

REF. 13

Summary of Data from Hatchery Inspections Conducted September-October, 2001

April 15, 2002

Background

A high priority assignment memorandum entitled "Use of the Veterinary Drug Ceftiofur and/or Other Antimicrobials in Poultry Hatcheries" was issued in August of 2001 as the result of report(s) of the misuse of ceftiofur in poultry hatcheries. Ceftiofur is the only cephalosporin approved for systemic use in food animals in the United States. The memo called for the inspection of 37 hatcheries (30 chicken, 7 turkey) in 23 states to determine their compliance with 21 CFR Part 530 (Extralabel Drug Use in Animals), with a focus on the use of ceftiofur and other antimicrobials. Each inspection was to be done jointly with an FDA field inspector and a member of the Division of Epidemiology at CVM. The inspections were conducted between September 6 and October 12, 2001. Six members of the Division of Epidemiology were on travel status for this assignment on September 11, 2001. The events of Sept. 11 necessitated extension of the field assignment beyond the FY01 deadline.

Included in the analysis are inspections of 27 hatcheries in 18 states. Twenty-three of the hatcheries produced chicks, 3 produced poults, and 1 hatchery produced both chicks and poults. One hatchery listed as a turkey hatchery in the assignment memorandum had new owners, and was operating as a chicken hatchery.

Hatcheries excluded from analysis include 4 closed hatcheries (1 substitution was made); 2 feed mills; 1 duck hatchery; 1 university hatchery which produced a small number of chicks for research purposes; 1 hatchery closed for the season; and 1 hatchery that produced show birds only. One hatchery produced both chicks and poults, but was listed as 2 different hatcheries; it reported that no antibiotics were routinely used.

For the purposes of this study, hatcheries were divided by size into small (10), medium (7), large (5), or very large (5) hatcheries. Very large hatcheries were defined as hatcheries that produce at least 60 million chicks or poults per year. Large hatcheries were defined as those producing between 40 and 60 million birds per year. Medium size hatcheries were defined as hatcheries producing between 20 and 40 million chicks or poults per year. Small hatcheries were defined as those producing less than 20 million birds per year; they included the 3 turkey hatcheries, the hatchery that produced both chicks and poults, and 6 chicken hatcheries. Two of these small hatcheries produced less than 1 million birds per year. One was a turkey hatchery and the other was the hatchery that produced both chicks and poults; the latter hatchery was in the mail order business (seasonal) and reported that many of their birds were sold to hobbyists. One small hatchery reported that they exported 90% of their birds to Canada. Another small hatchery was a shower-in shower-out facility which exported most of their chicks.

Among the 27 hatcheries, only 5 small hatcheries reported that they did not have a parent

company (4 chicken hatcheries and the hatchery that produced chicks and poults). Two of the 3 turkey hatcheries were owned by the same company. The 23 chicken hatcheries were owned by 15 companies; six companies owned 14 (52%) of the chicken hatcheries inspected. For most inspections (24), a local FDA field inspector accompanied a member of the Division of Epidemiology at CVM. Inspections were conducted in 12 FDA districts:

Two medium size chicken hatcheries owned by one company, were 4 miles apart and the chicks from one of these hatcheries were processed at the other hatchery; both used the same protocol for injecting eggs with ceftiofur. The chief veterinarian for this poultry producer reported doing 4 trials where they treated with ceftiofur every other week for 1 month. They found increased mortality in the weeks when eggs were not injected. They are still looking into this issue as the veterinarian thought the results were related to season. This company is injecting 0.0625 mg of ceftiofur into each egg.

Results: Introduction

Table 1 gives a line-listing of the antimicrobial(s) used by hatchery, while Table 2 summarizes this data. Table 3 summarizes antimicrobial use by region.

Twenty of 26* hatcheries used gentamicin or ceftiofur injections in the 30 days prior to inspection; none of the hatcheries injected both eggs and birds with antibiotics. The 6 hatcheries that reported no antimicrobial use in the 30 days prior to inspection included 5 chicken hatcheries (1 small, 1 medium, 1 large, and 2 very large) and the hatchery that produced both chicks and poults. Three of the chicken hatcheries that did not use antimicrobials were owned by the same company (1 medium sized in [redacted], 2 very large in [redacted]). Two hatcheries (1 small, 1 very large) reported alternating the use of ceftiofur and gentamicin egg injections every 6 months; one was using ceftiofur, while the other was using gentamicin at the time of the inspection. The small hatchery which exported most of their chicks reported that they tended to rotate ceftiofur and gentamicin for chick injections, but had been using ceftiofur for the last year because Garasol® was difficult to obtain.

The only antimicrobials the hatcheries reported administering within the previous 30 days were ceftiofur and gentamicin. Some hatcheries only used the antimicrobials in some of their chicks and poults. All chicken hatcheries that injected antimicrobials into eggs or chicks, mixed the antimicrobial with Marek's vaccine, diluent, and in some cases, a dye.

One small [redacted] hatchery that produced chicks and poults during certain times of the year, reported that they never used gentamicin or ceftiofur. They reported that they only use antibiotics if there is a problem. The last time antibiotics were used at that hatchery was 2 years ago when chicks were treated with oxytetracycline.

*Note: One hatchery injected eggs with gentamicin (and Marek's vaccine), but had recently discontinued this practice; since no records were kept, it was unclear if the hatchery used gentamicin in the 30 days prior to inspection.

One small hatchery was issued an FDA-483 form for Good Husbandry violations which included failure to maintain treatment records, not identifying or informing consignees of the birds medication status, not maintaining a drug inventory/accountability system, and for having expired drugs on hand.

It is important to note that more than a third of the hatcheries inspected kept poor or no treatment records. In addition, many hatcheries did not have written protocols for mixing antimicrobial solutions for injection. Several hatcheries used dilutions that did not match prescriptions, while other hatcheries provided doses to inspectors that did not match their records or had discrepancies in their records on the dose administered.

Data Summary by Routes of Antimicrobial Administration:

Egg Injections:

Ten of 26* hatcheries reported injecting eggs with ceftiofur or gentamicin within the last 30 days. Egg injections were done only in chicken hatcheries; none of the 3 turkey hatcheries inspected injected turkey eggs with antimicrobials. Four chicken hatcheries (2 medium and 2 very large) injected ceftiofur into eggs and 6 hatcheries (1 small, 3 medium, 1 large, and 1 very large) injected gentamicin.

Bird Injections:

Ten of 27 hatcheries reported injecting chicks or poults with ceftiofur or gentamicin within the last 30 days. Four small hatcheries (3 chicken, 1 turkey) injected ceftiofur. Seven hatcheries injected gentamicin; they included 4 chicken hatcheries (1 small, 3 large) and 3 small turkey hatcheries. One turkey hatchery used both antibiotics (not in the same birds).

Egg dips:

None of the hatcheries reported using egg dips within the last 30 days. Several hatcheries used aerosolized formaldehyde or hydrogen peroxide in the hatch rooms. One hatchery reported spraying eggs with hydrogen peroxide foam.

Spray:

Two chicken hatcheries (1 medium and 1 very large) mixed gentamicin with Newcastle/bronchitis vaccine and diluent and sprayed the solution onto chicks; one of these 2 hatcheries also injected eggs with gentamicin, while the other injected ceftiofur into eggs. The records from 1 very large hatchery (hatchery #12) indicated that in the past, they mixed either ceftiofur or gentamicin with Newcastle vaccine and sprayed the solution onto chicks; this hatchery did not use antimicrobials within the 30 days prior to

inspection.

*Note: One hatchery injected eggs with gentamicin (and Marek's vaccine), but had recently discontinued this practice; since no records were kept, it was unclear if the hatchery used gentamicin in the 30 days prior to inspection.

Other:

One small hatchery which exported most of their chicks, used a gentamicin oral lavage in approximately 10% of their chicks in addition to injecting them with ceftiofur; they also had a competitive exclusion product on the premises. One turkey hatchery reported using a competitive exclusion product in some of their poults.

Data Summary by Antimicrobial:

Ceftiofur: Approved dose: 0.08-0.2 mg/day-old broiler chicks; 0.17-0.5 mg/day-old poults

Has ceftiofur ever been used? 21 of 27 reported yes

Chicken: 18/23

Turkey: 3/3

Both: 0/1

Egg injections of ceftiofur within the last 30 days: 4/27

Chicken: 4/23

Doses: 0.0625 mg (2; same company), 0.0833 mg, 0.1

mg

Turkey: 0/3

Both: 0/1

Bird injections of ceftiofur within the last 30 days: 4/27

Chicken: 3/23

Doses: 0.0312 mg, 0.2 mg, 0.4 mg

Turkey: 1/3

Dose: 0.4 mg

Both: 0/1

Summary of ceftiofur use:

Twenty-one of 27 hatcheries reported using ceftiofur at some time. Eight of 27 hatcheries used ceftiofur injections in eggs (4 chicken hatcheries) or birds (3 chicken, 1 turkey) in the last 30 days. Egg were injected with ceftiofur in 2 medium size and 2 very large chicken hatcheries. All birds injected with ceftiofur were in small hatcheries (3 chicken, 1 turkey). Two chicken hatcheries which were injecting eggs with ceftiofur were using less than the recommended dose for chicks. One small chicken hatchery was apparently inadvertently injecting chicks with twice the maximum recommended dose; this hatchery was selling chicks internationally and was the same hatchery that used an oral lavage of gentamicin in some of their chicks.

Of note, six of the eight hatcheries that used ceftiofur in the last 30 days were located in

3). One very large hatchery in [] reported switching from penicillin to ceftiofur [see Table] because of problems with *E. coli* infections. They indicated that they planned to switch back to penicillin, which is much less expensive; their other local hatchery uses penicillin. In addition, inspections were conducted at 2 hatcheries (in [] owned by the same company; only the [] hatchery used ceftiofur; the hatchery inspected in [] injected gentamicin into eggs.

Gentamicin: Approved dose: 0.2 mg/day-old broiler chicks; 1 mg/1 to 3 day old poults

Has gentamicin ever been used? 26 of 27 reported yes

Chicken: 23/23

Turkey: 3/3

Both: 0/1

Egg injections of gentamicin within the last 30 days: 6 of 26 (1 unknown*)

Chicken: 6/22 (1 unknown*) Doses: 0.051 mg, 0.16 mg (2), 0.194 mg, 0.2 mg (2)

Turkey: 0/3

Both: 0/1

Bird injections of gentamicin within the last 30 days: 7 of 27

Chicken: 4/23

Doses: 0.16 mg, 0.2 mg (3)

Turkey: 3/3

Doses: 0.16 mg, 1 mg (2)

Both: 0/1

Summary of gentamicin use:

Twenty-six of 27 hatcheries reported using gentamicin at some time. Thirteen of 26 hatcheries used gentamicin injections in eggs (6 chicken hatcheries) or birds (4 chicken, 3 turkey) within the last 30 days. Eggs were injected with gentamicin in 1 small, 3 medium, 1 large, and 1 very large; all were chicken hatcheries. Birds injected with gentamicin were in 4 small hatcheries (3 turkey, 1 chicken) and 3 large chicken hatcheries. Of the 13 hatcheries that used gentamicin injections, 3 used products approved for poultry, while 10 used products labeled for use in horses only. Apparently, there was limited availability of gentamicin products approved for use in poultry at the time. Three chicken hatcheries were injecting eggs with less than the recommended dose for chicks, while one chicken and one turkey hatchery were injecting less than the recommended dose into chicks and poults.

In addition to injection of gentamicin, 2 chicken hatcheries mixed equine gentamicin products with Newcastle vaccine and diluent and sprayed the solution onto chicks; one of these 2 hatcheries also injected eggs with gentamicin, while the other injected ceftiofur into eggs. One hatchery used Garasol[®] as an oral lavage in approximately 10% of their chicks; this hatchery was the same one that was injecting 0.4 mg of ceftiofur (twice the maximum approved dose) into chicks and exporting them.

Table 1. Use of Antimicrobial Injections in 27 Hatcheries in the 30 Days Prior to Inspection: Line-Listing of Data

Record	State	Hatchery Type	Size	Egg Injections	Bird Injections (mg)	Dose
1*		Chicken	Medium	Unknown*	None	N/A
2		Chicken	Large	None	None	N/A
3		Chicken	Small	<i>Gentamicin</i>	None	0.2
4		Chicken	Small	None	None	N/A
5		Chicken & Turkey	Small	None	None	N/A
6		Chicken	Small	None	Ceftiofur	0.4
7		Chicken	Small	None	Ceftiofur	0.0312
8		Chicken	Very Large	Ceftiofur	None	0.1
9		Chicken	Small	None	Ceftiofur	0.2
10		Chicken	Medium	<i>Gentamicin</i>	None	0.2
11		Turkey	Small	None	<i>Gentamicin</i>	1.0
12		Chicken	Very Large	None	None	N/A
13		Chicken	Large	<i>Gentamicin</i>	None	0.16
14		Chicken	Medium	Ceftiofur	None	0.0625
15		Chicken	Medium	Ceftiofur	None	0.0625
16		Chicken	Small	None	<i>Gentamicin</i>	0.2
17		Chicken	Medium	<i>Gentamicin</i>	None	0.194
18		Chicken	Large	None	<i>Gentamicin</i>	0.2
19		Chicken	Very Large	<i>Gentamicin</i>	None	0.051
20		Chicken	Very Large	None	None	N/A
21		Turkey	Small	None	<i>Gentamicin</i>	0.16
22		Chicken	Medium	<i>Gentamicin</i>	None	0.16
23		Chicken	Very Large	Ceftiofur	None	0.0833
24		Chicken	Large	None	<i>Gentamicin</i>	0.2
25		Chicken	Large	None	<i>Gentamicin</i>	0.16
26		Chicken	Medium	None	None	N/A
27**		Turkey	Small	None	Ceftiofur & Gentamicin**	0.4 & 1.0

*This hatchery injected eggs with gentamicin (and Marek's vaccine), but had recently discontinued this practice. Since

no records were kept, it was unclear if the hatchery used gentamicin in the 30 days prior to inspection.

**This turkey hatchery used both ceftiofur and gentamicin (not in the same poult).

Table 2. Use of Antimicrobial Injections in 27 Hatcheries in the 30 Days Prior to Inspection: Summary Data

	Ceftiofur	Gentamicin	Total
Egg injections (chickens only)	4 chicken	6 chicken	10 hatcheries (chicken)
Bird injections	3 chicken 1 turkey	4 chicken 3 turkey	10* hatcheries (7 chicken, 3 turkey)
Total	8 hatcheries (7 chicken, 1 turkey)	13 hatcheries (10 chicken, 3 turkey)	20* hatcheries used ceftiofur and/or gentamicin

* Note: One turkey hatchery used both antibiotics (not in the same poult). In addition, 1 hatchery injected eggs with gentamicin (and Marek's vaccine), but had recently discontinued this practice. Since no records were kept, it was unclear if the hatchery used gentamicin in the 30 days prior to inspection; this hatchery was not included in the data table above.

Table 3. Use of Ceftiofur and Gentamicin in Poultry Hatcheries, by FDA Regional Offices

Region	Number of Inspections	Hatcheries Using Ceftiofur	Hatcheries Using Gentamicin
Central	12	6 []	3 []
Northeast	1	1 []	0
Pacific	3	0	2 []
Southeast	7	0	5 []
Southwest	4	1 []	3 []
Total	27	8*	13*

* Note: One turkey hatchery in [] used both antibiotics (not in the same poult)