highly concerned about that issue.

To read the complete findings of our survey click here: **http://notinmyfood.org/document/antibiotics-in-animal-feed**

Widespread use of antibiotics...	% Very/Extremely Concerned
...creating new superbugs that cause illnesses that antibiotics cannot cure	72%
...in livestock feed, allowing them to be raised in crowded and unsanitary conditions	67%
...leaving residues in the meat for human consumption	65%
...in feed leading to antibiotics polluting the environment through agricultural runoff	61%

What Supermarkets Offer

To find out what no-antibiotics meat and poultry products supermarkets are offering to consumers, we looked at company websites, contacted supermarket chains directly, and sent "secret shoppers" into the stores.

Supermarket Store Brands and Policies

We attempted to contact the 13 largest grocery retailers in the U.S. (by total sales)[38] to inquire about any public policies they have regarding the use of antibiotics in livestock and to find out about any store brands of raw beef, pork, chicken, or turkey products their stores carry that were raised without antibiotics (including organic meat). We wrote to the companies in February and March 2012 and asked them to respond within four weeks. We made attempts to follow up with all companies multiple times to ensure that our letter had reached the right person or department and to confirm our deadline. We received responses from six of the 13 companies addressing some or all of our questions: Ahold, Costco, Kroger, Safeway, Trader Joe's, and Whole Foods.

We checked company websites in search of information on policies and products as well, and compared what we found to what shoppers found in the field.

Store Brands

Most supermarkets have their own brands, exclusive to the chain, which generally offer good value and in which they often take special pride. We wondered whether chains would have store brands of meat and poultry that are organic or otherwise raised without antibiotics. We found that most of the supermarket chains have at least one store brand of "no antibiotics" meat or poultry (See Table 1).

The exceptions appear to be Wal-Mart and Meijer. Wal-Mart confirmed by e-mail that its Great Value store brand line does not include a no-antibiotics meat or poultry offering. Meijer did not respond to our requests for information, but our research on its website and our shopper research found no evidence that it has a line of no-antibiotics store-brand meat. But both chains carry other brands of meat and poultry raised without antibiotics, as do many of the other stores we surveyed (see Table 2).

TABLE 1: Store-Brand Meat and Poultry Products Raised Without Antibiotics for the 13 Largest (by Sales) Grocery Retailers

Company	Subsidiaries/ Chains Owned	Store-brand meat without antibiotics or organic
Ahold USA	Giant, Martin's, Peapod, Stop & Shop	Yes (*Nature's Promise*)
Costco	Costco	Yes (*Kirkland*)
Delhaize	Bloom, Bottom Dollar, Food Lion, Hannaford, Harveys, Sweetbay	Yes (*Nature's Place*)
Great Atlantic & Pacific Tea Company	A&P, Food Basics, Food Emporium, Pathmark, SuperFresh, Waldbaum's	Yes (*Green Way*)
H-E-B	Central Market, H-E-B, H-E-B Plus	Yes (*H-E-B Natural*)
Kroger	Baker's, City Market, Dillons, Food 4 Less, Foods Co., Fred Meyer, Fry's, Gerbes, JayC, King Soopers, Kroger, Owen's, Pay Less, QFC, Ralphs, Scott's, Smith's	Yes (Transitioning to *Simple Truth* brand, currently called *Private Selection*)
Meijer	Meijer	No
Safeway	Carrs, Dominick's, Genuardi's, Pavilions, Randalls, Safeway, Tom Thumb, Vons	Yes (*Open Nature* and *O Organics*)
Supervalu	Acme, Albertsons, Cub, Farm Fresh, Hornbacher's, Jewel-Osco, Lucky, Save-A-Lot, Shaw's/Star Market, Shop 'n Save, Shoppers	Yes (*Wild Harvest Natural*)
Publix	Publix	Yes (*GreenWise*)
Trader Joe's	Trader Joe's	Yes (*Trader Joe's All Natural* and *Trader Joe's Organic*)
Wal-Mart	Sam's Club, Walmart	No
Whole Foods	Whole Foods	Yes

SOURCES: COMPANY RESPONSES, COMPANY WEBSITES, AND SHOPPER FINDINGS.

Company Policies

Of the 13 companies we looked at, four—Whole Foods, Trader Joe's, Ahold, and Safeway—indicated to us their store policies regarding the use of antibiotics in livestock production. We were unable to locate policies for any other companies on their websites.

Whole Foods

Whole Foods has an excellent, comprehensive policy to sell only meat and poultry raised without antibiotics. The Whole Foods website states, "Our standards prohibit animal by-products in the animal's feed and both antibiotics and added hormones." The company partners with the Global Animal Partnership, a nonprofit third-party certification program, to verify claims about animal welfare practices made on Whole Foods meat, including its statements about antibiotics. The Global Animal Partnership uses a Five Step Animal Welfare Rating Standard to denote the quality of life of the chickens, pigs, and cows raised for meat.

Whole Foods' policy is strict. Its no-antibiotics stance includes ionophores, a class of antibiotics that is not used by humans but is sometimes given to animals by meat producers who claim not to use antibiotics. The policy also extends to ractopamine, a drug used for growth promotion in livestock that is common in the U.S. but banned in many other countries.

Whole Foods sent us this statement confirming its policy:

> **"We prohibit the use of antibiotics for all of our meat, regardless of whether there is a 5-Step standard for the species or not. There are no exceptions. We prohibit both sub-therapeutic and therapeutic antibiotics. If an animal becomes ill or is injured, we require that the animal is treated and then removed from the Whole Foods Market meat supply. We require records of all medication used so we can be assured our producers are following our standards."**

Trader Joe's

Trader Joe's also has a policy on antibiotics and meat, although it is not as encompassing as Whole Foods'. Trader Joe's organic products exclude antibiotics, as is required by USDA regulations. In addition, its "all natural" products also prohibit antibiotics—something that is not required by the government. Trader Joe's also says that it uses independent auditors to verify compliance with its policies, a very good step. It described its policy as follows:

> **"We not only require our suppliers to abide by governmental regulation but also our own strict standards. Trader Joe's branded raw meat and poultry products labeled 'all natural' or organic must not contain antibiotics in the hatchery, farm, feed, or water at any stage of broiler production for our products. Feed must also be provided by a designated FDA licensed feed mill. Finished feed samples are collected for antibiotics and pesticide residue analysis and evaluated by third party independent labs. Independent third party audits are also conducted to verify an antibiotic free system from hatchery, farm, feed mill and end product. We will not continue doing business with vendors who are not in compliance with these policies."**

Safeway

Safeway has a policy on antibiotics and meat that emphasizes compliance with existing law. Safeway's organic store brand excludes antibiotics, as required by the USDA. However, its Open Nature brand excludes antibiotics as well, and animals produced for the Safeway Rancher's Reserve Beef Program can only get antibiotics twice. Safeway provided the following statement on its policy:

> **"Safeway Inc. is committed to providing safe, wholesome food products and part of that commitment is in support of the responsible use of antibiotics as a health management tool for use with livestock to prevent and treat disease. The use of antibiotics is heavily regulated by the US Food and Drug administration (FDA) and the**

US Department of Agriculture (USDA). Safeway is in support of FDA approved product use in livestock production and supports the FDA's recommended withdrawal time and random residue testing conducted by USDA through the National Antimicrobial Resistance Monitoring System. Antibiotics are administered under the guidance of certified veterinarians or trained personnel who follow regulations set forth by the Animal Medicinal Drug Use Clarification Act and comply with the Judicious Use Guidelines established by the American Veterinary Medical Association. Withholding medicine from sick animals is inhumane and does not comply with our Animal Welfare program however; animals produced for Safeway's Rancher's Reserve Beef Program will be removed from the program if antibiotic treatment is administered more than twice in an animal's life-span."

Ahold USA

Ahold provided a very brief statement of its policy on antibiotics and meat, and did not indicate any special limitations about what is sold in its stores. Ahold does offer the Nature's Promise store brand, which prohibits use of antibiotics. The company said:

"The policy that governs product offerings is to give customers a selection across our major categories and to allow consumers to make informed choices. The clear communication of product attributes is part of our policy."

Shopper Findings

To get more in-depth information about the availability of meat raised without antibiotics at the 13 largest supermarket chains, in March and April 2012 we deployed a Consumer Reports team of "secret shoppers" to survey store meat departments. We wanted to know what products a consumer might find on a typical shopping day, and whether or not their findings were consistent with what the companies told us.

Shoppers were instructed to look for any raw beef, pork, chicken, or turkey product that had a claim about antibiotics or was labeled organic. Shoppers noted the brand, type, and cut of meat, price, and exact wording on the package about antibiotics for each product they reported.

Our 36 shoppers visited 136 grocery stores in 23 states. They reported back on more than 1,000 raw meat and poultry products that carried a claim about antibiotics or were labeled organic. (These products shall be referred to as "no antibiotics" products for the remainder of this report.) States and the number of stores visited were: Arizona (5), California (9), Florida (12), Georgia (2), Idaho (1), Illinois (5), Indiana (3), Maine (1), Massachusetts (11), Maryland (3), Michigan (5), Minnesota (3), North Carolina (4), New Hampshire (3), New York (12), Ohio (4), Oregon (3), Pennsylvania (7), Tennessee (4), Texas (21), Virginia (7), Washington (10), and the District of Columbia (1).

Shoppers visited at least five stores of each of the 13 major supermarket chains. Some companies own many regional subsidiary chains. Our shoppers were able to survey many, but not all, of those stores. Shopper findings represent a snapshot of offerings on the day shoppers visited a particular store and may not be indicative of products offered on other days or at other store branches.

Geographic Availability

The shoppers' experiences varied widely, from stores with entire sections devoted to meat raised without antibiotics to stores that had none. In general, however, meat and poultry raised without antibiotics were available to some degree almost everywhere. Such meat was available in every state we surveyed and in 72 of the 78 cities in which our shoppers surveyed stores.

Chain and Store Availability

Chains and stores varied widely, however, in availability of "no antibiotics" meat and poultry. Of the 136 stores visited, 119 offered at least one beef, chicken, turkey, or pork product in its meat department that had a "no antibiotics" claim of some sort on the package. Seventeen stores had none.

Our shoppers found the widest variety of products at five chains. The broadest range of offerings was at Whole Foods, where everything in the meat section is raised without antibiotics. In addition, all four types of meat and poultry surveyed—beef, pork, chicken, and turkey—were found at Giant, Hannaford, Shaw's, and Stop & Shop. Two of the chains, Giant and Stop&Shop, are subsidiaries of the Netherlands-based multinational company Ahold. Hannaford is a subsidiary of Delhaize, and Shaw's is a subsidiary of Supervalu.

Trader Joe's and Publix markets offered a good selection of chicken, beef, and turkey products without antibiotics, although neither offered any such pork products. However, those companies offered the highest average number of different cuts of meat products (drumsticks, breasts, chops, etc.) per store that were raised without antibiotics.

At the other end of the spectrum, our shoppers found no offerings of organic or other "no antibiotics" meat at four chains: Sam's Club, owned by Wal-Mart (6 stores surveyed); Food Lion, owned by Delhaize (3 stores surveyed); SaveALot, owned by Supervalu (3 stores surveyed); and Food4Less, owned by Kroger (1 store surveyed). In addition, several chains were inconsistent with their offerings—some of their store locations sold "no antibiotics" products while other locations did not. Those chains were Albertsons (Supervalu), HEB, and Tom Thumb (Safeway).

TABLE 2: Average Number and Type of "No Antibiotics" Meat and Poultry Products Offered at the 13 Largest Supermarket Chains and Subsidiaries

Company	Subsidiaries/Chains Owned	Number of Stores Surveyed	Different Products Found	Number Products/ Store	Co. Avg. Products/ Store	Chicken	Turkey	Beef	Pork
Ahold USA					13.2				
	Giant	5	68	13.6		X	X	X	X
	Stop & Shop	6	77	12.8		X	X	X	X
Costco	Costco	12	65	5.4	5.4	X	X	X	
Delhaize					8.4				
	Food Lion	3	0	0					
	Hannaford	4	64	16		X	X	X	X
	Sweetbay	1	3	3		X			
Great Atlantic & Pacific Tea Co.					4				
	A&P	2	11	5.5		X	X	X	
	Food Emporium	1	6	6		X	X	X	
	Pathmark	2	3	1.5		X			
H-E-B	H-E-B	6	46	7.7	7.7	X		X	X
Kroger					9.9				
	Food 4 Less	1	0	0					
	Fred Meyer	4	48	12		X		X	X
	Fry's	1	1	1				X	
	Kroger	7	66	9.4		X		X	X
	QFC	2	30	15		X		X	X
	Ralph's	1	13	13		X		X	X
Meijer	Meijer	5	25	5	5			X	
Publix	Publix	6	98	16.3	16.3	X	X	X	
Safeway					4.1				
	Dominick's Finer Foods	1	9	9		X			X
	Pavilions	1	2	2				X	X
	Randalls	4	18	4.5		X			X
	Safeway	7	35	5		X	*	X	X
	Tom Thumb	2	1	0.5					X
	Vons	1	1	1		X			
Supervalu					4.4				
	Albertsons	7	19	2.7		X		X	
	Cub	1	3	3				X	
	Jewel-Osco	1	4	4		X		X	
	Save-A-Lot	3	0	0					
	Shaw's	4	48	12		X	X	X	X
	Shop 'n Save	1	4	4		X			
	Shoppers	1	5	5		X		X	
Trader Joe's	Trader Joe's	11	191	17.4	17.4	X	X	X	
Walmart					4.1				
	Sam's Club	6	0	0					
	Walmart	11	69	6.3		X	X		
Whole Foods	Whole Foods	5	**	**	**	X	X	X	X

* SAFEWAY'S RESPONSE TO OUR INQUIRY NOTED THAT THE COMPANY OFFERS ORGANIC TURKEYS SEASONALLY.
** ALL MEAT AND POULTRY SOLD AT WHOLE FOODS ARE RAISED WITHOUT ANTIBIOTICS.

Types of Meat and Poultry

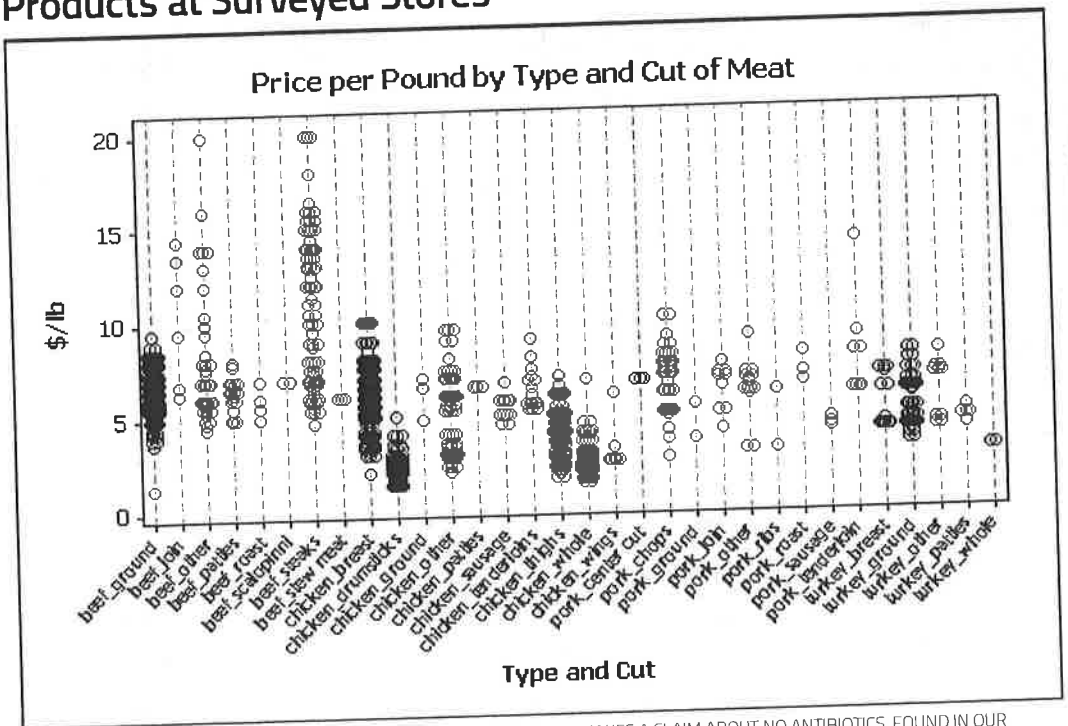
The Consumer Reports shoppers noted 1,158 individual meat and poultry products for sale that made some sort of claim about no antibiotics or were labeled organic in the 136 stores they visited (referred to in this report as "no antibiotics" products). Shoppers noted all beef, chicken, turkey, and pork products with "no antibiotics" labels except at the five Whole Foods stores. At Whole Foods, due to the wide variety of offerings, shoppers made note only of certain cuts. More than 200 of the products noted, or around 20 percent, were USDA organic products, which must by definition be raised without antibiotics (this is usually noted on the label). Most of the products available, however, were not organic but had other labels indicating they were raised without antibiotics—the shoppers noted more than 900 such products.

Chicken was by far the "no antibiotics" product most frequently encountered by our shoppers. Of the 1,158 "no antibiotics" products, more than half were chicken. Beef accounted for about a quarter of the total. Pork and turkey raised without antibiotics were found less often in the stores; shoppers found about 85 of each.

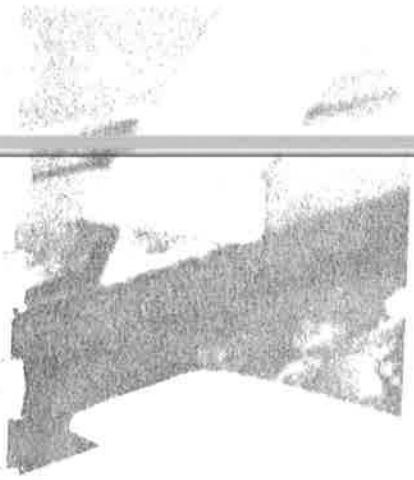
Prices of "No Antibiotics" Products

The Consumer Reports shoppers gathered data on the prices of "no antibiotics" products, including organic meat and poultry, at the 119 stores that carried them. Based on this data, it appears that "no antibiotics" meat and poultry is not as costly as many might assume. While shoppers found beef products priced up to $19.99 per pound for organic steak, virtually all of the "no antibiotics" chicken, turkey, and pork products found in the stores were priced under $10 per pound. Such chicken could be had at three chains—Trader Joe's, Jewel-Osco, and Publix—for as little as $1.29 per pound. Moderately priced "no antibiotics" products (under $5 per pound) were available at almost every chain that carried such meat.

FIGURE 1: Prices of "No Antibiotics" Meat and Poultry Products at Surveyed Stores



EACH CIRCLE REPRESENTS ONE SAMPLE OF MEAT, WITH A LABEL THAT MAKES A CLAIM ABOUT NO ANTIBIOTICS, FOUND IN OUR SHOPPER SURVEY. SHOPPERS VISITED 136 STORES AND FOUND 1158 PRODUCTS. OVERLAPPING CIRCLES APPEAR AS SOLID BARS



The average price of various types of organic and "no antibiotics" meat and poultry in the 13 chains was generally higher than the national average prices of the same type of meat as compiled by the U.S. Department of Labor Bureau of Labor Statistics (BLS). However, for all the cuts of chicken and pork we looked at, at least some stores' prices were equal to or lower than the average cost of the cut as determined by the BLS. For example, while the average price of whole chicken in March 2012 was $1.40 per pound, our shoppers found "no antibiotics" and organic whole chicken for prices ranging from $1.29 to $6.79 per pound. And while the average cost of pork chops was $3.50 per pound, our shoppers found "no antibiotics" and organic pork chops from $2.59 to $9.99 per pound.

In the case of ground beef, all "no antibiotics" and organic products noted by shoppers were above average in price, although some were close to average.

As there are more producers of meat and poultry raised without antibiotics, it is possible that the prices of such products in many stores may ultimately not differ in a major way from current average meat prices. Organic products may remain somewhat more expensive since they must comply with a broad range of environmental standards. But as noted earlier, studies of production facilities have estimated that pork can be produced without antibiotics for approximately 5 cents per pound more than pork grown using antibiotics, and chicken can be produced without using antibiotics for just a fraction of a cent per chicken additional. The cost data from the stores surveyed—which found some prices close to, and in a number of cases lower than, current average prices—bore this out.

TABLE 3: Prices of Five "No Antibiotics" and Organic Products at Stores Visited by CR Shoppers Compared with Average U.S. Price, March 2012 (Bureau of Labor Statistics)

Product & Cut	National Avgerage Price	"No Antibiotics" Minimum Price	"No Antibiotics" Maximum Price
Beef, Gound	$3.66	$3.75	$9.49
Chicken Breast	$3.17	$1.99	$9.99
Chicken Drumsticks	$1.59	$1.29	$4.99
Chicken Whole	$1.40	$1.29	$6.79
Pork Chops	$3.50	$2.59	$9.99

SOURCE: HTTP://WWW.BLS.GOV/RO3/APMW.HTM AND SHOPPER VISITS.

Barriers To Offering More Products

We asked grocery retailers about the limitations that prevent their stores from carrying more (or any) meat products raised without antibiotics. Kroger and Safeway pointed to limited availability, along with consumer cost concerns. Safeway also noted that "because consumer demand for natural and organic items is much higher for the premium cuts (e.g., loin cuts) and lower for the remaining portions, the value proposition is often skewed toward higher priced items."

Trader Joe's said that the company is "always looking to add to our selection of antibiotic free protein items; however, supply, pricing, and product quality have to fit our standards."

Costco stated that the overuse of antibiotics in meat production is a concern but that it is not able to say it doesn't want the use of antibiotics since it doesn't know enough about the claim.

Employee Confusion

It is perhaps due in part to the dizzying array of products and label claims that grocery store workers, when asked, did not always know where to direct shoppers looking for meat raised without antibiotics or offered answers about label claims that were incorrect.

One shopper who asked about a store's selection of meat without antibiotics was offered the explanation that "since chickens were small animals as compared to cows, the need for antibiotics in chickens is not as great." An employee at one store told another shopper that he thought the "all natural" label on their chicken meant no antibiotics were used. Neither of these answers is accurate.

An assistant store manager at one grocery store, when asked by a shopper for meats raised without antibiotics, responded, "Wait, you mean like veggie burgers?"

Reading the Labels

Consumers have a choice. They have the opportunity at many stores to buy meat and poultry that is raised without antibiotics, and thereby help preserve antibiotics for treatment of diseases in people. But doing so requires reading the labels.

Consumer Reports shoppers encountered many different labels related to antibiotics use, and Consumer Reports researchers uncovered a few more. We analyzed them and determined that most of the labels encountered provide meaningful information that consumers can rely on, at least to some degree. A few do not. Two labels to look for: Organic and No Antibiotics Administered. Four to be wary of: Natural, No Antibiotic Growth Promotants, Antibiotic Free, and No Antibiotic Residues.

Labels to Choose

Organic

The "organic" label, widely available in supermarkets, means that many healthful and environmentally sound practices were employed in the production of the food, including no antibiotic use on livestock. The USDA has, in fact, put out hundreds of pages of "do's" and "don'ts" that organic producers must follow to label their food as USDA organic. In addition, adherence to organic rules must be verified by an independent organic certifier via an on-site visit.

Consumers can therefore have a very high level of trust that any meat and poultry labeled "USDA Organic" has never been given any antibiotics at any stage of production.

No Antibiotics Administered (and its Many Variations)

The "no antibiotics administered" label also appears on meat and poultry in many supermarkets, and shows up in many variations. Consumer Reports shoppers in fact found more than 20 different labels about non-use of antibiotics in the stores they visited, including "raised without antibiotics," "never ever given antibiotics," and "humanely raised on family farms without antibiotics" (see box "What's in a Name?").

In general, consumers can rely on "no antibiotics administered" and similar labels, especially if they are accompanied by a "USDA Process Verified" shield. Any label that appears on meat and poultry is required to be approved by the USDA Food Safety and Inspection Service (FSIS), although we did find a few that had not been approved (see below). If a company wants to say "No Antibiotics Administered" on its package, the USDA requires that the company submit an affidavit substantiating that. The USDA told Consumer Reports that the producer must also indicate that it does not use ionophores, another growth-promoting, bug-killing drug, and that the drugs are not being used at any stage in the animal's life, including in the egg in the case of chickens. Variations on the wording are permitted but must be individually approved.

Once a company gets approval, however, the USDA does not routinely check up to see whether the company is actually avoiding antibiotic use as it claims. Nor is there any requirement that producers employ an independent certifier to verify on site that the claim is accurate. Companies can pay to have the USDA Agricultural Marketing

Service verify the claim, in which case they can earn the right to put "USDA Process Verified" on the label. A company can also employ private certifiers to check up. Whole Foods indicates on its website that it employs an independent certifier, the Global Animal Partnership.

Bottom line: Consumers can have a high level of trust in a "no antibiotics administered" or equivalent label if it is "USDA Process Verified" or it is backed up by another independent certifier. Other "no antibiotics" labels may also be meaningful, but consumers cannot be completely certain that such claims are 100 percent guaranteed without any outside verification by a certifier. Consumers may have to check on the supermarket's website to see whether the store's claims are verified by an outside entity.

Labels Not Meaningful with Regard to Antibiotic Use

Natural

The "natural" label appears on many products in many stores. Consumers may think it is the same as organic, or perhaps even better. Unfortunately, that is not the case. It can be unnatural in many ways, including being raised with antibiotics.

The "natural" label in fact has nothing to do with how an animal was raised. The USDA requires only that no coloring or artificial ingredients are added to the final meat or poultry product and that it be "minimally processed" (although salt water can be added). "Natural" meat or poultry products can definitely be given antibiotics in their feed or water while being raised—and can also be raised in confined spaces with thousands of other animals, given hormones and other drugs, fed animal by-products and subjected to many other unnatural practices.

No Antibiotics, with an asterisk

One other label that caused us concern was Naturewell "No Antibiotics*" with a footnote "*as verified by 120 day affidavit" found on Naturewell Natural Beef, sold at Meijer stores. Puzzled about the footnote, we went to Naturewell's website,[39] where on a Frequently Asked Questions page we found the following:

> **What does the statement on your label, "As verified by 120 day affidavit" mean?**
> **It is a common practice in the industry to ensure compliance with program protocols through legal affidavits. ...**
> **Naturewell is a 120-day withdraw program that delivers beef free of antibiotics and added hormones. Naturewell achieves this by prohibiting antibiotic and added hormone use during the final 120 days of feeding, ensuring ample time for any traces to be 100% metabolized out of the animal.**

In other words, this beef is only "No Antibiotics" for the last four months of its life. Since Naturewell indicates that the cattle are generally slaughtered between 18 and 24 months, that leaves 14 to 20 months in which the animals can get antibiotics. We asked the USDA whether this label was approved, and it responded s follows:

> **"Producers/Companies are allowed to make the claim 'raised without antibiotics 120 days prior to finish' without any further explanation. This tells the consumer that the animals may have received antibiotics prior to 120 days ... before slaughter."**

We're concerned, however, that consumers could be confused by this label, especially if they didn't have access to the fine print on the company website while making their purchase at the meat counter.

Grassfed

Shoppers found "grassfed" claims in a number of supermarkets, mainly on organic beef products. Organic grassfed, and two grassfed labels that are not yet widely available in supermarkets, certified by the Food Alliance and the American Grassfed Association, ensure the meat was raised without antibiotics.

USDA requires a meat product that has a "grassfed" label to come from an animal that was fed only grass, but antibiotics can have been given as well. An additional "organic" or verified "no antibiotics administered" label ensures no antibiotic use.

What's In A Name?

OUR SHOPPERS FOUND MANY VARIATIONS IN LABELS ON RAW MEAT AND POULTRY REGARDING THE USE OF ANTIBIOTICS. MOST OF THEM ARE USEFUL GUIDES TO PURCHASING, BUT SEVERAL ARE NOT.

HIGHLY USEFUL LABELS (MEANINGFUL AND VERIFIED)
ORGANIC
NO ANTIBIOTICS ADMINISTERED/ USDA PROCESS VERIFIED

USEFUL LABELS (MEANINGFUL BUT MAY NOT BE VERIFIED)
NO ANTIBIOTICS
NO ANTIBIOTICS EVER
NO ADDED ANTIBIOTICS
NO ANTIBIOTICS ADMINISTERED
NO ADDED ANTIBIOTICS EVER
NO ANTIBIOTICS EVER ADMINISTERED
NO ANTIBIOTICS ADDED
NEVER ANY ANTIBIOTICS ADMINISTERED
NEVER GIVEN ANTIBIOTICS
NEVER EVER ADMINISTERED ANTIBIOTICS
NEVER EVER GIVEN ANTIBIOTICS
HUMANELY RAISED WITHOUT ANTIBIOTICS
HUMANELY RAISED ON FAMILY FARMS WITHOUT ANTIBIOTICS
GROWN WITHOUT ANTIBIOTICS
GROWN WITHOUT THE USE OF ANTIBIOTICS
RAISED WITHOUT ANTIBIOTICS
RAISED WITHOUT ADDED ANTIBIOTICS

NOT USEFUL WITH REGARD TO ANTIBIOTIC USE
NATURAL
NO ANTIBIOTICS* AS VERIFIED BY 120-DAY AFFIDAVIT

UNAPPROVED LABELS
NO ANTIBIOTIC GROWTH PROMOTANTS
ANTIBIOTIC FREE
NO ANTIBIOTIC RESIDUES

Labels Unapproved by the USDA

Antibiotic Free

One label that the USDA specifically states that it never authorizes is "antibiotic-free." It therefore has no clear or consistent meaning in the marketplace and in fact should not appear on meat or poultry.

Given that the USDA never authorizes the "antibiotic-free" claim, we were surprised that several of our shoppers reported seeing an "Antibiotic Free" label on Ranger chicken at QFC and Trader Joe's stores during their surveys. They also spotted that label at a Publix meat counter in front of some steaks. We have reported this to the USDA and asked it to investigate. In the meantime consumers should be aware that there is no USDA definition of "antibiotic-free," and it is not approved by the USDA.

No Antibiotic Residues

Our researchers found a "no antibiotic residues" label on pork products in some stores. When we asked the USDA about it, it said the claim has not been approved.

This label is potentially very confusing. Antibiotics can be heavily used in the growing process for pigs and chickens, but must be withdrawn for a period of days or weeks prior to slaughter, so that residue levels are below FDA tolerance thresholds. Technically, meat could be free of antibiotic residue despite the earlier use of antibiotics. Consumers should be aware that this is not a USDA-approved label and should not appear in the marketplace.

No Antibiotic Growth Promotants

Another problematic label that our shoppers encountered is "No antibiotic growth promotants." Since antibiotics can be used for growth promotion, disease prevention, and treatment of sick animals, it is difficult to know whether antibiotics were used. This label appeared on pork products under the Farmland brand in Fred Meyer, QFC, and Ralphs stores (owned by Kroger). Farmland does not provide any explanation on its website of what it means.[40] When we asked the USDA about it, it said this claim has not been approved. Therefore it should not appear in the marketplace.

"No antibiotic growth promotants" could still mean large quantities of antibiotics are used in the feed and water given pigs if the stated purpose was to prevent disease (the main use in crowded growing facilities). When Consumer Reports checked with Farmland, the company indicated that it indeed used antibiotics for disease prevention. A consumer might think that the product was raised without any antibiotics, when that was in fact not the case.

Although a customer service representative told Consumer Reports that this was an approved label, when we checked, the USDA said that "No antibiotic growth promotants" was not an authorized label. We asked the agency to investigate this label as well.

Recommendations

Consumers Union, the public policy and advocacy arm of Consumer Reports, recommends the following actions for consumers, grocery retailers, the meat and pharmaceutical industries, Congress, and government agencies, to end the use of antibiotics in livestock production except for the treatment of sick animals.

For Consumers

Our findings show that consumers often have access to meat raised without antibiotics in many of their local supermarket chains, and those who don't would like the option. Consumers can make a significant contribution to ending use of antibiotics on animals by shopping at stores that carry meat without antibiotics and buying those products. If a store doesn't offer any of these products (or doesn't carry a preferred type or cut of meat) consumers should request that it do so. A quick conversation with the store manager, or even staff member in the meat department, can go a long way toward changing the store's practices.

Prices for these products are generally higher than conventional meat, especially if they are organic, but there are often more affordable cuts, such as chicken thighs, drumsticks, or whole birds, for shoppers on a budget. Even replacing just one conventionally raised cut of meat with one that was raised without antibiotics on each shopping trip (or even once per month) will help start moving the production system in the right direction.

Consumers must also be diligent label readers. In particular, consumers can have a high level of trust that organic meat and poultry, and meat labeled "no antibiotics" backed by "USDA Process Verified" or another independent certification, are products from animals that were not raised on these drugs. However, consumers should not rely on products with a "Natural" label—that term refers only to treatment of the end product and does not say anything about how an animal was raised. Help with deciphering the many other labels found in supermarkets appears in the "Reading the Labels" section of this report.

For Grocery Retailers

Supermarkets have an opportunity–indeed, an obligation–to be a part of the solution in the face of this growing public health crisis. As the link between livestock producers and consumers, grocery retailers have the capacity to turn the tide on the overuse of antibiotics by requiring that their suppliers avoid these drugs for both growth promotion and disease prevention in food animals. Supermarket chains should make "no antibiotic use on any meat and poultry sold in our stores" company policy.

Recognizing that this transition will not happen overnight, grocery retailers should begin to have conversations with meat suppliers to determine their policies for using antibiotics in raising livestock and urge them to begin phasing out this practice. Beginning with their store brands, retailers should set timetables for transitioning entirely to meat raised without antibiotics.

For Congress

While consumer pressure may be a more immediate catalyst for moving livestock producers away from using antibiotics, a long-term and more permanent legislative or regulatory solution would be ideal. A bill that has been introduced in Congress, the Preservation of Antibiotics for Medical Treatment Act (PAMTA), would prohibit the use of medically important antibiotics in livestock production (except when treating sick animals) and thereby protect the efficacy of these drugs for human use. In light of the public health implications of

losing the efficacy for people of these critical drugs, Congress should pass this legislation immediately.

For the Food and Drug Administration (FDA)

The FDA recognized decades ago the inherent problem with the overuse of antibiotics in livestock production. After years of inaction, the agency in early 2012 issued new guidelines for the livestock and pharmaceutical industries requesting the "judicious use" of antibiotics in animals. However, these guidelines are merely voluntary, and while they attempt to discourage the use of antibiotics for growth promotion in animals, they continue to support the widespread use of these drugs for disease prevention (albeit under the guidance of a veterinarian, which is a step in the right direction). The FDA states it will review these guidelines again in three years to gauge progress and take additional action if needed.

The FDA should strengthen these guidelines and establish a mandatory ban on the use of antibiotics in animal production except to treat sick animals.

For the U.S. Department of Agriculture (USDA)

Consumers who want to buy meat raised without antibiotics should be able to feel secure that the labels on those products are meaningful (i.e. that there is a definition for them) and that their truthfulness is verified by someone. Our shoppers found several instances of labels that could mislead consumers to believe they were buying meat from animals that were not given antibiotics, when in fact that is not necessarily the case. And although the USDA is supposed to approve all labels on meat and poultry packages prior to use, our shoppers and researchers found several unapproved labels in the marketplace.

The USDA should improve its supervision of labels related to antibiotic use in several ways.

The USDA/FSIS currently conducts its reviews behind closed doors and does not disclose what specific labels it has authorized or which companies have been authorized to use them. The USDA should post on its website all authorized labels, the products they are authorized for, and the label definition, to help consumers understand the labels.

The USDA should establish one approved phrasing for such labels, such as "no antibiotics ever used," and restrict all labels to that usage. That would significantly reduce consumer confusion.

The USDA should establish a formal standard defining this label (the USDA indicated to Consumer Reports that it does not allow use of ionophores and prohibits antibiotic use at any stage of an animal's life, if meat is to carry a "no antibiotics" label, but the full definition is not published on its website). This would help both companies and consumers understand label requirements and facilitate better enforcement.

The USDA should check up on "no antibiotics" labels to verify their truthfulness, and take action against labels that do not conform to its established definitions.

For the Meat and Poultry Industries

Giving cattle, pigs, turkeys, and chickens antibiotics in their food and water to improve their growth and prevent disease has become standard practice, especially at very large feedlots and mass-production facilities. For the sake of preserving these drugs for treatment of sick people, it is imperative for meat and poultry producers to stop treating animals with these drugs prophylactically and for growth promotion. In doing so, they will take a step toward solving the public health problem of antibiotic resistance and decrease the chance of "superbug" infection outbreaks.

The livestock industries in many other countries have already transitioned away from the use of antibiotics in food animals without detriment to production or sales. U.S. meat producers should follow suit.

For the Pharmaceutical Industry

To keep antibiotics effectively working to treat infections, there must be limits on their use for non-essential purposes. As the developers and manufacturers of these drugs, the pharmaceutical industry has a responsibility to limit their use in animals.

The FDA recently called on the drug industry to cease marketing antibiotics for use in animal feed and water for the purpose of growth promotion. Consumers Union fully supports this request. However, we urge the industry to go further and to cease selling antibiotics for disease prevention in animals. Drug companies would never market antibiotics to humans for routine continuous use to prevent disease or promote growth, without a prescription, nor should they continue this practice for animals. We call on the pharmaceutical industry to limit antibiotic sales to the livestock industry solely for therapeutic use on sick animals.

ENDNOTES

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Published on *Whole Foods Market* (http://www.wholefoodsmarket.com)

Our Meat: No Antibiotics, Ever

Body:

Whole Foods Market President and Chief Operating Officer A.C. Gallo is committed to sustainable agriculture and fostering the growth of foods with the purest ingredients.

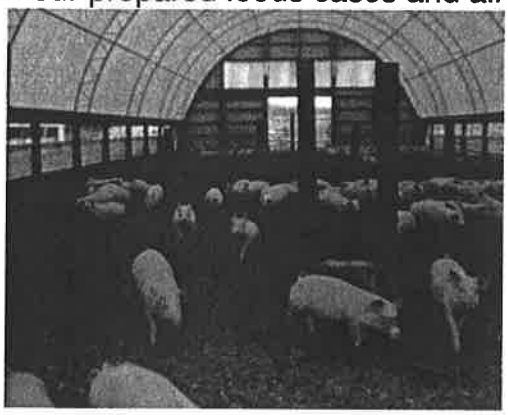
There's a good chance you've heard about or seen a story on the news lately about a leading consumer organization's report on the widespread use of antibiotics in the US meat supply.

A recent nationwide poll conducted by the Consumer Reports National Research Center states that "the majority of respondents were extremely or very concerned about issues related to the use of antibiotics in animal feed, including the potential creation of superbugs due to overuse of antibiotics, unsanitary and crowded conditions for livestock, human consumptions of antibiotic residue, and environmental effects due to agricultural runoff containing antibiotics. 86% of consumers indicated they thought that meat raised without antibiotics should be available in their local supermarket."

At Whole Foods Market, our standard is clear: No antibiotics, EVER!

We have worked with our suppliers to make sure that the people who produce our meat have raised their animals without the use of antibiotics, growth hormones* or animal byproducts in the

feed. This includes not only the fresh and frozen meat in our meat departments but also all meat used in our prepared foods cases and all meat used in our own store brand products that contain meat.



For the past 60 years antibiotics have been used to create efficiencies in meat production. Antibiotics are added to the animals' feed or water to prevent infection that can occur when animals are crowded in confined areas.

As well, antibiotics and hormones are given in this manner to promote rapid growth. For instance, conventionally raised cattle are ready for market in about 16 months, while cattle raised without antibiotics and hormones don't leave the farm until they're 20 to 24 months old. The extended growth period is a more expensive prospect for a farmer or rancher, but one we feel is well worth it.

At Whole Foods Market, finding farmers who go the extra mile and raise their animals without depending on antibiotics is simply what we do. We visit our North American farms and ranches to make sure they meet our standards. We prohibit both sub-therapeutic and therapeutic antibiotics, and we require records of all medication used. If an animal becomes ill or is injured, we require that the animal is treated and then removed from our North American meat supply.

We have been concerned for many years about issues with using antibiotics in farm animals and have worked hard to help our suppliers develop growing practices that eliminate the use of antibiotics while still insuring healthy animals. Our producers adopt practices such as giving the animals more room, keeping their living areas cleaner, allowing more access to the outdoors and to pasture, and feeding them a healthy diet that does not allow the use of any animal byproducts.

They also have to monitor the health of the animals much more carefully and insure that if there are any health issues, they are dealt with immediately versus waiting until there is a bigger

problem with the entire herd.

The overall benefits to the animals are significant as their overall welfare and health are improved. I hope you'll visit your local Whole Foods Market and ask our in-store butchers about our meat – the best-tasting beef, pork and poultry you'll find in a grocery store and no antibiotics. EVER!

**Federal regulations prohibit the use of growth hormones in raising pigs, veal calves, bison and poultry.*

Source URL: http://www.wholefoodsmarket.com/blog/whole-story/our-meat-no-antibiotics-ever-0

USDA United States Department of Agriculture
Food Safety and Inspection Service

About FSIS

MISSION STATEMENT: The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

Advisory Committees
FSIS manages the National Advisory Committees on:

- Meat and Poultry Inspection (NACMPI)
- Microbiological Criteria for Foods (NACMCF)

Congressional Testimony (Mar 13, 2013)
Learn more about the status of FSIS programs and policies to ensure food safety from these statements by the Administrator and Under Secretary.

Faces of Food Safety
Consumer confidence in our food supply comes as a result of the work of the men and women of FSIS. "Faces of Food Safety" introduces you to employees who play a key role in making our food safe.

Structure & Organization

More

Provides frontline contact information as well as a listing of the different offices that make up the Food Safety and Inspection Service.

Faces of Food Safety

More

Meet some of our FSIS employees—men and women who play a vital role in making our food safe.

FSIS Biographies

More

Contains the biographies of FSIS leadership.

Associated Agencies & Partners

More

This page lists FSIS' partners in securing the safety of the American food supply.

Cooperative Agreements

More

FSIS strengthens its public health capabilities and support for food safety innovation through the funding of cooperative

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agreements.

Agency History

More

This section notes milestones in FSIS' evolution, from the early days of USDA through passage of the Federal Meat Inspection Act (FMIA) and other Acts to the creation of a modern science-based inspection system.

Strategic Planning

More

Like all organizations, FSIS uses the strategic planning process to pave the way for meeting organizational goals and objectives over a future period of time.

Last Modified: May 2, 2013

Fact Sheets

Food Labeling

Meat and Poultry Labeling Terms

"What does 'mechanically separated meat or poultry' mean?"
"If chicken is labeled 'fresh,' how can it be so rock hard?"
"Does 'natural' mean 'raised without hormones'?"

These are just some of the questions consumers have asked USDA's Meat and Poultry Hotline about words which may be descriptive of meat and poultry. Can they be legally used on labels and, if so, what are their definitions?

Here from USDA's Food Safety and Inspection Service (FSIS) is a glossary of meat and poultry labeling terms. FSIS is the agency responsible for ensuring the truthfulness and accuracy in labeling of meat and poultry products. Knowing the meaning of labeling terms can make purchasing of meat and poultry products less confusing.

- BASTED or SELF BASTED
- CERTIFIED
- CHEMICAL FREE
- FREE RANGE or FREE ROAMING
- FRESH POULTRY
- FROZEN POULTRY
- FRYER-ROASTER TURKEY
- HALAL and ZABIAH HALAL
- HEN or TOM TURKEY
- KOSHER
- "MEAT" DERIVED BY ADVANCED MEAT/BONE SEPARATION AND MEAT RECOVERY SYSTEMS
- MECHANICALLY SEPARATED MEAT
- MECHANICALLY SEPARATED POULTRY
- NATURAL
- NO HORMONES (pork or poultry)
- NO HORMONES (beef)
- NO ANTIBIOTICS (red meat and poultry)
- ORGANIC
- OVEN PREPARED
- YOUNG TURKEY

BASTED or SELF BASTED:
Bone-in poultry products that are injected or marinated with a solution containing butter or other edible fat, broth, stock or water plus spices, flavor enhancers and other approved substances must be labeled as basted or self basted. The maximum added weight of approximately 3% solution before processing is included in the net weight on the label. Label must include a statement identifying the total quantity and common or usual name of all ingredients in the solution, e.g., "Injected with approximately 3% of a solution of _____ (list of ingredients)."

Use of the terms "basted" or "self-basted" on *boneless* poultry products is limited to 8% of the weight of the raw poultry before processing.

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CERTIFIED:
The term "certified" implies that the USDA's Food Safety and Inspection Service and the Agriculture Marketing Service have

Fact Sheets
- Safe Food Handling
- At-Risk Populations
- Meat Preparation
- Poultry Preparation
- Egg Products Preparation
- Seasonal Food Safety
- Appliances & Thermometers
- Foodborne Illness & Disease
- Emergency Preparedness
- FSIS Programs & Workforce
- Production & Inspection
- Food Labeling

officially evaluated a meat product for class, grade, or other quality characteristics (e.g., "Certified Angus Beef"). When used under other circumstances, the term must be closely associated with the name of the organization responsible for the "certification" process, e.g., "XYZ Company's Certified Beef."

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CHEMICAL FREE:
The term is ***not allowed*** to be used on a label.

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FREE RANGE or FREE ROAMING:
Producers must demonstrate to the Agency that the poultry has been allowed access to the outside.

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FRESH POULTRY:
"Fresh" means whole poultry and cuts have never been below 26 °F (the temperature at which poultry freezes). This is consistent with consumer expectations of "fresh" poultry, i.e., not hard to the touch or frozen solid.

In 1997, FSIS began enforcing a final rule prohibiting the use of the term "fresh" on the labeling of raw poultry products whose internal temperature has ever been below 26 °F.

The temperature of individual packages of raw poultry products labeled "fresh" can vary as much as 1 °F below 26 °F within inspected establishments or 2 °F below 26 °F in commerce.

Fresh poultry should always bear a "keep refrigerated" statement.

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FROZEN POULTRY:
Temperature of raw, frozen poultry is 0 °F or below.

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FRYER-ROASTER TURKEY:
Young, immature turkey usually less than 16 weeks of age of either sex.

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HALAL and ZABIAH HALAL:
Products prepared by federally inspected meat packing plants identified with labels bearing references to "Halal" or "Zabiah Halal" must be handled according to Islamic law and under Islamic authority.

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HEN or TOM TURKEY:
The sex designation of "hen" (female) or "tom" (male) turkey is optional on the label, and is an indication of size rather than the tenderness of a turkey.

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KOSHER:
"Kosher" may be used only on the labels of meat and poultry products prepared under rabbinical supervision.

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"MEAT" DERIVED BY ADVANCED MEAT/BONE SEPARATION AND MEAT RECOVERY SYSTEMS:
The definition of "meat" was amended in December 1994 to include as "meat" product derived from advanced meat/bone separation machinery which is comparable in appearance, texture and composition to meat trimmings and similar meat products derived by hand. Product produced by advanced meat

recovery (AMR) machinery can be labeled using terms associated with hand-deboned product, e.g., "beef" or "pork" trimmings and ground "beef" or "pork." The AMR machinery cannot grind, crush or pulverize bones to remove edible meat tissue and bones must emerge essentially intact. The meat produced in this manner can contain no more than 150 milligrams of calcium per 100 grams product. Product that exceeds the calcium content limit must be labeled "mechanically separated beef or pork."

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MECHANICALLY SEPARATED MEAT
is a paste-like and batter-like meat product produced by forcing bones with attached edible meat under high pressure through a sieve or similar device to separate the bone from the edible meat tissue. In 1982, a final rule published by FSIS on mechanically separated meat said it was safe and established a standard of identity for the food product. Some restrictions were made on how much can be used and the type of products in which it can be used. These restrictions were based on concerns for limited intake of certain components in MSM, like calcium. Due to FSIS regulations enacted in 2004 to protect consumers against Bovine Spongiform Encephalopathy, mechanically separated beef is considered inedible and is prohibited for use as human food. However, mechanically separated pork is permitted and must be labeled as "mechanically separated pork" in the ingredients statement.

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MECHANICALLY SEPARATED POULTRY
is a paste-like and batter-like poultry product produced by forcing bones with attached edible tissue through a sieve or similar device under high pressure to separate bone from the edible tissue. Mechanically separated poultry has been used in poultry products since 1969. In 1995, a final rule on mechanically separated poultry said it would be used without restrictions. However, it must be labeled as "mechanically separated chicken or mechanically separated turkey" (depending on the kind of poultry used) in the ingredients statement. The final rule became effective November 4, 1996.

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NATURAL:
A product containing no artificial ingredient or added color and is only minimally processed. Minimal processing means that the product was processed in a manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term natural (such as "no artificial ingredients; minimally processed").

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NO HORMONES (pork or poultry):
Hormones are not allowed in raising hogs or poultry. Therefore, the claim "no hormones added" **cannot be used** on the labels of pork or poultry unless it is followed by a statement that says "Federal regulations prohibit the use of hormones."

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NO HORMONES (beef):
The term "no hormones administered" **may** be approved for use on the label of beef products if sufficient documentation is provided to the Agency by the producer showing no hormones have been used in raising the animals.

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NO ANTIBIOTICS (red meat and poultry):
The terms "no antibiotics added" may be used on labels for meat or poultry products if sufficient documentation is provided by the producer to the Agency demonstrating that the animals were raised without antibiotics.

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ORGANIC:
For information about the National Organic Program and use of the term "organic" on labels, refer to these factsheets from the USDA Agricultural Marketing Service:

- Organic Food Standards and Labels: The Facts
- Labeling and Marketing Information (PDF Only)

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OVEN PREPARED:
Product is fully cooked and ready to eat.

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YOUNG TURKEY:
Turkeys of either sex that are less than 8 months of age according to present regulations.

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Last Modified: April 12, 2011

FSIS Statutes and Your Role

OBJECTIVES

Once you complete this module, you should be able to:

1. Understand the purpose of the Acts.
2. Identify key definitions from the Acts.
3. Understand the statutory authority for FSIS activities.
4. Understand how those activities plus authorities in the statutes support enforcement actions.

REFERENCES

1. Federal Meat Inspection Act
2. Poultry Products Inspection Act

IINTRODUCTION

The "Regulatory Framework" module provided an overview of the regulatory framework under which we operate in FSIS. This module will provide more detail about that regulatory framework and the statutory authority for day to day inspection, and verification activities.

Once you complete this module, you should be able to:

- Understand the purpose of the Acts.
- Identify key definitions from the Acts.
- Understand the statutory authority for FSIS activities.
- Understand how those activities; plus authorities in the statutes, support enforcement actions.

As we go through this module, keep in mind the inspection and verification activities you performed or supervised while in the plant working along side your mentor. Feel free to ask questions as we go. It's important for us to discuss some practical examples of how the statutory authorities apply to your work.

Overview of the Statutes

The statutes related to FSIS activities include the:

- Federal Meat Inspection Act (FMIA),
- Poultry Products Inspection Act (PPIA), and
- Egg Products Inspection Act (EPIA).

The FMIA was enacted first, in 1906 after the public outrage stirred up by the writings of Upton Sinclair's book, "The Jungle." How many of you are familiar with this book? It

contained graphic and detailed descriptions of the insanitary and abhorrent conditions that existed in meat plants at the turn of the century in the city of Chicago, which was the heart of the meat processing industry at the time. Excerpts from the book were published in newspapers. With this information as a background, Congress enacted the FMIA. The PPIA was modeled after the FMIA. When you read it, you will see a number of similarities between the two statutes. The PPIA enacted in 1957, was based on the growing poultry industry. Initially, there were two separate Agencies – one responsible for enforcing the provisions of the FMIA and one responsible for enforcing the provisions of the PPIA. This explains why, in some cases, establishments that process both meat and poultry products have two establishment numbers. We will not be covering the EPIA in our review.

Basis for FSIS as a Public Health Regulatory Agency

These Acts provide for the basis for FSIS's ability to perform as a public health agency. In Section 602 of the FMIA, Congressional statement of findings, states the following:

> **FMIA Sec. 602.** *"Meat and meat food products are an important source of the Nation's total supply of food. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed are wholesome, not adulterated and properly marked, labeled, and packaged. It is hereby in found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers."*

These three things - verifying that meat or poultry products are:

1. wholesome,
2. not adulterated,
3. properly marked/labeled, and packaged

are the essentials of the job you have in protecting public health. All of your inspection and verification activities focus around one or more of these things that are covered in the Acts.

The Congressional statement of findings in the Poultry Products Act (Section 451) is almost identical to that of the FMIA. Again, it emphasizes public health, and it emphasizes the four essentials – wholesome, not adulterated, properly marked/labeled, and packaged. We'll be going into each of these in more detail as we continue.

> **PPIA Sec. 451.** *"It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated and properly marked, labeled, and packaged."*

Another foundation principle is outlined in Section 452 of the PPIA, which indicates that inspection is authorized to prevent products from entering commerce that are adulterated or misbranded.

> **PPIA Sec. 452.** *It is hereby declared to be the policy of Congress to provide for the inspection of poultry products and otherwise regulate their processing and distribution…to prevent the movement or sale in interstate or foreign commerce of, or the burden upon commerce by, poultry products which are adulterated or misbranded.*

Remember, all the things you do or you supervise as part of your job can be traced back to the statutes to make sure that any meat, poultry, or egg product that is adulterated or misbranded does not enter commerce to protect the public health. You will do that through the enforcement authorities that we will discuss later.

Definition of "Adulterated"

One of the key provisions in the statutes is the provision related to the term "adulterated" product. What does the term "adulterated" mean, and how does it apply to the work that you do? The term "adulterated" is defined in the FMIA under Section 601, which contains all of the definitions for the statute. The definition is found in Section 601(m). This definition actually has 9 parts. We're going to focus on the first few parts of the definition because they have the greatest bearing on your daily work.

First, the term "adulteration" applies to any of the following:

- carcass,
- part thereof,
- meat or meat food product

under one or more of the circumstances described in Section 601(m) of the FMIA.

Now, let's look at some key parts of that definition.

> **FMIA Sec. 601(m)(1)**: *"If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance does not ordinarily render it injurious to health;"*

The definition of adulterated product in 601 m(1) focuses on added substances. Two examples of added substances that have been declared to be adulterants in meat products include *Listeria monocytogenes (Lm)* and *E. coli* O157:H7. *Lm* is an example of an adulterant in ready-to-eat (RTE) products. It represents an added substance that renders the product injurious to health. Scientific studies have shown that this pathogen is present in the product due to the way in which product is handled or produced. For example, *Lm* is typically present in RTE products because of recontamination that occurs during the processing of product, such as through contact with the environment or with plant employees, after an initial lethality treatment has been delivered. This pathogen is considered injurious to health because RTE products are not reheated by consumers before they are eaten. Therefore, if this substance is present, products are very likely to cause injury to human health and can even cause death. The only adulterant in non-intact raw meat or meat products is *E. coli* O157:H7.

Based on what we know from scientific studies, *E. coli* O157:H7 is considered to be an added substance because it is introduced into the product during processing. For example, it's spread from the hide or digestive tract of the animals during slaughter or processing. It's injurious to health because one of the normal ways of cooking this product includes "rare" which is not sufficient to destroy the pathogen. Again, the presence of this pathogen in the product under these conditions is likely to cause injury – and can even result in death.

> **FMIA Sec. 601(m)(2)(A)**: *"If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance other than one which is (i) a pesticide chemical in or on a raw agricultural commodity (ii) a food additive, or (iii) color additive which may, in the judgment of the Secretary, make such article unfit for human food;"*

The second definition of the term "adulterated" in Section 601(m)(2)(A) of the FMIA relates to the residues of drugs in live animals that have been declared to be harmful to human health. It's a little bit tricky when you read this, because the things listed in (i), (ii), and (iii) are NOT covered in this definition. Remember that the residue testing done by FSIS is based on the statutory authorities of the Food and Drug Administration (FDA). In its pre-market approval programs, FDA considers what, if any, residues of animal drugs should be viewed as safe. FSIS is responsible for enforcing the levels that are established by FDA. In your duties, you will conduct tests for animal drug residues; such as antibiotics, hormones, or sulfonamides. Because animal drug residues are not pesticides, food additives, or color additives, the Agency is left to prove that the animal drug residue makes the meat product unfit for food. The regulations that cover animal drug residues are found in 21 CFR 556, which are the FDA regulations.

> **FMIA Sec. 601(m)(2)(B):** *"If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;"*

The definition of the term "adulteration" found in Section 601(m)(2)(B) of the FMIA covers pesticide chemicals. The Environmental Protection Agency (EPA) has the statutory authority to, in its pre-market approval programs, consider what, if any, levels of pesticide residues, if found on food, can be viewed as safe. FSIS is responsible for enforcing the tolerances that are established by EPA. The regulations related to pesticide chemicals are found in 40 CFR 180. An example of a pesticide chemical for which a tolerance has been established is Daizinon; which is used in fields to eliminate fire ants, or the herbicide 2,4-D used in fields to eliminate undesirable grasses or weeds. These pesticides are not normally found in food animals. However, food animals may become exposed to them inadvertently; for example, through incidental contact such as drift in wind at the time when the pesticides are administered in a field, or through accidental ingestion. In your duties, you will sample products for pesticide residues and send the samples to the appropriate laboratory. In this case, if the residue level for the pesticide chemical is found to have exceeded the tolerance level set by EPA, the product (which may be a carcass or part) is considered to be adulterated based on this statutory definition.

> **FMIA Sec. 601(m)(2)(C)**: *"If it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;"*

Section 601(m)(2)(C) defines meat or meat products bearing any unsafe food additives to be adulterated. All food additives are reviewed for safety before use in food production by FDA. FDA establishes their conditions for use. An example of such a food additive approved under specified conditions is carcass washes used on the slaughter line. There are two types of food additives. One is direct and the other is indirect. Direct food additives are directly applied to the food, such as preservatives for meat products. Indirect food additives are those that are not used for food purposes, but come into contact with food; such as, sanitizers that are used on equipment or on food contact surfaces. All food additives used in federal establishments must be approved by FDA. FSIS Directive 7140 lists all food additives that have been approved for use. So, again, FSIS enforces the policy that is set by FDA. The following definition in section 601(m)(2)(D), color additives, is not important in relation to your duties.

> **FMIA Sec. 601(m)(3):** *"If it consists in whole or in part of any filthy, putrid, or decomposed substances or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food."*

This next section, 601(m)(3), of the definition of adulteration emphasizes health. This is the definition that FSIS has used as the statutory basis for taking all actions against BSE. The reason this definition was used is that scientific studies have shown that infectivity of the disease exists within the animals before they show clinical signs of the disease. Legally, the burden is on FSIS to prove that these conditions – filthy, putrid, and decomposed – exist. This is why being graphic and accurate in descriptions of conditions is very important on the NRs. Some examples of filthy conditions include rail dust, rust, or rodent droppings on product.

Be aware that the adulteration provisions of the statutes are not mutually exclusive. For example, a product may be adulterated under 603(m)(3) AND 603(m)(1) because it is positive for *E. coli* O157:H7.

> **FMIA Sec. 601(m)(4):** *"If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"*

Section 601(m)(4) covers the definition of "adulterated" related to insanitary conditions. The HACCP rule (regulation 417) is about ensuring that products are not adulterated through insanitary conditions. It's about ensuring that sanitary conditions are maintained throughout the production process. If we apply this to the slaughter process, establishments must ensure; for example, that their processes – such as de-hiding, and opening the digestive tract of livestock – do not create insanitary conditions that may contaminate the carcasses with filth. You will also be responsible for verifying that there are no insanitary conditions in the plant.

The inspection duties that you and other inspection program personnel perform after slaughter, that can be traced back to this part of the FMIA are those covered by the HACCP rule; including SSOPs and the Sanitation Performance Standards. This is obviously central too much of what you do. We'll come back to the HACCP regulation when we cover section 608 of the FMIA. Your inspection duties related to ensuring that the establishments maintain sanitary conditions are outlined thoroughly in FSIS Directive 5000.1, Revision 1, "Verifying and Establishment's Food Safety Systems." The

remainder of Section 601 of the FMIA covers additional definitions of the term "adulterated." You can review these, including the ones dealing with the term "misbranded" on your own time.

> **PPIA Sec. 453(g)(1)**: *"If it bears or contains any poisonous or deleterious substance which may render it injurious to health;"*

There are parallel definitions of the term "adulterated" in the PPIA. Like the FMIA, Section 453(g)(1) covers added substances that are poisonous or deleterious which may render a product injurious to health.

Section 453(g) (2)(A)(B) covers adulteration caused by a pesticide chemical or article, which make the poultry products unfit for human food. Just like the corresponding section of the FMIA, this represents the statutory authority for the residue testing procedures that you perform. Although the substances and tolerance levels vary from those in meat products; again, you must be aware that EPA is responsible for setting the tolerances for these substances and FSIS is responsible for enforcing that policy through the residue testing program.

> **PPIA Sec. 453(g)(2)(C):** *"If it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;"*

Section 453(g)(2)(C) of the PPIA covers adulteration caused by a food additive. Again, remember that you will be responsible for ensuring that any food additives used by the plant in the processing of poultry products have been approved by FDA.

> **PPIA Sec. 453(g)(3)**: *"If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;"*

Parallel to section 601(m)(3) of the FMIA, there is a section in the PPIA that emphasizes the importance of ensuring that poultry products do not injure human health in any way because they, "consist in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. "

> **PPIA Sec. 453(g)(4)**: *"If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"*

And finally, there is a parallel definition of "adulterated" in the PPIA that covers insanitary conditions.

We've highlighted the parts of the definition of adulteration in the Acts that are most relevant to your work. Now, let's briefly review the other parts of the definition. They include the following.

> FMIA Sec. 601(m):
> - (5) product of an animal which has died otherwise than by slaughter;
> - (6) product in a container that is composed of poisonous or deleterious substance;

- (7) product that has been intentionally subjected to radiation that does not conform to regulatory requirements;
- (8) product from which a valuable constituent has been omitted or abstracted, or a substance has been substituted;
- (9) margarine containing animal fat that is filthy, putrid, or decomposed.

This overview provides a very thorough basis for understanding what the statutory definition of "adulterated" is, and what it means in relation to FSIS inspection and verification activities. It is significant in relation to ensuring public health and food safety.

Statutory Provisions for Inspection Activities

Ante-mortem Inspection

Let's turn our attention to some our inspection activities. Sections 603(a) of the FMIA, and 455(a) of the PPIA are the statutory authorities for the inspection activities you and other inspection personnel conduct during ante mortem inspection. These are the provisions upon which the regulations for ante mortem inspection were promulgated. For example, the regulation that corresponds with the statute 603(a) regarding ante mortem inspection in livestock is 9 CFR 309. This regulation contains more specific information that you should use in judging whether an official plant that slaughters livestock is meeting the standard established by 603(a). For example, the inspection procedures include inspecting the livestock at rest; and then, in motion to detect abnormal conditions or symptoms of diseases that are identified in the regulations. If any of these animals are suspected of having abnormal conditions or diseases, they must be identified for further examination, and if necessary, identified for final disposition in post mortem inspection. Any animals found with symptoms of diseases must be disposed of properly. Remember, the authority for these actions as a result of ante mortem inspection comes from the section 603(a). Also remember that the purpose for conducting ante mortem inspection activities is to prevent animals that if slaughtered would result in adulterated product or would introduce insanitary conditions in the plant from entering the plant, and to ensure that if they do enter the plant, they do not adulterate products.

Post-mortem Inspection

> **FMIA Sec. 604:** "*...the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all (livestock)....to be prepared at any slaughtering...or similar establishment...which are capable of use as human food; and the carcasses and parts thereof all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed;" and...label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts...found to be adulterated;"*

The statutory authorities for post mortem inspection are found in section 604 of the FMIA, and in section 455 (b) and (c) of the PPIA. These provisions cover two important concepts. One is the jurisdiction for inspection. The other is inspection duties. For jurisdiction, post mortem inspection must be performed on all of the carcasses and parts prepared at an official establishment. The wording used in the poultry statutes is slightly different. Instead of "prepared" it uses the word "processed."

Regarding inspection procedures, this provision establishes the basis for the inspection procedures performed. As you recall from your training, post mortem inspection involves performing specific procedures that include observation and palpation or incision of lymph nodes in the head and viscera, and observation of the carcass. The purpose of inspection is to detect any carcasses or parts that exhibit signs of disease or conditions that otherwise make the carcass or parts unwholesome or unfit for human food. These procedures must be performed using methods that are safe and sanitary. The legal authority for these procedures can be traced directly back to this statutory provision.

This statute has been held in the court system to require that FSIS make a determination about each carcass during inspection. You may hear this called a "carcass by carcass" inspection legal requirement.

Post mortem inspection must be performed on all of the carcasses and parts prepared at an official establishment. The definition for the term "prepared" is found in Section 601(l) of the FMIA.. It includes, "slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processes." You should be aware that the only products FSIS inspects are those that are defined as "prepared" in the FMIA or "processed" in the PPIA. In other words, FSIS does not have jurisdiction to inspect warehouses or distribution centers, although FSIS has the authority to visit these facilities. The inspection of other types of products is covered by other federal agencies, such as FDA. You should also be aware that FSIS has statutory authorities to conduct activities other than inspection. For example, if we look at Section 624 of the FMIA, which is the same as section 453 of the PPIA, you'll see the authority to prescribe by regulations the conditions under which carcasses, parts, and meat products are stored or handled during buying, selling, freezing, storing, or transportation. While FSIS can conduct examinations at the out of plant locations where these processes are performed, these examinations are not "inspection."

The statutes continue by indicating that for those carcasses and parts that are found not to be adulterated, inspectors are to mark them as "inspected and passed." Inspectors are to mark those carcasses and parts that are found to be adulterated as "inspected and condemned." This is the statutory basis for your inspection duties. So, you apply the standards established by the definitions of adulteration; which, we have already discussed in making this judgment.

Exemptions from Inspection Requirements

The statutes also outline some exemptions to the inspection requirements. These are found in the FMIA in Section 623, and in Section 464 of the PPIA. For example, personal slaughtering and custom slaughter for personal, household, guest, or employee uses are except from inspection. However, the exempt products are still subject to the adulteration and misbranding provisions of the statutes.

In these except facilities, the plant performs activities that constitute preparation of meat products, or processing of poultry products, but they have been exempted from inspection by Congress.

Marks of Inspection

> **FMIA Sec. 606:** *"...said inspectors shall mark, stamp, tag, or label as "Inspected and passed" all such product found to be NOT adulterated, and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all such products found adulterated...."*

Several times we have referred to labeling, marking, stamping, or tagging product as "Inspected and passed." We call these labels, marks, stamps, and tags the marks of inspection. The purpose of post mortem inspection is to determine whether the products are wholesome, not adulterated, and properly marked, labeled, and packaged, as required by the statutes. This ensures that the public health is protected. Remember in section 604 of the FMIA and in section 455 (b) and (c) of the PPIA, the statutes state that the carcasses and parts that are found NOT to be adulterated are to be marked as "inspected and passed." This same concept is covered again in more detail in Section 606 of the FMIA. These marks of inspection, stating "Inspected and passed", show that all meat products are cleared to enter commerce after they are found to be fit for human consumption. This is very important. Remember that product cannot move out of the plant into commerce until it has been inspected and marked as passed. This means that you must be able to find that product is NOT adulterated. The burden of proof is on the plant. If you have questions about whether or not to pass the product, don't pass it and don't stamp it as "Inspected and passed" unless; and until, you get satisfactory answers to your questions by the plant. If you cannot find that the product is not adulterated, you must follow the Rules of Practice. So, Section 606 defines our product control authority.

To summarize, those carcasses and parts that are found to be adulterated are to be marked "inspected and condemned." They must be either reprocessed or destroyed, and cannot leave the plant to enter commerce to be used for human food. They must be destroyed in the presence of a USDA inspector. The statute also specifies that if the establishment fails to destroy a condemned carcass or part, the Secretary may remove the inspectors from the establishment. We call this removal of inspection "suspension" of inspection. We'll discuss this further in a few minutes when we talk about enforcement authorities.

Reinspection

Reinspection is covered in 605 of the FMIA and 455(b) in the PPIA. Reinspection covers the situation when products are shipped from one plant to another. For example, this could be carcasses coming from one plant to be fabricated into special cuts at another establishment. It could be ground beef and trimmings coming from one establishment to another to be ground more finely, or to be used as a meat ingredient in a fully cooked product. When you work in an establishment that receives meat or poultry products from another plant, part of your responsibility will be to ensure that those products entering the establishment are reinspected using the same standards that you use in the initial inspection – that products are wholesome, not adulterated, and properly marked, labeled, and packaged. Another condition requiring reinspection is when products are returned to the establishment for any reason. Again, your role is to ensure that these products are reinspected using the standards in the statutes, regulations, and Directives.

Under both of these conditions you should ask a lot of questions to ensure that the product is wholesome, not adulterated, and properly marked, labeled, and packaged. For example, if the product has been transported to the establishment, was it held under conditions in a manner that would ensure that it did not become filthy, putrid, or decomposed, or for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. Here are some examples of questions you might ask to make this determination. Was the temperature of the product controlled throughout transportation? Are there measures to prevent cross contamination of the product with the environment? These questions should be part of the decision making process you use in determining if product is wholesome and not adulterated.

Sanitation

Another statutory provision that is very important to your daily activities is the one dealing with the requirement for the establishment to maintain sanitary conditions – Section 608 of the FMIA and 456(a) of the PPIA. To paraphrase the FMIA, the statute indicates that if the sanitary conditions are found by inspectors to be such that the meat or meat food products are rendered adulterated, inspectors shall refuse to allow the meat or meat food products to be labeled, marked, stamped, or tagged as "Inspected and passed." These statutes give FSIS the ability to ensure that product is handled and held in a sanitary manner. This is one of the provisions upon which the HACCP regulations (417), the Sanitation Performance Standard Regulation and the Sanitation Standard Operating Procedures Regulation (both covered in 416) are based.

> **FMIA Sec. 608:** *"The Secretary shall prescribe the rules and regulations of sanitation under which establishments shall be maintained. The Secretary shall cause to be made by experts in sanitation or by other competent inspectors the inspection of all establishments where meat or meat products are prepared as may be necessary to inform concerning the sanitary conditions of these establishments."*

Let's look at the provision that sets forth the requirements for sanitation in meat plants a little closer. First, it authorizes the Secretary of Agriculture to promulgate regulations that describe what establishments must do to maintain sanitary conditions. It also authorizes inspections to ensure that establishments are in compliance.

First, let's look at the meaning of three key words. They are:

- Sanitation
- Sanitary
- Adulteration

We've talked about the definition of the term "adulterated." Remember that it has several definitions in the statute. But, the word "sanitation" is not defined in either the FMIA or the PPIA. Because the term is not defined in the statute, we have to look to its common meaning. A common definition of the term "sanitation" is, "keeping things clean." This definition is supported by FSIS regulations, which distinguish between sanitation and HACCP. When a term, such as "sanitation" is not defined in the statutes, the courts are required to turn to the common meaning for evidence. This is typically done by consulting the dictionary.

The dictionary definition of the term "sanitation" shows that it means something broader than just keeping things clean. According to Webster's Collegiate Dictionary, the word "sanitation" means, "the development and application of sanitary measures for the sake of cleanliness, protecting health, etc." So, the dictionary drives us back to one of the two key terms that are common to the PPIA and the FMIA, which is the term "sanitary." The statutes talk about "sanitary practices", and "sanitary measures?" What doesn't this term "sanitary" mean? According to the dictionary, the term "sanitary" means, "of or pertaining to health or the conditions affecting health, especially with reference to cleanliness, precautions against disease, etc."

So, are the HACCP regulations and the sanitation regulations sanitary measures? Clearly they are, and we can demonstrate that fact to a court. To ensure that products are handled and held in a sanitary manner, plants must follow the HACCP regulations. For example, the establishment must develop and implement a HACCP plan covering each product produced when the establishment's hazard analysis reveals one or more food safety hazards are reasonably likely to occur in the production process. This includes biological, chemical, and physical hazards.

The regulation outlines that establishments must follow the seven HACCP principles (417.2); which include conducting a hazard analysis, determining critical control points, establishing critical limits, establishing monitoring procedures, developing corrective action procedures, establishing recordkeeping and documentation procedures, and developing verification procedures. The regulation also specifies the conditions under which the establishment must reassess its HACCP plan. FSIS verification duties related to these regulations are described specifically in FSIS Directive 5000.1, Revision 1, "Verifying an Establishment's Food Safety System." It describes the inspection methods, regulatory decision making process, documentation, and enforcement procedures to use in relation to ensuring that the establishment complies with the regulations and statutes regarding sanitation. For example, the 01 and 02 HACCP procedures are performed to verify that the establishment is meeting the requirements of 9 CFR 417.

The HACCP regulations require establishments to identify the hazards to health that may arise as a result of their operation and to address those that are reasonably likely to occur. If those hazards are not properly addressed and prevented, the result is adulterated product. As you will remember, the term "adulterated" is defined in the statutes. In enforcing the HACCP rules, what the Agency needs to show is why, in not complying with the regulations, the establishment is not complying with the statutory provisions that underlie the regulation. Section 608 gives the Agency authority for enforcing HACCP. So, if the Agency is to enforce the HACCP and sanitation rules, we will need to show how an establishment's failure to follow the sanitary measures required by HACCP or sanitation rules creates insanitary conditions in its operation that resulted in the production of product that may be injurious to health.

It is important to note that under case law, the deleterious change in the product, that is, the change that may have the effect of making consumption of the product injurious to health, must occur while the product is being prepared, packed, or held; and, have occurred because of the insanitary conditions. How can we show that this is the case? We can show that having a sanitation standard operation procedure that is effective in preventing direct contamination of product with environment contaminants is a

necessary precaution against producing product that may be injurious to health. Moreover, a failure to implement an effective SSOP, or to ensure the on going effectiveness of the SSOP would create conditions under which such contamination may occur; and thus, product is rendered injurious to health. Similarly, a failure by on establishment to perform an adequate hazard analysis would create insanitary conditions because, without such an analysis, the establishments cannot be sure that it has identified and addressed conditions that could cause the product to be injurious to health.

> **PPIA Sec. 456:** *"Operation of premises, facilities, and equipment (a) Sanitary practices: Each official establishment slaughtering poultry…shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce or burdensome effect upon commerce, of poultry products which are adulterated."*

A parallel section is found in Section 456 of the PPIA. This section clearly gives FSIS the authority to adopt regulations to ensure that there are sanitary conditions in establishments where poultry products are prepared and packed so that the resulting product is not injurious to health.

Progression of Statutes

The statutes follow the processes that take place in the plant. For example, Section 603 of the FMIA covers ante-mortem inspection. Section 604 covers post mortem inspection, and the carcasses. Section 606 covers the inspection of all meat products – the carcasses, the parts, processed products, and cut up products. Each product must be inspected. Section 608 covers the requirement for the plant to maintain a sanitary environment for the slaughter and processing of animals to take place. The provisions in the PPIA follow this same progression.

Recordkeeping

The statutes outline requirements for recordkeeping related to the production of meat and poultry products. If you recall from your civics classes, the U.S. Constitution has a provision that protects citizens from unreasonable searches and seizure. The plant has this same right, and just like other rights, it must be protected. However, it's important for inspection personnel to have access to plant records, particularly records related to the implementation of HACCP. A review of those records can tell us important information about how product was handled and prepared to help us in making the determination about whether product that is being produced is wholesome and not adulterated. Section 642 of the FMIA and Section 460(b) of the PPIA gives FSIS the right to be in the plant and to have access to the plant facilities and records.

Establishments must maintain production records, and to provide the records within a reasonable amount of time when given notice. Tracing these authorities in regulations, Directives, and Notices, remember that the HACCP and sanitation regulations (417, 416) both outline more specific recordkeeping requirements. For example, the right of FSIS to access plant records is reflected in the HACCP regulations in 417.5, which outlines the recordkeeping requirements related to HACCP plans. FSIS Directive 5000.1, Revision 1, outlines inspection methods covering these recordkeeping requirements. An

example of a key directive dealing with plant records is FSIS Directive 5000.2, which reminds inspection personnel that they have access to any type of record that the plant maintains that relates to maintaining its food safety system, whether the records are referenced in the HACCP plan or not (e.g., records of microbiological sampling).

Enforcement Authorities and Actions

Now, let's review the statutory authority for taking enforcement action when establishments fail to comply with provisions outlined in the Acts. There are three basic enforcement authorities covered in the Acts:

- administrative,
- civil, and
- criminal

Among these, most of the enforcement actions in plant personnel are involved with are the ones that come from the administrative authority. For example, you or other inspection personnel may withhold the marks of inspection or retain product. Let's review each of these authorities in more detail.

Administrative Authorities

The administrative enforcement authorities covered in the statutes include retaining product, withholding the marks of inspection, suspending inspection, and withdrawing inspection. Remember that the Rules of Practice, which is found in section 500 of the FSIS regulations, outline the due process that we must ensure takes place to protect the rights of establishments. Let's review these regulations briefly.

Section 500.2 of the regulations covers the regulatory control actions that take place in the plant, such as tagging product, equipment, or facilities. Remember that these actions are taken to prevent product that has been determined through inspection, to be unwholesome or adulterated from leaving the plant and entering commerce. We are authorized to take these regulatory control actions when we find insanitary conditions or practices, product adulteration, conditions that prevent us from determining that product is not adulterated or misbranded, and when there is inhumane handling or slaughter of livestock. When a regulatory control action is taken, you must notify the establishment immediately orally or in writing of the action and the reason for the action. Remember that for any type of enforcement action, the plant has the right to appeal that action.

Section 500.3 of the Rules of Practice covers situations that warrant a withholding action or suspension without prior notification to the establishment. These actions are authorized when: the establishment has produced and shipped adulterated or misbranded product and there is an imminent hazard to health, the establishment does not have a HACCP plan, the establishment does not have an SSOP, sanitary conditions are such that products in the establishment are or would be rendered adulterated, the establishment violated the terms of a regulatory control action, someone associated with the establishment assaults or threatens to assault or intimidate or interfere with an FSIS employee or FSIS inspection, the establishment fails to destroy condemned product according to regulatory requirements, or the establishment handles or slaughters

animals inhumanely. Section 500.5(a) covers the notification that must be provided to the establishment as promptly as circumstances permit.

Section 500.4 of the Rules of Practice covers the conditions under which withholding actions are taken or when suspensions occur with prior notification to the establishment. The prior notification is called a "Notice of Intended Enforcement Action," or NOIE. Specifics about what is contained in the NOIE are covered in 500.5(b). The conditions that require prior notification include an inadequate HACCP plan, an SSOP has not been properly implemented or maintained, failure to maintain sanitary conditions due to multiple or recurring noncompliance, failure to collect generic *E. coli* samples, and failure to meet the *Salmonella* performance standards. Here's a simple, practical example. According to the Rules of Practice, if there is a condition that requires prior notice before the marks of inspection are withheld, you will provide the establishment a written notice of the enforcement action. The written notice (NOIE) gives the establishment three days to respond. During this time, the establishment can provide a corrective action plan, which if judged to be adequate will result in putting the suspension in abeyance. Or, the establishment can challenge the validity of FSIS actions through the appeals process.

Withdrawal of inspection, covered in 500.6, is a formal legal process that involves filing a complaint in an administrative proceeding at the Department level. This will be handled by a Program Investigator. However, the documentation you provide in the NRs that you write are the evidentiary basis upon which this action is taken.

Civil Authorities

The civil authorities covered in the acts are found in Section 677 of the FMIA and 467(c) of the PPIA. Under these authorities, FSIS can enforce, prevent, and restrain violations of the acts. The actions involve U.S. District courts. The primary actions will be detention, and seizure of product. On rare occasions, FSIS can obtain an injunction in a federal court to prevent or restrain an establishment engaging in violations of the acts.

Detention authorities, found in Section 672 of the FMIA, and Section 467(a) of the PPIA, cover unwholesome, adulterated, or misbranded product that has left the establishment and has entered commerce. Detention actions are taken by Program Investigators, or EIAOs. The role you might play in a detention action is that you might make a call about adulterated product that has left the establishment, which would lead to the detention action. For example, you may learn of test results that show product is adulterated with *E. coli* O157:H7. The detention action places the product on hold for 20 days. During this time, a decision is made on the ultimate disposition of the detained product.

The statutory authorities for seizure of product are found in FMIA section 673 and PPIA section 467(a). Seizure is also an action that is taken against product that is no longer in an establishment and has entered commerce. Typically, the first step in a civil action is detention, which is then followed by seizure and condemnation. It involves a court judgment that affirms that the product is in violation of the acts and must be condemned and destroyed. When the court determines that the product is to be condemned, it is released under bond to be destroyed. Court costs and fees, storage and other expenses are charged to the violator.

When there are violations of the Acts that are civil in nature, FSIS has the authority to obtain an injunction from a court to keep the plant from doing something (e.g., continuing its operations) -- although this rarely occurs.

Although you will not be involved in taking any civil enforcement action, some of the documentation created in the establishment, such as NRs or memoranda, may be included in a case file that is submitted to the court. Therefore, it's very important that you, and the inspection personnel you supervise, follow the instructions in the Directives; such as those in FSIS Directive 5000.1, on completing NRs accurately, completely, and in a timely manner. They are important pieces that may make a difference in court decisions.

Criminal Authorities

In addition to the administrative and civil authorities, there are criminal authorities granted under the acts. Again, you will probably not have a direct involvement in these kinds of actions. However, the documentation that you; and inspection personnel you supervise produce, may be used in actions. The acts cover the criminal acts of assault and intimidation of a person engaged in official duties, intent to defraud the public by distributing adulterated articles, and bribing or offering a bribe to an inspection official. All of these are prohibited acts. Let's look at each of these closer.

The statutory authority for criminal acts are outlined in the sections of the statutes dealing with the prohibited acts. The prohibited acts are listed in Section 610 of the FMIA and Section 458 of the PPIA. The acts that are prohibited include the following:

- Slaughter or preparation except in compliance with the Act.
- Inhumane slaughter or handling.
- Sale, transport, offering, or receipt, in commerce, of articles capable for use as human food that are either adulterated, misbranded, or not inspected.
- Causing products to become adulterated or misbranded.
- Misuse or unauthorized use of official marks, certificates, labels or devices of inspection.
- The knowing misrepresentation of any article as inspected and passed or exempt under the Act.

These prohibitions apply to persons, firms and corporations. Perpetrators of any violation of these prohibited acts are subject to fines and other penalties.

FMIA Sec. 675; PPIA Sec. 461(c) covers criminal acts related to assault, and intimidation of inspection personnel. Under these statutes, no person shall forcibly assault, resist, oppose, impede, intimidate, or interfere with any USDA employee engaged in or on account of official duties. Therefore, it is prohibited for plant employees to impede you, or interfere in any way with your work. Assault and intimidation are conditions result in immediate withdrawal of inspection with no requirement to notify the establishment (Rules of Practice, 9 CFR 500). If you or any other inspection personnel in the plant are threatened in any way by a person at the establishment, consider safety first. Report it immediately to your supervisor as you have been instructed. The acts outline that these conditions can result in fines and prison time for violators. These types of violations may result in a $5,000 fine, 3 years

prison or both. There are more severe penalties for use of a deadly or dangerous weapon. These statutes also cover the murder of FSIS employees on duty.

Section 676 of the FMIA and Section 461(a) of the PPIA define that persons who intend to defraud or distribute, or attempt to distribute a meat or poultry article that is adulterated is subject to fines, imprisonment, or both.

Section 622 of the FMIA covers the criminal act of bribery. It prohibits any person, firm or corporation from paying or offering to pay any money or other thing of value to an agency employee with the intent to influence his/her discharge of duties. Bribery is defined as a felony act, and violators are subject to a fine ranging from $5,000 to $10,000, and imprisonment for 1 to 3 years. In addition to these penalties, FSIS will withdraw inspection. This section also prohibits FSIS employees from accepting or receiving money or something of value from representatives of the establishment, or industry. As you may recall from the unit on ethics, you are not to accept any item of value from a plant employee. Other felonies include failing to destroy condemned product, having an owner/operator who has been convicted on a felony, or two or more misdemeanors. Be aware that the USDA's Office of the Inspector General (OIG) conduct investigations into allegations of bribery. The investigations are usually initiated as a result of an anonymous call to the OIG's hotline.

The Secretary may refer criminal violations to the Department of Justice for prosecution. The Secretary has discretion to forego criminal referral for minor violations where it is determined that the public interest will be served by a suitable written notice of warning. Discretion also applies to libel and injunction authorities. Violators of any provisions for which no other criminal penalty is provided shall be guilty of a misdemeanor, and subject to fine and up to one year imprisonment.

Other Statutory Authorities

In the previous sections, we covered the statutory authorities that were most significant in relation to ensuring the protection of public health. In this section, we will review some additional statutory authorities that relate to your work.

Humane Handling of Livestock

Section 603(b) covers the authorities related to the humane handling of livestock. The Section outlines inspection authority over the methodology of humane handling, and slaughtering of animals. It states that FSIS can establish rules and regulations to oversee that the requirements of the Humane Methods of Slaughter Act are being met at establishments. It also gives FSIS authority to suspend or refuse inspection for violations of the Humane Methods of Slaughter Act. FSIS may refuse to grant inspection, or temporarily suspend inspection for slaughter or handling; other than, in accord with Humane Methods of Slaughter Act.

Labeling

Labeling is also covered in the Acts. Remember that these authorities are secondary to you in your focus. The Agency is ensuring that inspection program personnel focus on food safety first (including SSOP, HACCP, Sanitation Performance Standards, and food safety sampling) followed by food security (when specific heightened security threat

condition is declared), and into other activities we call "other consumer protection". Labeling is one of those other consumer protection activities, as is exports. The Directive that covers your inspection responsibilities for labeling is the 7000. Section 607 of the FMIA and Section 457 of the PPIA outline the following:

- All meat and meat food products must be properly labeled, marked and packaged.
- Labels must not be false or misleading.
- FSIS can withhold the use of any false or misleading labels or marks.

As is true of any other provision, these statutes provide for hearing and appeal rights on FSIS decisions.

Exported Product

Section 606 of the FMIA covers exported product. The Act requires FSIS to inspect meat, and meat food products prior to export. It gives the Secretary broad authority to determine time and manner of inspection. It also covers the certification of products by FSIS prior to shipping.

The Directive that relates to your inspection responsibilities for exported product is 9000.1. This directive describes what you should do to access the Export Library on the FSIS web site to check the current export requirements. You should do this frequently, as the requirements change regularly. It also covers your role in export certification. The forms that you are to use when performing your inspection duties related to exported products are also found in this Directive.

Summary

Now that we have completed our review of the statutes, you should be able to:

- Understand the purpose of the Acts.
- Identify key definitions from the Acts.
- Understand the statutory authority for FSIS activities.
- Understand how those activities plus authorities in the statutes support enforcement actions.

These Acts provide for the basis for FSIS's ability to perform as a public health agency. Although you find direction for your day-to-day activities in FSIS Directives, the statutes we have reviewed underlie all of these activities and provide the legal basis for them. As you perform your inspection and verification duties, you should always be conscious of the Acts, as they are the foundation for all that we do.

WORKSHOP

Instructions: For each scenario, describe the statutory authority, regulation, and Directive that is associated with it.

Scenario 1:

While performing ante mortem inspection, he PHV observes establishment personnel using a sharp object to drive hogs to slaughter. When questioned, the establishment employee says he did not know that he was not permitted to use the sharp object – in other words he was not properly trained to perform his duties. The PHV verifies that the establishment takes immediate and further preventive actions to address this situation. The PHV also completes an NR using procedure code 04C02 with the trend indicator of "protocol." The use of the sharp object is discontinued.

What is the Directive that guides your activities for this scenario? _____

What is the regulation that relates to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 2:

The PHV is performing a review of plant records. As directed, the PHV reviews the records associated with the establishment's testing program for E. coli O157:H7 in its raw ground product. The establishment records indicate that no positive results have been found this week.

What is the Directive that guides your activities for this scenario? _____

What is the regulation that relates to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 3:

The PHV observes the off-line inspectors to determine if they are using the appropriate inspection methods and decision making to verify that the meat from heads, cheeks, and weasands of beef are free of fecal material, ingesta, and milk.

What is the Directive that guides your activities for this scenario? _____

What regulations relate to this scenario? _____
What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 4:

The PHV observes a cow during ante mortem inspection in very poor condition. The animal is identified as a Suspect. At post mortem inspection, the PHV observes a lesion in the carcass suggestive of an injection site. The PHV retains the carcass, collects kidney tissue samples and conducts the FAST test. After a presumptive positive FAST test, the PHV proceeds to follow the unified sampling directive 10,210.1 to process all the tissues collected. After freezing, all samples with the form are packaged for shipping to the Midwest Lab in St. Louis MO.

What is the Notice that guides your activities for this scenario? _____

What regulations relate to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 5:

The Consumer Safety Inspector (CSI) comes into the government office and tells the PHV the following: After the establishment had completed its preoperational sanitation procedures, the CSI observed residue of the previous day's operation on the conveyor belt that comes into direct contact with product. The CSI took a regulatory control action and issued an NR.

What is the Directive that guides your activities for this scenario? _____

What regulation relates to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

Scenario 6

You are performing the 03J01 procedure in a poultry slaughter operation, and have randomly selected to verify the establishment's verification requirements for the chilling CCP. You review the establishment's HACCP plan, and find that it specifies verification personnel will review the temperature records and observe the monitoring procedures at this CCP once per shift. It also specifies that maintenance personnel will verify the accuracy of the temperature recording charts once per shift by taking an independent temperature check. Based upon your review of the HACCP plan, you determine that the establishment is in compliance with regulatory requirements.

What is the Directive that guides your activities for this scenario? _____

What regulations relate to this scenario? _____

What is the statutory authority that provides FSIS with the authority to address this scenario? _____

▷

United States Court of Appeals,
Eighth Circuit.
UNITED STATES of America, Appellee/
Cross–Appellant,
v.
Gregory L. JORGENSEN, Appellant/
Cross–Appellee.
National Cattlemen's Beef Association; the CATL
Fund, Amici Curiae.
UNITED STATES of America, Appellee/
Cross–Appellant,
v.
Martin F. JORGENSEN, Jr., Appellant/
Cross–Appellee.
National Cattlemen's Beef Association; the CATL
Fund, Amici Curiae.
UNITED STATES of America, Appellee/
Cross–Appellant,
v.
Deborah L. JORGENSEN, Appellant/
Cross–Appellee.
National Cattlemen's Beef Association; the CATL
Fund, Amici Curiae.
UNITED STATES of America, Appellee/
Cross–Appellant,
v.
DAKOTA LEAN, INC., doing business as Dakota
Lean Meats, Inc., a corporation, Appellant/
Cross–Appellee.
National Cattlemen's Beef Association; the CATL
Fund, Amici Curiae.

Nos. 96–2939, 96–2940, 96–2941, 96–2942 and
96–3064.
Submitted May 21, 1997.
Decided May 7, 1998.

Defendant cattle producers and their corporation were convicted in the United States District Court for the District of South Dakota, Charles B. Kornmann, J., of conspiracy, mail fraud, wire fraud, and fraudulent sales of misbranded meat. Defendants appealed, and government cross-appealed. The Court of Appeals, Hansen, Circuit Judge, held that: (1) evidence supported misbranding convictions; (2) Federal Meat Inspection Act misbranding provision does not require that false or misleading statements be "material," and lack of materiality element did not render statute overly broad or vague, in violation of due process; (3) district court's jury instructions and evidentiary rulings were not erroneous; (4) submitting unredacted indictment to jury was not abuse of discretion; and (5) district court calculated reasonable estimate of losses attributable to each defendant, under sentencing guideline applied to fraud offenses.

Affirmed.

West Headnotes

[1] Criminal Law 110 ⚿1144.13(2.1)

110 Criminal Law
110XXIV Review
110XXIV(M) Presumptions
110k1144 Facts or Proceedings Not Shown by Record
110k1144.13 Sufficiency of Evidence
110k1144.13(2) Construction of Evidence
110k1144.13(2.1) k. In general. Most Cited Cases

Criminal Law 110 ⚿1144.13(5)

110 Criminal Law
110XXIV Review
110XXIV(M) Presumptions
110k1144 Facts or Proceedings Not Shown by Record
110k1144.13 Sufficiency of Evidence
110k1144.13(5) k. Inferences or deductions from evidence. Most Cited Cases

In reviewing sufficiency of evidence claims, appellate court considers evidence in light most favorable to verdict and grants government benefit of

all reasonable inferences.

[2] Criminal Law 110 ⚿552(1)

110 Criminal Law
110XVII Evidence
110XVII(V) Weight and Sufficiency
110k552 Circumstantial Evidence
110k552(1) k. In general. Most Cited Cases

Elements of crime may be proven by either direct or circumstantial evidence.

[3] Criminal Law 110 ⚿1159.2(7)

110 Criminal Law
110XXIV Review
110XXIV(P) Verdicts
110k1159 Conclusiveness of Verdict
110k1159.2 Weight of Evidence in General
110k1159.2(7) k. Reasonable doubt. Most Cited Cases

Court of Appeals will reverse conviction only if reasonable fact finder could not have found defendant guilty beyond a reasonable doubt; this standard is a strict one, and jury verdict should not be overturned lightly.

[4] Food 178 ⚿21

178 Food
178k17 Criminal Prosecutions
178k21 k. Evidence. Most Cited Cases

Evidence supported defendant cattle producers' convictions for fraudulent sales of misbranded meat under Federal Meat Inspection Act, where producers' own meat had been blended with outside beef trim that did not have hormone-free and other health qualities specified in claims contained in producers' brochures, customers testified literature describing producers' meat arrived with the product, and defendants caused misbranded meat to be distributed in commerce when they sold products to customers in various states. Federal Meat Inspection Act, §§ 1(n)(1), (p), 10, 16, as amended, 21 U.S.C.A. §§ 601(n)(1), (p), 610, 676.

[5] Food 178 ⚿15

178 Food
178k11 Violations of Regulations
178k15 k. Misbranding or want of notice to purchasers or public. Most Cited Cases

Brochures that accompanied defendant cattle producers' meat products qualified as "labeling" within meaning of Federal Meat Inspection Act misbranding provisions. Federal Meat Inspection Act, § 1(n)(1), (p), as amended, 21 U.S.C.A. § 601(n)(1), (p).

[6] Food 178 ⚿21

178 Food
178k17 Criminal Prosecutions
178k21 k. Evidence. Most Cited Cases

Intent to defraud, supporting defendant cattle producer's conviction for fraudulent sales of misbranded meat, was established by evidence that, on tours of processing plant, boxes of outside beef trim were hidden behind boxes of his company's marked product to create illusion that beef was all bred from company's cattle, producer gave final order to purchase outside beef trim and to blend it with company's own product, he told employees that company was mixing outside beef trim but that this information was not to leave the plant, and he approved continued use of false and misleading brochures. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[7] Food 178 ⚿21

178 Food
178k17 Criminal Prosecutions
178k21 k. Evidence. Most Cited Cases

Intent to defraud, supporting defendant's conviction for fraudulent sales of misbranded meat, was established by evidence that defendant knew of blending of outside beef trim with cattle company's product, he told sales manager to represent blended product as it was described in misleading bro-

these same representations, and he loaned company $25,000 so it could buy outside beef. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[8] Food 178 ⚿21

178 Food
178k17 Criminal Prosecutions
178k21 k. Evidence. Most Cited Cases

Intent to defraud, supporting defendant's conviction for fraudulent sales of misbranded meat, was established by evidence that defendant was actively involved in daily operations of cattle company, including sales to customers, she knew that company was blending its own meat with outside beef trim, she was personally involved in purchasing of some outside beef trim, she represented company's product as it was described in misleading brochures, and she was company contact person for advertising firm that produced many of the false and misleading brochures. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[9] Postal Service 306 ⚿49(11)

306 Postal Service
306III Offenses Against Postal Laws
306k49 Evidence
306k49(8) Weight and Sufficiency
306k49(11) k. Use of mails to defraud. Most Cited Cases

Telecommunications 372 ⚿1018(4)

372 Telecommunications
372III Telephones
372III(I) Offenses and Prosecutions
372k1015 Prosecutions
372k1018 Evidence
372k1018(4) k. Weight and sufficiency. Most Cited Cases
(Formerly 372k363)

Evidence that affiliates of cattle company each had used telephones and the mails to carry out scheme to defraud customers by misrepresenting and misbranding company's meat supported their convictions under mail and wire fraud statutes. 18 U.S.C.A. §§ 1341, 1343.

[10] Conspiracy 91 ⚿47(3.1)

91 Conspiracy
91II Criminal Responsibility
91II(B) Prosecution
91k44 Evidence
91k47 Weight and Sufficiency
91k47(3) Particular Conspiracies
91k47(3.1) k. In general. Most Cited Cases

Evidence that affiliates of cattle company each knowingly contributed to furtherance of conspiracy to misbrand company's meat, and that they all had voluntarily agreed to join in conspiracy to misbrand and misrepresent their product, supported their convictions for conspiracy under statute making it crime for two or more persons to conspire to commit any offense against the United States. 18 U.S.C.A. § 371.

[11] Conspiracy 91 ⚿28(1)

91 Conspiracy
91II Criminal Responsibility
91II(A) Offenses
91k28 Conspiracy to Commit Crime
91k28(1) k. In general. Most Cited Cases

Under statute making it crime for two or more persons to conspire to commit any offense against the United States, government must prove that there was agreement to achieve illegal purpose, that defendant knew of this agreement, and that defendant intentionally joined conspiracy. 18 U.S.C.A. § 371.

[12] Food 178 ⚿15

178 Food
178k11 Violations of Regulations
178k15 k. Misbranding or want of notice to

purchasers or public. Most Cited Cases

Federal Meat Inspection Act misbranding provision, stating that meat is misbranded "if its labeling is false or misleading in any particular," does not require that false or misleading statements be "material"; statutory language does not contain materiality element, and judicially rewriting statute to add such a requirement would not be consistent with public policy underlying Meat Inspection Act. Federal Meat Inspection Act, § 1(n)(1), as amended, 21 U.S.C.A. § 601(n)(1).

[13] Statutes 361 ⇐1108

361 Statutes
361III Construction
361III(C) Clarity and Ambiguity; Multiple Meanings
361k1107 Absence of Ambiguity; Application of Clear or Unambiguous Statute or Language
361k1108 k. In general. Most Cited Cases
(Formerly 361k190, 361k188)

When interpreting statute, beginning point must be language of statute, and, when statute speaks with clarity to an issue, judicial inquiry into statute's meaning, in all but the most extraordinary circumstance, is finished.

[14] Food 178 ⇐5

178 Food
178k5 k. Purity and quality. Most Cited Cases

Food 178 ⇐15

178 Food
178k11 Violations of Regulations
178k15 k. Misbranding or want of notice to purchasers or public. Most Cited Cases

Companies and people engaged in the food business have affirmative duty to insure that food they sell to the public is safe and properly labeled. Federal Meat Inspection Act, § 1(n)(1), as amended, 21 U.S.C.A. § 601(n)(1).

[15] Constitutional Law 92 ⇐4269

92 Constitutional Law
92XXVII Due Process
92XXVII(G) Particular Issues and Applications
92XXVII(G)12 Trade or Business
92k4266 Particular Subjects and Regulations
92k4269 k. Agriculture and crops. Most Cited Cases
(Formerly 92k296(1))

Food 178 ⇐1.10

178 Food
178k1 Power to Make Regulations
178k1.10 k. Meat and poultry. Most Cited Cases

Federal Meat Inspection Act misbranding provision, stating that meat is misbranded "if its labeling is false or misleading in any particular," is not overly broad or vague, so as to violate due process, despite lack of materiality requirement; statute simply prohibits any false or misleading statements in meat labeling without limiting prohibition to any particular types of false or misleading claims, and those in the food business may comply without difficulty, simply by not including any false or misleading statements in their meat labeling. U.S.C.A. Const.Amend. 5; Federal Meat Inspection Act, § 1(n)(1), as amended, 21 U.S.C.A. § 601(n)(1).

[16] Corporations and Business Organizations 101 ⇐2016

101 Corporations and Business Organizations
101VII Directors, Officers, and Agents
101VII(E) Liability for Corporate Debts and Acts
101k2016 k. Criminal responsibility of directors, officers, and agents for corporate acts. Most Cited Cases
(Formerly 101k369)

In prosecution of cattle producers and their corporation for fraudulent sales of misbranded meat and related charges, defendants' proposed jury instruction, which would have informed jury that a

person is not responsible for acts performed by other people on behalf of corporation, even if those persons are officers, employees, or other agents of the corporation, did not accurately state applicable law regarding corporate officers' liability for federal food law violations. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[17] Criminal Law 110 ⚖822(1)

110 Criminal Law
110XX Trial
110XX(G) Instructions: Necessity, Requisites, and Sufficiency
110k822 Construction and Effect of Charge as a Whole
110k822(1) k. In general. Most Cited Cases

When reviewing challenge to jury instructions, Court of Appeals recognizes that district court has wide discretion in formulating instructions and will affirm if entire charge to jury, when read as a whole, fairly and adequately contains law applicable to the case.

[18] Corporations and Business Organizations 101 ⚖2016

101 Corporations and Business Organizations
101VII Directors, Officers, and Agents
101VII(E) Liability for Corporate Debts and Acts
101k2016 k. Criminal responsibility of directors, officers, and agents for corporate acts. Most Cited Cases
(Formerly 101k369)

Corporate officer who is in "responsible relationship" to an activity within a company that violates provisions of federal food laws, such as meat misbranding, can be held criminally responsible even though that officer did not personally engage in that activity. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[19] Corporations and Business Organizations 101 ⚖2016

101 Corporations and Business Organizations
101VII Directors, Officers, and Agents
101VII(E) Liability for Corporate Debts and Acts
101k2016 k. Criminal responsibility of directors, officers, and agents for corporate acts. Most Cited Cases
(Formerly 101k369)

Jury could convict defendant corporate officer on charges of fraudulent sales of misbranded meat if it found defendant: (1) had intent to defraud; and (2) either personally participated in misbranding or was in "responsible relationship" within company regarding the misbranding of meat. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[20] Food 178 ⚖22

178 Food
178k17 Criminal Prosecutions
178k22 k. Trial and review. Most Cited Cases

In prosecution of cattle producers and their corporation for fraudulent sales of misbranded meat and related charges, jury instructions given by district court correctly required jury to find that each individual defendant had specific intent to defraud and that each of them had caused misbranding of meat to occur. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[21] Criminal Law 110 ⚖1038.2

110 Criminal Law
110XXIV Review
110XXIV(E) Presentation and Reservation in Lower Court of Grounds of Review
110XXIV(E)1 In General
110k1038 Instructions
110k1038.2 k. Failure to instruct in general. Most Cited Cases

Criminal Law 110 ⚖1173.2(1)

110 Criminal Law

110XXIV Review
110XXIV(Q) Harmless and Reversible Error
110k1173 Failure or Refusal to Give Instructions
110k1173.2 Instructions on Particular Points
110k1173.2(1) k. In general. Most Cited Cases

In prosecution for fraudulent sales of misbranded meat, even assuming trial court failed to instruct on findings necessary to hold corporation criminally liable for acts of its officers, agents, or employees, defendant corporation was not prejudiced thereby, and there was no plain error, given evidence showing that, on all counts of which corporation was convicted, an officer, agent, or employee of corporation was acting within scope of his or her employment when act charged against corporation was committed. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[22] Criminal Law 110 ⚖1038.2

110 Criminal Law
110XXIV Review
110XXIV(E) Presentation and Reservation in Lower Court of Grounds of Review
110XXIV(E)1 In General
110k1038 Instructions
110k1038.2 k. Failure to instruct in general. Most Cited Cases

There is plain error if omitted jury instructions should have been given, and error affected defendant's substantial rights and seriously affects fairness, integrity, or public reputation of judicial proceedings.

[23] Corporations and Business Organizations 101 ⚖2613

101 Corporations and Business Organizations
101IX Corporate Powers and Liabilities
101IX(G) Crimes and Prosecutions
101k2611 Nature and Grounds of Corporate Responsibility
101k2613 k. Acts or omissions of officers and agents. Most Cited Cases
(Formerly 101k526)

Corporation is criminally responsible for acts of its officers, agents, and employees committed within scope of their employment and for benefit of the corporation.

[24] Food 178 ⚖22

178 Food
178k17 Criminal Prosecutions
178k22 k. Trial and review. Most Cited Cases

In prosecution for fraudulent sales of misbranded meat, defendants' proposed "theory of defense" instructions, regarding government's alleged failure to give them notice of their violations of Federal Meat Inspection Act and failure to bring administrative proceedings against them before bringing criminal charges, were inadequate and incomplete, as they did not state that government must give defendants notice prior to bringing criminal charges, and also failed to tell jury what to do if jury found government did not give notice. Federal Meat Inspection Act, §§ 7(e), 10, 16, as amended, 21 U.S.C.A. §§ 607(e), 610, 676; 9 C.F.R. § 355.40(a).

[25] Food 178 ⚖15

178 Food
178k11 Violations of Regulations
178k15 k. Misbranding or want of notice to purchasers or public. Most Cited Cases

In prosecution for fraudulent sales of misbranded meat, defendants' claimed theory of defense, i.e., that government failed to abide by its own regulations by failing to provide notice and commence administrative proceedings before seeking indictment, was not defense submissible to jury, but, rather, was the kind of attack on indictment that was to be made by motion to dismiss before trial, based on purported defect in the institution of the prosecution. Federal Meat Inspection Act, §§ 7(e), 10, 16, as amended, 21 U.S.C.A. §§ 607(e),

610, 676; 9 C.F.R. § 355.40(a).

[26] Criminal Law 110 ⚿1038.2

110 Criminal Law
110XXIV Review
110XXIV(E) Presentation and Reservation in Lower Court of Grounds of Review
110XXIV(E)1 In General
110k1038 Instructions
110k1038.2 k. Failure to instruct in general. Most Cited Cases

Criminal Law 110 ⚿1173.2(1)

110 Criminal Law
110XXIV Review
110XXIV(Q) Harmless and Reversible Error
110k1173 Failure or Refusal to Give Instructions
110k1173.2 Instructions on Particular Points
110k1173.2(1) k. In general. Most Cited Cases

In prosecution for conspiracy and fraudulent sales of misbranded meat, defendants were not prejudiced by any error in district court's failure to instruct jury that they had to be unanimous in determining which overt acts they found supported conspiracy count conviction, and thus there was no plain error, since, in finding all defendants guilty of certain acts when they were alleged as substantive misbranding counts, jury also unanimously found that defendants had committed those overt acts in furtherance of conspiracy. 18 U.S.C.A. § 371.

[27] Criminal Law 110 ⚿1038.2

110 Criminal Law
110XXIV Review
110XXIV(E) Presentation and Reservation in Lower Court of Grounds of Review
110XXIV(E)1 In General
110k1038 Instructions
110k1038.2 k. Failure to instruct in general. Most Cited Cases

Criminal Law 110 ⚿1038.3

110 Criminal Law
110XXIV Review
110XXIV(E) Presentation and Reservation in Lower Court of Grounds of Review
110XXIV(E)1 In General
110k1038 Instructions
110k1038.3 k. Necessity of requests. Most Cited Cases

Defendants' challenge to jury instructions given in conspiracy prosecution, contending that district court erred in failing to instruct jury that they had to be unanimous in determining which overt acts they found supported conspiracy count conviction, would be reviewed for plain error, where defendants did not object to conspiracy instruction given, and they did not offer unanimity instruction regarding overt acts.

[28] Criminal Law 110 ⚿1130(2)

110 Criminal Law
110XXIV Review
110XXIV(I) Briefs
110k1130 In General
110k1130(2) k. Specification of errors. Most Cited Cases

Court of Appeals would not address defendants' contention that trial court erred in initially admitting hearsay statements of coconspirators, since defendants failed to specify by record references any particular coconspirator statements which court allegedly erroneously admitted. Fed.Rules Evid.Rule 801(d)(2)(E), 28 U.S.C.A.

[29] Criminal Law 110 ⚿428

110 Criminal Law
110XVII Evidence
110XVII(O) Acts and Declarations of Conspirators and Codefendants
110k428 k. Proof and effect of acts or declarations. Most Cited Cases

District courts should be careful to make sure that final *Bell* rulings are made with respect to ad-

missibility of statements of coconspirators, and prosecutors who offer coconspirator statements under nonhearsay exception have duty to protect their record by making sure they request final *Bell* rulings at close of all evidence. Fed.Rules Evid.Rule 801(d)(2)(E), 28 U.S.C.A.

[30] Criminal Law 110 ⚿427(5)

110 Criminal Law
110XVII Evidence
110XVII(O) Acts and Declarations of Conspirators and Codefendants
110k427 Preliminary Evidence as to Conspiracy or Common Purpose
110k427(5) k. Weight and sufficiency. Most Cited Cases

With respect to admissibility of statements of coconspirators, final *Bell* ruling determines whether or not government has shown by preponderance of evidence: (1) that conspiracy existed; (2) that declarant and defendant were members of conspiracy; and (3) that declarant's statements were made during and in furtherance of conspiracy, thereby satisfying nonhearsay exception. Fed.Rules Evid.Rule 801(d)(2)(E), 28 U.S.C.A.

[31] Criminal Law 110 ⚿1130(2)

110 Criminal Law
110XXIV Review
110XXIV(I) Briefs
110k1130 In General
110k1130(2) k. Specification of errors. Most Cited Cases

Because defendants failed to identify by record references any particular hearsay statement by coconspirator which trial court allegedly erroneously admitted, Court of Appeals was unable to test whether statements were made during course of and in furtherance of conspiracy so as to be admissible under nonhearsay exception, and, thus, reviewing court was also unable to say that trial court's failure to make explicit final *Bell* ruling on statements' admissibility so affected defendants' substantial rights as to constitute reversible error. Fed.Rules Evid.Rule 801(d)(2)(E), 28 U.S.C.A.

[32] Food 178 ⚿21

178 Food
178k17 Criminal Prosecutions
178k21 k. Evidence. Most Cited Cases

In prosecution of cattle producers and their corporation for fraudulent sales of misbranded meat, trial court did not abuse its discretion in admitting evidence of United States Department of Agriculture policy memo, despite defendants' contention that, by admitting memo, jury was allowed to convict them for violation of memo, rather than for violation of statute; memo was relevant to show defendants' knowledge and intent, and court cautioned jury that memo itself did not set out the law, and it properly instructed jury on elements of misbranding, including required intent to defraud. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[33] Criminal Law 110 ⚿661

110 Criminal Law
110XX Trial
110XX(C) Reception of Evidence
110k661 k. Necessity and scope of proof. Most Cited Cases

Criminal Law 110 ⚿1153.1

110 Criminal Law
110XXIV Review
110XXIV(N) Discretion of Lower Court
110k1153 Reception and Admissibility of Evidence
110k1153.1 k. In general. Most Cited Cases
(Formerly 110k1153(1))

District court has broad discretion in determining what evidence to admit, and its decision will be overturned on appeal only if there has been abuse of discretion.

[34] Food 178 ⚿21

178 Food
178k17 Criminal Prosecutions
178k21 k. Evidence. Most Cited Cases

United States Department of Agriculture policy memo, purportedly sent to all meat producers who had obtained grant of federal meat inspection, was relevant evidence in prosecution for fraudulent sales of misbranded meat, despite defendants' contention that they never received memo; memo was relevant to show defendants had been told the literature accompanying their meat shipments could be considered labeling and that it should not be false or misleading, it was relevant as to whether defendants acted with intent to defraud, and it was for jury to determine whether defendants ever saw the memo. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[35] Criminal Law 110 ⇐673(1)

110 Criminal Law
110XX Trial
110XX(C) Reception of Evidence
110k673 Effect of Admission
110k673(1) k. In general. Most Cited Cases

Trial court did not abuse its broad discretion in admitting testimony of government witness despite limited relevancy of that testimony, given cautionary and limiting instruction that court gave to jury concerning the testimony.

[36] Criminal Law 110 ⇐1174(6)

110 Criminal Law
110XXIV Review
110XXIV(Q) Harmless and Reversible Error
110k1174 Conduct and Deliberations of Jury
110k1174(6) k. Taking documents or evidence to jury room. Most Cited Cases

District court did not commit reversible error in submitting unredacted indictment to jury in prosecution of cattle producers and their corporation for fraudulent sales of misbranded meat and conspiracy, since court had admonished and instructed jury that indictment did not constitute evidence of any kind, and defendants were not prejudiced in any event, even assuming some overt acts alleged in conspiracy count were not proven, since there was ample proof of at least one overt act in furtherance of conspiracy, sufficient in itself to convict. Federal Meat Inspection Act, §§ 10, 16, as amended, 21 U.S.C.A. §§ 610, 676.

[37] Criminal Law 110 ⇐858(3)

110 Criminal Law
110XX Trial
110XX(J) Issues Relating to Jury Trial
110k858 Taking Papers or Articles to Jury Room
110k858(3) k. Documents or demonstrative evidence. Most Cited Cases

Submission of indictment to the jury is matter within sound discretion of trial court, provided jury is admonished that indictment does not constitute evidence of any kind.

[38] Criminal Law 110 ⇐858(3)

110 Criminal Law
110XX Trial
110XX(J) Issues Relating to Jury Trial
110k858 Taking Papers or Articles to Jury Room
110k858(3) k. Documents or demonstrative evidence. Most Cited Cases

Criminal Law 110 ⇐1174(6)

110 Criminal Law
110XXIV Review
110XXIV(Q) Harmless and Reversible Error
110k1174 Conduct and Deliberations of Jury
110k1174(6) k. Taking documents or evidence to jury room. Most Cited Cases

Although "better course" is for trial court to redact indictment submitted to the jury if government has not presented evidence supporting allegations in indictment, reversal is required only if defendant

suffered prejudice as a result.

[39] Conspiracy 91 ⚖47(1)

91 Conspiracy
91II Criminal Responsibility
91II(B) Prosecution
91k44 Evidence
91k47 Weight and Sufficiency
91k47(1) k. In general. Most Cited Cases

Proof of one overt act in furtherance of conspiracy is sufficient to convict under statute making it crime for two or more persons to conspire to commit any offense against the United States. 18 U.S.C.A. § 371.

[40] Postal Service 306 ⚖51

306 Postal Service
306III Offenses Against Postal Laws
306k51 k. Sentence and punishment. Most Cited Cases

Sentencing and Punishment 350H ⚖736

350H Sentencing and Punishment
350HIV Sentencing Guidelines
350HIV(B) Offense Levels
350HIV(B)3 Factors Applicable to Several Offenses
350Hk736 k. Value of loss or benefit. Most Cited Cases
(Formerly 178k23, 91k51)

Telecommunications 372 ⚖1022

372 Telecommunications
372III Telephones
372III(I) Offenses and Prosecutions
372k1015 Prosecutions
372k1022 k. Sentencing and punishment. Most Cited Cases
(Formerly 372k363)

District court calculated reasonable estimate of losses attributable to each defendant, in sentencing them for fraudulent sales of misbranded meat, conspiracy, and mail and wire fraud, where court first ruled that price victims would have paid for defendants' products if they had been properly labeled could not be determined from evidence presented, and it instead calculated loss by using estimate of loss to each victim, based on its finding of one percent retail profit margin on meat bought from defendants. U.S.S.G. §§ 2F1.1(b), 2F1.1, comment. (nn. 7(a), 8), 18 U.S.C.A.

[41] Criminal Law 110 ⚖1158.34

110 Criminal Law
110XXIV Review
110XXIV(O) Questions of Fact and Findings
110k1158.34 k. Sentencing. Most Cited Cases
(Formerly 110k1158(1))

Court of Appeals reviews district court's factual determination of amount of loss, for purposes of fraud sentencing guideline, under clearly erroneous standard. U.S.S.G. § 2F1.1(b), 18 U.S.C.A.

[42] Sentencing and Punishment 350H ⚖736

350H Sentencing and Punishment
350HIV Sentencing Guidelines
350HIV(B) Offense Levels
350HIV(B)3 Factors Applicable to Several Offenses
350Hk736 k. Value of loss or benefit. Most Cited Cases
(Formerly 184k69(1))

Under sentencing guideline used for fraud offenses, proper loss amount is either the amount of loss defendant intended to inflict or actual loss resulting from the fraudulent conduct, whichever is greater. U.S.S.G. § 2F1.1, 18 U.S.C.A.

[43] Food 178 ⚖23

178 Food
178k17 Criminal Prosecutions
178k23 k. Sentence and punishment. Most Cited Cases

Postal Service 306 ⚖51

306 Postal Service
306II Offenses Against Postal Laws
306k51 k. Sentence and punishment. Most Cited Cases

Sentencing and Punishment 350H ⚖978

350H Sentencing and Punishment
350HIV Sentencing Guidelines
350HIV(H) Proceedings
350HIV(H)2 Evidence
350Hk974 Sufficiency
350Hk978 k. Amount and degree of loss or injury. Most Cited Cases
(Formerly 91k51)

Telecommunications 372 ⚖1022

372 Telecommunications
372III Telephones
372III(I) Offenses and Prosecutions
372k1015 Prosecutions
372k1022 k. Sentencing and punishment. Most Cited Cases
(Formerly 372k363)

In estimating losses attributable to each defendant, in sentencing them for fraudulent sales of misbranded meat, conspiracy, and mail and wire fraud, district court was not clearly erroneous in finding that evidence supporting higher loss calculation was not persuasive. U.S.S.G. § 2F1.1, 18 U.S.C.A.

***556** James R. Wyrsch, Kansas City, MO, argued (David R. Gienapp, Rick Johnson, and W. Brian Gaddy, on the brief), for Appellants/ Cross–Appellees.

John Seiler, Assistant United States Attorney, Pierre, SD, argued (Robert A. Mandel and John Ulrich, on the brief), for Appellee/Cross–Appellant.

Before McMILLIAN, FAGG, and HANSEN, Circuit Judges.

HANSEN, Circuit Judge.

The defendants appeal their convictions and sentences for conspiracy, mail fraud, wire fraud, and fraudulent sales of misbranded meat. They make numerous claims on appeal, including insufficiency of the evidence, improper jury instructions, erroneous evidentiary rulings, abuse of discretion in providing the jury with a copy of the indictment, and improper sentencing. The government cross-appeals, claiming error in sentencing. We affirm the district court.[FN1]

FN1. The Honorable Charles B. Kornmann, United States District Judge for the District of South Dakota.

I.

In the mid–1980s, Gregory Jorgensen conceived the idea of gathering a group of South Dakota cattle producers together to market and sell the processed beef derived from their own cattle, hoping to increase the net return from their raised cattle while enabling them to better control their own production. Acting on this idea, Gregory and his father, Martin Jorgensen, incorporated Dakota Lean, Inc., in South Dakota and began slaughtering cattle raised by them and their neighbors. Deborah Jorgensen became involved in the company after its initial organization. The company decided to concentrate on marketing and selling "heart healthy" meat products, produced from cattle raised on the Jorgensen ranch or from Jorgensen-bred animals.

When Dakota Lean sold its meat to customers, the product was accompanied by brochures making various claims about the product. Included in these claims were statements that the cattle were "genetically selected," that "strict quality control [was] maintained through individualized tracking and processing of each animal," and that the cattle were "raised on a wholesome diet of native prairie grass and selected feed stuffs without any growth hormones or implants." (Trial Ex. 3 at 15–16.) Other brochures sent to customers stated that the meat had "No Substitutes" and "No Additives" and came from cattle "selectively bred for over 30 years to yield a much lower fat and cholesterol content." (

Id. at 2, 4.) Some brochures also claimed Dakota Lean meat was produced from cattle which had been "raised on a carefully controlled diet of mother's milk and prairie grasses" which was "supplemented with corn and milo, a coarse, rough-seeded*557 sorghum, grown and milled on Dakota Lean's 16,000 acre ranch in South Dakota" as the cattle matured. (*Id.* at 36–37.) Additionally, according to the brochures, "computerized records keep track of each animal's food, and fat and cholesterol content levels are measured every three months." (*Id.*)

In 1989, when demand for their products outstripped their capacity to fill the orders from slaughtering their own cattle and those of their neighbors having the same attributes as their own cattle, the Jorgensens decided to start buying commercial beef trim from outside suppliers. Beef trim is meat purchased from packing plants which is ordinarily used to make hamburger. None of the outside suppliers claimed their beef trim was hormone or antibiotic free, or that the cattle producing the meat had been genetically bred or fed a special diet. The Jorgensens blended this ordinary commercial outside beef trim with their own Dakota Lean meat product. Dakota Lean then sold this blended product to its customers while at the same time making the representations outlined above to its customers in the accompanying brochures. The company did not tell its customers that it was blending outside beef trim with its own meat. All told, it purchased more than a million pounds of outside beef trim to blend with its own meat.

Following a jury trial, the Jorgensens and the corporation were each convicted of conspiracy in violation of 18 U.S.C. § 371 (1994), and of several counts charging the fraudulent sale of misbranded meat in violation of 21 U.S.C. §§ 610 and 676. The jury acquitted each defendant of one or more counts of the 25–count indictment. Additionally, Gregory and Deborah Jorgensen and the corporation were each convicted of two counts of mail fraud and three counts of wire fraud in violation of 18 U.S.C. §§ 1341 and 1343. The district court sentenced Gregory to 24 months of imprisonment, Martin to 15 months, and Deborah to 12 months and one day. The court also imposed substantial fines and periods of supervised release on the individual defendants. The defendants appeal and the government cross appeals.

II.

A. Sufficiency of the Evidence.

The defendants first argue that there was insufficient evidence to support any of the counts of conviction and, therefore, that the district court erred in denying their motions for judgment of acquittal.

[1][2][3] We apply familiar standards in our review of sufficiency of the evidence claims. We consider the evidence in the light most favorable to the verdict and grant the government the benefit of all reasonable inferences. *United States v. Berndt,* 86 F.3d 803, 809 (8th Cir.1996). The elements of the crime may be proven by either direct or circumstantial evidence. *United States v. Hankins,* 931 F.2d 1256, 1258 (8th Cir.), *cert. denied,* 502 U.S. 886, 112 S.Ct. 243, 116 L.Ed.2d 198 (1991). "We do not judge the credibility of witnesses." *Id.* at 1258–59. We reverse a conviction only if a reasonable fact finder could not have found the defendant guilty beyond a reasonable doubt. *Id.* at 1259. "This standard is a strict one, and a jury verdict should not be overturned lightly." *United States v. Sykes,* 977 F.2d 1242, 1247 (8th Cir.1992).

[4] The defendants' misbranding convictions were for violations of the Federal Meat Inspection Act. *See* 21 U.S.C. §§ 601–695. It is a felony under 21 U.S.C. § 676(a) for any person, firm, or corporation to violate any provisions of 21 U.S.C. § 610 with an "intent to defraud." Section 610(c) prohibits any "person, firm or corporation" from distributing in commerce meat or meat products "capable of use as human food" which are "misbranded at the time of ... sale, transportation, offer for sale or transportation, or receipt for transportation." Meat or meat product is "misbranded" under the Act "if

its labeling is false or misleading in any particular." 21 U.S.C. § 601(n)(1). "Labeling" is defined as "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 601(p).

[5] The evidence supports the jury's verdicts in this case. First, the brochures that *558 accompanied the Dakota Lean meat products qualify as "labeling" within the meaning of 21 U.S.C. § 601(p). The brochures were "written matter" that was "accompanying" Dakota Lean's meat product when it was distributed in commerce. *See* 21 U.S.C. § 601(p). Contrary to the defendants' assertions, Dakota Lean customers testified at trial that the literature describing the meat arrived with the product. Second, the Dakota Lean meat products sold were "misbranded" within the meaning of 21 U.S.C. § 601(n)(1). Dakota Lean's own meat had been blended with outside beef trim that did not have the qualities specified in the claims contained in the brochures. Thus, the labeling was false and misleading resulting in the misbranding. Third, the defendants caused the misbranded meat to be distributed in commerce when they sold the products to customers in various states.

[6] There was evidence that each defendant had the requisite intent to defraud. When tours were given of the processing plant, boxes of outside beef trim were hidden behind boxes of Dakota Lean marked product to create the illusion that it was all Jorgensen-bred beef. Gregory Jorgensen gave the final order to purchase outside beef trim and to blend it with Dakota Lean's own product. He told employees that the company was mixing the outside beef trim with the company's own product but that this information was not to leave the plant. He also approved the continued use of the false and misleading brochures.

[7] Martin Jorgensen knew of the blending of outside beef trim with the Dakota Lean product. He told the sales manager to represent the blended product as it was described in the misleading brochures. He loaned the corporation $25,000 so it could buy outside beef. Martin himself also promoted the blended product by making these same representations.

[8] Deborah Jorgensen was actively involved in the daily operations of the company. This included selling the product to customers. She also knew that the company was blending its own meat with outside beef trim. She was personally involved in the purchasing of some of the outside beef trim. She represented the product as it was described in the misleading brochures. She was also the contact person within Dakota Lean for an advertising firm that produced many of the false and misleading brochures. While her involvement with the company was interrupted, the jury convicted her on substantive counts that occurred only after she returned to the company in September 1992, and of the conspiracy count.

[9] Gregory and Deborah also challenge the sufficiency of the evidence to support their convictions under the mail and wire fraud statutes. The mail fraud statute, 18 U.S.C. § 1341, makes it a crime to use the mails to execute "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent ... representations." The wire fraud statute, 18 U.S.C. § 1343, makes it a crime to "transmit[ ] or cause[ ] to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing" a "scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent ... representations."

The record contains sufficient evidence to support the mail and wire fraud convictions. Gregory and Deborah each had used telephones and the mails to carry out the scheme to defraud customers by misrepresenting and misbranding Dakota Lean meat for each count upon which they were convicted.

[10][11] The defendants also challenge their

convictions for conspiracy. The federal conspiracy statute, 18 U.S.C. § 371, makes it a crime for "two or more persons" to "conspire to commit any offense against the United States" when "one or more of such persons do any act to effect the object of the conspiracy." Under this section the government must prove "that there was an agreement to achieve an illegal purpose, that the defendant knew of this agreement and that the defendant intentionally joined the conspiracy." *United States v. Agofsky*, 20 F.3d 866, 870 (8th Cir.), *cert. denied*, 513 U.S. 909, 115 S.Ct. 280, 130 L.Ed.2d 196, *and cert. denied*, 513 U.S. 949, 115 S.Ct. 363, 130 L.Ed.2d 316 (1994). ***559**

The evidence is sufficient to prove each element of conspiracy. There was evidence that each defendant knowingly contributed to the furtherance of the conspiracy to misbrand. Contrary to the defendants' claims, our review satisfies us that there is evidence in the record from which a reasonable jury could infer that all the defendants had voluntarily agreed to join in the conspiracy to misbrand and misrepresent their product. *See United States v. Murphy*, 957 F.2d 550, 552 (8th Cir.1992) (agreement can be an informal tacit understanding between coconspirators).

B. Jury Instructions.

[12] The defendants next argue that the district court erred in failing to give their proposed jury instruction requiring the government to prove materiality as an element of misbranding. The defendants claim that without a material false or misleading statement in the labeling, the meat is not "misbranded." The defendants further argue that without such a materiality requirement the misbranding statutes, as applied to them in this criminal prosecution, are overly broad and vague, thus violating their due process rights. Because this claim requires us to interpret the misbranding statutes, we review the claim de novo. *See United States v. Brummels*, 15 F.3d 769, 771 (8th Cir.1994).

[13] When we interpret a statute, "the beginning point must be the language of the statute, and when a statute speaks with clarity to an issue judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished." *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475, 112 S.Ct. 2589, 2594, 120 L.Ed.2d 379 (1992). We thus examine the language of the statute in question to resolve this claim. The relevant language provides that meat is misbranded "if its labeling is false or misleading in *any* particular." 21 U.S.C. § 601(n)(1) (emphasis added). The statutory language does not require that the false or misleading statements be "material," and we decline to judicially rewrite the statute to add such a requirement.

[14] Not requiring a materiality element is also consistent with the public policy underlying the Federal Meat Inspection Act. Congress has determined that the companies and people engaged in the food business have an affirmative duty to insure that the food they sell to the public is safe and properly labeled. *See United States v. Park*, 421 U.S. 658, 670–73, 95 S.Ct. 1903, 1910–12, 44 L.Ed.2d 489 (1975); *United States v. Cattle King Packing Co.*, 793 F.2d 232, 240 (10th Cir.), *cert. denied*, 479 U.S. 985, 107 S.Ct. 573, 93 L.Ed.2d 577 (1986). Judicially adding a materiality requirement when none exits in the statutory text would not further congressional intent and would instead hinder it.

[15] We also reject the argument that the statute, as applied in this criminal case, violates due process because it is overly broad and vague. The "in any particular" language of 21 U.S.C. § 601(n)(1) is not overly broad or vague. It simply prohibits any false or misleading statements in meat labeling without limiting the prohibition to any particular types of false or misleading claims. This is not a difficult provision for those in the food business to follow. They may comply simply by not including any false or misleading statements in their meat labeling. We therefore hold that the district court did not err in rejecting the defendants' proposed jury instruction on materiality.

[16] The defendants next argue that the district court abused its discretion in refusing to give a proposed jury instruction concerning when a corporate officer may be held criminally responsible for the actions of the company. The proposed instruction would have informed the jury that "a person is not responsible for the acts performed by other people on behalf of a corporation, even if those persons are officers, employees or other agents of the corporation." (Appellants' App. at 83).

[17] "When reviewing a challenge to the jury instructions, we recognize that the district court has wide discretion in formulating the instructions and will affirm if the entire charge to the jury, when read as a whole, ***560** fairly and adequately contains the law applicable to the case." *United States v. Casas*, 999 F.2d 1225, 1230 (8th Cir.1993), *cert. denied*, 510 U.S. 1078, 114 S.Ct. 894, 127 L.Ed.2d 86 (1994).

[18][19] A corporate officer who is in a " 'responsible relationship' " to an activity within a company that violates provisions of the federal food laws, such as meat misbranding under 21 U.S.C. §§ 610 and 676, "can be held criminally responsible even though that officer did not personally engage in that activity." *Cattle King*, 793 F.2d at 240 (quoting *Park*, 421 U.S. at 673–74, 95 S.Ct. at 1912–13). As previously noted, the misbranding provisions of which the corporate officers were convicted require the officer to act with an "intent to defraud." 21 U.S.C. § 676(a). Thus, the jury could convict a defendant corporate officer if it found a defendant: (1) had an intent to defraud; and (2) either personally participated in the misbranding or was in a "responsible relationship" within the company regarding the misbranding of meat.

We first note that the defendants' proposed jury instruction does not accurately state the law set out above as it applies in this case. Under the proposed instruction the jury could not have convicted a defendant based on the actions of any officers, employees, or other agents of Dakota Lean, Inc. However, a defendant *can* be held criminally responsible for the acts of other people who are officers, employees or other agents of the company if the defendant is in a "responsible relationship." *See Cattle King*, 793 F.2d at 240. Thus, the district court did not abuse its discretion in refusing to give the proposed instruction.

[20] We also find no error in the instructions that were given. They correctly required the jury to find that each defendant had a specific intent to defraud and that each of them had caused misbranding of meat to occur. Because the jury found the corporation guilty of six counts of misbranding without also finding any of the Jorgensens guilty of these counts, we are convinced that the jury did not find any of the Jorgensens guilty of misbranding merely because they held positions of authority in the company. We cannot say the district court abused its discretion in giving these instructions. We reject the defendants' claims on this issue.

[21][22] The corporate defendant next claims that the district court erred by failing to instruct the jury on the findings necessary to hold a corporation criminally liable for the acts of its officers, agents, or employees. Because the corporation did not offer such an instruction in the district court, nor object to the court's failure to give such an instruction, we review this claim for plain error. There is plain error if the omitted instructions should have been given and the error affected the defendant's "substantial rights" and "the error 'seriously affect[s] the fairness, integrity or public reputation of judicial proceedings.' " *United States v. Olano*, 507 U.S. 725, 736, 113 S.Ct. 1770, 1779, 123 L.Ed.2d 508 (1993) (quoting *United States v. Atkinson*, 297 U.S. 157, 160, 56 S.Ct. 391, 392, 80 L.Ed. 555 (1936)) (alteration in original).

[23] A corporation is criminally responsible for the "acts of its officers, agents, and employees committed within the scope of their employment and for the benefit of the corporation." *United States v. Richmond*, 700 F.2d 1183, 1195 n. 7 (8th Cir.1983) (citing *United States v. Demauro*, 581 F.2d 50, 53 (2d Cir.1978)) *abrogated on other*

grounds, United States v. Raether, 82 F.3d 192 (8th Cir.1996).

The evidence shows that on all counts of which Dakota Lean, Inc. was convicted an officer, agent, or employee of the corporation was acting within the scope of his or her employment when the act charged against the corporation was committed. Thus, even assuming arguendo that the jury was improperly instructed on this issue, Dakota Lean suffered no prejudice from this error. The integrity and fairness of the trial was not so affected as to produce a miscarriage of justice. We therefore hold the district court did not commit plain error.

[24][25] The defendants next contend that the district court erred in failing to submit their "theory of defense" instructions regarding the government's alleged failure to give them notice of their violations of the Federal ***561** Meat Inspection Act. The defendants claim that the government was required to give them notice of any violation of the Federal Meat Inspection Act and to bring administrative proceedings against them before the government could bring criminal charges against them, citing 21 U.S.C. § 607(e) and 9 C.F.R. § 355.40(a). The proposed instructions did not state that the government must give the defendants notice prior to bringing criminal charges, and also failed to tell the jury what to do if the jury found that the government did not give the defendants the notice referred to in the instruction. (*See* Appellants' App. at 60, 92.) [FN2] The proposed instructions were inadequate and incomplete. We further hold that this claimed theory of defense, i.e., that the government failed to abide by its own regulations before seeking the indictment, is not a defense submissible to the jury. Rather, it is the kind of attack on the indictment that should be made by a motion to dismiss before trial pursuant to Federal Rule of Criminal Procedure 12(b)(1) since it is a claimed defense or objection based on a defect "in the institution of the prosecution." *See United States v. Henderson–Durand*, 985 F.2d 970, 973 (8th Cir.) (holding a defendant's failure to raise a claim of outrageous government conduct in a pretrial motion pursuant to Rule 12(b)(2) constituted waiver of the claim), *cert. denied*, 510 U.S. 856, 114 S.Ct. 164, 126 L.Ed.2d 125 (1993). The district court properly declined to submit these proposed instructions.

FN2. Martin Jorgensen's proposed jury instruction provided:

> If the Secretary of Agriculture has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Meat Inspection Act is false or misleading in any particular, he may direct that such use be withheld unless that marking, labeling, or container is modified in such manner as he many prescribe so that it will not be false or misleading. If the person, firm, or corporation using or proposing to use the marking, labeling or container does not accept the determination of the Secretary, such person, firm, or corporation may request a hearing, but the use of the marking, labeling, or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person, firm, or corporation adversely affected thereby appeals.

(Appellants' App. at 60.) The defendants' joint proposed jury instruction provided:

> You are instructed that the law establishing the crime of misbranding also provides that the Secretary of Agriculture does not need to report for prosecution cases where it is believed that the public interest will be adequately served by a suitable written notice of warning.

[26][27] The defendants next argue that the district court erred in failing to instruct the jury that they had to be unanimous in determining which overt acts they found supported the conspiracy count conviction. The defendants did not object to the conspiracy instruction given and they did not offer a unanimity instruction regarding the overt acts. Thus, we review for plain error. We reject the argument because the defendants suffered no prejudice from any claimed error. The jury unanimously found all the defendants guilty of several of the same substantive misbranding counts. The facts of those misbranding counts were alleged in the indictment as overt acts done in furtherance of the conspiracy to misbrand. Thus, in finding all the defendants guilty of these acts when they were alleged as substantive counts, the jury also unanimously found that the defendants had committed these overt acts in furtherance of the conspiracy.

C. Evidentiary Rulings.

[28][29][30] The defendants first claim the district court erred in admitting hearsay statements of coconspirators. The defendants also claim the court erred when it failed to make an explicit ruling of admissibility regarding these statements at the close of all the evidence, in violation of *United States v. Bell,* 573 F.2d 1040, 1044 (8th Cir.1978). District courts should be careful to make sure that final *Bell* rulings are made. Prosecutors who offer coconspirator statements under the nonhearsay exception have a duty to protect their record by making sure they request final *Bell* rulings at the close of all the evidence. A final *Bell* ruling determines whether or not the government has shown by a preponderance of the evidence: (1) that a conspiracy existed; (2) that the declarant ***562** and the defendant were members of the conspiracy; and (3) that the declarant's statements were made during and in furtherance of the conspiracy, thereby satisfying Federal Rule of Evidence 801(d)(2)(E). *Bell,* 573 F.2d at 1043.

[31] Because the defendants have failed to specify by record references any particular coconspirator statements which the court allegedly erroneously admitted, we do not address their contention that the court erred in initially admitting them. *United States v. England,* 966 F.2d 403, 407 (8th Cir.), *cert. denied,* 506 U.S. 1025, 113 S.Ct. 668, 121 L.Ed.2d 592 (1992). Likewise, because no particular hearsay statement has been called to our attention, we are unable to test whether or not the statements were made during the course of and in furtherance of the conspiracy as required by *Bell.* Lacking such information (and it not being our responsibility to dig through 20 volumes of trial transcript to ferret out and examine each such statement as it may appear), we are unable to say that the failure of the district court to make a final *Bell* ruling so affected the substantial rights of any of the defendants as to constitute reversible error.

[32][33] The defendants next claim the district court abused it discretion in admitting evidence of the Department of Agriculture's Policy Memo 114. In reviewing this evidentiary ruling, we note the district court "has broad discretion in determining what evidence to admit and its decision will be overturned on appeal only if there has been an abuse of discretion." *United States v. Rogers,* 939 F.2d 591, 594 (8th Cir.) *cert. denied,* 502 U.S. 991, 112 S.Ct. 609, 116 L.Ed.2d 632 (1991).

Testimony at trial indicated that Policy Memo 114 was sent to all meat producers who had obtained a grant of federal meat inspection, although the defendants denied ever receiving it. The federal meat inspector assigned to the Dakota Lean plant said he had not seen it either. The memo advised producers that "point of purchase" literature should only make claims that could also be made on meat wrappers or labels. The defendants argue that by admitting the memo the jury was allowed to convict them for a violation of this policy memo, rather than for a violation of the statute. We reject this argument.

First, the district court cautioned the jury prior to the admission of the policy memo that the memo

itself did not set out the law. Also, the district court properly instructed the jury on the elements required to be proven for misbranding, including the required intent to defraud. The court specifically set out what "intent to defraud" meant. We are therefore confident that the jury did not use the memo for the improper purpose of using a standard different from the statute whose violation could be punished criminally.

[34] The memo was also relevant. The government's proffered reason for admission of Policy Memo 114 was to show "discourse between [the] Dakota Lean Meat plant and [the] Food Safety Inspection Service regarding claims that they would put on a product that may relate to nutrition, and diet, and so forth regarding the labeling." (Trial Tr. 144.) The memo, dated July 1988, was relevant to show the defendants had been told the literature accompanying their meat shipments could be considered labeling and that it should not be false or misleading. There was testimony that the defendants had planned to put their claims of "no hormones" and "no antibiotics" on their meat package labels, but the federal meat inspector "wasn't going to allow that." Instead, the company decided to put the claims in the literature accompanying the meat, and in the so-called "point of purchase materials" distributed at meat counters. The memo was relevant because it tended to show that the defendants acted with an intent to defraud when they made the representation on the accompanying literature. It was for the jury to determine whether the defendants ever saw the memo. We hold the district court's admission of Policy Memo 114 into evidence was not an abuse of discretion.

[35] With respect to the admission of the testimony of the government's witness Mel Coleman, we agree with the district court that it was of limited relevancy. Given the cautionary and limiting instruction that court gave to the jury concerning Coleman's testimony,***563** we do not believe the court abused its broad discretion in permitting the jury to hear it.

[36][37][38] The defendants next claim the district court erred in submitting an unredacted indictment to the jury because they claim some overt acts alleged in the indictment were not proven. "Submission of the indictment to the jury is a matter within the sound discretion of the trial court provided the jury is admonished that the indictment does not constitute evidence of any kind." *United States v. Wagoner,* 713 F.2d 1371, 1377 (8th Cir.1983). Although the "better course" is for the trial court to redact the indictment "if the government has not presented evidence supporting allegations in the indictment," reversal is required only if the defendant suffered prejudice as a result. *England,* 966 F.2d at 408. The district court admonished the jury that the indictment did not constitute evidence of any kind. The district court instructed the jury at both the beginning and the end of the trial that the indictment was not evidence.

[39] Further, even assuming arguendo that no evidence was presented for some of the overt acts alleged in the conspiracy count, we find there was no prejudice to the defendants. Proof of one overt act in furtherance of the conspiracy is sufficient to convict under the statute in this case. *See United States v. Parker,* 586 F.2d 1253, 1258 n. 2 (8th Cir.1978). There was ample proof of at least one overt act here. We hold the district court did not abuse its discretion in submitting the indictment to the jury.

D. Sentencing.

[40][41] The defendants next challenge the district court's sentencing order. They argue the district court erred in determining the amount of loss caused by the defendants' fraud. *See* U.S. Sentencing Guidelines Manual § 2F1.1(b) (1995). The government cross appeals the sentencing order, claiming the district court calculated too low of a loss figure. We review the district court's factual determination of the amount of loss under the clearly erroneous standard. *United States v. Strassburger,* 26 F.3d 860, 862 (8th Cir.1994).

[42] To determine the amount of loss attribut-

able to each defendants' mislabeling of meat, we consider the actual loss suffered by the victims as provided in Application Note 7 of USSG § 2F1.1. *Id.* This note states that when a fraud involves "the misrepresentation of the value of an item that does have some value ... the loss is the amount by which the [item] was overvalued." USSG § 2F1.1, comment. (n. 7(a)). In other words, the loss is the amount the victim paid for the misrepresented item minus the price the victim would have paid for the item absent the misrepresentation. *Strassburger,* 26 F.3d at 862–63. However, "if an intended loss that the defendant was attempting to inflict can be determined, this figure will be used if it is greater than the actual loss." USSG § 2F1.1 comment. (n.7). Thus, the proper loss amount under section 2F1.1 is "either the amount of loss the defendant intended to inflict or the actual loss resulting from the fraudulent conduct, *whichever is greater.*" *United States v. Prendergast,* 979 F.2d 1289, 1292 (8th Cir.1992)

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The Sentencing Guidelines allow the court to calculate the amount of loss with a view towards practicality, providing "the loss need not be determined with precision. The court need only make a reasonable estimate of the loss, given the available information. This estimate, for example, may be based on the approximate number of victims and an estimate of the average loss to each victim." USSG § 2F1.1, comment. (n.8).

In this case the district court first ruled that the price the victims would have paid for the defendants' products if they had been properly labeled could not be determined from the evidence presented. The court instead calculated the loss by using an estimate of the loss to each victim. The court found that the retail profit margin on the meat bought from the defendants was one percent. The court then calculated the total amount of misbranded meat sales attributable to each defendant by totaling the misbranded meat sales in dollars under each count in which the jury had found the particular defendant guilty. The court then determined that the retail profit margin represented an estimate *564 of the actual loss suffered by the victims who received the mislabeled meat from the defendants. The court multiplied the total dollar amount of mislabeled meat attributed to a particular defendant by the one percent profit margin to determine the amount of loss under section 2F1.1 attributable to that particular defendant.

Although the district court employed a somewhat novel approach in calculating the loss value, we cannot say that it resulted in a clearly erroneous loss amount. As explained above, the loss figure is only required to be an estimate; it need not be determined with precision. *See* USSG § 2F1.1, comment. (n.8). We conclude that the district court calculated a reasonable estimate of the losses attributable to each defendant.

[43] We also reject the government's argument on the cross appeal that the loss figures were too low. The government points to evidence in the record supporting a higher loss calculation. The district court found this evidence was not persuasive. We hold this finding was not clearly erroneous and affirm the district court's sentencing orders.

III.

We have considered all other arguments raised by the defendants in their appeal and find them to be without merit. We therefore affirm the judgments of the district court.

C.A.8 (S.D.),1998.
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144 F.3d 550

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C

Supreme Judicial Court of Massachusetts, Suffolk.
GROCERY MANUFACTURERS OF AMERICA, INC. et al.[FN1]
v.
DEPARTMENT OF PUBLIC HEALTH et al.[FN2]

FN1. The Grocery Manufacturers of America, Inc., is an incorporated trade association whose membership includes approximately 145 companies. The other plaintiffs are the American Frozen Food Institute, an incorporated trade association, whose membership includes 409 companies, and the following corporations engaged in the manufacture of labeled food products: Consolidated Foods Corporation, ITT Continental Baking Company, Nabisco, Inc., Ore-Ida Foods, Inc., The Pillsbury Company, The Quaker Oats Company, Seabrook Foods, Inc., Sioux Honey Association, Standard Brands Incorporated, and Stouffer Foods Corporation.

FN2. The interim Commissioner of the Department of Public Health.

Argued May 8, 1979.
Decided Aug. 28, 1979.

Plaintiffs challenged validity of Department of Public Health's food-labeling regulation requiring vendors of food products to disclose "last date of use" or "pull date." The Supreme Judicial Court, Suffolk County, Abrams, J., reported the case. The Supreme Judicial Court, Wilkins, J., held that: (1) Department had authority to adopt such regulation; (2) delay of approximately 18 months between date of hearing and date of adoption of regulation was not excessive and did not create procedural infirmity; (3) changes made in regulation during such 18-month period did not require that a further public hearing be held; (4) Department was not required to include in the record a statement of legislative facts supporting the regulation; (5) evidence failed to establish that operation of regulation would impose impermissible burden on interstate commerce; (6) federal law was not shown to have preempted field of activity governed by the regulation; (7) regulation was not unconstitutionally vague on its face; and (8) regulation bore reasonable relation to goal of consumer protection.

Judgment entered accordingly.

West Headnotes

[1] Administrative Law and Procedure 15A 385.1

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(C) Rules, Regulations, and Other Policymaking
15Ak385 Power to Make
15Ak385.1 k. In general. Most Cited Cases
(Formerly 15Ak385)
Issuance of regulation by agency may be authorized even where it cannot be traced to specific statutory language.

[2] Administrative Law and Procedure 15A 303.1

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(A) In General
15Ak303 Powers in General
15Ak303.1 k. In general. Most Cited Cases
(Formerly 15Ak303)
Powers granted to agency include those necessarily or reasonably implied.

[3] Administrative Law and Procedure 15A 429

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(C) Rules, Regulations, and Other Policymaking
15Ak428 Administrative Construction of Statutes
15Ak429 k. In general. Most Cited Cases
(Formerly 15Ak330)

Agency has considerable leeway in interpreting statute it is charged with enforcing.

[4] Constitutional Law 92 2411

92 Constitutional Law
92XX Separation of Powers
92XX(B) Legislative Powers and Functions
92XX(B)4 Delegation of Powers
92k2410 To Executive, Particular Issues and Applications
92k2411 k. In general. Most Cited Cases
(Formerly 92k62(5.1), 15Ak209)

Legislature may delegate to an agency the authority under proper statutory guidelines to define more precisely by regulation the nature of an offense.

[5] Administrative Law and Procedure 15A 303.1

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(A) In General
15Ak303 Powers in General
15Ak303.1 k. In general. Most Cited Cases
(Formerly 15Ak303)

If agency has not been granted broad authority to deal with an entire area of activity, closer scrutiny of the authority of the agency is required.

[6] Food 178 5

178 Food
178k5 k. Purity and quality. Most Cited Cases

Department of Public Health's statutory authority to regulate sale of food with a label "misleading in any particular" includes authority to regulate sale of food with labels containing omissions of fact as well as sale of food with labels containing express misstatements of fact. M.G.L.A. c. 94 §§ 187, 192.

[7] Food 178 5

178 Food
178k5 k. Purity and quality. Most Cited Cases

Department of Public Health's authority to regulate sale of food with a label "misleading in any particular" included authority to adopt label regulation requiring vendors of food products to disclose "last date of use" or "pull date"; fact that certain statutory provisions granted Department authority to prescribe regulations in great detail on particular subjects did not limit Department's authority to deal with other matters under more general statutory guidelines. M.G.L.A. c. 94 §§ 1 et seq., 187, 187, subds. 9, 11, 12, 14, 192.

[8] Administrative Law and Procedure 15A 305

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(A) In General
15Ak303 Powers in General
15Ak305 k. Statutory basis and limitation. Most Cited Cases

Agency's specific statutory authority to act in particular respect does not bar consistent action under general statutory authority.

[9] Declaratory Judgment 118A 204

118A Declaratory Judgment
118AII Subjects of Declaratory Relief
118AII(K) Public Officers and Agencies
118Ak204 k. State officers and boards.

Facial attack on Department of Public Health's regulation consisting of claim that such regulation, which required vendors of food products to disclose "last date of use" or "pull date," was in conflict with certain statutory provisions did not involve an actual controversy, as required for issuance of a declaratory judgment. M.G.L.A. c. 94 §§ 189, 189A, 194; c. 231A § 1.

[10] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
Even if Department of Public Health's food-labeling regulation, which required vendors of food products to disclose "last date of use" or "pull date," conflicted with certain statutory provisions, such conflicts would have gone only to details of the procedural operation of regulation and would not have warranted invalidation of entire regulation. M.G.L.A. c. 94 §§ 189, 189A, 194.

[11] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
Delay of approximately 18 months between date of hearing and date of Department of Public Health's adoption of regulation, which required vendors of food products to disclose "last date of use" or "pull date," was not excessive and did not create procedural infirmity, in light of complexity of regulation and significant amount of industry opposition expressed at hearing, in light of fact that Department used such time to evaluate basis of the opposition, to obtain additional material and to encourage a voluntary program, that channels of communication were kept open and that Department had been urged by interested parties to postpone its decision.

[12] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
Health's regulation during period between date of hearing and date of adoption of such regulation, which required vendors of food products to disclose "last date of use" or "pull date," did not require that a new hearing be held, in view of indication that such changes, which were made in response to suggestions at the hearing, were not so extensive as to make the regulation a different regulation from the one as to which the proceeding was held.

[13] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
In action in which plaintiffs challenged validity of Department of Public Health's food-labeling regulation requiring vendors of food products to disclose "last date of use" or "pull date" and in which plaintiffs contended that regulation as approved by public health council differed from regulation as it appeared in final form in state register, plaintiffs failed to rebut statutory presumption of legitimate adoption of the regulation as published in register. M.G.L.A. c. 30A § 6.

[14] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
Department of Public Health, which adopted food-labeling regulation requiring vendors of food products to disclose "last date of use" or "pull date," was not required to include in the record a statement of legislative facts supporting the regulation. M.G.L.A. c. 30A § 1 et seq.

[15] Administrative Law and Procedure 15A ⚿485

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(D) Hearings and Adjudications
15Ak484 Findings
15Ak485 k. Necessity and purpose.

Most Cited Cases

Administrative Procedure Act does not require agency findings of legislative facts in the record in a regulatory proceeding. M.G.L.A. c. 30A § 1 et seq.

[16] Health 198H ⚿382

198H Health
198HII Public Health
198Hk379 Judicial Review of Administrative Proceedings
198Hk382 k. Scope of judicial review of agency decision. Most Cited Cases
(Formerly 199k20 Health and Environment)

On review of regulation adopted by Department of Public Health, it was not open to parties challenging regulation to argue that it was unsupported by substantial evidence, but, rather, they had to show that regulation was arbitrary or capricious. M.G.L.A. c. 30A §§ 7, 14(7).

[17] Commerce 83 ⚿13.5

83 Commerce
83I Power to Regulate in General
83k11 Powers Remaining in States, and Limitations Thereon
83k13.5 k. Local matters affecting commerce. Most Cited Cases

Where state agency's regulation does not discriminate between in-state and out-of-state businesses and its effects on interstate commerce are only incidental, regulation will be upheld unless burden imposed on such commerce is clearly excessive in relation to putative local benefits.

[18] Commerce 83 ⚿60(2)

83 Commerce
83II Application to Particular Subjects and Methods of Regulation
83II(B) Conduct of Business in General
83k60 Manufacture and Sale of Goods
83k60(2) k. Food products. Most Cited Cases

In action in which plaintiffs challenged validity of Department of Public Health's food-labeling regulation requiring vendors of food products to disclose "last date of use" or "pull date," evidence failed to establish that operation of the regulation would impose impermissible burden on interstate commerce.

[19] Administrative Law and Procedure 15A ⚿750

15A Administrative Law and Procedure
15AV Judicial Review of Administrative Decisions
15AV(D) Scope of Review in General
15Ak750 k. Burden of showing error. Most Cited Cases

In a declaratory relief proceeding involving a challenge to regulation, plaintiff must prove its case in the judicial proceeding; facts represented in material submitted to an agency, unless stipulated as admitted, may not be relied on in the judicial challenge to the regulation. M.G.L.A. c. 30A § 7.

[20] States 360 ⚿18.65

360 States
360I Political Status and Relations
360I(B) Federal Supremacy; Preemption
360k18.65 k. Product safety; food and drug laws. Most Cited Cases
(Formerly 360k4.10)

Federal law was not shown to have preempted field of activity governed by Department of Public Health's food-labeling regulation requiring vendors of food products to disclose "last date of use" or "pull date."

[21] States 360 ⚿18.3

360 States
360I Political Status and Relations
360I(B) Federal Supremacy; Preemption
360k18.3 k. Preemption in general. Most Cited Cases
(Formerly 360k4.10)

comprehensive character of federal legislation.

[22] States 360 ⚿18.5

360 States
360I Political Status and Relations
360I(B) Federal Supremacy; Preemption
360k18.5 k. Conflicting or conforming laws or regulations. Most Cited Cases
(Formerly 360k4.13)

In cases involving state and federal regulation of same subject, criterion for determining whether state and federal laws are so inconsistent that state law must give way is whether, under circumstances of the case, state's law stands as an obstacle to accomplishment and execution of full purposes and objectives of Congress.

[23] States 360 ⚿18.5

360 States
360I Political Status and Relations
360I(B) Federal Supremacy; Preemption
360k18.5 k. Conflicting or conforming laws or regulations. Most Cited Cases
(Formerly 360k4.11)

In a case in which it is asserted that state agency's regulation is in conflict with federal objectives, court must consider relationship between state and federal laws as they are interpreted and applied, not merely as they are written.

[24] States 360 ⚿18.5

360 States
360I Political Status and Relations
360I(B) Federal Supremacy; Preemption
360k18.5 k. Conflicting or conforming laws or regulations. Most Cited Cases
(Formerly 360k4.11)

Party asserting that state agency's regulation is in conflict with federal objectives is required to prove his case with hard evidence of conflict and not merely with unsupported pronouncements as to federal policy.

[25] States 360 ⚿18.65

360 States
360I Political Status and Relations
360I(B) Federal Supremacy; Preemption
360k18.65 k. Product safety; food and drug laws. Most Cited Cases
(Formerly 360k4.10)

In action in which plaintiffs challenged validity of Department of Public Health food-labeling regulation requiring vendors of food products to disclose "last date of use" or "pull date," Supreme Judicial Court would not determine scope of federal preemption in regard to meat and poultry products, in light of fact that there was no controversy over existence of such preemption and that stipulated facts did not furnish sufficient information concerning specific meat and poultry products. M.G.L.A. c. 231A § 1.

[26] Statutes 361 ⚿1514

361 Statutes
361VIII Validity
361k1514 k. Certainty and definiteness; vagueness. Most Cited Cases
(Formerly 361k47)

In a statute regulating business activities, broad words of general meaning may be sufficiently definite so as not to render the statute void for vagueness. M.G.L.A. Const. Pt. 1, Art. 10; U.S.C.A.Const. Amend. 14.

[27] Criminal Law 110 ⚿13.1

110 Criminal Law
110I Nature and Elements of Crime
110k12 Statutory Provisions
110k13.1 k. Certainty and definiteness. Most Cited Cases
(Formerly 110k13.1(1))

Criminal statute failing to give person of ordinary intelligence fair notice that his contemplated action is forbidden must be treated as void for vagueness but even criminal statutes need not be drafted with mathematical precision; test is whether the

standard is comprehensible to persons of common intelligence, not whether it may be imprecise. M.G.L.A. Const. Pt. 1, Art. 10; U.S.C.A.Const. Amend. 14.

[28] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
Department of Public Health's food-labeling regulation, which required vendors of food products to disclose "last date of use" or "pull date," which afforded substantial deference to manufacturers' judgment concerning date to be disclosed and under which the proposed effective date was earlier for perishable foods than for nonperishable foods, was not unconstitutionally vague on its face. M.G.L.A. Const. Pt. 1, Art. 10; U.S.C.A.Const. Amend. 14.

[29] Criminal Law 110 ⚿13.1

110 Criminal Law
110I Nature and Elements of Crime
110k12 Statutory Provisions
110k13.1 k. Certainty and definiteness. Most Cited Cases
(Formerly 110k13.1(1))
Uncertainty as to whether marginal offenses are included within coverage of a statute does not render it unconstitutional if its scope is substantially clear. M.G.L.A. Const. Pt. 1, Art. 10; U.S.C.A.Const. Amend. 14.

[30] Administrative Law and Procedure 15A ⚿749

15A Administrative Law and Procedure
15AV Judicial Review of Administrative Decisions
15AV(D) Scope of Review in General
15Ak749 k. Presumptions. Most Cited Cases
All rational presumptions are to be made in favor of validity of regulation.

[31] Food 178 ⚿5

178 Food
178k5 k. Purity and quality. Most Cited Cases
Department of Public Health's food-labeling regulation, which required vendors of food products to disclose "last date of use" or "pull date," bore reasonable relation to goal of consumer protection.

****884 *71** John J. Curtin, Jr., Boston (Irvin D. Gordon and Janis M. Berry, Boston, with him), for plaintiffs.

S. Stephen Rosenfeld, Asst. Atty. Gen. (Terry Jean Seligmann and Robert Gaines, Asst. Attys. Gen., with him), for defendants.

Before ***70** HENNESSEY, C. J., and BRAUCHER, WILKINS, LIACOS and ABRAMS, JJ.

WILKINS, Justice.

The plaintiffs, who shall be referred to collectively as the GMA (Grocery Manufacturers of America, Inc.), brought this action under G.L. c. 231A, to challenge the validity of a food labeling regulation adopted in July, 1978, by the Department of Public Health (department). A single justice reported the case to the full court on the pleadings and a statement of agreed facts.

The challenged regulation appears in s 101.19 of the Massachusetts Register under the heading "FOOD, OPEN DATE LABELING" and is set forth in an appendix to this opinion. The basic purpose of the regulation is to require persons who offer a food product for sale in package form to ****885** disclose a date on the package to provide the consumer with information about the quality of the product as it may be adversely affected by the passage of time. Disclosure of this ***72** type is generally known as "open date labeling." The vendor, or potential vendor, must disclose either of two dates. It may set forth the "last date of use," defined in s 101.19(a)(2) as the "date beyond which the product may not be fit for consumption" when "stored under those conditions recommended for storage of the product on the label." In determining this date,

the manufacturer is to consider factors listed in (a)(2), which may significantly change the product after the date of its packaging. Alternatively, the vendor may disclose a "pull date," defined in s 101.19(a)(5) as "the date after which the product may not be of the quality which the manufacturer represents it to be," determined by the manufacturer on consideration of factors relating to the quality of the product, again on the assumption that the product will be stored as recommended on its label. FN3

FN3. Open date labeling discloses a product's "shelf life," defined in s 101.19(a)(6) as "the period of time during which a food product is of unimpaired quality." All food products are subject to deterioration or alteration, but the regulation makes a distinction between "perishable" and "non-perishable" food products, dividing food products between those with a shelf life of sixty days or less ("perishable") and those with a shelf life of more than sixty days ("non-perishable"). The only significance of this distinction is the effective date of the regulation as to each class. It became effective as to "perishable" foods on July 1, 1979. By extensions granted since the adoption of the regulation, it will become applicable to frozen "non-perishable" foods on May 1, 1981, and to other "non-perishable" foods on May 1, 1982. The GMA's challenge here is directed only toward the application of the regulation to "non-perishable foods," although many, if not all, of its arguments appear applicable to "perishable" foods as well.

The GMA advances a multitude of challenges to the regulation. It contends that the department lacked statutory authority to adopt the regulation, and that, even if the department had that authority, the regulation is invalid because the department failed to conform with various procedural requirements. Additionally, the GMA argues on constitutional grounds that (a) the regulation impermissibly intrudes on an area preempted by the Federal government, (b) the regulation improperly burdens interstate commerce, ***73** and (c) the regulation denies due process of law because it is void for vagueness and lacks a rational basis for its enactment as a police power measure. We reject all these contentions.

As far back as 1973, the department undertook consideration of the adoption of food labeling regulations, including open date labeling, and held a public hearing on the subject. After receiving numerous comments and criticisms, in the fall of 1976 the department proposed food labeling regulations and held another public hearing. After this hearing, the department requested further information from the GMA itself and from the National Canners Association, among others, concerning (a) the economic impact of the proposed open date labeling regulations for "non-perishable" foods and (b) the nutritive loss or deterioration (such as loss of color, flavor or aroma) in non-perishable foods. In April, 1977, the Public Health Council of the department adopted regulations concerning ingredient labeling, nutrition labeling, and labeling of "organic" foods, but adopted no open date labeling regulations. In May, 1977, the National Canners Association (now the National Food Processors Association) undertook consideration of a voluntary open date program and asked the department to delay action on its regulation. The department received numerous comments on the regulation between November, 1976 and July 26, 1978.

In July, 1978, the Public Health Council of the department provisionally approved an open date regulation, and by July 25, 1978, further comments had been received from several sources. On that date, the Public Health Council approved certain modifications in the regulation it had provisionally approved, and adopted the modified ****886** regulation, which was published in the Massachusetts Register on August 31, 1978. FN4

FN4. The GMA's claim that the Public Health Council did not adopt the regulation in the form in which it was published in the Massachusetts Register is discussed below.

***74** The parties have filed a statement of agreed facts which we summarize in part. All food manufacturers agree that a food product may not be of that quality which a manufacturer expects of its product at the time of consumption if it is subjected to adverse conditions of temperature, humidity, light, handling, or some combination of these elements. Most food manufacturers have an opinion as to the minimum period during which, under normal conditions, their products will be of the quality which they expect at the time of consumption. Various manufacturers have identified the shelf lives of their products. Most food packages include coded information which identifies the place and date of packaging. Some openly show dates of packaging. Some local supermarket chains and several national companies voluntarily use open dates for some or all of their non-perishable food products, although most manufacturers do not open date their non-perishable products. The National Food Processors Association has undertaken a voluntary open date program for canned goods. There is an indication of substantial consumer interest in open date labeling. Although there are requirements for open date labeling of perishable food products in some other jurisdictions, we are advised that open date labeling is not required for "non-perishable" foods anywhere else in the country.

1. The department's authority to promulgate the regulation. The GMA argues that the department lacked statutory authority to adopt any regulation requiring open date labeling. It contends that G.L. c. 94, s 187, which defines the term "misbranded," cannot be read to authorize a regulation requiring disclosure of "the pull date or the last date of use" of non-perishable food. In short, the GMA contends that misbranding speaks only to active misrepresentations. In support of this view, the GMA argues that the Legislature has enacted affirmative disclosure requirements, containing specific details, in those situations where active representations must be made and that open date labeling is not one of these situations. The GMA further contends that the regulation is invalid because, in particular ***75** respects, it is inconsistent with portions of G.L. c. 94, ss 186-195.

[1][2][3][4] The general principles governing agency authority to issue a regulation are not in substantial dispute. A regulation may be authorized even where it cannot be traced to specific statutory language. See Levy v. Board of Registration & Discipline in Medicine, — Mass. —, — [FNA], 392 N.E.2d 1036 (1979); Opinion of the Justices, 368 Mass. 831, 834-835, 333 N.E.2d 388 (1975); Cambridge Elec. Light Co. v. Department of Pub. Utils., 363 Mass. 474, 494, 295 N.E.2d 876 (1973). "An agency's powers are shaped by its organic statute taken as a whole." Commonwealth v. Cerveny, 373 Mass. 345, — [FNB], 367 N.E.2d 802, 808 (1977). Powers granted include those necessarily or reasonably implied. Opinion of the Justices, supra. Bureau of Old Age Assistance of Natick v. Commissioner of Pub. Welfare, 326 Mass. 121, 124, 93 N.E.2d 267 (1950). An agency, of course, has considerable leeway in interpreting a statute it is charged with enforcing. Consolidated Cigar Corp. v. Department of Pub. Health, 372 Mass. 844, — [FNC], 364 N.E.2d 1202 (1977). The Legislature may delegate to an agency "the authority under proper statutory guidelines to define more precisely by regulation the nature of an offense." Commonwealth v. Racine, 372 Mass. 631, — [FND], 363 N.E.2d 500, 503 (1977).

FNA. Mass.Adv.Sh. (1979) 1857, 1862.

FNB. Mass.Adv.Sh. (1977) 1943, 1952.

FNC. Mass.Adv.Sh. (1977) 1419, 1427.

FND. Mass.Adv.Sh. (1977) 1101, 1106.

[5] In certain situations, of which this is not

thority to deal with an entire **887 area of activity. See, e. g., Warner Cable of Mass. Inc. v. Community Antenna Television Comm'n, 372 Mass. 495, 362 N.E.2d 897 (1977) (regulation of cable television throughout Commonwealth); Colella v. State Racing Comm'n,360 Mass. 152, 153-154, 274 N.E.2d 331, 333 (1971) ("full power to prescribe rules, regulations and conditions under which all horse or dog races . . . shall be conducted in the commonwealth"); Universal Mach. Co. v. Alcoholic Beverages Control Comm'n, 301 Mass. 40, 44, 16 N.E.2d 53 (1938) ("comprehensive and exclusive jurisdiction" over businesses engaging in sale of alcoholic beverages). Where no such broad statutory grant exists, closer scrutiny of the authority of the agency is required and has been applied. Commonwealth v. Racine, 372 Mass. 631, 363 N.E.2d 500 (1977) (regulation *76 imposing a fine upheld as furthering goal stated in statute). Commonwealth v. Cerveny, 373 Mass. 345, 367 N.E.2d 802 (1977) (power to require forms to be signed under oath implied from power to subpoena and to administer oaths). Commonwealth v. Rivkin, 329 Mass. 586, 109 N.E.2d 838 (1952) (power to prohibit sales not granted by authority to regulate conditions under which sales could be made). Commonwealth v. Johnson Wholesale Perfume Co., 304 Mass. 452, 24 N.E.2d 8 (1939) (regulation purporting to add additional requirement to statute, held invalid).

[6][7] We conclude that the authority granted by G.L. c. 94, s 192, [FN5] to regulate the sale of misbranded food, that is, a food with a label " misleading in any particular" (G.L. c. 94, s 187), includes an omission of fact as well as an express misstatement of fact. The regulation seeks to eliminate the implied representation, which derives from the item's availability for sale, that the food is fit for consumption ("last date of use") or that it is of the quality which the manufacturer represents it to be ("pull date"). Plainly, misbranding as defined in s 187 may include an omission. Various portions of s 187 relate to misbranding by omission. See, e.

FN5. Section 192, as amended through St.1961, c. 600, s 8, reads in relevant part as follows:

> "The department of public health shall enforce sections one hundred and eighty-six to one hundred and ninety-five, inclusive. . . . Said department, after a public hearing, shall adopt and promulgate rules and regulations consistent with said sections, and, except as to standards fixed by law, may adopt standards, tolerances and definitions of purity or quality or identity for articles of food, drugs or devices, and may adopt rules and regulations consistent with said section for cosmetics."

[8] The fact that various sections of G.L. c. 94 grant the department authority to prescribe regulations in great detail on particular subjects does not limit the department's authority to deal with other matters under more general statutory guidelines. Specific statutory authority to act in a particular respect does not bar consistent action under general statutory authority. See Levy v. Board of Registration & Discipline in Medicine, —Mass. —, — [FNE], 392 N.E.2d 1036 (1979); *77 Cambridge Elec. Light Co. v. Department of Pub. Utils., 363 Mass. 474, 496, 295 N.E.2d 876 (1973). Acceptance of the GMA's argument that detailed statutory language in G.L. c. 94 concerning a subject bars regulation of that subject under the general statutory authority of s 192 would completely and illogically free the subjects of specific statutory regulation from treatment as "misbranded" (s 187) products.

FNE. Mass.Adv.Sh. (1979) 1857, 1863.

[9][10] The GMA makes several claims that the regulation is in conflict with certain statutory provisions. In this facial attack on the regulation we do not have an actual controversy, as required for

the issuance of a declaratory judgment (G.L. c. 231A, s 1), concerning the conflict of the regulation with specific statutes. Even if the alleged conflicts do exist, they go only to details of the procedural operation of the regulation and would not warrant the invalidation of the entire regulation. We should not be understood as implying the validity or invalidity of the GMA's challenges.[FN6]

FN6. Some of the arguments are as follows: (1) The regulation conflicts with s 189 because it does not incorporate the procedural requirements of that section. It is not clear that the procedural requirements of s 189, if they are applicable to open date labeling, cannot be complied with as well as those of the regulation. (2) Section 194 requires the department to refer certain violations "to the proper national authorities for their action," not to ban the product, a practice the regulation permits. Section 194 appears to relate to penalties for certain dealers who sell a misbranded product, not to the consequences to the misbranded product. (3) Section 189A provides for a court determination that an article is misbranded before it may be ordered destroyed or directed to be relabeled. Subsection (f) of the regulation allows the department to determine that a date selected for any food product is not justified and, after a hearing, to order the packer or manufacturer to change the date in accordance with the department's findings. The GMA claims that the regulation conflicts with s 189A. It may be that s 189A's requirement of a judicial determination of misbranding as a prerequisite to remedial action would make ineffective any department direction to correct the label date, in the absence of a court order. If this potential conflict is not resolved before the issue arises, the courts may have to settle the issue.

****888** 2. Procedural challenges. The GMA makes a series of procedural challenges to the regulation, none of which has merit.

[11] The GMA alleges procedural deficiencies in the public hearing held prior to the adoption of the regulation. The ***78** statute contains no requirement that the Public Health Council itself hold the hearing. "Hearings of the department may be held by the commissioner, or his designee." G.L. c. 111, s 3; as amended through St.1973, c. 1168, s 19. Neither the delay between the date of the hearing and the date of the adoption of the regulation nor the changes made in the regulation during that period created a procedural infirmity. The delay of approximately eighteen months was not excessive, in light of the complexity of the regulation and the significant amount of industry opposition expressed at the hearing. The department used this time to evaluate the basis of industry opposition, to obtain additional material from interested parties, and to encourage a voluntary program of open date labeling. The channels of communication between the GMA and the department were kept open through a series of meetings and through correspondence. The GMA was not deprived of an opportunity to comment on the proposed regulation, nor does it appear to have been prejudiced by any delay. Contrast Gricus v. Superintendent & Inspector of Bldgs. of Cambridge, 345 Mass. 687, 691, 189 N.E.2d 209 (1963) (five-year lapse and change in composition of majority of board); Rep.A.G., Pub.Doc.No. 12, at 34 (1955) (five-year lapse and change in interested parties). We note, moreover, that on more than one occasion the department was urged by interested parties to postpone its decision on open date labeling.

[12] The changes in the regulation, made in response to suggestions at the public hearings, were not so extensive as to make the regulation "in effect, a different regulation from the one as to which the proceeding was held" so as to require a new hearing, as the GMA contends. "The requirement of submission of a proposed rule for comment does

comment merely because the rule promulgated by the agency differs from the rule it proposed, partly at least in response to submissions." International Harvester Co. v. Ruckelshaus, 155 U.S.App.D.C. 411, 428, 478 F.2d 615, 632 (D.C.Cir. 1973) (footnote omitted). "A hearing is intended to educate an agency to approaches different***79** from its own; in shaping the final rule it may and should draw on the comments tendered." South Terminal Corp. v. Environmental Protection Agency, 504 F.2d 646, 659 (1st Cir. 1974). Many of the changes in the regulation were made in response to industry criticisms and suggestions. The regulation as adopted is "a logical outgrowth of the hearing and related procedures." Id. A further public hearing was not required.

[13][14][15] The GMA argues that the regulation as approved by the Public Health Council differs from the regulation as it appears in its final form in the Massachusetts Register. The statement of agreed facts provides that all the exhibits in this case "may be considered by the Court as ****889** authentic and genuine." One of those exhibits, the minutes of the Public Health Council meeting of July 25, 1978, contains a copy of the regulation as adopted on that date. That copy is identical to the one published in the Massachusetts Register. The GMA's argument that the regulation as it appears in the Massachusetts Register differs from the draft regulation that was presented at the July 25 meeting overlooks the fact that the regulation as approved at that meeting incorporated "amendments of Council made on that date." Obviously, these amendments, which were trivial, could not have already been incorporated in the draft that was then physically before the Council. The Council discussed and agreed to these amendments at the July 25 meeting, and approved the regulation in the form in which it appears in the Massachusetts Register. The GMA has failed to rebut the statutory presumption of legitimate adoption of the regulation as published in the Massachusetts Register (G.L. c. 30A, s 6), and the record shows no defect in the department's procedures in any event.

The GMA seeks to impose on the department a requirement of including in the record a statement of the legislative facts supporting the regulation. There is no such requirement in the law of the Commonwealth. "(F)or the court to check back on the agency's 'reasons' and 'determination(s)' of fact and law would have an unhealthy tendency to substitute***80** the court for the agency as policymaker." Cambridge Elec. Light Co. v. Department of Pub. Utils., 363 Mass. 474, 491, 295 N.E.2d 876, 886 (1973). The GMA's reliance on cases decided under the Federal Administrative Procedure Act is misplaced because this State's Administrative Procedure Act (G.L. c. 30A) does not require agency findings of legislative facts in the record in a regulatory proceeding. Compare 5 U.S.C. s 553(c) (1976) with G.L. c. 30A, s 2. The United States Supreme Court has recently held that a reviewing court should not impose procedural requirements on administrative agencies in addition to those imposed by Congress. Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 524-525, 98 S.Ct. 1197, 55 L.Ed.2d 460 (1978). We have recently stated that "the approach of a court to an agency regulation is as deferential as that to a legislative enactment." Greenleaf Fin. Co. v. Small Loans Regulatory Bd., — Mass. —, — [FNF], 385 N.E.2d 1364, 1371 (1979).

FNF. Mass.Adv.Sh. (1979) 356, 368.

[16] The answer to the GMA's claim that fairness demands that it be given an opportunity to challenge "crucial legislative facts" is that it was given just such an opportunity at the public hearing and in its continued communications with the department. On review of the regulation, it is not open to the GMA to argue that the regulation was unsupported by substantial evidence; the GMA must show that the regulation was arbitrary or capricious. Greenleaf Fin. Co., supra, and cases cited. Compare G.L. c. 30A, s 7, with Id. s 14(7). As discussed below, the GMA has made no such showing.

3. Constitutional arguments. The GMA presents a variety of challenges to the regulation based on asserted constitutional violations. None of them has merit.

[17][18][19] The GMA has failed to prove that the operation of the regulation will impose an impermissible burden on interstate commerce. Where, as here, the regulation does not discriminate between in-State and out-of-State businesses and its effects on interstate commerce are only incidental, the regulation "will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Pike v. Bruce Church, Inc., 397 U.S. 137, 142, 90 S.Ct. 844, 847, 25 L.Ed.2d 174 (1970). The record does not establish that the regulation ***81** will burden interstate commerce and certainly does not demonstrate any excessive burden. In a challenge under G.L. c. 30A, s 7, to a regulation, the plaintiff must prove its case in the judicial proceeding. See ****890**Greenleaf Fin. Co. v. Small Loans Regulatory Bd., — Mass. —, —, 1364 - —, 385 N.E.2d 1364 (1979).[FNG] Cf. Tober Foreign Motors, Inc. v. Reiter Oldsmobile, Inc., —Mass. —, —[FNH], 381 N.E.2d 908 (1978). Aeration Processes, Inc. v. Commissioner of Pub. Health, 346 Mass. 546, 554 n.7, 194 N.E.2d 838 (1963). Facts represented in material submitted to an agency, unless stipulated as admitted, may not be relied on in a judicial challenge to an administrative regulation.

FNG. Mass.Adv.Sh. (1979) 356, 368, 377-378.

FNH. Mass.Adv.Sh. (1978) 2468, 2478.

[20][21] The GMA's argument that Federal law has preempted the field of activity governed by the regulation must fail. There is no Federal statutory provision expressly precluding State regulation of open date labeling. Nor is there any Federal statute impliedly preempting the field. Preemption is not " to be inferred merely from the comprehensive character of (Federal legislation)." New York State Dep't of Social Servs. v. Dublino, 413 U.S. 405, 415, 93 S.Ct. 2507, 2514, 35 L.Ed.2d 255 (1973).

[22][23][24] The typical preemption case involves State and Federal regulation of the same subject. In such a case, "(t)he criterion for determining whether state and federal laws are so inconsistent that the state law must give way is . . . 'whether, under the circumstances of this particular case, (the State's) law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " Jones v. Rath Packing Co., 430 U.S. 519, 526, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977), quoting from Hines v. Davidowitz, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941). If there is somehow a conflict with objectives of the Federal Food, Drug, and Cosmetic Act, and related regulations, the GMA has not demonstrated what that conflict is. In a case where a conflict with Federal objectives is asserted, the court must "consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." Jones v. Rath Packing Co., supra. See De Canas v. Bica,424 U.S. 351, 363-365, 96 S.Ct. 933, 47 L.Ed.2d 43 (1976); New York State Dep't of Social Servs. v. Dublino, supra 413 U.S. at 417, 93 S.Ct. 940. Plaintiffs are "required to prove their case with hard ***82** evidence of conflict, and not merely with unsupported pronouncements as to (Federal) 'policy.' It is on the basis of the record evidence in this case that we must determine whether there is an actual, impermissible conflict between the local and federal law." Kargman v. Sullivan, 552 F.2d 2, 6 (1st Cir. 1977). See Aeration Processes, Inc. v. Commissioner of Pub. Health, 346 Mass. 546, 554 n.7, 194 N.E.2d 838 (1963). The record in this case does not warrant, much less require, a conclusion that there is an improper conflict between the regulation and any Federal law.

The regulation acknowledges the preemption of labeling of "meat food products" and "poultry products" by the Federal Meat Inspection Act and the Poultry Products Inspection Act. See 21 U.S.C. ss 453(e)-(f); 601(j) (1976) and the specific pree-

emption provisions of 21 U.S.C. ss 467e and 678 (1976). The definition of "food" in 105 Code Mass.Regs. 520.023(J), which is incorporated into s 101.19, exempts "meat food products and poultry products as defined in (G.L. c. 94, s 118)." The definitions in s 118 track the definitions in the Federal statutes.

[25] The GMA seeks a determination of the extent of the preemption concerning meat and poultry food products. Relief through a declaratory judgment proceeding requires an actual controversy. G.L. c. 231A, s 1. Because the department and the regulation acknowledge this Federal preemption, there is no controversy over its existence. Although the parties disagree over the interpretation of the relevant statutory provisions, the stipulated facts do not furnish sufficient information concerning specific meat and poultry products for us to determine the extent of Federal preemption. The scope of that preemption will have to be determined case by case on a ****891** consideration of facts which have not been shown on this record. FN7

> FN7. The GMA argues that the department should have made findings indicating its careful consideration and resolution of the interstate commerce and Federal preemption issues. The Administrative Procedure Act imposes no such obligation in a regulatory, as opposed to an adjudicatory, proceeding. Compare G.L. c. 30A, s 7, with Id. s 14. The GMA relies on Penn Cent. Co. v. Department of Pub. Utils., 356 Mass. 478, 253 N.E.2d 339 (1969), where this court sent a regulatory proceeding back to the administrative agency for findings in a case involving an agency regulation said to run afoul of the interstate commerce clause and Federal preemption of the area. We have never since applied the principle of the Penn Cent. case. We declined to expand the requirement of agency findings in Cambridge Elec. Light Co. v. Department of Pub. Utils., 363 Mass. 474, 492-493, 295 N.E.2d 876, 887 (1973), saying that the "Penn Cent. case can apply only to extraordinary situations." Id. at 492, 295 N.E.2d at 887.
>
> It is not necessary to decide whether we would today perpetuate the judicial embellishment on the Administrative Procedure Act which the Penn Cent. case represents. It is sufficient to note that the apparent tensions with, and agency indifference to, Federalism concerns that the Penn Cent. case presented are not present here. The possible conflict with Federal law and the possible imposition of an unacceptable burden on interstate commerce are not so apparent here as to require agency findings, even if the principle of the Penn Cent. case is still viable. In short, this is not an "extraordinary" situation.
>
> In any event, the record demonstrates the department's attention to the problems of Federalism. The department prepared a brief memorandum adverting specifically to the requirements of the Penn Cent. case and concluding that "there seems to be no discernable conflict with federal law." The regulation itself contains a reciprocity provision that grants an exemption for products that comply with equivalent open date labeling requirements of another agency. s 101.19(g). The department also expressly excluded meat and poultry products from the regulation's ambit.

***83** [26] The GMA argues that the regulation is void for vagueness, and thus violates the Fourteenth Amendment of the Constitution of the United States and art. 10 of the Declaration of Rights. In a statute regulating business activities, broad words of general meaning may be sufficiently definite in the circumstances to meet the constitutional test. Commonwealth v. Gustafsson, 370 Mass. 181, 187, 346

N.E.2d 706 (1976).

We have assumed, without deciding, that a regulation whose violation is a criminal act is tested by a higher standard of definiteness than a noncriminal regulation. See Aristocratic Restaurant of Mass., Inc. v. Alcoholic Beverages Control Comm'n (No. 1), — Mass. —, — [FNI], 374 N.E.2d 1181, appeal dismissed, 439 U.S. 803, 99 S.Ct. 58, 58 L.Ed.2d 96 (1978). In our analysis we shall continue to make that assumption. Further, we shall treat the regulation as one whose violation might lead to criminal prosecution, although a manufacturer who makes a good faith attempt to comply with the regulation appears unlikely ***84** e subjected to criminal proceedings prior to an administrative analysis of, and decision concerning, its conduct. Where there is an opportunity to resolve ambiguities of application administratively prior to criminal prosecution, the threat of unfair indefiniteness is greatly reduced. Cf. Tober Foreign Motors, Inc. v. Reiter Oldsmobile, Inc., —Mass. —, — [FNJ], 381 N.E.2d 908 (1978).

FNI. Mass.Adv.Sh. (1978) 558, 564.

FNJ. Mass.Adv.Sh. (1978) 2468, 2489.

[27] A criminal statute that fails to give a person of ordinary intelligence fair notice that his contemplated action is forbidden must be treated as void for vagueness. Opinion of the Justices, — Mass. —, — - — [FNK], 393 N.E.2d 313 (1979), and cases cited. Yet even criminal statutes need not be drafted with "mathematical precision." Commonwealth v. Bohmer, — Mass. —, — [FNL], 372 N.E.2d 1381 (1978). The test is whether the standard is comprehensible to persons of common intelligence, not whether it may be imprecise. Commonwealth v. Orlando, 371 Mass. 732, 734, 359 N.E.2d 310 (1977).

FNK. Mass.Adv.Sh. (1979) 1781, 1785-1786.

FNL. Mass.Adv.Sh. (1978) 316, 320.

[28][29] The regulation is not unconstitutionally vague. Certainly, every manufacturer is placed on notice that it must ****892** disclose either "the pull date" or "the last date of use" of any food product governed by the regulation, as it chooses. The alleged imprecision of the regulation concerning the method for determining the proper date for each product is eliminated by the regulation's substantial deference to the manufacturer's judgment concerning the date to be disclosed. We regard the regulation as sufficiently definite to give a manufacturer fair notice of what is required. The regulation is not unconstitutionally vague on its face, and the record does not disclose any particular product as to which it is unconstitutionally vague as applied.[FN8]

FN8. The proposed effective date of the regulation is earlier for "perishable" foods than for "non-perishable" foods. The question whether a product has a shelf life of sixty days or less, and is thus a "perishable food," or has a longer shelf life and is therefore a "non-perishable food" may be a close one in given instances. However, "(u)ncertainty as to whether marginal offenses are included within the coverage of a statute does not render it unconstitutional if its scope is substantially clear." Commonwealth v. Bohmer, — Mass. —, — (Mass.Adv.Sh. (1978) 316, 320), 372 N.E.2d 1381, 1386 (1978). "Shelf life" is defined as "the period of time during which a food product is of unimpaired quality." Reg. 101.19(a)(6). Admittedly, the shelf life of a particular food item will vary depending on a number of factors in its handling. The parties have stipulated that most food manufacturers "have an opinion as to the minimum period during which assuming normal conditions of temperature, humidity, light and handling their respective products will be of the quality which each manufacturer expects of its product at the time of consumption."

quiring, in the first instance, only a good faith judgment of the shelf life of a food product.

***85** [30][31] There is no merit to the GMA's argument that the regulation is invalid because it does not bear "a real and substantial relation to the public health, safety, morals, or some other phase of the general welfare." Coffee-Rich, Inc. v. Commissioner of Pub. Health, 348 Mass. 414, 422, 1204 N.E.2d 281, 287 (1965), quoting from Sperry & Hutchinson Co. v. Director of the Div. on the Necessaries of Life, 307 Mass. 408, 418, 30 N.E.2d 269 (1940). See also Mobil Oil Corp. v. Attorney Gen., 361 Mass. 401, 412-413, 280 N.E.2d 406 (1972). All rational presumptions are to be made in favor of the validity of the regulation. Coffee-Rich, Inc. v. Commissioner of Pub. Health, supra. "(T)he approach of a court to an agency regulation is as deferential as to that of a legislative enactment." Greenleaf Fin. Co. v. Small Loans Regulatory Bd., — Mass. —, — FNM, 385 N.E.2d 1364, 1371 (1979). Requiring information concerning the nutrition and quality of food promotes the public health and safety, as those words are used in defining the police power of a State. The question for our consideration is not whether open date labeling is good policy but whether the regulation bears a reasonable relation to the goal of consumer protection. The parties have stipulated that all foods, even "non-perishable" foods, are altered with the passage of time. A regulation that requires the disclosure of otherwise unavailable information concerning the quality of food products has a rational basis. The GMA has failed to meet its heavy burden of demonstrating that the regulation is irrational. See Commonwealth v. Henry's Drywall Co., 366 Mass. 539, 541-542, 320 N.E.2d 911 (1974).

FNM. Mass.Adv.Sh. (1979) 356, 368.

4. Judgment shall be entered declaring that the department was authorized to adopt the regulation and did so in ***86** conformity with the requirements of law. Additionally, the judgment shall declare that the unconstitutionality of the regulation has not been demonstrated in this proceeding.

So ordered.

APPENDIX.

SECTION 101.19 FOOD, OPEN DATE LABELING

(a) For the purpose of this section, the following terms shall have the following meanings:

(1) "Frozen foods" shall mean articles used for food or drink which have been packaged and preserved by freezing.

(2) "Last date of use" shall mean that date beyond which the product may not be ****893** fit for consumption. In establishing the last date of use, the manufacturer shall assume that the product will be stored under those conditions recommended for storage of the product on the label, and shall consider:

(A) significant change in the texture, color or aroma of the product from and after the date of pack;

(B) staleness of the product;

(C) loss of functional property(ies) of the product;

(D) the likelihood of container deterioration;

(E) the likelihood of decomposition or spoilage;

(F) any other change in the product which, in the opinion of the manufacturer, renders the product not fit for consumption.

(3) "Non-perishable food" means food that has a shelf life of more than 60 days after manufacture.

(4) "Perishable food" means food that has a shelf life of 60 days or less after manufacture.

(5) "Pull date", means the date after which the

product may not be of the quality which the manufacturer represents it to be. The phrases "last date of sale" or "for best quality use by" shall be synonymous with "pull date." This date shall be determined by the manufacturer upon consideration of factors pertaining to quality, including but not limited to nutritive loss, or loss of flavor, texture, color or aroma, as evaluated by any testing procedures currently utilized by the food industry to determine the quality of food. In determining this date, the manufacturer shall assume that the product will be stored under those conditions recommended*87 for storage of the product on the label. In no event shall the date established hereunder be later than the last date on which the product can be sold without a significant risk that it will exceed its last date of use if stored by the purchaser prior to consumption for the period and in the manner which such a product can reasonably be expected to be stored.

(6) "Shelf life" means the period of time during which a food product is of unimpaired quality.

(b) No person shall sell, offer for sale, or have in his possession with intent to sell, a food product in package form unless the package of said food has legibly been stamped, printed, or otherwise conspicuously marked in bold face type of contrasting color and in letters at least 1/8 inch in height in a manner set forth below, except that when the letters are embossed in a can, bottle, or plastic container, they need not be in a contrasting color.

(c) The manufacturer of a food product shall place on the package either the pull date or the last date of use of the food and labeled as follows:

(1) The date shall consist of the common abbreviation for the calendar month and numerals for the day and year, or numerals for the month, day and year, e. g., Feb. 10, 77 or 2/10/77, for February 10, 1977. A perishable food need not have the year identification included in the date and a nonperishable food need not have the day identification included in the date.

(2) Fresh bakery products may be dated with only the day designation, e. g., Monday, Tuesday, or an abbreviation thereof, e. g., Mon., Tues., which shall be attached to the package by a tie or clip. If dated in this fashion, fresh bakery products shall be exempt from the requirements of section 101.19(c)(1).

(3) An explanation describing the meaning of the date must be in close proximity to the date. Examples of explanations are "use before ", "sell by ", or "for best quality use by ", the blank space filled with the date specified in Sections 101.19(c)(1) or (c)(2).

(4) If the date does not appear on the principal display panel, the information panel, or on another conspicuous portion of the package, a statement must appear on the principal display panel or information panel indicating where on the package the date can be found. This statement shall also contain the information required in **894 Section 101.19(c)(3) if because of technical problems, e. g., embossing on a can, it is impractical to have the explanatory statement in close proximity to the date. Examples of such a statement would be: "Last date of sale on lid", or "use before date on end", or "sell by date on bottom".

(5) If a condition(s) of storage affects the date, the recommended storage condition(s) must be stated on the label.

(d) Food which has passed its pull date may be sold, Provided, That, the food is segregated from food which has not passed its date, and Provided, further, that the food is clearly and conspicuously marked either on *88 each package or through the use of shelf markers or place cards, as being offered for sale "PAST DATE". This section shall not be construed to allow the sale of adulterated food or food which has passed its last date of use.

(e) Any product subject to Section 101.19 which is not dated and labeled in accordance with the provisions of said section, shall be deemed

"misbranded" under General Laws Chapter 94 Section 187.

(f) Upon request of the Department, the packer or manufacturer shall file a statement as to the period of time between the date of manufacture and either the last date of sale or the last date of use, whichever is used for that food. If the food package bears a lot identification code indicating the date of manufacture, the Department may also require the packer or manufacturer to file the interpretation of said code. If, after conducting an investigation, the Department determines that the date selected is not supported by its findings, it shall direct the packer or manufacturer to change the date in accordance with such findings. Any packer or manufacturer aggrieved by such an order shall be afforded the opportunity for hearing. The order shall not be overturned unless the appellant establishes by clear and convincing evidence that the date originally selected is in fact justifiable under sections 101.19(a)(2) or (5). The order shall be considered final unless reversed upon such review. Pending review, the affected product may not be offered for sale unless the date is modified in accordance with the order of the Department.

(g) Any packer or manufacturer may apply to the Department for an exemption from the provisions of Section 101.19. An exemption shall be granted if:

(1) The product for which the exemption is sought is open dated in accordance with the regulations of another agency; and

(2) compliance with the regulations of the other agency will result in the disclosure to consumers of substantially the same information as is required by these regulations;

(h) The following foods are exempt from this section:

(1) Fresh meat, fresh poultry, fresh fish, fresh fruits, and fresh vegetables.

(2) Food products shipped in bulk form for use solely in the manufacture of other foods and not for distribution to the consumers in such bulk form or container.

(3) Sugar.

(4) Salt.

(5) Food in a hermetically sealed container which has been heat sterilized so that it may be stored without refrigeration. It is the understanding of the Department that such food shall be open dated under a voluntary plan formulated by the National Food Processors Association, and that a substantial portion (85% To 90%) of such food products are expected to be in compliance with these regulations no later ***89** than July 1, 1981. In the event the voluntary program fails to produce satisfactory progress toward and attainment of this goal, the Department shall promulgate a mandatory compliance date for such food products.

(i) Notwithstanding any other effective dates set forth in the Labeling Regulations, Section 101.19 shall take effect in accordance with the following schedule:

(1) For perishable foods, the effective date shall be July 1, 1979.

(2) For frozen foods, the effective date shall be July 1, 1980.

****895** (3) For remaining non-perishable foods, the effective date shall be July 1, 1981.

(j) Any packer or manufacturer who voluntarily dates a food product which is not subject to Section 101.19 shall nevertheless be subject to the provisions of subsection (f).

Approved and adopted by the Department of Public Health at its meeting of July 25, 1978. Incorporates amendments of Council made on that date.

Attest: (s) Barbara Corcoran

Attest: Barbara Corcoran

Attest: Secretary to the

Attest: Department

Attest: August 21, 1978

Mass., 1979.
Grocery Mfrs. of America, Inc. v. Department of Public Health
379 Mass. 70, 393 N.E.2d 881

END OF DOCUMENT

SUBJECT: **Illegal Residues In Meat, Poultry, Seafood, and Other Animal Derived Foods**	IMPLEMENTATION DATE 08/01/2005 COMPLETION DATE Continuous

DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
Industry codes: 16, 17, 67-69	71006, 71S006 71004 71003A

FIELD REPORTING REQUIREMENTS

1. Hardcopy Reporting

For all Federal and State investigations/inspections submit, Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G), to the Compliance Information Management Team, HFV-235, Attention: Fran Pell.

2. FACTS Reporting

a. Report time for all Federal drug residue follow-ups against Program Assignment Code (PAC) 71006. For state inspections of residue violations conducted under contract report time against PAC 71S006. For state inspections of residue violations conducted under cooperative agreements report the time under PAC 71006 with a state position class to identify the work as state-performed. For all inspections include the FSIS sample number in the description field of FACTS.

b. Report time for follow-up at medicated feed mills against PAC 71004.

c. Report time for Contamination Response System (CRS) investigations of non-drug residues against PAC 71003A.

PART I – BACKGROUND

This Compliance Program was developed to provide a cohesive framework for the Field to use that would include inspectional priorities, helpful technical information, and resources to facilitate the investigation of residue violations routinely reported to the Food and Drug Administration (FDA) by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). To protect consumers from potentially harmful residues in the food that they eat it is important that inspections are conducted to determine the cause of the illegal drug residues and to develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development. This program also provides guidance for enforcement measures.. The Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321(f)) defines food as "(1) articles used for food or drink for man or other animals...and (3) articles used for components of any such article." (Section 201(f)). Food-producing animals and fish, even though not in their final, edible form, have been held to be food under the statute United States v. Tomahara Enterprises Ltd., Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and United States v. Tuente Livestock, 888 F. Supp. 1416, 1423-26 (S.D. Ohio 1995) (live hogs are food). More generally, courts have long held that unprocessed or unfinished articles are or can be food. *See* Otis McAllister & Co. v. United States, 194 F.2d 386, 387 (5th Cir. 1952) and cases cited there (unroasted coffee beans are food). Thus, live animals raised for food are "food" under the Act.

Tissue residue investigations may reveal:

- the illegal sale of veterinary prescription drugs
- the illegal use of bulk drugs
- the extra-label use of drugs (which includes inadequate pre-slaughter withdrawal period)
- cross-contamination of animal feeds due to poor Good Manufacturing Practices (GMPs) (21 CFR Parts 225 or 226)
- failure to follow good animal husbandry practices
- the misuse of drugs in medicated animal feeds
- the marketing of treated/medicated animals intended for rendering purposes being diverted to slaughter for human consumption
- inadequate animal identification

Protection of the public by assuring a safe meat and poultry supply is a responsibility shared by the USDA Food Safety and Inspection Service (FSIS), the Grain Inspection, Packers and Stockyards Administration (GIPSA), the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), The FSIS exercises supervision over the slaughter and processing of meat and poultry products in federally inspected

establishments and is responsible for the safety of these food products. FSIS reports violative residues of drugs, and both violative and non-violative reisidues of pesticides, and other contaminants in meat and poultry to FDA for follow-up.

The GIPSA works closely with FSIS in regulating animal marketing practices. GIPSA is an enforcement agency within USDA charged with enforcing the Packers and Stockyards Act of 1921 (7 U.S.C. §181) through economic regulation. GIPSA has also assisted FDA in securing producer identification when sales are through auction barns or dealers.

A final rule on swine identification became effective on November 14, 1988. All swine in interstate commerce must be identified and records concerning identification must be maintained. USDA (APHIS and FSIS) is responsible for enforcement. (53 FR 40378, October 14, 1988).

The EPA establishes the tolerances for pesticide residues in meat and poultry. FDA enforces these tolerances.

FDA is responsible for the approval of new animal drugs, including the establishment of tolerances for residues of those drugs in edible tissues. FDA conducts investigations of FSIS-reported residues to determine the party responsible for causing the tissue residue violation and the party responsible for introducing the adulterated food into interstate commerce. The results of FDA investigations have shown that, in most instances, the animal producer is primarily responsible for the illegal drug residues because of failure to comply with drug withdrawal times, other label warnings, use of contaminated animal feeds, use of drugs for unapproved purposes, and employing poor animal husbandry practices. Investigations may also lead to other individuals such as a hauler, buyer, dealer, auction barn, veterinarian, or slaughter house.

FDA has the responsibility to ensure the safety of the seafood supply. In 1995, FDA published the final HACCP (Hazard Analysis and Critical Control Points) regulations for seafood processors (53 FR 40378, December 18, 1995) (21 CFR Parts 123 and 124). The final rule became effective on December 18, 1997. Primary processors of aquaculture products are responsible for ensuring that their HACCP Plans address systems for drug residue control. The Center for Food Safety and Applied Nutrition (CFSAN) issued a Compliance Program Guidance Manual (7304.018), Chemotherapeutics in Seafood, in FY 2002 outlining procedures for sampling aquaculture products to be tested for drug residues. This compliance program addresses sampling of product from both domestic and imported sources.

In 1994, Congress passed legislation that would allow veterinarians to prescribe drugs in a manner inconsistent with the approved new animal or new human drug labeling. This act is called the Animal Medicinal Drug Use Clarification Act (AMDUCA)(21 U.S.C. §360b(a)) and the regulations that implement AMDUCA are published in Title 21 Code of Federal Regulations Part 530. These regulations describe the specific conditions under which extralabel use is permitted.

Expansion of the Tissue Residue program has paralleled the Agency's growing concern about consumer exposure to drug residues in the edible products of food animals. For example, in 2002, the Agency became aware of the use of drugs in the production of honey, to treat diseases of honey bees. This Compliance Program has been expanded to address this concern.

In an effort continually to improve the program, CVM develops new training courses for Federal and State investigators to address identified training needs. CVM also organizes national cooperative meetings with officials from FDA, FSIS, GIPSA, APHIS and individual states, writes educational articles, and conducts industry outreach programs in an effort to provide message-specific information to educate firms on sound drug use and residue prevention practices.

CVM encourages the District Offices to develop cooperative agreements (i.e., contracts, partnership agreements, memoranda of understanding, and informal arrangements) with their state agencies to conduct initial inspections. These inspections are predominantly educational in nature and are extremely important in the prevention of future residues.

For residues detected in seafood products the ultimate goal is to determine the cause of the residue and pursue regulatory action. The current CFSAN sampling program focuses on drugs that are not approved for use in aquaculture.

There are currently only two drugs approved for use in honey bees, oxytetracycline and fumagillin. If a residue is reported of a drug other than the two approved drugs, then the residue was caused by an extra-label use, and may be considered a violation of AMDUCA .

PART II – IMPLEMENTATION

A. INTRODUCTION

This program provides a framework from which each District can fashion its own drug residue control initiatives. CVM requests that Districts receiving reports of violative tissue residues from USDA/FSIS take steps to protect the consumer by either conducting Federal or assigning State onsite investigations at the farm level and other points of responsibility throughout the marketing chain, and to initiate actions commensurate with the findings.

CVM will issue FACTS assignments to request Federal investigation of repeat violators. CVM will also issue inspectional assignments via FACTS for violative residues detected in seafood and other animal derived human food. The Districts are encouraged to recommend enforcement action for such violations.

B. OBJECTIVES

- To conduct investigations/inspections to determine the cause of illegal drug residues and/or shipment of adulterated food.
- To develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development.
- To obtain correction through voluntary and/or enforcement actions.

C. PROGRAM MANAGEMENT INSTRUCTIONS

1. Inspectional

FDA Districts conduct on-site inspections in the follow-up of violative tissue residue findings of public health concern reported to them by FSIS. In association with these assignments the Districts should investigate all those in the marketing chain who may have acted irresponsibly.

Districts are encouraged to watch for trends or patterns in types of residues or involved parties; for example, the same buyer/dealer involved in a number of residues or a sudden increase in residue reports involving the same drug. The Residue Violation Information System (RVIS) is an excellent source for this type of data on residues.

The Agency's approach to focusing on individual firms for case development will be to use a coordinated team approach when determining which case(s) to pursue. If the District believes that it should develop a case on a specific producer or someone in the marketing chain please contact the Compliance Information Management

Team, HFV-235, Randy Arbaugh or Deborah Cera to discuss investigational approach/priority.

Districts should request intensified sampling of egregious firms in an effort to obtain timely residues to facilitate case development. Please submit such requests via email to the Compliance Information Management Team, HFV-235, Deborah Cera, who will handle coordination with the FSIS Technical Services Center. In order to facilitate successful sample collection please be sure to provide as much relevant information as possible regarding the firm's marketing practices, e.g., what slaughter plant(s) they use, are animals delivered directly to slaughter, or through a middleman (provide name), and on what day of the week do the animals generally go to slaughter.

NOTE:
The current CFSAN Compliance Program, 7304.018, Chemotherapeutics in Seafood, is a sample collection program designed to test for drugs that that are not approved for use in aquaculture. If a domestic sample is found to be positive, CVM will issue an assignment for follow-up to document the violation. Case development should be considered for such residues with all questions directed to the Compliance Information Management Team, HFV-235, Fran Pell.

To discuss case development for drug residues in meat and poultry contact the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker. For all other residues detected in animal derived foods, contact Compliance Information Management Team, HFV-235, Fran Pell, to discuss case development.

Pesticide and industrial chemical residues, mycotoxin contamination, microbiological residues, and heavy metals reported to the Districts by FSIS under its Contamination Response System (CRS) will be covered under the Feed Contaminants Program (7371.003). Under unique conditions, certain violative drug residues may be reported through the CRS. Follow-up investigational time for CRS drug residues should be charged to this program (7371.006). Contact the Enforcement and Regulatory Policy Team, HFV-232, Sandra Washington before initiating a follow-up to a CRS report.

a. On-Site Inspections by FDA of Meat and Poultry Violations

1) **Repeat Violators:** This is the **top priority** for FDA inspections/investigations. Firms or individuals who repeatedly present adulterated animals for slaughter may represent a significant public health risk. Therefore, CVM will issue an assignment to the District in FACTS requesting an FDA on-site investigation for each repeat violator. A repeat violator is an individual who sells a slaughter animal whose carcass is found to contain a violative concentration of a drug, pesticide, or environmental contaminant within a 12-month period after the first violation and after receiving the FSIS Notification Letter.

2) **First-time Violators:** As resource allow, conduct an on-site inspection/investigation for first-time violators when FSIS reports violative tissue residues for the following situations:

- Drugs prohibited from extra-label use in food-animal use - chloramphenicol, diethylstilbestrol (DES), nitrofurans (furazolidone, nitrofurazone), or nitroimidazoles (e.g., dimetridazole, ipronidazole), clenbuterol, sulfonamides in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine), fluoroquinolines, glycopeptides, and phenylbutazone in female dairy cattle 20 months of age or older.

- Drugs not approved for food animal use: beta agonists (e.g., fenoterol, salbutamol), tranquilizers, etc.

- Very high level residues, indicating intentional misuse of the drug and/or a complete disregard for the withdrawal period.

- Drug tissue residues reported under the CRS. These assignments will be issued from CVM.

NOTE:
If none of the above criteria is met on an initial residue violation then resource constraints do not allow for an FDA investigation. Cooperating State agencies should be assigned inspections of all other first-time violators to determine the cause of the residue and to attempt to prevent a repeat violation through education and/or any regulatory action deemed appropriate by the State.

b. On-Site Inspections by FDA of Seafood.

The drugs that are being tested for in Seafood are for unapproved drugs. All violations require an FDA follow-up and a FACTS assignments will be issued by CVM.

c. Investigation of Food Animal Marketing Firms

Focusing on firms/people responsible for the delivery for introduction or the introduction into interstate commerce of adulterated products is an important concept under this program. Experience has shown that investigations can lead to producers, haulers, dealers, auction barns, and buyers, any one of which may be held responsible for the violation. Parties throughout the chain of distribution may act irresponsibly by not determining if animals they handle are medicated or not forwarding this information to the next person or firm in the marketing chain. For example, a dealer or auction barn can take precautions by determining if animals are medicated and selling them as such. Dealers have been found to purchase medicated animals supposedly for dog food and then offer them for sale at a slaughterhouse for human food. Please relay these incidences to the local Grain Inspection Packers and Stockyards Administration. Any animal offered for sale at a USDA licensed slaughter facility is for human food. Implementation of the marketing chain strategy should be coordinated at the local and national levels between FDA, FSIS, APHIS, and GIPSA and State agencies. For example, we can request that FSIS increase sampling of a producer or dealer's animals. The goal is to use the expertise and the legal tools possessed by each group. FDA is the lead agency in collecting evidence and initiating regulatory action.

Districts should work closely with the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker at the onset of selecting a firm or individual for possible regulatory action.

d. Inspections at Aquaculture Farms

There are six drugs approved for use in aquaculture. They are: oxytetracycline, sulfadimethoxine/ormetoprim, formalin, chorionic gonadotropin, tricaine methanesulfonate and sulfamerazine. Sulfamerazine is not currently marketed. The brand names, species approved for and conditions of use can be found at:

http://www.fda.gov/cvm/aqualibtoc.htm#ApprovedDrugs

All of the drugs in the current CFSAN testing program are not approved for aquaculture use in the United States. The drugs may be labeled for non-food fish and later diverted to food fish producers. It is important to determine if the drug manufacturer or distributor is marketing these drugs for this use. If an FDA approved drug was used in an extra label manner determine if a veterinarian was involved. If so, follow-up with the veterinarian as appropriate. Determine why the producer used the drug and, if not prescribed by a veterinarian, what information was used by the producer to determine how to use the drug.

e. Inspection of other Animal-Derived Products

During inspections of other animal-derived product producers, the drug identified by the residue may have been used in an extra-label manner, so determine if there was a veterinarian involved with the use, and whether all of the conditions of AMDUCA were met.

f. Extra-label Use

The Animal Medicinal Drug Use Clarification Act became law in 1994 and the regulations implementing this law can be found in Title 21 Code of Federal Regulations Part 530 (21CFR 530). The regulations describe the conditions under which FDA approved drugs can be used in a manner inconsistent with the approved labeling as long as such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a Veterinary-Client-Patient Relationship (VCPR). This regulation only applies to FDA approved drugs and the use must be therapeutic in that the animal must be sick or might die if not treated, and there needs to be a valid veterinarian client patient relationship. For more details refer to the 21CFR 530.

While AMDUCA does not permit the extra-label use of an FDA approved drug in or on feed, CVM recognizes that for some species of animals this is not always practical. FDA published a Compliance Policy Guide (CPG Sec. 615.115), 'Extra-Label Use of Medicated Feeds for Minor Species', which permits the extra-label use of medicated feed for minor species under specific circumstances. Briefly, this extra-label use can only be done upon the order of a veterinarian, the feed must be manufactured according to the approval and there is no reformulating of the feed. For aquaculture species there are two approved medicated feeds for food fish. More details can be found at:

http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-115.html

g. FSIS Special Programs

(1) FAST

FAST (Fast Antimicrobial Screen Test) is a microbial inhibition screening test. It was designed to be used by an FSIS veterinarian or a designated food inspector in a slaughter plant, for the detection of antibiotic and sulfonamide residues in livestock kidney tissue. The FAST test reacts with at least 56 different antimicrobials.

The FAST test is based on the principle that if animal tissue contains a residue of previously administered antimicrobial, fluid from the tissue will inhibit the growth of a sensitive organism on a bacterial culture plate. The plates are examined for zones of inhibition around the sample, which constitutes a positive test. The significance of the FAST test is its high degree of sensitivity over the old CAST (Calf Antibiotic Sulfa Test) test and the fact that test results can be obtained after a minimum of **6 hours** incubation to a maximum of 24 hours from the time the plate is incubated.

If the result is negative the carcass is released. If the result is positive, tissue samples (muscle, kidney, and liver) are sent to the laboratory for bioassay testing and the carcass is retained pending laboratory results.

(2) STOP

STOP (Swab Test on Premises) is an in-plant test currently being used by FSIS plant inspectors on suspect animals to test for antibiotic microbial inhibitors. STOP-positive carcasses are retained pending the receipt of results of confirmatory tests, which are automatically conducted in FSIS laboratories.

h. FSIS Condemnation Practices

Where FDA has established a tolerance for a marker residue in a target tissue FSIS will condemn the entire carcass when a violative residue is confirmed in the target tissue. For other drugs, if the liver or kidney is found to contain violative residues, they alone are condemned. In all cases if the muscle contains a violative residue then the entire carcass is condemned.

An exception to the above is the routine condemnation of the entire carcass of any non-ruminating veal calf found to contain a hormonal implant.

2. District Monitor Responsibilities

Each District should assign an individual to serve as a monitor for this compliance program. The monitor's duties should include the following:

- Review Weekly Residue Report. CVM, in consultation with the District Program Monitor, will issue assignments to the District in FACTS for FDA Investigations and enter the appropriate assignment activity code in RVIS. The Monitor should enter all activity codes for assignments and follow-ups.

- Once an investigation is completed. The Program Monitor should, review the EIR for newly identified sources, name/address, firm-type corrections, and additional middleman information. This information should then be entered into RVIS.

- The Monitor should promptly enter appropriate activity codes covering Repeat Violator Status, Completed Investigations, Regulatory Reserve Samples, and Regulatory Actions taken. Every violation followed up by an FDA or State investigator should have the FDA Responsibility Flag entered into RVIS as responsible, not responsible, or involved. This information is needed before FSIS can post a firm to its Web Report of Repeat Violators.

- Periodically review RVIS for violator/violation trends, e.g., specific middleman involvement in a number of violations or an increase in the number of residues for a specific drug. Notify the Compliance Information Management Team, Deborah Cera, Fran Pell, or Randy Arbaugh if you believe that an investigation is warranted. Keep abreast of RVIS enhancements.

- Assign State investigations per guidance contained in Part II.C.1.a. of this program. Provide the state with computer-generated Attachment C forms for TRIMS data collection and remind them to complete the Drug Inventory Survey Form (Attachment G).

- Review completed EIRs/Attachment C forms and Drug Inventory Survey forms to determine if required fields have been completed. Discuss any incomplete reports with the appropriate parties to improve the quality of future data reported.

- For all Federal and State investigations/inspections submit a copy of the Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G), to the Compliance Information Management Team, HFV-235, Attention: Fran Pell

- Request that the inspectors/investigators contact the District Program Monitor before the start of an on-farm follow-up so that they can get an updated violator history to ensure that additional residues have not occurred since the assignment date.

- Request the Regulatory Reserve Portion of samples for all firms that might become the subject of an enforcement action. Requests should be timely to ease FSIS's burden of sample retention. All samples not requested will be destroyed after 12 months. All requests should be directed to Don Gordon, Donald.Gordon@FSIS.USDA.Gov, Tel. No. 314-263-2680 ext. 341.

- Monitors should maintain a list of samples that they have requested to be stored in an FDA laboratory. Periodically review this list and request a Sample Destruction Notices (SDNs) be prepared through the appropriate channels in your Districts once it becomes clear that the District will not be initiating enforcement action against a firm.

- Provide the District Director, and Directors of Compliance and Investigations, where appropriate, with a list of local Repeat Violators and associated District activities, at least twice annually.

- Serve as a clearinghouse for distribution of information to cooperating State officials.

- Inform District management of all CVM/ORA-sponsored training initiatives. Recommend training of all Federal/State personnel conducting residue investigations.

- Maintain routine communications with local representatives from FSIS, APHIS, GIPSA, and the States.

- Work with CVM to distribute Industry outreach materials appropriate to address local residue concerns.

3. Analytical

   Ordinarily FSIS will analyze tissues and conduct confirmatory analyses. FDA confirmatory analyses of tissue samples collected, analyzed, and confirmed by FSIS are not necessary to support regulatory action. Other tissue samples **should not** routinely be sent to the Denver District Laboratory. FSIS has agreed to run confirmatory tests on those samples that the FDA District needs to support casework. For example, if during an investigation of a neomycin residue it is revealed that a sulfa was used in combination with neomycin, a portion of the reserve sample can be sent back to FSIS for analysis for sulfas.

One exception to the above would be when FSIS reports finding a hormone implant in a veal calf submitted by a "Repeat Violator". The District should request that the reserve sample of the actual implant be shipped to the Denver District Laboratory where hormones present in the implant will be identified.

Please contact the Compliance Information Management Team, HFV-235, Deborah Cera, to facilitate requests for additional analyzes.

4. Program Interaction

When the investigation implicates a medicated feed produced by either a commercial feed mill or an on-farm mixer/feeder, conduct a comprehensive GMP inspection. For example, carbadox residues in swine generally result from feed and not dosage form drugs. Charge all time expended for GMP inspections to the Feed Manufacturing Program PAC 71004, regardless of whether done at the feed mill or the mixer-feeder. Remember, the regulations in 21 CFR Part 225 sections 225.10 to 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in 21 CFR Part 225 sections 225.120 to 225.202 apply to facilities solely manufacturing medicated feeds for which an approved medicated feed mill license is not required.

When the tissue residue results from a non-drug chemical contaminant, such as pesticides, metals, mycotoxins, or microbiological contaminants, charge the time expended for follow-up investigations to PAC 71003A - Feed Contaminants Program.

The success of the Agency's program to support the prevention of the introduction and amplification of BSE in the United States is dependent on the ability of investigators to identify violative firms and operations. While initial efforts by Federal and State investigators have identified and inspected most renderers and commercial feed mills, continued efforts are needed to identify and continue to inspect all firms subject to the regulation. Ruminant feeders are an important obligation that should receive additional attention. Unless another BSE inspection has recently been conducted, add-on BSE inspections should be conducted for each ruminant feeder visited during a tissue residue follow-up. Charge time expended for such inspections to PAC 71009 – BSE/Ruminant Feed Ban Inspections.

Tissue residue monitors should maintain close contact with their Regional Milk Specialists and State milk authorities. RVIS reports of dairy animal violations are supplied to these individuals on a quarterly basis. One long-term goal is for involved agencies to share all available information related to drug residues (milk and meat) in dairy animals. This effort can maximize resource utilization in targeting enforcement actions and promoting effective residue controls.

5. Inter-Agency Agreements

See MOU 225-85-8400 - MOU between FDA, FSIS, and EPA regarding regulatory activities concerning residues of drugs, pesticides and environmental contaminants in foods, which went into effect on February 1, 1985.

6. Federal/State Relations

States participate in this program under agreements (contract, MOU, partnership, and informal) to conduct inspections. The emphasis of the State programs is to determine the cause of the residue and to provide producer education in an effort to prevent future violations.

Regions/Districts are urged to develop cooperative work sharing agreements with **each of their** states. General guidance for the development of work-sharing agreements is found in RPM Chapter 3-20. Maintain a high level of communication with cooperating States and share with them the periodic RVIS reports of State findings and results of program evaluations.

For information on the formation of agreements with States, contact the Division of Federal-State Relations, HFC-150.

547 F.Supp.2d 491, 2008-1 Trade Cases P 76,159
(Cite as: 547 F.Supp.2d 491)

H

United States District Court,
D. Maryland.
SANDERSON FARMS, INC. and Perdue Farms, Inc., Plaintiffs,
v.
TYSON FOODS, INC., Defendant.

Civil Case No. RDB–08–210.
April 22, 2008.

Background: Sellers of chicken meat products sued competitor, alleging violations of the Lanham Act, specifically claiming that advertisements containing the claims "Raised Without Antibiotics" and "Raised Without Antibiotics that impact antibiotic resistance in humans" were false and misleading. Sellers moved for a preliminary injunction.

Holding: The District Court, Richard D. Bennett, J., held that sellers were entitled to preliminary injunctive relief.

Ordered accordingly.

West Headnotes

[1] Injunction 212 ⇐1078

212 Injunction
212II Preliminary, Temporary, and Interlocutory Injunctions in General
212II(A) Nature, Form, and Scope of Remedy
212k1077 Discretionary Nature of Remedy
212k1078 k. In general. Most Cited Cases
(Formerly 212k135)

Decision whether to issue a preliminary injunction is committed to the sound discretion of the trial court. Fed.Rules Civ.Proc.Rule 65, 28 U.S.C.A.

[2] Injunction 212 ⇐1092

212 Injunction
212II Preliminary, Temporary, and Interlocutory Injunctions in General
212II(B) Factors Considered in General
212k1092 k. Grounds in general; multiple factors. Most Cited Cases
(Formerly 212k138.1)

To determine whether a preliminary injunction is appropriate, the court must apply the four-factor hardship balancing test, considering the following: 1) the likelihood of irreparable harm to the plaintiff if injunctive relief is denied, 2) the likelihood of harm to the defendant if injunctive relief is granted, 3) the likelihood that the plaintiff will succeed on the merits, and 4) the public interest. Fed.Rules Civ.Proc.Rule 65, 28 U.S.C.A

[3] Antitrust and Trade Regulation 29T ⇐104(2)

29T Antitrust and Trade Regulation
29TII Unfair Competition
29TII(C) Relief
29Tk101 Injunction
29Tk104 Preliminary or Temporary Relief, Grounds, Subjects, and Scope
29Tk104(2) k. Particular cases. Most Cited Cases

Sellers of chicken meat products were entitled to preliminary injunctive relief against a competitor alleged to have made false and misleading claims in advertisements, in violation of the Lanham Act; an unqualified "Raised Without Antibiotics" claim was literally false, given the use of ionophores in chicken feed and the injection of other antibiotics into chicken eggs two to three days before hatch, the claim was likely to be misleading to consumers, the qualified language "Raised Without Antibiotics that impact antibiotic resistance in humans" was not likely to have been understood by a significant portion of the consumer public, and the advertising campaign had affected sales dramatically. Lanham Act, § 43(a), 15 U.S.C.A. § 1125(a).

[4] Antitrust and Trade Regulation 29T ⇐22

29T Antitrust and Trade Regulation
29TII Unfair Competition

29TII(A) In General

29Tk21 Advertising, Marketing, and Promotion

29Tk22 k. In general. Most Cited Cases

Elements of a false advertising claim under the Lanham Act are as follows: (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products. Lanham Act, § 43(a), 15 U.S.C.A. § 1125(a).

***492** Randall Karl Miller, Arnold and Porter LLP, McLean, VA, Nicholas M. Depalma, Ross S. Goldstein, Arnold and Porter LLP, Washington, DC, for Plaintiffs.

Helene D. Jaffe, Laura J. Protzmann, Randi W. Singer, Weil Gotshal and Manges LLP, New York, NY, John J. Connolly, William J. Murphy, Murphy and Shaffer LLC, Baltimore, MD, Joshua D. Janow, Weil Gotshal and Manges LLP, Washington, DC, for Defendant.

MEMORANDUM OPINION

RICHARD D. BENNETT, District Judge.

Plaintiffs Sanderson Farms, Inc. ("Sanderson") and Perdue Farms, Inc. ("Perdue") (collectively, "Plaintiffs") bring this suit against their competitor, Tyson Foods, Inc. ("Tyson" or "Defendant"), alleging violations of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Plaintiffs' Amended Complaint alleges that Tyson's advertisements containing the claims "Raised Without Antibiotics" and "Raised Without Antibiotics that impact antibiotic resistance in humans" are false and misleading to the consumer. Plaintiffs specifically allege that Tyson uses ionophores in its chicken feed and that ionophores are antibiotics.

Pending before this Court is Plaintiffs' Supplemental Motion for a Preliminary Injunction. Plaintiffs' Motion seeks to require that Tyson immediately cease all non-label advertising using the unqualified "Raised Without Antibiotics" claim and the qualified "Raised Without Antibiotics that impact antibiotic resistance in humans" claim. Plaintiffs' Amended Complaint requests injunctive relief against "any claim, direct or indirect, qualified or unqualified, in words or in substance, that Tyson's chicken is raised without antibiotics."

This Court held a hearing over four days, commencing on Monday, April 7, 2008 and concluding on Thursday, April 10, 2008, to allow the parties to present oral argument, testimony, and evidence.[FN1] Having heard the testimony of numerous witnesses, including experts proffered by the parties, and having reviewed hundreds of exhibits, this Court finds that consumers are being misled by Tyson's advertisements proclaiming that its chicken is "Raised Without Antibiotics." Based largely on Plaintiffs' consumer survey, this Court also finds that the qualified language "Raised Without Antibiotics that impact antibiotic resistance in humans" is not likely to be understood by a significant portion of the consumer public. This Court further finds that there is a strong likelihood of success by Plaintiffs on the merits of this case when it proceeds to trial. Moreover, this Court finds that the public interest compels the issuance of a preliminary injunction during the pendency of this case. Accordingly, for the reasons set forth in the following findings of fact and conclusions of law, Plaintiffs' ***493** Supplemental Motion for a Preliminary Injunction is GRANTED.

FN1. The parties also addressed the Defendant's Motion to Dismiss (Paper No. 50), which was denied on the record on April 10, 2008. That denial was supplemented by a Memorandum Opinion (Paper No. 72) and accompanying Order (Paper No. 73) issued by this Court on April 15, 2008, 549 F.Supp.2d 708, 2008 WL 1733607.

FINDINGS OF FACT

At the hearing, Plaintiffs offered the testimony of the following witnesses: 1) Dr. Bruce Stewart Brown, Perdue's Vice President of Food Safety and Quality; 2)

Hilary Burroughs, Sanderson's Manager of Marketing; 3) John Bartelme, Perdue's Chief Marketing Officer; 4) Michael B. Mazis, Ph.D., Professor of Marketing at American University's Kogod School of Business; and 5) David Hogberg, Tyson's Senior Vice President of Product Marketing.[FN2] Defendant offered the testimony of the following witnesses: 1) Steve Roth, a market research consultant; 2) Dr. Patrick Pilkington, Tyson's Vice President of State and Government Affairs; and 3) David Hogberg. In addition, both parties submitted a substantial amount of evidence, with hundreds of exhibits being introduced.

FN2. Plaintiffs' counsel read into the record portions of Walter Leggett's deposition in lieu of his live testimony. Mr. Leggett took the photographs introduced as evidence by Plaintiffs.

I. Ionophores, the USDA, and Tyson's Labels

A. Ionophores Are Antibiotics

It is undisputed in this case that ionophores are antibiotics. The United States Department of Agriculture ("USDA"), the Food and Drug Administration ("FDA"), and the American Veterinary Medical Association ("AVMA") are all in agreement on this point. The Food Safety and Inspection Service ("FSIS"), the USDA agency to which Congress has delegated the authority to regulate poultry labels, confirmed this fact on several occasions. After FSIS notified Tyson in September 2007 of its classification of ionophores as antibiotics, it reiterated its position on December 19, 2007, explaining as follows:

> It is longstanding FSIS policy that ionophores are antibiotics because they meet the AVMA definition. The Food and Drug Administration (FDA) agrees that by strict definition, ionophores are antibiotics thus; poultry meat from birds to which ionophores have been administered is not eligible to bear a "RWA" claim.
>
> (Pls.' Ex. 1.)

Moreover, both Plaintiffs' and Defendant's witnesses uniformly testified that ionophores are antibiotics. Dr. Bruce Stewart-Brown, Perdue's Vice President of Food Safety and Quality, testified that it is indisputable that ionophores are antibiotics, as the scientific literature supporting this conclusion is voluminous and consistent. Dr. Patrick Pilkington, Tyson's Vice President of State and Government Affairs, acknowledged that ionophores are antibiotics because the FDA classifies them as such. David Hogberg, Tyson's Senior Vice President of Product Marketing, also acknowledged that ionophores are antibiotics.

The potential that humans might develop antibiotic resistance is behind the public's fear of so-called "superbugs," strains of bacteria that become impervious to antibiotic treatment. Because ionophores are not used in human drugs, however, the use of ionophores in chicken products presents only a minuscule threat to antibiotic resistance in humans. Dr. Pilkington testified that the inability of ionophores to cause antibiotic resistance in humans is as close to a scientific certainty as possible, although he could not rule out the possibility.[FN3]

FN3. Dr. Pilkington acknowledged that fluoroquinolones, once thought by experts to have no impact on human antibiotic resistance, were pulled for use by the FDA when it was learned that they did, in fact, impact human antibiotic resistance.

***494 B. The Chicken Industry and Ionophores**

All three chicken producers in this case—Sanderson, Perdue, and Tyson—use ionophores in their chicken feed. In fact, the use of ionophores is a widespread industry practice. Ionophores effectively prevent coccidiosis, a disease caused by a protozoan-type parasite that lives and multiplies in the intestinal tract of animals, including chicken. Coccidiosis may cause severe symptoms, such as the inhibition of food digestion and nutrient absorption, as well as dehydration and blood loss. Coccidiosis may also result in death. The spread of coccidiosis is a significant concern in the industry.

In addition to using ionophores in its chicken feed, it was clearly established at the hearing that Tyson in-

jects a vaccine containing antibiotics into its chicken eggs two or three days before the egg hatches. Tyson technically defines "Raised Without Antibiotics" to mean from hatch until slaughter, a definition that was not revealed in Tyson's USDA application for label approval. Tyson also does not inform the consumer public that the term "Raised" does not refer to the period before hatch, nor does Tyson inform the consumer public that it injects its chicken eggs with antibiotics.

Among the three chicken producers involved in this case, only Perdue's Harvestland brand does not use any antibiotics at any time. Therefore, Perdue truthfully markets this brand using the slogan "No Antibiotics Ever." Harvestland chicken products are more expensive for Perdue to produce in terms of both husbandry and raising, because, without ionophores, costly precautions are needed to prevent against the risk of coccidiosis. This increased cost is passed to the consumer in the form of higher retail prices, a price premium that certain consumers are willing to pay for antibiotic-free chicken.

The evidence established that Tyson is able to directly compete with Perdue's more expensive Harvestland brand by using the unqualified "Raised Without Antibiotics" claim and the qualified "Raised Without Antibiotics that impact antibiotic resistance in humans" claim. This Court is satisfied by a preponderance of the evidence that consumers are misled into believing that Tyson's mass-marketed chicken and Perdue's specialty chicken are both antibiotic-free, when, in fact, Tyson feeds its chicken ionophores and injects its chicken eggs with antibiotics. Tyson executives have acknowledged that this permits them to "price up," meaning that the company can raise the price of its "Raised Without Antibiotics" chicken without seeing a corresponding decrease in sales figures.

C. FSIS Approves and Subsequently Revokes Tyson's "Raised Without Antibiotics" Label

The Food Safety and Inspection Service erroneously approved Tyson's unqualified "Raised Without Antibiotics" label application on May 16, 2007. (Def.'s Exs. 65–68.) Tyson's application listed three ionophores (salinomycin, narasin, and monensin) in the feed ingredient list. This approval resulted in Perdue seeking similar agency approval for the same label language.[FN4] (Def.'s Exs. 173–177.)

> FN4. Perdue's application remains pending. This is highly unusual, as most applications are resolved within a week. Dr. Brown and John Bartelme both testified that it is industry practice to engage the USDA in dialogue through the application process. By reviewing which applications are approved and which are denied, a company can glean USDA's internal policy.

***495** On September 12, 2007, FSIS unambiguously informed Tyson that it had made a mistake and intended to revoke its prior approval. According to a letter drafted on September 26, 2007 by Tyson's outside counsel, Nancy S. Bryson, the agency had "contacted Tyson [on September 12, 2007] to advise that FSIS had subsequently determined that approval of the ["Raised Without Antibiotics"] labels was a mistake and should be rescinded." (Def.'s Ex. 62.) Therefore, as early as September 12, 2007, Tyson was on clear notice that FSIS believed it had made a mistake and intended to revoke its approval.

On September 19, 2007, Tyson executives, along with Ms. Bryson, met with FSIS officials. After the meeting, FSIS permitted Tyson to formally respond to its concerns, which Tyson did by way of Ms. Bryson's September 26, 2007 letter. On November 6, 2007, Philip S. Derfler, Assistant Administrator of FSIS, replied to Ms. Bryson. In the letter, Mr. Derfler, on behalf of FSIS, stated that

> [i]t is longstanding FSIS policy that ionophores are antibiotics and, therefore, FSIS has not approved labels bearing a "Raised Without Antibiotics" claim if the source animals were fed ionophores. The Tyson labels at issue were thus approved in error by FSIS staff. Accordingly, we advised Tyson that FSIS intended to revoke their approval. Your letter dated September 26, 2007, asks us to reconsider this decision and to permit the continued use of these labels.

(Def.'s Ex. 35.) Mr. Derfler formally denied Tyson's request for reconsideration: "Because ionophores are antibiotics under the AVMA definition, FSIS will not change its longstanding policy regarding ionophores." (*Id.*) FSIS did, however, provide four different options to Tyson: 1) remove all "Raised Without Antibiotics" labels within forty-five days; 2) stop using ionophores in its feed formulation, in which case the "Raised Without Antibiotics" label would be technically accurate; 3) petition FSIS to initiate a public notice and comment process on the use of ionophores in poultry and meat; or 4) submit a revised label application. (*Id.*)

D. FSIS Approves a Qualified "Raised Without Antibiotics" Label

On December 18, 2007, Tyson submitted an application to FSIS seeking approval of a revised label containing qualifying language. On December 19, 2007, FSIS approved Tyson's application seeking permission to use "Raised Without Antibiotics that impact antibiotic resistance in humans" on its labels.

On January 7, 2008, the Under Secretary of the USDA, Richard A. Raymond, sent a letter to the Senior Vice President of Tyson, Archie Shaffer III, confirming that Tyson and the USDA "reached an agreement" on the qualified label. (Def.'s Ex. 36.) Mr. Raymond stated that FSIS believed the qualified "Raised Without Antibiotics" claim described "the situation in a truthful and non-misleading way." (*Id.*) The letter also indicated that FSIS would be willing to grant a period of time for Tyson to transition from the unqualified label to the qualified label. On February 25, 2008, FSIS formally approved Tyson's temporary use of the unqualified "Raised Without Antibiotics" through a date that has been redacted for this litigation.

II. Tyson's Aggressive Advertising Campaign

During the same time period that Tyson was actively involved with the USDA in having both the unqualified and qualified ***496** language approved for use on its labels, it was also incorporating both the unqualified and qualified language into a multimillion-dollar nationwide advertisement campaign that utilized television, radio, billboards, print media, posters, and point-of-purchase materials.

A. Tyson's Advertising Campaign Uses the Unqualified "Raised Without Antibiotics" Claim

After Tyson's unqualified "Raised Without Antibiotics" claim was initially approved by FSIS, the company initiated a multimedia advertising campaign that was internally termed "Project Sting." A subsection of Project Sting, the "Thank You" campaign, placed significant importance on the "Raised Without Antibiotics" language. The advertisements uniformly featured smiling children, often accompanied by a parent. Many of the advertisements included a heading in large print declaring "Chicken your family deserves, raised without antibiotics." (*See, e.g.*, Pls.' Exs. 14–18.) Project Sting was clearly intended to "[s]trengthen [the] emotional connection to [the] Tyson brand" by appealing to the public's safety and health concerns. (Pls.' Ex. 122.)

Tyson received overwhelmingly positive consumer feedback and believed this multimedia campaign was a large-scale success. From the advertisements, consumers understood that Tyson did not use antibiotics, and many consumers indicated that Tyson's chicken was "better" or "safer" than competitors' chicken. (Pls.' Ex. 119.) After conducting market research in the form of consumer reaction groups, Mr. Hogberg relayed to coworkers specific consumer quotes that he believed "summarize[d] how this campaign makes people feel [.]" (*Id.*) Among the sample quotes was the following: "It [Tyson's 'Raised Without Antibiotics' chicken] is safer chicken than others." (*Id.*) In a separate internal document, Tyson quoted another consumer as saying the following: "[Tyson's 'Raised Without Antibiotics' chicken] has made me very happy as I am a cancer survivor and I believe that all the antibiotics and artificial ingredients contribute to this major disease." (Pls.' Ex. 31.)

Tyson's data also indicated that nine out of ten consumers considered it important to have antibiotic-free chicken; in fact, it was the second most important claim that consumers looked for when shopping for chicken. (Pls.' Exs. 122, 126.) As a result of the advertising campaign, sales of Tyson chicken increased by almost thirty-five million pounds. (Pls.' Ex. 95.) The "Raised Without Antibiotics" advertising campaign was intern-

ally described as having a "dramatic" effect on sales. (Pls.' Ex. 108.)

Project Sting's success is also strongly corroborated by the fact that advertisements containing the unqualified "Raised Without Antibiotics" claim remained in the marketplace months after September 12, 2007, the date in which the USDA clearly communicated that it had made a mistake in approving the label. Indeed, as late as November 30, 2007, weeks after the USDA refused to reconsider its revocation, Mr. Hogberg was telling other Tyson employees that "no one should be holding up anything because of the RWA labeling issue." (Pls.' Ex. 108.) Indeed, he was encouraging others to "GO! GO! GO!" onward with the campaign. (*Id.*) This Court finds that Tyson's continuation of Project Sting was done with full knowledge that the USDA intended to revoke the unqualified "Raised Without Antibiotics" label. Indeed, Mr. Hogberg's "GO! GO! GO!" directive is demonstrated by the fact that Tyson purchased additional television advertisements featuring the "Raised Without Antibiotics" language on September ***497** 27, 2007, to run through January 20, 2008. This decision was made despite the fact that the USDA unambiguously indicated its intent to revoke the unqualified "Raised Without Antibiotics" label.

Moreover, Tyson distributed point-of-purchase materials to supermarkets across the country. Hilary Burroughs of Sanderson Farms attached sixty-one photographs to her affidavit that purport to show point-of-purchase materials with the unqualified "Raised Without Antibiotics" language. The photographs were all taken between January 29, 2008 and February 18, 2008, in stores located in seven states (Alabama, Arizona, California, Colorado, Mississippi, Georgia, and South Carolina).[FN5] Despite Tyson having constant communication with the USDA from September 2007 until December 2007, Tyson took no action to remove unqualified point-of-purchase materials from the market until February 28, 2008. On that date, Tyson sent out an internal "action notice" intended to begin the phase out all point-of-purchase materials that contained the unqualified "Raised Without Antibiotics" language. Mr. Hogberg, Senior Vice President of Product Marketing, testified about this delay, and this Court finds his explanation unacceptable. It is quite clear to this Court that it was in Tyson's financial interest to delay the phase-out period as long as possible.[FN6]

FN5. Defendant argued in support of its Motion to Dismiss (Paper No. 50) that point-of-purchase materials are beyond the scope of Plaintiffs' Amended Complaint because they are exclusively within the purview of the USDA under the Poultry Products Inspection Act ("PPIA"), 21 U.S.C. § 451, *et seq.* Addressing the qualified claim, this Court determined in its Memorandum Opinion dated April 14, 2008 (Paper No. 72) that "Plaintiffs' Amended Complaint fairly encompasses any labeling that, despite including language approved by the USDA, contains additional images and promotional slogans that effectively turn the labeling into an advertisement." (Mem. Op. 15.)

FN6. Mr. Hogberg testified that Tyson set an internal deadline to remove all point-of-purchase materials using the unqualified "Raised Without Antibiotics" language from the marketplace no later than April 14, 2008, before the temporary window authorized by FSIS had expired.

Additional advertisements containing the unqualified "Raised Without Antibiotics" language appeared in other media outlets long after Tyson's original label was revoked by FSIS. A billboard in Mississippi containing the unqualified "Raised Without Antibiotics" language was not taken down until mid-January 2008. (Pls.' Ex. 110.) Ironically, Joe Sanderson, the Chairman and CEO of Sanderson Farms, received at his home a retail store circular advertisement containing Tyson chicken coupons that included unqualified "Raised Without Antibiotics" language during the week of March 9, 2008 (Pls.' Ex. 117), approximately *six months* after Tyson received unambiguous notice from the USDA that the unqualified label would be revoked and *five months* after it was made clear to Tyson that the USDA, FDA, and the AVMA all agreed that ionophores were antibi-

eties. Although Tyson did not pay for the circular advertisement, it is certainly well within the company's power to insist, with little more than a phone call or email, that retail stores cease all use of the unqualified claim in circular advertisement.

B. Tyson Begins Using Variations of the Qualified "Raised Without Antibiotics" Claim

Further evidencing the aggressiveness of its marketing campaign, Tyson began purchasing advertisements using qualified "Raised With Antibiotics" language before FSIS approved Tyson's application on December 19, 2008. For this reason, many of the most recent Tyson advertisements contain***498** qualifying language that differs from the approved qualified language "Raised Without Antibiotics that impact antibiotic resistance in humans."

For example, the March/April 2008 edition of Weight Watchers magazine contains an advertisement using the language "raised without antibiotics that *create* antibiotic resistance in humans." (Pls.' Exs. 70–71. (emphasis added)) Other magazine advertisements and free-standing newspaper inserts purchased by Tyson do not include the qualifying language immediately following the unqualified "Raised Without Antibiotics" claim. For instance, in some advertisements, the unqualified claim was followed by an asterisk, leading the reader elsewhere on the page to a similar, but not USDA-approved, qualification typed in small print. (Def.'s Exs. 47–48.) This Court finds that the addition of qualifying language does little to correct the initial deception resulting from the early stages of the Project Sting campaign.

C. Tyson's Raised Without Antibiotics Advertising Campaign Has a Negative Impact on Sanderson and Perdue

Tyson's advertising campaign correspondingly had a negative financial impact on both Sanderson and Perdue. Ms. Burroughs testified that Sanderson lost approximately $4.1 million as a result of Tyson's advertising campaign utilizing the unqualified and qualified "Raised Without Antibiotics" claims. (Pls.' Ex. 47.) She testified that a large supermarket retail account that had been using Sanderson for a decade switched to Tyson during the time period Tyson was airing the "Raised Without Antibiotics" advertisements. Despite increased revenues in the final months of 2007, Sanderson's revenues and sales have decreased thus far in 2008. As far as the consumer effect, Ms. Burroughs testified that it typically takes eight to twelve months for an advertising campaign to actually penetrate the market, so the largest consumer effect of Tyson's "Raised Without Antibiotics" campaign will not be felt by Sanderson for some time.

Mr. Bartelme testified that Tyson's advertising campaign has been a "big problem" for Perdue, resulting in "truckloads of lost volume." Perdue has lost three major retail accounts to Tyson as a result of Tyson's "Raised Without Antibiotics" advertising campaign, causing a net loss to the company of approximately $10 million. (Pls.' Exs. 46, 116.) Unlike Sanderson, Perdue did not receive any new accounts during the same time period.

At the four-day hearing, evidence was introduced clearly reflecting Tyson's marketing strategy and the financial harm inflicted on Perdue. Internal Tyson documentation indicates that the "Raised Without Antibiotics" advertising campaign had "wrecked Perdue's overall enterprise strategy" and that "elevating the Tyson brand with RWA has also devalued the Perdue brand." (Pls.' Ex. 106.)

III. Plaintiffs' Consumer Survey

Professor Michael B. Mazis's consumer survey, submitted on Plaintiffs' behalf, presents compelling evidence of consumer confusion with respect to both the unqualified and qualified "Raised Without Antibiotics" claims and stands uncontradicted in all important respects. Professor Mazis's testimony at the four-day hearing also clearly established that the qualified language is not understood by a substantial percentage of consumers.

The consumer survey included 608 consumers in twenty-eight shopping malls ***499** across the United States.[FN7] The 608 participants were broken down into four equally distributed cells, each with approximately 150 people. The participants were assigned randomly to

the four cells. Each cell was shown a different stimulus. The first two cells were shown an unqualified "Raised Without Antibiotics" Tyson advertisement—the first cell was shown a television commercial and the second cell was shown a print stimulus, such as would appear in a magazine. The third cell was shown a print stimulus with the qualified "Raised Without Antibiotics" claim, using the language approved by the USDA, *i.e.*, "Raised Without Antibiotics that impact antibiotic resistance in humans." The fourth cell was shown a control print stimulus containing the following promotional statement: "chicken with great taste, high quality and unmatched variety." The fourth cell was not shown anything relating to Tyson's "Raised Without Antibiotics" claim, whether unqualified or qualified.

> FN7. Professor Mazis's consumer survey was completed with sufficient procedures to ensure accuracy. Participants qualified for the survey if they had purchased fresh raw chicken in the past three months and expected to purchase fresh raw chicken in the next three months. Potential respondents were excluded if (a) they or members of their households worked for an advertising agency or public relations firm, a marketing research firm, a law firm, or a manufacturer, distributor, or retailer of food products, or (b) if they wore eyeglasses or contact lenses but did not have their corrective eye wear with them at the time of the interview. The study was "double blind," in that neither the interviewers nor the respondents were aware of the identity of the client or the purpose of the study. The responses to all questions were then entered into a data file using 100% keypunch verification— *i.e.*, all data were keypunched twice to avoid any errors.

Professor Mazis reached two conclusions based on the consumer survey. First, the individuals that participated in the survey largely responded the same way to the qualified "Raised Without Antibiotics that impact antibiotic resistance in humans" claim as they did to the unqualified "Raised Without Antibiotics" claim. Second, participants viewed both the unqualified and qualified claims as implying that Tyson's chicken is safer and healthier than competitors' chicken.[FN8]

> FN8. Steve Roth testified for Defendant regarding Professor Mazis's consumer survey. This Court finds his testimony to be of limited value. More importantly, his testimony did not cast any doubt on Professor Mazis's findings. To a large extent, the thrust of Mr. Roth's testimony was simply that he would have asked more open-ended questions because he prefers them over close-ended questions. On cross examination, he admitted that more participants viewed Tyson's chicken as "better" or "safer" than competitors' chicken than he had previously acknowledged on direct examination, and he also admitted that it is statistically significant that over half (54.9%) of respondents in cell three referred to "no antibiotics" without mentioning anything about antibiotic resistance. In fact, he testified that he was aware that 54.9% is greater than what has been deemed sufficient in other Lanham Act cases.

A. Open–Ended Questions—Participants Interpreted the Unqualified Language and the Qualified Language the Same

Participants were asked "[w]hat is the main idea that the advertisement is trying to communicate?" Respondents who indicated that the advertisement communicated something about Tyson's chicken and antibiotics were then asked "[w]hat does the advertisement imply or state about Tyson and antibiotics?" Professor Mazis concluded from the responses to these open-ended questions that consumers process the "unqualified" and "qualified" messages in the same fashion. In short, ***500** consumers believe that there are no antibiotics given to Tyson's chickens.

In the first cell (unqualified "Raised Without Antibiotics" television commercial), 71.4% of respondents felt that the commercial communicated a "no antibiotics" claim. In the second cell (unqualified "Raised Without Antibiotics" print advertisement), 85.1% of respondents felt that the advertisement communicated a "no antibiotics" claim. In the third cell (qualified