Helpful Tips for Extralabel Drug Use:

Food Animals

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What are the criteria that must be met to enable veterinarians to use an antibiotic preparation approved for use in humans in an extralabel manner in food animals?

The drug must not be on the prohibited list. There must not be any drug(s) labeled for use in food animals that fulfills all of the following: contains the needed ingredient, in the proper dosage form, labeled for the indication, and clinically effective. Food safety must be ensured; therefore, there must be data available to enable veterinarians to determine a withdrawal time for milk, meat, or eggs. Veterinarians must maintain required records and label the drug appropriately. Extralabel use of a drug approved for use in humans in a food animal is not permitted if there is a drug approved for use in food animals that can be used in an extralabel manner.

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### Broiler Performance Data (Region)

**Live Production Cost**

<table>
<thead>
<tr>
<th></th>
<th>SW</th>
<th>Midwest</th>
<th>Southeast</th>
<th>Mid-Atlantic</th>
<th>S-Central</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feed cost/ton w/o color</td>
<td>$145.45</td>
<td>$143.17</td>
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<tr>
<td>Feed cost/lb meat</td>
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<td>$14.88</td>
<td>$15.41</td>
<td>$15.01</td>
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<tr>
<td>Days to 4.6 lbs</td>
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<td>46</td>
<td>46</td>
<td>46</td>
<td>46</td>
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<tr>
<td>Med. cost/ton</td>
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<td>$2.30</td>
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<td>$3.97</td>
<td>$4.20</td>
<td>$3.91</td>
<td>$3.91</td>
</tr>
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<td>Vac–Med cost/lb</td>
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<td>$0.07</td>
<td>$0.10</td>
<td>$0.09</td>
<td>$0.07</td>
</tr>
<tr>
<td>WB &amp; 1/2 parts condemn. cost/lb.</td>
<td>$0.21</td>
<td>$0.31</td>
<td>$0.27</td>
<td>$0.32</td>
<td>$0.35</td>
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<tr>
<td>% mortality</td>
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<td>5.28</td>
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<td>4.96</td>
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<td>Sq. Ft. @ placement</td>
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<td>Lbs./Sq.Ft.</td>
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<td>Down time (days)</td>
<td>15</td>
<td>11</td>
<td>**</td>
<td>12</td>
<td>11</td>
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</tbody>
</table>

Data for week ending 05/23/98.
Helpful Tips for Extralabel Drug Use: Food Animals
(continued from page 1)

If veterinarians need to use a drug in an extralabel manner in food animals, and the only drugs available are a drug approved for use in humans and a drug approved for use in nonfood animals, are veterinarians required to use the drug labeled for use in animals? For example, a veterinarian may need to use a trimethoprim-sulfonamide product. Trimethoprim-sulfamethoxazole is available as a product approved for use in humans and trimethoprim-sulfadiazine is a product approved for use in horses. Would veterinarians be required to use the product approved for horses?

To use these drugs in an acceptable manner in food animals, there must not be another drug approved for use in food animals (even one that must, in this case, be used in an extralabel manner) that would be clinically effective in this situation. Assuming a veterinarian has fulfilled this criterion, they may use the drug approved for use in nonfood animals or the drug approved for use in humans. Scientific information on the food safety aspect of the drug must be available to allow veterinarians to determine an adequate withdrawal time for milk, meat, or eggs or the treated animal and its products must not enter the human food supply. Veterinarians should be advised that the aforementioned trimethoprim-sulfonamide products are included on the list of drugs that are prohibited for extralabel use in lactating dairy cattle.

**Which drugs are prohibited for extralabel use in food animals?**

Enactment of AMDUCA resulted in the creation of a list of prohibited drugs, which can be found in Section 530.41 of the final regulations. The following drugs are currently on that list:

- chloramphenicol
- clenbuterol
- diethylstilbestrol (DES)
- dimetridazole
- ipronidazole
- other nitroimidazoles
- furazolidone (except for approved topical use)
- nitrofurazone (except for approved topical use)
- sulfonamides in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfathoxypryridazine)
- fluoroquinolones
- glycopeptides (eg, vancomycin)

**Has there been a recent change in the status of fluoroquinolone antibiotics and their use in food animals?**

The FDA-Center for Veterinary Medicine (FDA-CVM) banned extralabel use of fluoroquinolone antibiotics in food animals in 1996. Effective August 20, 1997, fluoroquinolone (eg, enrofloxacin, sarafloxacin) and glycopeptide (vancomycin) antibiotics were included on the list of drugs prohibited for extralabel use in food animals.

If veterinarians must use only approved drugs that are currently available, which drugs can be used for dairy goats in which the approved anthelminic is thiabendazole, but other anthelmintics not approved for use in goats are needed for rotational deworming programs to prevent development of parasitic resistance and illness of members of the herd?

The AMDUCA regulations require that veterinarians use drugs approved for use in food animals, except for situations in which the veterinarian finds that such a drug is clinically ineffective. When a veterinarian judges that a drug will be clinically ineffective (eg, development of parasitic resistance), he or she can opt to use another drug in an extralabel manner (eg, anthelminic not approved for use in dairy goats).

**Is medication used in an extralabel manner in the milk of calves considered feed treatment?**

Extralabel use of drugs in feed is disallowed by AMDUCA, mainly on the basis of issues for feed mills regarding pharmacy laws, liability, and rules for drug-residue flushing at feed mill facilities. Because feeding calves medicated milk does not involve a feed mill, this practice is acceptable.

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Helpful Tips for Extralabel Drug Use: Food Animals
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Extralabel use of drugs to improve reproductive efficiency in dairy cattle is not included in the AMDUCA regulations, yet a cow that is infertile will be prematurely culled and sent to slaughter. Why aren't these cows included under AMDUCA?

The law allows for extralabel use of approved drugs to prevent suffering of animals. Improving reproductive efficiency does not reduce animal suffering. Hence, the regulations would not include such drugs.

Because there is a lack of FDA-approved follicle-stimulating hormone (FSH) products for use in superovulation of cattle, how do veterinarians involved in the embryo transfer industry address this problem?

Currently, the manufacturer of an FSH product that is approved for use in the United States has discontinued production of that product. Consequently, the FDA has lifted the import ban on FSH products that have been approved for use in another country through distributors in the United States or other countries.

Which anesthetics are available for use in food animals? Is information available about withdrawal times for these products?

A list of drugs approved by the FDA-CVM for use in food animals as well as withdrawal times recommended by the Food Animal Residue Avoidance Databank (BARAD) for tranquilizers and anesthetics commonly used in cattle, sheep, goats, and swine was provided in an excellent report published in the FARAD Digest of the August 1, 1997 JAVMA.¹

When a veterinarian prescribes a drug for use in an extralabel manner in food animals, what professional judgment must they use to assure that there will not be residue violations in milk, meat, or eggs?

The veterinarian must obtain information and determine the appropriate withdrawal time before using a drug in an extralabel manner in a food animal. When adequate data on food safety are not available, the drug must not be used or the treated animal and its products must not enter the human food supply.

The policy of the USDA national residue program emphasizes testing for approved drugs. How will illegal residues that could result from extralabel use of a drug be detected?

The FDA-CVM would expect these residues to be detected in basically the same manner as for residues previously detected under the FDA discretionary policy. Each year, information on drug use is collected from many sources.

(continued on page 4)

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### Reference


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### Broiler Performance Data (Company)

#### Live Production Cost

<table>
<thead>
<tr>
<th></th>
<th>Average Co.</th>
<th>Top 25%</th>
<th>Top 5 Co's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feed cost/ton w/o color</td>
<td>149.85</td>
<td>146.53</td>
<td>144.78</td>
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<tr>
<td>Feed cost/lb meat</td>
<td>14.74</td>
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<td>14.06</td>
</tr>
<tr>
<td>Days to 4.5 lbs</td>
<td>46</td>
<td>46</td>
<td>45</td>
</tr>
<tr>
<td>Med. cost/ton</td>
<td>2.93</td>
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<td>1.54</td>
</tr>
<tr>
<td>Chick cost/lb</td>
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<td>3.72</td>
</tr>
<tr>
<td>Vac-Med. cost/lb</td>
<td>0.06</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>WB &amp; 1/2 parts condemnations cost/lb</td>
<td>0.28</td>
<td>0.17</td>
<td>0.19</td>
</tr>
<tr>
<td>% Mortality</td>
<td>4.89</td>
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<td>3.35</td>
</tr>
<tr>
<td>Sq. Ft. @ placement</td>
<td>0.80</td>
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<td>0.83</td>
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<tr>
<td>Lbs/Sq. Ft.</td>
<td>6.11</td>
<td>5.92</td>
<td>6.14</td>
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<tr>
<td>Down time (days)</td>
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<td>13</td>
<td>11</td>
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### Broiler Whole Bird Condemnation (Region)

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<tr>
<th></th>
<th>SW</th>
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<th>S. East</th>
<th>Mid-Atlantic</th>
<th>S. Central</th>
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<tr>
<td>% Septox</td>
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<td>0.185</td>
<td>0.328</td>
<td>0.270</td>
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<tr>
<td>% Airsac</td>
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<td>0.256</td>
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<tr>
<td>% I.P.</td>
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<td>0.093</td>
<td>0.169</td>
<td>0.320</td>
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<tr>
<td>% Leukosisa</td>
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<td>0.004</td>
<td>0.030</td>
<td>0.042</td>
<td>0.032</td>
</tr>
<tr>
<td>% Bruise</td>
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<td>0.009</td>
<td>0.017</td>
<td>0.012</td>
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<tr>
<td>% Other</td>
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<td>0.017</td>
<td>0.086</td>
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</tr>
<tr>
<td>% Total</td>
<td>0.475</td>
<td>0.609</td>
<td>0.743</td>
<td>0.892</td>
<td>0.934</td>
</tr>
<tr>
<td>% 1/2 parts condemnations</td>
<td>0.351</td>
<td>0.639</td>
<td>0.344</td>
<td>0.374</td>
<td>0.468</td>
</tr>
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Data for week ending 05/23/98.

Data for week ending 05/23/98.
Helpful Tips for Extralabel Drug Use: Food Animals  
(continued from page 3)

The FDA-CVM then meets with personnel from the USDA-Food Safety and Inspection Service (USDA-FSIS) through the surveillance advisory team to share drug use information and identify drugs that should be considered for inclusion in the USDA monitoring program. When residues for drugs that are currently included in the USDA-FSIS monitoring program are detected, additional testing programs may be instituted or the drug may be included in the USDA-FSIS “for-cause” testing program, a battery of tests performed as part of the USDA-FSIS surveillance program.

Does AMDUCA allow use of aspirin and other noncorticosteroid drugs in the water of food animals to reduce fever?

The AMDUCA regulations provide for legal extralabel use of any approved drug, including noncorticosteroid drugs unless the particular drug is included in the list of prohibited drugs.

Some drugs, such as aspirin, are not approved for use in animals. There are many products (eg, injectable vitamin products, products for topical use, aspirin) labeled for use in cattle that are below the FDA level of regulatory concern, as determined on the basis of the prioritization process that considers resources needed to regulate such products. These products are allowed to be marketed through a policy of regulatory discretion, because the FDA does not believe there is a health risk to animals or the public associated with their use at the current time.

Will administration of phenylbutazone to food animals prohibit them from entering the human food supply?

No, provided appropriate withdrawal times are observed and there are no phenylbutazone residues in the animal at the time of slaughter. Phenylbutazone is approved for use in horses and dogs and is not a drug prohibited for extralabel use in food animals. A veterinarian may use phenylbutazone in food animals when all of the required provisions for extralabel use are met.

Is there an interpretation for use of ionophores in diets of nonlactating dairy cows to enhance the transition into lactation?

The AMDUCA regulations do not allow extralabel use of drugs in feed. Therefore, use of ionophores in diets for nonlactating cows is illegal.

Is use of spectinomycin in feedlot cattle permitted?

Spectinomycin hydrochloride is not labeled for use in cattle. To use this drug in an extralabel manner, there must not be any drug(s) approved for use in food animals that fulfills all of the following: contains the needed ingredient, in the proper dosage form, labeled for the indication, and clinically effective.

Additional questions and answers on extralabel drug use will be published in upcoming issues of the JAVMA. Concerns or queries about extralabel drug use and AMDUCA should be directed to Dr. Elizabeth Curry-Galvin, Assistant Director, Division of Scientific Activities (800/248-2862, ext. 290, egalvin@avma.org, or FAX 847/925-9329).

Excerpts from the latest National Agricultural Statistics Service USDA Reports

“Livestock, Dairy and Poultry Situation and Outlook (ERS)”

“Broiler Hatchery” and “Chicken and Eggs” (NASS)

Lower Feed Costs Improve Poultry Producers’ returns

According to Economic Research Reports (ERS) lower feed costs in 1998 are expected to offset lower poultry and egg prices, improving net returns to broiler producers, while returns to egg and turkey producers will be nearly unchanged from last year. Feed costs for the second quarter of 1998 are estimated to be 15-22 percent lower than a year ago for turkey, broiler and egg producers.

Broiler Production Increasing More Slowly

Broiler production increases in 1998 are now forecast at about half the level that was expected a year ago. Some of the breeding stock for the heavier strains of birds, used primarily for deboning, have been affected by increased disease susceptibility. This susceptibility has caused increased mortality in the hatchery supply flock, which has limited its growth rate, reduced egg production, and reduced the hatching rate of eggs produced by infected birds. Solutions to this challenge appear to be long-term in nature.

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Excerpts from the Latest ERS and NASS USDA Reports
(continued from page 4)

as selection of birds for desirable production traits also brought this undesirable trait into part of the breeding flock. No quick fixes, such as vaccination or medications, appear to be effective.

Production increases of less than 3 percent are expected in the first half of 1998. But the increases are expected to strengthen in the second half of the year as stronger increases in placements of birds for the hatchery supply flock will be coming into egg production. Slower production increases have been beneficial in limiting the amount of increased product that has been available for the market. Record domestic meat supplies and slower export growth than during the mid-1990s would have made it difficult to move large increases in broiler supplies at profitable prices.

Broiler production is expected to continue growing slowly in 1999. Production is expected to increase about 4 percent in 1999 after increases of about 3.5 percent in 1997 and 1998. Broiler producers will likely remain cautious when making production decisions, as there will continue to be very large domestic meat supplies and uncertainty in the export market. Expansion also may be difficult in some areas as stricter environmental laws are enacted and labor and contract grower associations become more active.

Turkey Production Increasing Slowly

Record production and lower exports brought a new high in per capita consumption of 3.9 pounds for the first quarter of 1998. The increase was also aided by lower retail prices. Whole birds sold for about 5 cents per pound less than a year ago during the first quarter. Wholesale prices were about 4 cents per pound lower, which narrowed the wholesale-to-retail price spread slightly from last year. Last year this spread was at its second-highest level ever, only exceeded in 1987.

Turkey production is expected to decline in 1999 after 3 years of negative returns to producers. Weaker export markets and competition from large pork supplies on the domestic market are expected to keep prices under pressure. Planned conversion of some turkey production facilities to chicken production could give an alternative use for some of the assets currently in turkey production and encourage the anticipated reduction in production.

Egg Production Increasing

Egg Production increased nearly 3 percent in the first quarter of 1998 and is expected to maintain this pace throughout 1998. Per capita consumption of eggs is expected to be the highest since 1988, although the composition of that consumption will be much different. In 1988 about 44 eggs per person (less than 20 percent) were consumed as eggs that had been processed by the egg breaking industry, then used in other food products, served as scrambled eggs in food service, or bought as a liquid or dried egg product at retail. In 1996, about 70 eggs per person (nearly 30 percent) are expected to be consumed after processing.

Egg production is expected to continue increasing in 1999. Lower feed costs are expected to offset lower wholesale egg prices and keep the egg industry earning the attractive net returns that it has since 1995. Large increases in chicks hatched for table egg production signal a continuation of larger flock sizes for the next year.

Broiler Eggs Set Up 1 Percent

National Agricultural Statistics Service (NASS) reports commercial hatcheries in the 15-state weekly program set 177 million eggs during the week ending May 16, 1998. This was up 1 percent from the eggs set the corresponding week a year ago.

Broiler Chicks Placed Up 1 Percent

Broiler growers in the 15-state weekly program placed 142 million chicks for meat production during the week ending May 16, 1998. Up 1 percent from the comparable week in 1997.

(continued on page 6)
Excerpts from the Latest ERS and NASS USDA Reports
(continued from page 5)

**April Egg Production Up 3 Percent**

U.S. egg production totaled 6.57 billion during April, 1998, up 3 percent from the 6.35 billion produced in 1997. Production included 5.53 billion table eggs and 1.04 billion hatching eggs, of which 979 million were broiler-type and 62.0 million were egg-type. The total number of layers during April 1998 averaged 311 million, up 2 percent from April 1997. April egg production was 2,116 eggs per 100 layers, up 1 percent from April 1997.

**Egg-Type Chicks Hatched Up 3 Percent**

Egg-type chicks hatched during April totaled 39.9 million, up 3 percent from April 1997. Eggs in incubators totaled 36.3 million on May 1, 1998, down 1 percent from a year ago.

Domestic placements of egg-type pullet chicks for future hatchery supply flocks by leading breeders totaled 338,000 during April 1998, up 7 percent from the 316,000 of April 1997.

**Broiler Hatch Up 2 Percent**

The April 1998 hatch of broiler-type chicks, at 709 million, was up 2 percent from April of the previous year. There were 613 million eggs in incubators on May 1, 1998, up 3 percent from a year earlier.

Leading breeders placed 6.69 million broiler-type pullet chicks for future domestic hatchery supply flocks during April 1998, up 11 percent from April 1997.

**Broiler Whole Bird Condemnation (Company)**

<table>
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<tr>
<th></th>
<th>Average Co.</th>
<th>Top 25%</th>
<th>Top 5 Co.'s</th>
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<tbody>
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<td>% Septox</td>
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<td>% Alrsac</td>
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<td>% I.P.</td>
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<td>0.070</td>
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<tr>
<td>% Leukosis</td>
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<tr>
<td>% Bruise</td>
<td>0.013</td>
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</tr>
<tr>
<td>% Other</td>
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<tr>
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</table>

Data for week ending 05/23/98.
Meetings, Seminars and Conventions

1998
June
June 4-6: Alabama Poultry & Egg Convention, Birmingham, AL. Contact: Alabama Poultry & Egg Assn., P.O. Box 240, Montgomery, AL 36101. Phone 334-265-2732.

June 4-7: 6th Asian Pacific Poultry Congress & Exhibition, Nagoya Trade & Industry Center, 6-3-2 Chikusa-ku, Nagoya 464, Japan. Contact: 6th APCC Secretariat, C/o Congress Corporation, Hirokoji YMD Bldg. 1-20-25 Nishiki, Nakagawa, Nagoya 460, Japan. Phone 81 52 222-1297. Fax 81 52 222-4187. E-mail: shibata@conreg.co.jp.

June 5-6: Arkansas Poultry Festival, Arlington Hotel, Hot Springs, AR. Contact: Judy Kimmell, Arkansas Poultry Federation, P.O. Box 1446, Little Rock, AR 72203. Phone 501-375-6131.


June 9-12: ABIC '98 Conference, Delta Bessborough Hotel, Saskatoon, Sask. Contact: Colleen Jaeger, ABIC '98, c/o The Signature Group, 608 Duchess St., Saskatoon, Sask. 7SK OR1; signatur @eagle.wbm.ca.

June 9-12: Agricultural Biotechnology International Conference (ABIC), Delta Bessborough Hotel, Saskatoon, Sask. Contact: Sharon Murray, ABIC '98, c/o Signature Group, 608 Duchess St., Saskatoon, Sask. 7SK OR1; siggroup@ak.sym pathetic.ca, www.lights.com/abic.

June 12-13: Delmarva Chicken Festival & Delmarva Chicken Cooking Contest, Millboro, DE 19947-9575. Contact: Connie Parvis, Delmarva Poultry Industry, P.O. Box 47, Georgetown, DE. 19947-9575. Phone (302) 856-9037.

June 13-17: Institute of Food Technologists Annual Meeting & Food Expo, Atlanta, GA. Contact: IFT, 221 N. LaSalle St., Ste. 300, Chicago, IL 60601. Phone (312) 782-8424. Fax (312) 782-8348.


June 18-20: Minnesota Turkey Growers Association Summer Leadership Conference, Rutiger's Bay Lodge, Deerwood, MN. Contact: MTGA. Phone (612) 646-4559. Fax (912) 646-4554.

June 21-26: 10th European Poultry Conference, Jerusalem, Israel. Contact: Organizing Committee, WPFA - Israel Branch, P.O. Box 50006, Tel Aviv 61500, Israel. Phone +972 3 514000. Fax +972 3 5175674/5140077. E-mail Compuserve users: cc mail: POULTRY at Kennes; Internet users: Poultry@kennes.com; compuserve.com.

June 22-26: The 8th World Conference on Animal Production, Hotel Intercontinental, Seoul, Korea. Contact: Dr. Jong K. Ha, Chairman, 8th WCAP Dept of Animal & Life Sciences, Seoul National University, Seoul, Korea 411-744. Phone +82 331 290 2348. Fax +82 331 292 3801 or 291 7722.

June 25: International Symposium on "Modern Standards of Quality Management of Feed and Animal Products", Veterinary University, Vienna, Austria. Contact: Dr. J. Bohm, Veterinary University, Vienna, Austria. Fax +43-1-25077 3290. E-mail Josef.Boehm@vuvien.ac.at or Ms. Sigrid Pasteyer, Biomin, Industriestrasse 21, A-1310 Herzogenburg, Austria. Phone +43 2782 2247. Fax +43 2782 2060. E-mail biomin@noet.at.


1998
July
July 9-12: AAMP Convention, Hyatt Regency Hotel, Minneapolis, MN. Contact: American Assn. of Meat Processors, P.O. Box 269, Elizabethtown, PA 17022. Phone (717) 367-7768.


July 16-19: South Carolina Poultry Federation Annual Conference, Charleston Place Hotel, Charleston, S.C. Contact: South Carolina Poultry Federation, AT&T Building, Suite 1220, 1201 Main St., Columbia, S.C. 29201. Phone (803) 748-1283.


July 31-August 2: Oklahoma Egg Council Annual Mtng., Lake Texoma Lodge. Contact: Joe Barry, 201 Animal Science Bldg., Oklahoma State University, Stillwater, OK 74074. Phone (405) 744-6058.

July 31-August 2: HACCP SMNR, For Small & Medium-sized Plants, Texas Tech University, Lubbock, TX. Also concurrent Spanish seminar. Contact: American Assn. of Meat Processors, P.O. Box 269, Elizabethtown, PA 17022. Phone (717) 367-1168.

1998
August

August 24-28: 10th International Conference on Production Diseases in Farm Animals (ICPD), Veterinary Faculty, Utrecht Univ., Utrecht, the Netherlands. ICPD Conference, R.N.V.A., P.O. Box 14031, 3508 SB Utrecht, the Netherlands.

August 25: Fall Turkey Conference, Kearney Ag Center, Parlier, CA. Contact: Dr. John C. Voris, University of California Cooperative Extension Service, Kearney Ag Center, 9240 S. Riverbed Ave., Parlier, CA 93648. Phone (209) 646-6500.


August 27-28: NCPF Annual Convention, Holiday Inn Four Seasons/Koury Convention Center, Greensboro, N.C. Contact: North Carolina Poultry Federation, 4020 BARnett Dr., Suite 102, Raleigh, N.C. 27609. Phone (919) 783-8218.