

# ***Complementary Relationships in Animal Agriculture***

One in a Series of Educational Programs Presented by the

## **Future Trends in Animal Agriculture**

United States Department of Agriculture  
Jefferson Auditorium, South Agriculture Building  
Washington, DC

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Edited by

Richard Reynnells  
USDA/CSREES/PAS

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## Preface

**Richard Reynnells**  
USDA/CSREES/PAS

Animal welfare issues continue to be clouded by the full spectrum of ethical considerations and philosophies on how animals ought to be treated, confused with animal rights dogma, and influenced by production agriculture and scientific concerns. Our intent is that these proceedings will serve to better inform the reader about the various often competing issues and values of people, and background considerations that have led to present day situations and disagreements. We hope the reader will utilize this information to evaluate potential appropriate actions, and thus improve our food animal production and processing system and ultimately the welfare of animals and humans.

The organizing committee recognizes the exceptional contributions of all speakers in providing their time and resources in the development of the current Future Trends in Animal Agriculture symposium, and creation of these proceedings. The proceedings contain speaker contact information and the Power Point slides from several speakers, as black and white images.

Copies of the proceedings are provided by the Cooperative State Research, Education and Extension Service, and are available on their internet site (<http://www.csrees.usda.gov/animalwellbeing.cfm>). Proceedings may also be found at the USDA Agricultural Research Service, National Agricultural Library, Animal Welfare Information Center ([http://awic.nal.usda.gov/nal\\_display/index.php?info\\_center=3&tax\\_level=2&tax\\_subject=187&topic\\_id=1535#Cooperative State Research, Education, and Extension Service \(CSREES\) Publications](http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=2&tax_subject=187&topic_id=1535#Cooperative%20State%20Research,%20Education,%20and%20Extension%20Service%20(CSREES)%20Publications)). You may also contact me at 202.401.5352, or [reynnells@csrees.usda.gov](mailto:reynnells@csrees.usda.gov) for additional copies of the proceedings.

We also hope the proceedings prove to be enjoyable, educational, and beneficial.

## **SPONSORS**

The organizing committee gratefully acknowledges support from:

All speakers for their significant time and effort, with all waiving the requirement for reimbursement of expenses

Financial support of the USDA Animal and Plant Health Inspection Service for providing the hearing impaired translator, the extra security and the publicity posters

USDA/CSREES for providing the on-site proceedings and sending the revised proceedings to a large number of interested persons

The American Humane Certified program for providing the coffee break

The **Mission** of the FTAA is to foster and enhance balanced and enlightened public dialogue on topics related to the nature and future of animal agriculture.

The **Vision** is: to develop programs that are inclusive and national in scope, with the committee consisting of individuals from organizations representing academia, agribusiness, animal welfare, environment, university, government and others. The FTAA seeks to present timely issues in a balanced, innovative and thoughtful manner. The Committee also seeks to enhance public dialogue and understanding about the nature and future direction of animal agriculture, and the impact of their personal decisions on this process.

FTAA **Goals** are: 1. To facilitate genuine collaboration and the ability of farmers to produce food for society, while improving animal well-being. 2. To provide opportunities for dialogue and understanding of animal well-being, environmental and other issues in an atmosphere of mutual respect of consumers, farmers, advocates, commodity organizations, and others. 3. To provide information to identify critical animal production issues and enhance greater understanding of societal desires and trends that impact production agriculture.

## Welcome

**Richard Reynnells**  
USDA/CSREES/PAS

The organizing committee for the Future Trends in Animal Agriculture (FTAA), welcomes you to the 2008 symposium, "Complementary Relationships in Animal Agriculture". We appreciate your participation and attendance at these symposia since their revival in 2002. We hope and feel that these symposia have filled a gap and served a need by fostering discussion on controversial issues in animal agriculture. It is now time to reevaluate these symposia and I look forward to working with the organizing committee regarding the timing, venue, and leadership of future symposia.

Since the revival of this series of meetings in 2002, the FTAA has been a forum for open discussion of topics related to animal welfare. Our intent has been to focus on how our individual decisions in the marketplace and other areas of our lives impact the animals, industries, structure of agriculture, food security and ultimately our society. Previous FTAA meetings, held from 1990 to 1996, had similar goals.

It is essential to understand that as in previous years, the symposium today is not a mechanism to announce, formulate, influence, promote or to in any way, intentionally or unintentionally, reflect USDA position or policy regarding animal welfare, animal rights or any other related area. The basis and intent of the meetings is strictly scientific and educational.

As agreed to many years ago, and publicized, the **Mission** of the FTAA is:  
to foster and enhance balanced and enlightened public dialogue on topics related to the nature and future of animal agriculture.

The **Vision** of the FTAA is:

to develop programs that are inclusive and national in scope, with the committee consisting of individuals from organizations representing academia, agribusiness, animal welfare, environment, university, government and others.

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3. To provide information to identify critical animal production issues and enhance greater understanding of societal desires and trends that impact production agriculture.

These ideals have not changed over the years. They will not in the future.

Presentations include: Introductory Comments by David Brubaker, The University of Pennsylvania; discussions on the roles of regulations in the United States and Europe that are related to animal welfare; legislative impact on animal welfare; management of slaughter facilities, including treatment of non-ambulatory animals; an industry animal care program; and, ending with discussions of responsible antibiotic use.

The need for everyone to understand animal welfare issues is clear, but has been complicated by the numerous conflicting animal welfare and animal rights philosophies. The Future Trends in Animal Agriculture continues in our tradition of attempting to define issues of concern, then develop programs to allow persons of diverse backgrounds to discuss these issues and to examine potential alternative solutions to problems.

The FTAA organizing committee is Co-Coordinated by David Brubaker, University of Pennsylvania; Ken Klippen, Klippen and Associates; Marie Wheatley, American Humane; Richard Wood, Food Animal Concerns Trust; Gail Golab, American Veterinary Medical Association, and, Richard Reynnells, USDA, Cooperative State Research, Education and Extension Service (CSREES), Plant and Animal Systems (PAS). The FTAA organizing committee also includes representatives from other animal welfare and industry organizations, universities, USDA, and others. These individuals represent diverse views on animal production and work together to bring about benefits for animal agriculture and society.

The organizing committee gratefully acknowledges support from several entities that allowed the symposium to take place, particularly the contributions of speakers for their significant time and effort, with all speakers waiving reimbursement of expenses. Financial support of the USDA Animal and Plant Health Inspection Service provided for the costs related to extra security personnel and the hearing impaired translators, while USDA/CSREES/PAS provided copies of the proceedings to a large number of interested persons. American Humane Certified provided the coffee break and skirting for the tables. These financial contributions facilitated our ability to provide this important opportunity for improved networking and understanding.

Please remember to fill out your evaluation form. We require your ideas to improve programs in the future.

Please note we have to adhere to a strict schedule to ensure all speakers have their allotted time. Therefore, please limit your questions to 20 seconds or less. Speakers will likewise stay within their time limitations and provide complete yet concise answers to questions. We appreciate your cooperation.

Again, the symposium today is not a mechanism to announce, formulate, influence, promote or to in any way, intentionally or unintentionally, reflect USDA position or policy regarding animal welfare, animal rights or any other related area. The basis and intent of the meetings is strictly scientific and educational.

*These comments are personal opinion and may or may not reflect USDA Position or Policy.*

## INTRODUCTION

**David R. Brubaker**  
Organizational Dynamics  
University of Pennsylvania

Welcome to the 2008 Future Trends in Animal Agriculture (FTAA) symposium. This series of meetings began in the mid-1980's, conceived by a group of industry representatives, activists, government personnel and academicians to provide a vehicle for all people interested in animal agriculture to be able to discuss the issues honestly and openly. I have long believed that such meetings are important, a view that has been reinforced through my fifteen year tenure with an agribusiness trade association and five years with activist groups.

During my work in agribusiness, I noticed a strong tendency for business owners to dismiss the concerns of activists out of hand, usually with the caveat that industry must follow science, not hysterical claims of people who do not understand animal agriculture. When working in an activist capacity, I found the reverse to be true, and the portrayal of agribusiness as cruel, totally dollar-driven and without ethics.

We cannot afford the current confrontational situation where rhetoric trumps reason, and where economic reality and the global economy are ignored. We need to find a synthesis of ethics, science and economics, and we need anticipatory leadership to do so. The questions we face are complex and interdisciplinary. Their solution will require ethically-informed reason, and a willingness to listen and hear those with whom we disagree.

## BACKGROUND

The 2008 FTAA symposium represents a continuation of the organizing committee's attempt to provide an opportunity for persons of differing views to express their opinions about animal welfare issues. This year the revised theme is "Complementary Relationships in Animal Agriculture". While food safety and animal welfare are not always related, there are instances where they are. For example, recent activist videos exposing the mistreatment of non-ambulatory ("downer") animals suggest that the issue is not only about cruelty but perhaps about food safety (e.g., including the potential for Bovine Spongiform Encephalopathy—BSE). Hence the processing of these animals appeared to be the basis for the massive recall of beef products from a California processing plant. Yet, the recent recall of hamburger from an upscale specialty retail outlet apparently was not from non-ambulatory animals, but from steak ground on location. Many people believe these recall situations to be an inexcusable waste of our resources. Years of videos of the mistreatment of non-ambulatory animals prove that a negative animal welfare condition exists, independent of food safety concerns, and this appears to be moving the industry toward more inclusive and intrusive regulations at the farm, and through the slaughterhouse.

Currently, the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) inspectors have the responsibility of providing ante-mortem inspection of animals in the queue for slaughter. A May 20, 2008 ruling removed the provision for the FSIS inspection program to determine the disposition of cattle that become non-ambulatory (disabled) after the anti-mortem inspection, but prior to slaughter, on a case-by-case basis, which authority had come from a July 13, 2007 ruling. The August 27, 2008 proposed rule by USDA, which would amend the federal meat inspection regulations initiates a complete ban on the slaughter of cattle that become non-ambulatory after the initial inspection by FSIS inspection personnel. Establishments are also required to notify FSIS personnel when cattle become disabled after passing the ante-mortem inspection. Thus, no non-ambulatory animal can go through the slaughter facility for human consumption, but must be killed and disposed of properly.



Admittedly the cliché regarding the accuracy of hindsight is valid, but one still wonders if the animal welfare issue had been taken seriously, with proactive holistic programs in place twenty years ago, would we be in this situation today? By taken seriously, I mean industry should have provided the following for all employees: 1. Orientation to include the company's goals and reasons their position is important; 2. Formal training/education; 3. Evaluations tied to job proficiency and/or product quality (including perhaps bonuses for constantly exceeding expectations), with some scheduled and some random evaluations; 4. Retraining/reeducation based on performance; 5. Owners/managers being visible to employees by getting out of the office and walking through the facilities and talking to employees, with owners/managers enforcing animal welfare standards, including termination for repeated violations; 6. Following up on reports of poor animal welfare practices and/or food safety violations, and 7. Checking all references of all potential employees. Could this type of program prevent animal mistreatment or a recall? Which approach would be more expensive, an aggressive educational and monitoring program or a system that historically has resulted in recalls? Which would be more responsible? Today this type of educational program would include routinely discussing the animal welfare situation with managers and FSIS inspectors, perhaps on a daily basis, and letting these people know upper level management depends on their feedback and quality work to help ensure the welfare of individual animals and the safety of the food products. Variations of this type program exist today at some companies, but need to exist and be implemented at all food animal related companies.

As good stewards of our resources we need to recall that negative stresses are additive (e.g., management techniques, animal to animal interactions, transportation, feed quality and quantity, environment, pathogen load, etc.). We are morally obligated to treat animals humanely, to produce safe products from food animals and to deliver them safely to consumers. We depend on each person in the production, transportation, processing and delivery components of the industry to do the best job possible. And we depend on the USDA/FSIS inspectors to continue to fulfill their responsibilities at all levels. Will errors still occur? Of course –human error will occur. But no blatant disregard for the animals' welfare or the safety of our food should ever happen. The same concept of human error applies if these were fruit or vegetable products where chemicals were used improperly, or contamination occurred during harvest or processing or if we are discussing organic products.

Numerous questions exist regarding the relationship between animal welfare and food safety. There is inadequate understanding of how decisions imposed on producers, as well as independent management decisions may impact food safety and animal welfare. This Introduction will include some of these questions, including potential consequences and unintended consequences for animals, owners, and society.

## REGULATIONS, RESULTS AND RESPONSIBILITIES

Europe has a history of greater dependence on regulations than does the United States. We see how Europe's rules and regulations are used to ensure animal welfare according to their perception of what is ethical and required for food safety, and how the USA is moving in that direction. There is a fear that proposed Federal changes will eliminate more small farmers and processors, simply because of their inability to spread regulatory or certification costs over sufficient units of output, thus reducing already marginal profits. Recall the small farm of today was the huge farm of the 1950's where the farmer made a living on what would seem today to be a small number of animals. Farm size is time-dependent and relative to current profit margins. It is interesting that some activist groups, which lamented the decline in the number of small farms due to vertical integration, and contract growers who were "serfs on their own land", now appear to have moved on to other issues after certification programs (non-government imposed regulations) were created. A few big companies are probably easier to control than a lot of little farmers. Also recall that large fast food corporations buy most if not all of their products from larger farms that can provide timely delivery of products having consistent quality

and quantity, probably using a certification program. Certification programs are not free, but are a wonderful tool to create animal welfare standards. Is there a related food safety standard other than USDA certified products? What size farm is exempt from these inspections?

Some moderate animal welfare groups “walk the talk”, and manage successful food animal certification programs meant to facilitate survival of smaller farms and provide for niche markets. Slaughter facilities likewise must have sufficient throughput to reduce costs and stay in compliance with the cheap food demands of retail and wholesale buyers, food distributors, and consumers. At what point will consumers pay for their demands, which would facilitate small and medium size farmers’ and local abattoirs ability to stay in business—after regulations from various sources eliminate these smaller businesses? Will these changes make food safer and protect our food security?

What are the consequences of industry “winning” the war for society’s and government’s support for their agenda? In this case, probably the status quo of safe, inexpensive and abundant food for all of society. While errors are present at a distinct minority of operations, there will probably be the occasional instance of animal welfare violations and undercover exposes from activist groups. Certification programs will undoubtedly continue to grow in importance, particularly for larger facilities. The intended result of these programs is to confirm welfare standards, and which also allows persons who prefer animals raised under specific management standards to pay the farmer for their extra effort and costs. Market demand, partially based on the ability to pay for a particular product, would dictate housing, space and other management options. Dictated state or federal standards for food animal production may hurt public welfare due to costs and perhaps availability.

Gestation stalls for swine and stalls for veal are being phased out. Veal is moving to group housing. Floor housing for layers is becoming popular based on consumer demand, but this demand has reached a plateau for some producers. Even though many questions exist regarding efficacy and safety, activist demands for gas stunning/killing of poultry continue. Changes in this regard are now being contemplated through the demands of fast food and grocery chain buyers. The large food retailers like Wal-Mart are in a position to dictate production practices without the need for state or federal regulations. Is this the least offensive and preferred approach by industry and activists to change food animal production? Have we considered activists’ demands for the fish industry? Does anyone know what they are? Or care? Are certification programs for fish next? When they arrive, will Federal regulations include all animal food sources?

What are the intended and unintended consequences of activists “winning” and putting table egg hens on the floor and perhaps under a roof? There are concerns in Europe and the USA regarding disease spread (e.g., Avian Influenza) to and from poultry being raised on range, or exposed to the out of doors, so there is a demand that these birds be raised under the protection of a roof. Simple calculations to put one million hens under roof, at even a tight one square foot per bird, is  $1,000,000/43,560$  square feet per acre = 22.96 acres of housing/1 Million hens; at roughly 280 Million hens in the USA that is about 6,400 acres just for the laying hens. At 1.5 sq. ft./hen the total is about 9,640 acres. Replacement pullets would add to that land resource commitment. In addition to the building costs and environmental impacts, has anyone calculated any increased need for labor, and the availability and costs of other inputs? Clearly there is a need for new production systems which reflect our economic realities, scientific knowledge and ethical concern.

Proposition 2 in California, if it passes, would require birds to be able to stretch their wings without touching another bird or enclosure (“Requires that calves raised for veal, egg-laying hens and pregnant pigs be confined only in ways that allow these animals to lie down, stand up, fully extend their limbs and turn around freely; <http://ballotpedia.org/wiki/index>). Since birds do not “take turns” stretching, the absurd assumption must be made that all birds can stretch their wings at the same time. Has anyone mentioned that a hen does not naturally fully extend

her wings? Thus the regulation does not appear appropriate for poultry. Will the same regulations be applied to broilers, turkeys and all breeder hens? At a  $\pm$  28 inch wing span, that is about 784 square inches or approximately 5.4 square feet per table egg hen, which far exceeds the generous space allotment for floor birds in flocks providing eggs for niche markets. Can anyone produce table eggs under these conditions at a price the consumer will pay? This 5.4 square feet per bird translates to approximately 124 acres under roof/1 Million table egg hens or about 34,700 acres if required in the entire USA. One was estimated that putting all the caged layers on the floor at that spacing was similar to additional housing equivalent to putting a roof over Delaware (actually that would be about 4.5% of Rhode Islands' 776,957 acres). The construction and facility maintenance economics and labor requirements alone make this untenable, yet 63% of Californians at this time apparently will vote to implement Proposition 2 by 2015. The demands will drive poultry production out of California without necessarily improving the aggregate welfare of the birds.

To paraphrase a speaker's observation in response to a "no-good-answer", "what-if", question crafted by an animal activist regarding use of horses versus dogs and cats as food for humans at the "The Unwanted Horse Issue: What Now?" forum held in the USDA Jefferson Auditorium on June 18, 2008. "You have won. Are you willing to take responsibility for the effects of that win (on the horses)?" The answer was evaded. The speaker's response would be valid for society to ask the animal activist corporations who intend to dictate through the proposition/referendum process, or the concession of state governments, their standards for cattle, swine and poultry. All hens will be allowed to stretch their wings and not be in cages but housed on the floor. The long sought after goal is Federal regulation of all food animal production and an Animal Welfare Council (committee, etc.) at USDA at which activists would have prominent representation. What are the food safety implications of this move? How can we create a sustainable production system?

Older hens lay eggs having thinner shells, which readily break and which result in severely contaminated eggs, a certain potential food safety issue. Today, we have better rations, better facilities that may include roll-out nests placed on the slated portion of the house, etc. But there will be floor eggs and some broken eggs in the nests. Floor eggs are laid in the manure contaminated litter or the manure soiled slats. When several hens lay their eggs in a secluded area some eggs will break and contaminate the others. Any eggs laid outside the building would probably be a loss. Floor birds are a demanded animal welfare goal but the eggs produced in this system may be more of a potential food safety issue. Also, it should be noted that no management system is perfect, but the floor bird option is promoted and perceived to be without a significant downside.

In our discussions it is also appropriate to remember the words of Henry Spira (1): "If you see something wrong, you've got to do something about it." More of us should consider this a worthy personal goal. Henry was the founder of Animal Rights International, and I believe initiated or at least popularized the concept of buying one share of stock in a company so he could attend the annual meeting and submit resolutions. He created several highly successful and influential campaigns, which resulted in creation of the Center for Alternatives to Animal Testing and the Center for a Livable Future at Johns Hopkins University. A hallmark of Henry's campaigns was to offer viable alternatives to the practice he questioned. Henry and I agreed strongly on this point. Have people considered the existence of food safety issues associated with changes in management to achieve potential animal welfare benefits? Henry lived simply, and simply for the cause of protecting animals. How many people who are in the middle of the debates today can say that?

Have these debates become a cottage industry around welfare issues for people on both sides? If we had a viable plan that solved the animal welfare and food safety problems of animal production and processing, and came to a solution that was best for the animals and society, would that be allowed to occur? Is it in the best interest of some activists and some consultants

to not “win”, or at least not immediately; would over regulation or eventual elimination of the industry kill the cash cow? Perhaps more importantly, a philosophical or intellectual stimulation would be removed from people’s lives. Would some other sinister defect be found or imagined on which to base corporate animal rights campaigns? Or, is this characterization of the situation not accurate?

Could it be that activists are indeed correct about how we produce food animals? Obviously-one needs only to look at the expose videos of non-ambulatory livestock. Could industry simply accept the need for change and pass along the costs? Or are there truly debatable aspects of the demands of activists, and if so, why are their demands becoming “voluntary” certification programs or legislated mandates for the food animal industries? If voluntary, there is assumed to be a market demand for the change, even though the demand may be driven by corporate food buyers and ultimately by corporate activist organization’s publicity campaigns that include exceptional web sites. Our present economic situation obviously adds a level of complexity to this discussion.

Is the eventual result of these debates a benefit to animals to not exist, for anointed humans to “play God” with our food security through manipulation of the system and human emotions? Or should we have a more utilitarian approach to animal welfare and food safety and thus human welfare, one of respect for the animals and our responsibility as good stewards of our resources, and one where the welfare of the animal is a priority rather than human agendas? Hans Selye, the father of the stress syndrome/general adaptive syndrome, (2) observed:

“A detached analytical debate helps to point out and correct errors; but criticism must always remain objective. It should be offered in the friendly tone which behooves colleagues in the same field of learning, who merely want to promote science by mutual constructive advice. Above all, debate must, as far as our human limitations permit, not be directed by considerations of personal prestige. The question is not, “Who is right”, but “What is right”.

The same concept applies to animal welfare and food safety—not whose agenda sells best to the public, but what is best for society and the animal’s welfare, recognizing the answer will not be perfect nor black and white. Reputable people will not use these situations as opportunities for manipulation, or an incremental approach or positional bargaining to “win”.

## FUTURE OF THE FUTURE TRENDS IN ANIMAL AGRICULTURE

What to do next? Everyone go to their corner and come out fighting? Should we focus on the welfare of society and of the animals in relation to their use to benefit humans? Should we try to find solutions that allow farmers of all sizes to earn a living, which means society must pay for their altruistic demands on owners of food animals? Or should we give up and accept that corporate activist groups will instigate creation of state and Federal regulations for food animal production that some people believe can later be manipulated to reduce animal use and perhaps force farmers out of business? Is this a case of animal rights activist egocentrism and management of other people’s property without any of the risks, and if so what is the impact on individual animals and society? Would welfare regulations be better if industry inspired or demanded, and should they include a food safety component that funds an extension of FSIS responsibilities to the farm level? How would these regulations eventually differ from corporate activist group inspired regulations? Or, are all these concerns for the food animal industry misplaced?

Has a precedent been defined through the various proposition/referendum processes? Based on these successes, and negotiations with state governments, is Federal legislation now justified? Should we just give up attempting to define or create common ground that benefits animals and society? Should we give up attempting to provide a neutral venue to create

opportunities for persons from all points of view to present their ideas, including justification regarding ethical animal use? Should we just “cut to the chase” and stop eating animals, and give up “exploiting” animals for human benefit?

Radicalization. Increased polarization. Questions of misplaced credibility. Apathy on the part of activists and industry. The economics and politics of surrender by industry (note the “no contest” decision by swine and veal industries in the California question and the brokered agreement in Colorado). Imminent Federal regulations (industry led, or corporate activist group led) based on state precedents achieved through the state proposition or referendum process. All and more have been cited as additional reasons to justify terminating the Future Trends in Animal Agriculture symposium series with the 2008 event.

Should the Future Trends in Animal Agriculture die, or shift gears and provide educational programs on specific concepts such as bioethics? The organizing committee discussed this situation and is considering shifting gears to create a program for 2009 that will focus on agricultural bioethics in relationship to animal rights and animal welfare. Many animal welfare groups continue to support the FTAA concept and goals, as do some industry members who seek to educate decision makers, congressional personnel and the public about these important issues that affect animal welfare and our food safety and food security.

## PROGRAM

The proceedings include speaker contact information, which is provided as Appendix A. The primary audience members are: agency decision makers and other government personnel, representatives from animal advocacy organizations, universities, the agricultural industries, and congressional staffers. The public is welcome to attend all FTAA events. We hope that you find the proceedings enjoyable and educational. Feel free to contact any committee member for details of future programs. Contact Dr. Richard Reynnells at 202.401.5352 ([rreynells@csrees.usda.gov](mailto:rreynells@csrees.usda.gov)) for additional copies of the proceedings from this or previous years.

## REFERENCES

1. Singer, Peter, 1998. “Ethics into Action: Henry Spira and the Animal Rights Movement, introductory quote. Bowman & Littlefield Publishers, Inc., Lanham, Maryland. ISBN 0-8476-9073-3.
2. Selye, Hans, 1976. “The Stress of Life”, revised edition, page 281. McGraw-Hill Book Company, NY/St. Louis/San Francisco/London/Toronto. ISBN 0-07-056208-3.

# **Regulatory Roles that Enhance Food Safety and Animal Welfare**

**James Hodges**  
American Meat Institute

The meat industry has both a regulatory and moral obligation to produce safe, wholesome products and treat animals humanely. Humane handling is good for livestock and good for business, but it will not assure that the food derived from humanely treated animals is safe to eat.

Considerable confusion has resulted from events during the past year that has unfortunately blurred the lines between food safety and animal welfare. The widely publicized recall of beef products from a plant in which the illegal abuse of cattle occurred served to reinforce an erroneous belief that unsafe food is derived from animals that are treated inhumanely.

Food safety is assured by plants implementing effective control procedures that are designed to prevent unsafe product from entering the marketplace. Appropriate oversight and enforcement by USDA's Food Safety and Inspection Service is a key element to assure all facilities that manufacture meat and poultry products meet their regulatory obligations to produce only safe and wholesome food products.

Proper treatment of animals is also an industry responsibility. For more than four decades, the industry has been subject to the federal Humane Slaughter Act of 1958. Federal inspectors continuously enforce this act's requirements. Violations are noted and companies must show the federal inspectors what actions will be taken to prevent problems from occurring again.

In the last decade, the industry initiated a number of voluntary initiatives that include enhanced animal handling training, implementation of voluntary guidelines and the use of self-audits to assess welfare and maintain continuous improvement. In addition, retail and restaurant customers have taken an increasing interest in animal welfare, creating animal welfare advisory committees and requiring animal welfare audits. Taken together, these developments have spurred the industry to implement new practices and to make animal welfare a top priority. The end result has been documented improvements in animal handling.

All USDA-inspected meat products are subject to both the Federal Meat Inspection Act and the Humane Slaughter Act. If a product bears the USDA seal, it has met both food safety and humane regulations. Producing safe food and properly handling animals is a business necessity to maintain consumer confidence of our products.

# European Policies, Research and Assessment Activities Related to Animal Welfare: Lessons for the US?

**E. A. Pajor**  
Department of Animal Sciences  
Purdue University

## INTRODUCTION

In recent years animal welfare has emerged as a serious public concern leading to the development of legislation, assessment programs and guidelines. Individual European countries and European multi-national institutions (such as the European Union (EU) and the Council of Europe) have introduced a number of initiatives promoting legislation to define minimum standards of farm animal welfare (Table 1). In contrast, the development of animal welfare policies in the United States tends to be voluntary and driven by retailers and producer organizations. However, an increase in legislation is also occurring at local and state levels. In this article, I will briefly highlight the legal protection and private sector initiatives to protect farm animals in Europe, and the US, suggest some limitations to legislative approaches, and finally identify areas of needed attention and future direction for developing animal welfare policies in the US.

1974/1993	Stunning and Killing
1977/1995	Transportation protection
1988	Laying Hens
1991	Calves/Pigs protection
1997	Amsterdam Treaty (animal sentience)
1998	General Farm animal protection
1999	Ban on cages for laying hens
2001	Grouping of pregnant sows
2005	Council Regulation 1/2005 on animal transport
2005	Broiler chickens
2006	Community Action Plan
2007	Broiler chickens

## ANIMAL WELFARE POLICIES IN EUROPE

### Multi-national Institutions

#### *Council of Europe*

The Council of Europe was founded in 1949 and began to address animal welfare issues in the 1960. The Council of Europe is made up of 46 member states and a Parliamentary Assembly of 315 representatives. The Council of Europe issues conventions (which if ratified by member or non-member states are legally binding) and recommendations (non-binding guidelines). The Council has developed 3 European Conventions (Table 2) which detail minimum requirements for animal transportation, provide general principles for keeping animals in intensive farm systems and improving handling, slaughter, and stunning conditions. For each of the conventions the council subsequently developed recommendations for a variety of species.

## European Union (EU)

The EU, formally the European Economic Community, drafts directives to protect animals and allow fair competition within the marketplace. Prior to issuing directives, the EU will often consult with a scientific committee which will provide a report, review the existing scientific literature, and make recommendations to improve animal welfare. After the scientific recommendations are made and various other bodies consulted the EU may decide to issue a directive. Currently, EU directives have been developed for a variety of species as well as slaughter and transport. According to Veissier et al. (2008), EU directives tend to be guided by the Five Freedoms and their approach in improving animal welfare is provided in Table 3. One of the most important pieces of legislation introduced in the EU is the Amsterdam Treaty which established new fundamental rules for the European Union's animal protection measures. It also officially recognized animals as sentient beings and requires that European Institutions and Member States to give full regard to the welfare requirements of animals in developing legislation. This requirement is clear in the four year (2006-2010) EU action plan (Table 4).

1968	Protection of Animals during international Transport
1976	Protection of Animals kept for Farming Purposes
1978	Protection of Animals For Slaughter

1. Increase space allowance per animal
2. Encourage social interaction and group housing
3. Increase freedom of movement
4. Provide Enriched environments
5. To feed a diet consistent with physiological and behavioral needs
6. To limit painful interventions

## National regulations and quality assurance programs

### *National Regulations*

EU directives are often adopted as national regulations but vary from country to country. EU directives are often expected to represent a minimum national standard. Countries may set more stringent standards. For example, current regulations for castration are higher in Norway than other EU countries.

### *Quality Assurance Programs*

In addition to national regulations there are a variety of quality assurance programs that can be found within any one country. Assurance programs can be developed for a variety of reasons by industry, and retailers. Some programs are designed to identify niche markets and many programs are stricter than other regulations including national regulations. In Europe, quality assurance programs can be divided in 3 types, i) general quality, ii) animal welfare, and iii) organic (Veissier et al., 2008). In general quality assurance programs the focus is on food safety, product quality and traceability, animal welfare is part of the criteria but not the main focus as welfare standards tend to meet basic legal requirements. In animal welfare quality assurance programs, animal welfare is without question the main focus, and standards easily surpass national regulations and those standards found in general quality assurance programs.



Finally in Organic programs animal welfare is included but these programs also include environmental, human health, and food safety and quality components. For a more detailed discussion of animal welfare programs and regulations in Europe, please see Veissier et al., (2008).

Table 4. EU Community Animal Welfare Action Plans
1. Upgrading existing minimum standards for animal protection and welfare
2. Giving a high priority to promoting policy orientated future research on animal protection and welfare and application of the 3R principle
3. Introducing standardized animal welfare indicators
4. Ensuring that animal handlers and the public are more informed on current standards
5. Support international initiatives to raise awareness on animal welfare

## THE OIE AND STANDARDS BEYOND EUROPE

The World Organization for Animal Health (OIE) was initially created in 1924 and included 28 countries. Its main mission was to develop standards to combat the outbreak of animal diseases. Over its history the OIE has grown to 172 member countries. It is an extremely influential organization with their standards used as the international reference in the field of animal diseases for the WTO. Recognizing the link between animal diseases and the suffering and welfare of animals the OIE received a mandate to develop standards in animal welfare in 2002. The aim of the OIE is to produce standards in the area of animal welfare that could be used for international trade and serve as a foundation for legislation in countries that currently do not have legislation in animal welfare. The OIE insists that their guidelines be science based and their efforts are guided by 8 principles. These include the 5 freedoms (principle 1-5), the 3R (principle 6), the recognition of value assumptions as being part of animal welfare (principle 7) and finally that animal based criteria rather than design criteria should be the basis for comparing standards. To date the OIE has developed 4 sets of codes dealing with (1) land and (2) sea transport as well as the humane killing of animals for (3) disease control and (4) human consumption. OIE future activities include developing standards for the housing and production of farm animals. For additional information on OIE activities please see Bayvel (2004, 2005) and Petrini and Wilson (2005).

## UNDERSTANDING EUROPEAN ATTITUDES AND DEVELOPING ANIMAL WELFARE STANDARDS

### **Eurobarometer**

The Eurobarometer is a series of surveys commissioned by the European Commission Health and Consumer Protection Directorate General. It produces reports of public opinion of certain issues relating to the European Union across the member states. In 2005 a survey, focusing on the attitudes of consumers to the welfare and protection of farmed animals was performed. The survey and report focused on three main themes 1) the welfare of farmed animals, 2) purchasing behavior and the welfare of farmed animals and 3) animal welfare at the European level. In 2006, a second Eurobarometer survey was carried out on the attitudes of EU Citizens towards Animal Welfare. The results of the surveys demonstrate two major findings 1) that instinct realities exist in the consideration of animal welfare in various member states. There is a great deal of interest in animal welfare and animal welfare standards. The specifics of the surveys are beyond the scope of this paper. However, the data clearly identifies how values and concerns about animal welfare vary across countries and cultures. This information will be incredibly valuable in developing successful strategic plans for communication, education and research in animal welfare for individual member states. Information on the Eurobarometers

dealing with animal welfare can be found at  
[http://ec.europa.eu/food/animal/welfare/euro\\_barometer25\\_en.pdf](http://ec.europa.eu/food/animal/welfare/euro_barometer25_en.pdf) and  
[http://ec.europa.eu/food/animal/welfare/survey/sp\\_barometer\\_aw\\_en.pdf](http://ec.europa.eu/food/animal/welfare/survey/sp_barometer_aw_en.pdf).

### **Welfare Quality Project**

The Welfare Quality project represents the largest piece of integrated research work carried out in the Animal Welfare in Europe. It includes 17 EU countries, 5 Latin American countries and has a budget of over 17 million Euros. Two main goals of the project include 1) the development of practical approaches and measures to improve animal welfare, and 2) to develop a European standard for the assessment of animal welfare. The development of appropriate measures is essential for the project to have both internal and external validity. In order to address this issue organizers of the project developed four welfare criteria based on the Eurobarometer that capture the public description of animal welfare. Furthermore 12 animal welfare principles were identified that should be covered in the measurement systems. These welfare criteria and principles are independent of the species or type of production system used. The development of these criteria and principles is an important step in standardizing an approach to improving animal welfare. Information on the Welfare Quality Project can be found at <http://www.welfarequality.net/everyone>.

## **ANIMAL WELFARE IN THE US**

### **Federal and State Legislation in the US**

In the United States federal regulation of the treatment of farm animals is limited to 2 major laws, the Humane Methods of Slaughter Act (HMSA) and the Twenty-Eight Hour Law. The HMSA stipulates that livestock be insensible to pain prior to slaughter. The act applies to all animals used for food in the US except poultry which are excluded from the USDA enforcement program. The Twenty-Eight Hour Law, originally passed in 1873 requires that livestock be unloaded and fed, watered, and rested for at least 5 consecutive hours prior to the resumption of transport after 28 hours. This law did not extend to the transportation of livestock by trucks until 2006. The lack of federal regulations, reflects cultural differences between the US and Europe in both the role that legislation is expected to play in people lives as well as people relationship with food and farm animals.

Many states have cruelty to animal statutes but many states exempt some or all common agricultural practices from the definition of cruelty. Other mechanisms being used to regulate or outlaw these include constitutional amendments, voter referenda, and legislative action, all of which have now been used in several states and cities to ban practices such as the use of sow gestation crates (for example in Florida and Arizona) or *foie gras* production (California) or consumption (Chicago) (Mench, 2008).

### **Voluntary regulations and assurance programs**

In contrast to the legislative approach taken in Europe, the primary drivers of improved animal welfare standards in the U.S. are the producers and food retailers. Producer initiatives have taken the form of standards implemented at the level of particular companies, integrators, cooperatives, or commodity groups. All of the major producer groups now have animal welfare guidelines or animal welfare quality assurance (QA) programs; these are detailed in Table 5. The level of input from independent experts into these guidelines is highly variable.

## PROBLEMS WITH LEGISLATION

According to Mench et al., (2008) legislation is likely to be the least effective vehicle for implementing improvements in farm animal welfare, for several reasons including:

1. Size and number of farms make the development of a systematic enforcement program difficult and costly. Regulation without enforcement would fail to assure the public that the regulations were being followed.
2. The U.S. regulatory process is cumbersome, non-consultative, and lacks transparency. This creates a situation where there is an adversarial relationship rather than a consultative relationship between the stakeholders, and ultimately a lack of buy-in by those stakeholders.
3. Legislative standards tend to be rigid and difficult to change once implemented.
4. Legislative recommendations, by their nature, are engineering-based. It has become obvious in the last few years that specific engineering-type provisions enacted in other countries to try to improve animal welfare often have not had the intended effects.

## CONCLUSIONS

The US situation varies significantly from a European approach. First, the emphasis on legislation is both culturally unappealing to many Americans and it is not clear that it result in improving animal welfare in the long run. However, unlike the US approach of using a variety of approaches to animal welfare standards, Europeans have developed a systematic approach to developing animal welfare standards across various countries, cultures, production systems and species. This systematic approach, altered to reflect North American values, needs to be considered within a national dialogue on animal welfare. Developing such a system needs to a) be based on the an understanding of the concerns, attitudes and knowledge of US consumers and citizens, b) assure consumers of animal products that animals have been raised appropriately, c) include all relevant stakeholder in the discussion and d) be based on ethical principles

Mench et al. (2008) outlined the following goals for a successful national process:

1. Set standards for current production practices where there is already sufficient scientific information available to ensure that those standards will have the desired effect in improving welfare. For example, the standards adopted by the UEP were based on a review of a rich scientific literature on poultry behavior, health, and welfare.
2. Develop and validate scientifically determined and performance-based standards of animal welfare that can provide benchmarks for improvement.
3. Include follow-up mechanisms to ensure that any changes are having effects that meet the desired goal.
4. Incorporate mechanisms to increase and sustain a dialogue among producers, scientists, veterinarians, and other stakeholders to allow the kind of innovation that is necessary in order to continue to improve animal welfare on-farm.
5. Facilitate transparency and ethical consistency.
6. Provide incentives (e.g. subsidies, tax breaks, low-income loans) for producers to encourage them to adopt and follow improved welfare practices.

TABLE 5. Major U.S. Animal Welfare Standards (from Mench et al., 2008).

Source	Scope	Program/Document	Purpose	Reference
American Meat Institute	Livestock slaughter plants	*Recommended Animal Handling Guidelines Audit Guide	Guidelines Voluntary audit	<a href="http://www.meatami.org">www.meatami.org</a>
American Sheep Industry	Sheep	Sheep Care Guide	Guidelines	<a href="http://www.sheepusa.org">http://www.sheepusa.org</a>
Animal Welfare Institute	Pigs, beef cattle & calves, rabbits, ducks, sheep	Animal Friendly Standards (for each species)	Voluntary guidelines for small family farmers	<a href="http://www.awionline.org/farm/standards.htm">http://www.awionline.org/farm/standards.htm</a>
Certified Humane Raised & Handled	Egg-laying hens, broilers, turkeys, beef, dairy, sheep, swine	(detailed standards for each species)	ISO-certified third party labeling program	<a href="http://www.certifiedhumane.com/">http://www.certifiedhumane.com/</a>
Free Farmed (AHA)	Egg-laying hens, broilers, turkeys, beef, dairy, sheep, swine	(detailed standards for each species)	Third-party labeling program	<a href="http://www.americanhumane.org">http://www.americanhumane.org</a>
Milk and Dairy Beef Quality Assurance Program	Dairy	*Caring for Dairy Animals Technical Reference Guide On-The-Dairy Self-Evaluation Guide	Guideline and self-evaluation; voluntary certification	<a href="http://www.dqacenter.org/dcare/dcare00.htm">http://www.dqacenter.org/dcare/dcare00.htm</a>
National Cattlemen Beef Association	Beef Cattle	*Guidelines for Care and Handling of Beef Cattle	Voluntary guidelines 3 <sup>rd</sup> party audit available	<a href="http://www.beef.org/ncbaanimalwelfare.aspx">http://www.beef.org/ncbaanimalwelfare.aspx</a>
National Chicken Council	Broiler chickens	*Animal Welfare Guidelines Audit Checklist	Voluntary guidelines Voluntary audit	<a href="http://www.nationalchickencouncil.com/files/AnimalWelfare2005.pdf">http://www.nationalchickencouncil.com/files/AnimalWelfare2005.pdf</a>
National Organic Standards	All livestock and poultry	National Organic Standards & Guidelines	USDA labeling program; main focus is organic although contains some animal husbandry standards	<a href="http://www.ams.usda.gov/nop/indexIE.htm">http://www.ams.usda.gov/nop/indexIE.htm</a>
National Turkey Federation	Turkeys	Animal Care Guidelines for the Production of Turkeys	Guidelines Part of overall QA program	<a href="http://www.eatturkey.com/foodsrv/pdf/NTF_animal_care.pdf">http://www.eatturkey.com/foodsrv/pdf/NTF_animal_care.pdf</a>
Pork Board	Pigs	Swine Welfare Assurance Program which includes the *Swine Care Handbook	Self-education program for producers; auditing program to be developed	<a href="http://www.porkboard.org/SWAPHome/default.asp">http://www.porkboard.org/SWAPHome/default.asp</a>
United Egg Producers	Caged layers	*Animal Husbandry Guidelines for U.S. Egg Laying Flocks UEP Certified program	Guidelines for caged hens Third-party auditing and labeling program	<a href="http://www.uepcertified.com/">http://www.uepcertified.com/</a>

\* Approved by FMI-NCCR as guidelines appropriate for the development of retail auditing programs. Individual retailers may also have their own standards and/or auditing programs, and these may differ significantly from the programs approved by the FMI-NCCR committee.

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**Panel: Pro's and Con's of Using Legislation to Advance  
Views of Farm Animal Welfare and Food Safety**

**Paul Shapiro**  
Humane Society of the United States

A paper was not provided.

# Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety

## Impact of Legislation on Animal Research

**Marcos H. Rostagno**  
USDA, ARS, MWA, Livestock Behavior Research Unit

The use of animals in research has become one of the most important issues in research because it presents an ethical dilemma to the scientific community: scientists do not want to lose scientific benefits, nor do they want to cause animals to suffer.

The regulation of animal-based research occurs through a variety of mechanisms with a great deal of variation between countries. In the United States, the Animal Welfare Act constitutes the center piece of the regulatory mechanisms regarding the humane treatment of the animals used for experimental purposes. The Animal Welfare Act (AWA) was signed into law in 1966. While its original intent was to regulate the care and use of animals in the laboratory, it has become the only Federal law in the U.S. that regulates the treatment of animals in research, exhibition, transport, and by dealers. Other laws, policies, and guidelines may include additional species coverage or specifications for animal care and use, but all refer to the Animal Welfare Act as the minimum acceptable standard. The Act was amended four times (1970, 1976, 1985, 1990), and is enforced by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Animal Care (AC). The Animal Welfare Act describes the responsibilities and functions of the attending veterinarian(s), the institutional official, the principal investigator, and the Institutional Animal Care and Use Committee (IACUC) in research facilities. It also includes regulation of field research, and specifies reports, notifications and record-keeping needs, in addition to qualifications and training required for research personnel. Detailed information about the Animal Welfare Act is available through the internet at the following websites: Animal Welfare Information Center of the USDA (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>), and USDA, APHIS ([http://www.aphis.usda.gov/animal\\_welfare/index.shtml](http://www.aphis.usda.gov/animal_welfare/index.shtml)).

Whatever the type of animal-based research conducted or regulation mechanism(s) adopted, the general principles of humane treatment of animals to be followed are based on the "3 R's". The principles of the 3R's were originally published by William Russell and Rex Burch (*The Principles of Humane Experimental Technique*; 1959), and are now widely accepted by the international scientific community as the fundamental criteria for humane animal use in research. The "3 R's" stands for:

**Replacement** – refers to methods which avoid or replace the use of animals where animals would otherwise have been used, including both absolute and relative replacements.

**Refinement** – refers to improvements to husbandry and procedures which minimize actual or potential pain, suffering, distress or lasting harm and/or improve animal welfare in situations where the use of animals is necessary.

**Reduction** – refers to methods which minimize animal use and enable researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals (e.g., experimental design and statistical analysis, research techniques, etc.).

Fundamentally, the guiding question to be asked by any scientist planning a research project (or experiment) is: "Can I reach my goal(s) while causing the animals less suffering, using fewer animals or without using animals at all?"

Researchers are required to consult with the institution's attending veterinarians and its IACUC, which every research facility is obliged to maintain. Based on the Animal Welfare Act and the "*Guide for the Care and Use of Laboratory Animals*" (NRC, 1996), the IACUC must ensure that alternatives, including non-animal alternatives, have been considered, that the experiments are not unnecessarily duplicative, and that pain relief is given unless it would interfere with the study.

A remarkably visible impact upon research institutions was made by the National Institutes of Health (NIH) adopting and enforcing a policy of suspending funding to research programs that do not follow the standards of the "*Guide for the Care and Use of Laboratory Animals*" (NRC, 1996). Several associations, societies, and other research funding sources have followed the NIH's policy. The end result has been an impressively rapid upgrading and standardization of animal care and use policies and programs at all types of institutions that use animals in their work.

Reducing the adverse effects of scientific protocols ("refinement") is crucial in animal-based research. It is especially important that researchers share knowledge on how to avoid causing suffering. Until recently, scientists often failed to report measures to minimize animal distress. However, this scenario is rapidly changing as scientific journals publishing animal-based research increasingly require more information and compliance regarding animal welfare. Journal publishing policy play an important role, ensuring that referees seriously consider whether submitted studies were carried out with the smallest achievable negative impact on the animals, and encouraging scientists to share refinement approaches and techniques in papers publishing the results of animal-based research.

In summary, the impact of animal welfare regulations through a combination of legislation and guidelines can be presented as:

- 1) decreased number of animals used in research;
- 2) increased development and use of *in vitro* models;
- 3) increased bureaucracy (with a consequent increased time between planning and execution of experiments);
- 4) increased quality of experiments (study design, protocol planning, reviews);
- 5) increased control and accountability; and
- 5) increased overall awareness of an animal's needs, and respect for the animals (consequently, better animal care).



**Panel: Pro's and Con's of Using Legislation to Advance  
Views of Farm Animal Welfare and Food Safety**

**Tony Pescatore**  
University of Kentucky

A paper was not provided.

## **Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety**

**Marie Belew Wheatley**  
American Humane Association

American Humane Association is the oldest humane organization in the United States, dedicated to protecting the welfare of both children and animals. Founded in 1877, the organization began with the need to address the inhumane treatment of workhorses. In 1879, American Humane began inspecting stockyards, rail cars, and slaughterhouses in an effort to improve the welfare of farm animals.

Over 13 decades, American Humane has evolved and grown to encompass an array of services and programs that protect and enhance the well being of those without voices – children and animals. Through education, advocacy, and motivation, we encourage humane behavior. Our headquarters are in Denver, Colorado, with regional offices in Washington, DC, and in Los Angeles, CA.

Among our programs are “No Animals Were Harmed” that monitors film and TV productions for the welfare of animals in entertainment; Red Star Animal Emergency Services that originated to protect horses during World War I; The Link , that raises awareness of the positive benefits of the bond between animals and people, as well as the connection between animal abuse and other forms of violence; and American Humane Certified that audits and verifies farm animal welfare standards.

American Humane Certified is the first and original certification program created in the United States to ensure the humane treatment of farm animals. It provides independent verification that the care and handling of farm animals by a certified producer meets the science-based animal welfare standards of American Humane. Those standards, based on generally accepted animal husbandry guidelines, were developed in collaboration with animal science experts, veterinarians, farmers, and ranchers. They are reviewed regularly by the American Humane Certified Scientific Committee to ensure that advances in technologies, best practices, and new methods are incorporated.

Throughout our history, American Humane has held balanced, reasonable, and moderate policies in support of animal welfare. We believe that people have the right to choose what they eat. Eliminating food choices is not our agenda. Our mission is to ensure that animals raised for food are treated humanely; that producers who meet these animal welfare standards are recognized by the American Humane Certified label, and that consumers are made aware of the products that are certified through promotion of the label.

Over the last year, the American Humane Certified program has grown over 300% with the certification of new producers in the United States and Canada, across all species. The exceptional growth of the program is based on working with agriculture producers to develop new solutions to welfare problems; to bring new technology to the audit process resulting in increased productivity, reduced costs, transparency and consistency; and to create support among consumers and retailers for humanely raised protein products.

Regarding the use of legislation to advance views of farm animal welfare, historically, American Humane has turned to legislative action when we believed that it was the only appropriate course to address egregious animal handling practices and necessary to effect change in national animal welfare policy. Two significant examples of our legislative advocacy are the 28 Hour Rule for transportation of animals and the Humane Methods of Slaughter Act. Our work in the past 10 years with protein producers has been focused on collaboration, rather than

regulation. We believe that working with agriculture to develop animal welfare solutions not only benefits more animals, but it is more conducive to positive outcomes than mandating changes. People who are part of the solution process have more ownership and are more proactive in adopting new technology and practices.

To be clear, American Humane addresses the use of legislation to advance views from the animal welfare stand point and not food safety. While our American Humane Certified program does not monitor food safety, public perception holds that food safety is closely related to animal welfare. A recent industry study cited that almost 60% of consumers believe food safety is directly tied to animal welfare. We strongly favor regulation and inspection to ensure food safety. We have concerns about excessive farm animal welfare legislation that, among other unintended consequences, may prompt major producers to take their operations off shore, resulting in increased importation of food to meet demand and uncertain animal welfare conditions.

American Humane is a strong proponent of educating, motivating, and collaborating with people to bring humane standards and practices to agriculture rather than legislating, intimidating, and litigating action. Agriculture is an industry based on traditions and long-established practices. We know that there are substantial costs to retrofit and that changes cannot be made immediately. While we may not always agree on best practices for animal welfare, generally, most farmers and ranchers want to be good stewards. If producers can be shown how different, more humane, practices can increase productivity and efficiency, as well as benefit the animals, most producers will embrace and adopt new practices. The key idea is to embrace and adopt, rather than be mandated and co-opted.

American Humane believes that solutions and new practices must be economically viable and achievable for the producers if animal welfare certification is to be successful. It must be good for business and people, as well as animals. We believe in forming positive partnerships with agricultural alliances, trade organizations, and producers to share knowledge and technology. Through these partnerships will come best practices for the welfare of farm animals, as well as profitable businesses.

We offer three solution-based alternatives in order to impact greater numbers of farm animals raised humanely:

***Work with national agriculture trade groups and individual producers*** in order to understand the practical, social, and economic barriers. Provide solutions that are achievable and economically viable. The size of the operation is not a measure of humane treatment of animals. Many large corporate farms are comprised of smaller producers who contract their animals to the larger entities. Producers, large and small, are recognizing that the welfare of animals is a major concern with socially aware consumers who vote with their purchasing power and the retailers who depend upon that power. Collaborating to create improved industry animal welfare standards is more efficient and effective than circumventing legislation and litigating interpretation.

***Improve audit technology*** to achieve transparency and consistency, reduce costs, and ensure compliance. American Humane Certified has developed a three-tier audit system to certify producers that consists of annual on site visits, daily or weekly on line self-monitoring and reporting of key factors, and video monitoring of barns, transportation, and live areas of processing facilities. This technology provides management with tools to identify and resolve problems in a timely manner, as well as ensure compliance with American Humane Certified standards.

***Create markets for humanely labeled food choices*** by building consumer and retailer awareness and demand. As the number of American Humane Certified producers has increased, so too has consumer awareness and demand for humanely raised food. Our

research shows that consumers are concerned not only about how and where the food they buy is grown, but how farm animals have been treated. The humane treatment of farm animals is a fast growing part of the social, ethical, and environmental purchase equation among socially aware consumers.

American Humane uses education and marketing to reach the growing number of people who disdain cruelty and will make humane choices when provided with information and motivation. While American Humane Certified is a value added proposition for producers, it is becoming a value added quotient in buyer consideration. Again, our research shows that consumers expect and are willing to pay more for humane certified labeled food.

American Humane will continue to work collaboratively with agriculture to bring welfare to the forefront of best practices in raising and handling animals for the production of food and to find solutions to welfare issues that benefit animals and are productive and economically viable for producers. We will commission research to evaluate alternatives to improve the welfare of farm animals, such as aviary group housing systems. We commend efforts by agriculture to promote continued improvement of animal welfare standards and we will provide support for those efforts wherever we can. We believe that by discretionary participation by agricultural producers, the greatest number of animals will be treated humanely and consumers will have abundant humane choices of protein products.

# **Slaughter Facility Management**

**Janet M. Riley**  
American Meat Institute

A paper was not provided.

# **Treatment of Sick and Injured Animals: Should They be Moved and if So, How?**

**Jim Reynolds**  
University of California  
American Association of Bovine Practitioners

Sick and injured farm animals represent a small number of cases on any farm but can be a very real and large welfare and management issue. Livestock farms engage veterinarians to help develop programs and procedures to prevent and minimize illness and injuries and to develop and manage protocols to identify sick animals and provide appropriate treatment. When animals become ill to the point of suffering or are expected to not recover with treatment they should be humanely euthanized. Smaller livestock like pigs, goats and sheep can usually be moved relatively easily to treatment facilities if they become non-ambulatory. Larger animals, such as cattle, can be difficult to move humanely when non-ambulatory and require careful procedures and protocols to ensure their welfare. This paper will address the current issue of non-ambulatory cattle being sent to market, including reasons for becoming down cattle, treatment needs and issues with handling, moving and euthanasia.

Down cattle are non-ambulatory livestock, or cattle that cannot stand or walk without assistance. Down cattle present welfare, food safety and economic problems to the cattle industry. It is in the best interest of the animals, the consumers and the cattle industry to prevent non-ambulatory animals and, when they do happen, to make decisions to either care for them properly or to humanely euthanize them. Cattle of all ages become non-ambulatory but replacement stock are at low risk and, because they are not as large as adults, do not present the livestock industry with the issues associated with down adult cattle. This discussion will be primarily concerned with non-ambulatory adult cattle, although the welfare, food safety and economic concerns hold true for calves as well.

Solid data related to causes and numbers do not currently exist. The USDA is in the process of finishing an interview survey of the US dairy industry that will provide some national and regional data. Information available now is limited or anecdotal. It is apparent that dairy cattle are much more at risk than beef cattle for becoming non-ambulatory. The USDA estimated that approximately 200,000 down cattle were presented to slaughter facilities in the US in 2003, or about 0.5% of 36 million cattle processed (Stull, personal communication). Current USDA estimates from the 2005 survey report almost 5% of dairy cattle becoming non-ambulatory per year. Dr. Pam Hullinger conducted an unreported survey in a single California abattoir for the year 1996-1997 and found the following: 519 down cattle; incidence rate of 0.01%; 91% were dairy cattle, only 9% beef cattle; 40% of the down cattle passed USDA inspection and entered the food chain (Hullinger, personal communication).

Causes of down cattle probably vary by region, herd size and herd management. The major categories of causes for non-ambulatory cattle are injuries related to dystocia (nerve damage, muscle and ligament damage), other injuries (fractures, muscle and ligament damage, "slip and fall" from estrus behavior or poor footing), infectious diseases (toxic mastitis, toxic metritis, lymphoma, peritonitis, septicemia) and metabolic disorders (hypocalcemia, hypomagnesemia, hypophosphatemia, hypokalemia, acidosis).

Dr. John Maas conducted a necropsy and farm interview survey on 50 down cows presented to slaughter at an abattoir in Southern California in 1995. The data has not been published but was presented at the Livestock Conservation Institute 1996 meeting. The data is presented in Table 1.

**Table 1. Necropsy findings and outcome of 50 down dairy cows presented to slaughter in Southern California.**

<u>Diagnosis</u>	<u>#Cows</u>	<u>#Condemned</u>
Injury	19	1
Calving paralysis	12	3
Mastitis	6	3
Lymphosarcoma	5	4
Metritis	2	--
Other	5	--
(pneumonia, gastroenteritis, LDA, septicemia)		
Unknown	1	--

(Presented by Dr. C. Stull at Livestock Conservation Institute 1996 annual meeting)

Once an adult bovine has become non-ambulatory it is imperative to assess the case and make a tentative diagnosis and prognosis. Diagnosis is difficult due to the size of the animals, limiting effective manipulation of legs and muscles, and the overlap of clinical signs from various diseases. Many veterinary practitioners approach down cattle diagnosis with the four "M's" in mind: mastitis, metritis (uterine infection), musculoskeletal (fractures, ligament and muscle injury) and metabolic (hypocalcemia). Careful examination and evaluation of each case with respect to these areas can often result in a diagnosis, but many cases remain undiagnosed. Detailed descriptions for diagnostics can be found elsewhere.

The prognosis for the animal is very important because it will determine if treatment and nursing care is warranted or if the animal should be humanely euthanized. If the animal is suffering and the pain or distress cannot be controlled or is not likely to be controlled quickly, the animal should be euthanized. Acceptable euthanasia methods can be found in the American Association of Bovine Practitioners (AABP) and American Veterinary Medical Association (AVMA) recommendations on euthanasia and include pentobarbital, captive bolt and gunshot. The use of high doses of agents such as potassium, to stop the heart, must only be used after the animal is definitely unconscious. The method of euthanasia and carcass disposal may be affected by local regulations and rendering plant requirements.

The welfare problems are associated with the pain and suffering of the animals from the causes of the non-ambulatory condition, the nursing care provided and transportation while non-ambulatory. The suffering (pain and distress) of the animal must be considered early in the case.

Basic initial treatment for non-ambulatory cattle includes nursing care that provides comfortable bedding, shelter, food and water and protection from other cattle and wildlife as well as medical care. Down cattle can be moved on sleds, belts or carefully in tractor buckets. Down livestock should not be dragged except in emergency situations. California has a specific law prohibiting dragging down cattle during transportation. Down cattle must be housed out of the sun, rain and elements and separately from other cattle so that water and feed is truly available to them. Non-ambulatory cattle cannot be left without water, feed and shelter.

Medical treatment decisions have to be made considering pain management, prognosis, withdrawal times and final disposition of the animal. In the US, pain can be controlled with anti-inflammatory drugs such as flunixin, aspirin or dexamethasone. More severe pain, such as from fractures, may require extra-label use of analgesic drugs or euthanasia. Many rendering companies in the US will not accept animals treated with or euthanized with barbiturates because of the possible effect on pet foods made from the rendered materials. This is also a concern with wildlife that may feed on the carcass of such animals. Specific medical treatment is determined by the clinical signs and diagnosis for each case and will not be presented in detail in this paper.

The weight of down cattle compromises blood flow from muscle tissues and can result in secondary muscle and nerve damage from tissue compression. Compartmentalization syndrome (also called pressure damage and crush syndrome) is the local tissue damage resulting from pressure build-up in an osteo-facial compartment. Muscle damage from compartmentalization syndrome can have systemic effects including renal damage, cardiac arrhythmias from hyperkalemia and elevated creatinine kinase levels. The systemic effects of muscle damage are referred to as crush syndrome (Cox, 1982). Down cattle must therefore be provided soft bedding and attempts made to decrease the effects of compartmentalization or crush syndrome. This can be accomplished by several methods: rolling the animal from side-to-side every 2 hours can relieve circulation and tissue pressure; supporting the animal from a sling for a few hours; or supporting the animal in a water bath. The use of slings or hip-lifts can be beneficial but care must be taken to not damage the pelvis or skin. Water baths must be kept at body temperature and the animal removed every 6 to 8 hours. Cattle down in acute situations often cannot stand due to local pain and some assistance during the standing process or lifting from a sling or hip-lift can help them stand and can facilitate recovery.

Public health issues associated with non-ambulatory cattle involve increasing pathogen loads and tissue residues at slaughter. Pathogens associated with down cattle include *Salmonella*, *E. coli*, and Bovine Spongiform Encephalopathy (BSE). Down cattle were shown by Waterman (1987) to increase the recovery of salmonella within slaughter plants. The European Union has determined that non-ambulatory cattle are at high risk of having BSE, and consequently the USDA has used down cattle for the primary surveillance of BSE in the US. After diagnosing BSE in a cow in the US, USDA published a ruling in January, 2004 that requires all non-ambulatory cattle presented for slaughter to be condemned. This ruling effectively curtailed transport of down cattle to slaughter in the US.

The economic issues related to down cattle involve the cost to the farm to replace the animal, costs for treatment and nursing care and potential effects on milk and meat markets (consumer acceptance). Dr. Hullinger, in the 1997 abattoir survey, determined that 40% of the down cows presented to the plant passed inspection and 60% were condemned. Down cattle typically have considerable bruising and therefore have less prime cuts and require more trimming than ambulatory cattle. Non-ambulatory cattle therefore have less value at the slaughter house. Dr. Hullinger estimated that farmers received about \$28.70 from the slaughter house for each down animal presented, factoring in the condemnation rate and the low value for those passed through inspection.

Farm Sanctuary sponsored a poll of consumers in 2003 (Zogby International Poll) and found that 77% of the consumers polled replied that they found it unacceptable that downed animals were used for food.

In conclusion, non-ambulatory cattle represent welfare, food safety and economic issues to the livestock producers. Veterinarians should help their clients understand these issues and provide assistance and training to prevent non-ambulatory cattle, properly move, treat and care for them when they do occur, and humanely euthanize the animals that are suffering.



AMERICAN ASSOCIATION OF BOVINE PRACTITIONERS (AABP) POSITION STATEMENT  
ON DISABLED LIVESTOCK

(Endorsed and accepted by the AABP Board of Directors September, 2002)

The AABP recommends that disabled livestock be handled humanely in all situations.

1. Ambulatory Animals

- A. If an otherwise healthy animal has been recently injured, and the animal is ambulatory, it should be treated, shipped directly to a state or federally inspected slaughter plant, humanely slaughtered on the farm (where state laws permit) or euthanatized. Injured ambulatory animals should not be commingled with other animals during transport.
- B. Care should be taken during loading, unloading, and handling of these animals to prevent further injury or stress.

2. Non-ambulatory Animals

Non-ambulatory animals must not be dragged while alive.\*

- A. If an animal is down on a farm
  - 1. If the animal is not in extreme distress and continues to eat and drink, the producer should contact a veterinarian for assistance and provide food, water, shelter, and appropriate nursing care to keep the animal comfortable.
  - 2. If the animal is in extreme distress and the condition is obviously irreversible, the animal should be euthanatized immediately or humanely slaughtered on the farm (where state laws permit).
- B. If an animal is down at a non-terminal market (e.g., sale yard or auction)
  - 1. If the animal is not in extreme distress, but is disabled, treatment measures should be initiated. If and when it becomes apparent the animal will not recover, it should be euthanatized.\*
  - 2. If the animal is in extreme distress or the condition is obviously irreversible, the animal should be euthanatized immediately.
- C. If the animal is down at a terminal market (e.g., slaughterhouse or packing plant)
  - 1. The animal should be euthanatized immediately.

(Endorsed and accepted by Board action on recommendation of the AABP Animal Welfare Committee, September 2002)

(\*Additions approved by Board action on recommendation of the AABP Animal Welfare Committee, September 2005)

AMERICAN VETERINARY MEDICAL ASSOCIATION (AVMA) POLICY ON DISABLED LIVESTOCK

(Oversight: AWC; EB 06/2001; revised 06/2002, 11/2003, 11/2006, 06/2008)

The AVMA recommends that disabled livestock be handled humanely in all situations:

1. Ambulatory Animals

- A. If an otherwise healthy animal has been recently injured, and the animal is ambulatory, it should be treated, shipped directly to a state or federally inspected slaughter plant, humanely slaughtered on the farm (where state laws permit), or euthanatized. Injured, ambulatory animals should not be commingled with other animals during transport.
- B. Care should be taken during loading, unloading, and handling of these animals to prevent further injury or stress.

2. Non-ambulatory Animals

At no time is a non-ambulatory animal to be dragged.

- A. If an animal is down on a farm
  - 1. If the animal is not in extreme distress and continues to eat and drink, the producer should contact a veterinarian for assistance and provide food, water, and appropriate shelter and nursing care to keep the animal comfortable.
  - 2. If the animal is in extreme distress and the condition is obviously irreversible, the animal should be euthanatized immediately or humanely slaughtered on the farm (where state laws permit).
- B. If an animal is down at a non-terminal market (e.g., sale yard or auction)
  - 1. If the animal is not in extreme distress, but is disabled, treatment measures should be initiated.
  - 2. If the animal is in extreme distress or the condition is obviously irreversible, the animal should be euthanatized immediately.
- C. If an animal is down at a terminal market (e.g., slaughterhouse or packing plant)
  - 1. If swine are down, and are not in extreme distress or do not have an obviously irreversible condition, they may be allowed up to 2 hours to recover. Acceptable interventions to assist in this recovery include rest, cooling, or other treatments that do not create drug residue concerns.
  - 2. Swine that do not recover and other animals should be euthanatized immediately and not taken to slaughter.

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# Animal Care in the Dairy Industry

**Jamie S. Jonker**  
National Milk Producers Federation

U.S. dairy producers have a long history of providing excellent care to their dairy cattle. This responsibility is not only a moral imperative, but it also pays dividends, since healthy, comfortable cows perform more effectively. Dairy farmers recognize that proper animal care practices lead to the production of high quality milk. Simply put, what's good for the cows is good for our dairy businesses. Too often, people not familiar with, or those with an ideological bias against livestock production, assume that farmers can afford to be cavalier about the health of their herds. To the contrary, today we understand more than ever how interconnected animal well-being and economic well-being are, for farmers and their cows.

Every day all dairy farmers, regardless of the size of their operation, invest a great deal of time and resources to ensure their cows are provided the best health care, housing conditions, and proper nutrition. While specific animal care practices vary depending on geographic region and climate, proper animal care is practiced throughout the industry.

## CARING FOR DAIRY ANIMALS: TECHNICAL REFERENCE GUIDE AND ON-THE-DAIRY SELF-EVALUATION GUIDE

In 2002, the National Milk Producers Federation (NMPF) and the Milk and Dairy Beef Quality Assurance Center (DQA Center) came together to revise the *Caring for Dairy Animals Technical Reference Guide*. This is a comprehensive set of dairy animal well-being guidelines that covers all aspects of dairy animal care. The manual addresses all key elements of dairy animal care and recommends best management practices based on the most current science. Also included is a voluntary self-audit in a checklist format that producers can complete. The self-audit addresses quality control points that can be objectively observed by the producer. The DQA Center offers a third party verification component of the program. Many dairy farmers choose to go through the on-farm audit to verify that their farm is following the animal care practices.

These guidelines, recognized by the Food Marketing Institute and the National Council of Chain Restaurants, were developed using the most current animal well-being research. The guidelines have been extensively reviewed by dairy animal welfare experts and are endorsed by the American Association of Bovine Practitioners (AABP). Since the inception of the guidelines, a strong promotional effort led by NMPF was initiated and these guidelines have been widely distributed to dairy farmers, veterinarians, dairy nutritionists, milk cooperative field staff and others who interact with dairy farmers on a daily basis.

To start the program, dairy producers complete a self-evaluation, which is designed to evaluate their Best Management Practices along with their dairy management team (consisting of the producer, herd health veterinarian, nutritionist, and other dairy consultants). The self-evaluation is the initial step in examining animal care practices that are detailed in the *Technical Reference Guide*. Upon completion of the self-evaluation, dairy producers are urged to register with the DQA Center that this step has been completed and proceed with the Dairy Quality Assurance Program.

The Dairy Quality Assurance Program verification review is normally made with a licensed veterinarian as a monitoring tool, and is a record of the steps taken on the farm related to animal care. This also provides benchmark scores and a detailed plan of action for ensuring quality animal care. The licensed veterinarian provides the third party verification that producers are following a recognized quality assurance program for dairy animal care.

The *Caring for Dairy Animals Technical Reference Guide* describes husbandry practices that foster the well-being of dairy animals and explains why the animals' comfort, safety, and good health may be the reason for designing the animals' living environment in a particular way or for using certain animal handling and management practices. The *Guide* is divided into 10 chapters that cover various aspects of proper dairy animal care. Management tips for evaluating practices and proper care are also provided. The chapters include:

1. Producer and Employee Attitudes including training employees and family members; emergency, weekend, and holiday care; monitoring the care provided to animals; and visitors
2. Evaluating Animal Health Care including establishing a herd health program; udder health; breeding; sanitation and waste management; hygiene and locomotion scoring; parasites; pest control; animal identification and health records; husbandry practices; and administration of medication
3. Environment for Dairy Animals including environmental temperature; monitoring air temperature, humidity, quality, and movement; heat stress; lighting; noise; animal activity; and stray voltage
4. Facilities Provided for Dairy Animals including floor space; bedding; flooring; mud; social environment; hospital facilities; breeding facilities; restraint facilities (gates and fences)
5. Dairy Nutritional Care including water and waterers; feed nutritional quality; feeders or feed bunks; feed storage; and sanitation of eating areas
6. Milking Procedures and Equipment including milking facility; milking equipment; and udder sanitation
7. Transporting and Handling Animals including animal handling; restraint equipment; loading and unloading; transportation factors; vehicles; in-transit care; and flight zone
8. Birth and Management of Calves including calving area; navel care; nutritional care of calves; marketing and transportation; and body condition scoring
9. Sick, Hospitalized, Nonambulatory, and Dead Animals including sick and injured animals; prevention of and care for nonambulatory animals; euthanasia; and dead animals and disposal
10. Annual Evaluation including self-evaluation; HACCP principle review; and Dairy Quality Assurance walk-through and verification.

#### TOP 10 CONSIDERATIONS FOR CULLING AND TRANSPORTING DAIRY ANIMALS TO A PACKING OR PROCESSING FACILITY

In 2008, the NMPF Animal Health and Welfare committee, along with Dairy Management Inc. (DMI) and the American Association of Bovine Practitioners (AABP), developed a basic educational poster to serve as common industry guidelines for dairy producers to follow when they need to handle, transport, or cull their dairy animals. The legal-sized poster, entitled "Top 10 Considerations for Culling and Transporting Dairy Animals to a Packing or Processing Facility," is printed on a barn-safe plastic sheet in both English and Spanish.

The "Top 10" poster is part of a series of programs and measures supported by the dairy industry to highlight the importance of conscientious care of cattle at all stages of their lives and was derived in part from the science-based recommendations of the DQA program. The poster has been distributed through milk cooperatives, independent milk processors, and directly to milk producers. Additionally, the "Top 10" posters have been distributed to our partners in animal care including AABP, the Livestock Marketing Association, extension agents, nutritionists, and others.

## FUTURE ENDEAVORS

This fall, the DQA Center will become fully integrated into and become part of the National Milk Producers Federation. Current DQA Center programs will serve as the foundation for the dairy industries on-going commitment to animal care. This integration will lead to new opportunities to educate and assist dairy producers with comprehensive on-farm animal health and welfare programs.

## **Panel: Responsible Antibiotic Use**

### **Antimicrobial Use in Animals: Multiple Layers of Protection Safeguard Human Health**

**Prepared by the Animal Health Institute**

**Richard Carnevale**  
Animal Health Institute

The author acknowledges the significant contributions of Dr. Thomas Shryock (Elanco), Dr. Jeremy Mathers (Alpharma), Dr. Michael Vaughn and Dr. Barry Kelly (Bayer), and Dr. Sue Kotarski (Pfizer), in preparing this paper.

#### **EXECUTIVE SUMMARY**

Antimicrobials have been used in food producing animals for over 40 years to improve animal health and to ensure a safe and healthful supply of high protein meat and poultry products. Over the past 10 years, there have been significant steps taken along the so called “farm to table” continuum to safeguard the continued efficacy of antimicrobials for animals and humans. The concern for the use of antimicrobials in food animal production to select for resistant bacteria that could compromise human treatment has led to numerous meetings and reports (e.g. the US Public Health Action Plan, World Health Organization (WHO) and The World Organization for Animal Health (OIE)) that have similar recommendations to minimize and contain antimicrobial resistant food borne bacteria. Risk assessment, risk management (including responsible use programs, resistance monitoring, regulatory evaluations, replacement with alternatives or discontinuation of certain uses) and research were consistent themes. In a short span of time in the U.S., the veterinary medical community, animal health pharmaceutical industry, producer organizations, public health agencies, regulatory authorities, USDA researchers, consumer groups, and many other stakeholders have worked to develop and implement new regulatory guidance for microbial food safety evaluations, conduct risk assessments, implement national antimicrobial resistance monitoring systems, develop responsible use guidelines for key animal species, conduct research into non-antimicrobial alternatives and other related initiatives. Concomitant with those efforts there has been significant progress on reducing bacterial contamination in food processing plants and retail food facilities, as well as consumer education, all of which have led to overall reductions in foodborne illness. Together, these multiple layers of protection serve to mitigate and contain antimicrobial resistant food borne bacteria that may come from food animal production.

#### **INTRODUCTION (BACKGROUND)**

Antimicrobials are used in food animal production to treat, control, and prevent bacterial infections caused by a wide variety of primarily respiratory and enteric pathogens. They are administered via feed, water, or by individual injection or oral medication depending on the species and production system in use. Herd and flock health management is therefore heavily dependent on preventative treatments to quell an infection before it can take hold in the population and cause significant morbidity and mortality. Because there may be hundreds to thousands of animals in the population at risk of infection during their lifetime, antimicrobials are frequently administered on a herd or flock basis. It is impractical, if not impossible, to administer certain medications in a timely fashion to all exposed individual animals when an infectious disease occurs and has the potential to spread rapidly through these animal groups.

In the case of poultry, most medications are administered via feed or water simply due to the numbers of birds in a house or flock numbering into the tens of thousands. The major use of antimicrobials is in preventing coccidiosis, a parasitic disease that responds well to drugs called the ionophores, a type of antimicrobial that has no known application in human medicine. Day-old chicks experience vaccination stress to their immature immune system, so antimicrobials may be administered to prevent secondary bacterial infections.

Respiratory and enteric disease in pigs is treated via feed and water but in smaller pigs injections are also an option. The timing of treatment relative to the disease onset is important particularly when there is a previous history of a disease outbreak on the premises or when stress due to animal movement and changes in weather may take place.

Feedlot cattle are particularly prone to shipping fever, also known as bovine respiratory disease complex, which leads to pneumonia and death if not treated. This disease is primarily managed by intramuscular or subcutaneous injection of one of several antimicrobials available. Feedlot cattle may also receive feed medications to control “hidden” diseases that can significantly affect production such as liver abscesses and metabolic disorders.

Dairy cattle are administered antimicrobials by injection or by intramammary infusion during lactation to treat moderate to severe mastitis. Cows in the dry or non-lactating periods may be administered intramammary infusions which have shown to be highly effective in preventing infections as the cow transitions into lactation. Intestinal infections caused by *Salmonella* and *E. coli*, are a problem in dairy calves. Antimicrobial formulations available for administration orally or parenterally have been shown to be effective in reducing morbidity and preventing mortalities in these animals.

For many years, antimicrobials have also been added to the feed of animals to enhance productivity by improving the feed-to-weight gain ratio. Older drugs like the tetracyclines, ionophores, and streptogramins are still used for this purpose. None of the newer therapeutic agents in humans and animals such as the fluoroquinolones or cephalosporins are approved for growth enhancement purposes by the FDA.

Since issuance of the Swann Report in 1969 debates have been on-going regarding the contribution of antimicrobial use in food animals and subsequent adverse effects on treatment of human food borne bacterial infections ([http://www.fda.gov/cvm/HRESP106\\_157.htm#swanncte](http://www.fda.gov/cvm/HRESP106_157.htm#swanncte)). There continue to be some areas of disagreement. However, the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), the Centers for Disease Control and Prevention (CDC), and the food production industry have begun new initiatives in improving food safety, antibiotic use management and surveillance programs as well as research efforts designed to close important data gaps. These activities have generated greater and greater confidence that the food production systems in the United States are getting safer. Even though it is and will always be possible for resistant pathogens in food to give rise to human infections, the public health risk from antimicrobial use in food animals is substantially less than the risk which CDC already attributes to resistant infections resulting from antimicrobial use in the human setting. The CDC estimates that 90,000 people die as a result of a hospital acquired infections and that 70% of these infections are resistant to at least one of the drugs most commonly used to treat them (<http://www.cdc.gov/drugresistance/healthcare/problem.htm>).

The risk to public health by exposure to antibiotic resistant bacteria of food animal origin is much lower than the risk from antibiotic use in humans. This is due to the fact that many species of bacteria carried by animals do not pose a substantial risk of infecting humans, or, for those bacteria that are capable of infecting humans, the selection pressure exerted by veterinary use may be insignificant. (1) Bywater and Casewell have estimated that food borne pathogens are less than 4% of the resistant bacterial population causing problems to human



health. (2) The survey also revealed that the main concern with physicians were with those infections that were resistant due to the use of antibiotics in humans.

The purpose of antimicrobial use in food animals, whether for bacterial disease treatment or improved growth response, has been an important component of the discussion. In Europe, the debate centered on the growth response applications. In the U.S. the focus has been on the risks to human health of which drug classes are critically important and how and whether these drug classes are used in certain animal groups, as well as growth promotion use. There has even been debate on the risk analysis methods used to evaluate the relative contribution of antibiotic use in animals to human resistance problems via food. All bacteria located on and in the animal at the farm do not survive in the final food product (meat, milk, eggs, etc.). Rather, there are many processes which kill and remove bacteria before the food product reaches the consumer. Contamination may also arise from non-farm sources, which can likewise impact the risk evaluation. Thus, there are many factors that must be taken into account to estimate the risk that resistant bacteria on the farm may cause human illness and treatment failures. In any event open debate and discussion has resulted in clear actions by the FDA and USDA in developing and implementing risk management strategies, as well as initiatives developed by the veterinary community, and animal and food producers to work to improve food safety and reduce the risk of resistant organisms present in food from animals.

The purpose of this review is to highlight the multiple public agency, research and industry-wide programs that have been developed in the past ten years and are now active at various points in food production from animals. There are safeguards and hygiene standards that have been strengthened in recent years, and are routinely used and accepted by producers within the “food chain”, but are perhaps little understood by the general public. In brief, these actions include the FDA animal drug approval process and post-approval review (including risk analysis); food safety monitoring programs; responsible antimicrobial use; and, pathogen reduction during food processing. Collectively they work to ensure antimicrobials can be safely used to keep animals healthy while not putting public health in jeopardy. In many instances, these “layers of protection” mirror efforts in human medicine to slow the spread of antimicrobial resistant bacteria. They support and complement several actions outlined in the U.S. Public Health Action Plan on Antimicrobial Resistance (<http://www.cdc.gov/drugresistance/actionplan/index.htm>) which is centered on the four basic themes of surveillance, prevention and control, research, and product development. In some instances, protections for using animal antimicrobials, already built into the animal production system, are more stringent than those found in human health. For example, due to food safety concerns, extra-label use of antimicrobials in food animals is far more restricted under FDA law and regulations than in human medicine.

#### LAYER 1: ANIMAL DRUG APPROVAL PROCESS

The development of a new antimicrobial or other animal drug for food animals is a daunting process from discovery of a potentially useful compound to final approval and marketing. Very few compounds get past the initial screening process and are developed further. When an initial determination is made that a compound is safe and effective and will fill an important animal health need it can then take between 7- 10 years and many millions of dollars to develop the final product, conduct all the required testing, and gain federal agency approval.

The Food and Drug Administration has authority for reviewing all drug applications for products that are to be marketed in the U.S. The Center for Drug Evaluation and Research (CDER) is responsible for approval of human antimicrobial products and the Center for Veterinary Medicine (CVM) reviews veterinary antimicrobial agents.

Three general components are assessed; safety, efficacy, and quality. Quality consists of manufacturing facility inspections, assurance of product stability, adherence to Good Manufacturing Practices (GMPs), chain of custody of product, etc. Safety includes assessment of human and animal safety, in terms of toxicological effects and environmental assessments, etc. For antimicrobial products, human safety includes assessing effects of residues on gut flora and potential impacts of antimicrobial resistant bacteria to human health. Efficacy refers to geographically diverse, statistically-designed trials that allow for demonstration of clinical improvement or cure vs. a comparator group.

Antimicrobials administered in feed must also meet other requirements to ensure that the drug is properly mixed and labeled. Many feed use antimicrobials can only be mixed at FDA licensed feed mills. These operations must meet adequate GMPs for mixing the drug into the final feed formulation and are periodically inspected by FDA field personnel. The “finished” feed must carry appropriate directions for use in accord with the FDA approved drug label.

### **Efficacy**

CVM approves antimicrobial drug products for various uses, such as treatment, control, prevention and for performance enhancement claims. The American Veterinary Medical Association has issued a position on terms for describing antimicrobial use in animals ([http://www.avma.org/issues/policy/jtua\\_feeds.asp](http://www.avma.org/issues/policy/jtua_feeds.asp)). The AVMA defines antimicrobial use to prevent infections as well as using them to control an outbreak of disease in exposed animals (so called metaphylactic treatment) as “therapeutic use”. Doses to prevent or control a disease are specifically developed to be “therapeutic” to those animals exhibiting signs of disease and to prevent those animals incubating the disease from exhibiting full blown clinical signs. Even those antimicrobials added to animal feed to improve weight gains or feed to weight gain ratios indicate some disease prevention benefits since withdrawing them in some European countries have led to increases in certain animal diseases. (3)

### **Safety**

There are important differences between the way human and animal antimicrobials are reviewed for safety by FDA. (<http://www.ahi.org/content.asp?contentid=706>).

First, FDA’s CDER conducts a risk-benefit assessment in human medicine to help make its approval decision. FDA weighs the benefits of a human antimicrobial against its risks; in contrast, there is no consideration of benefits in the review of antimicrobials administered to animals. This means that the risk to human health for products under review must be exceptionally low because FDA does not consider any benefits to counterbalance those risks.

Secondly, for food animal antimicrobial products, human food safety studies and drug metabolism studies in the animals are required to set withdrawal periods post-treatment to avoid unsafe levels of residues in edible tissues. This requires not only extensive documentation for the potential toxic effects, such as carcinogenicity of the compound in more than one animal species, but also an assessment of the potential for antimicrobial activity associated with the trace residue amounts on human gut microbes. Extensive studies are conducted to document the metabolism of the compound and elimination from the animals, as well as to show the rate of elimination of drug residues from different edible tissues, milk, or eggs of treated animal. These metabolism studies are conducted on a number of animals and the slowest rate of elimination from the slowest residue-depleting tissue are used as a basis for determining the withdrawal time, which is the time between when an animal is treated and when milk or meat from the animals can be used for human consumption.

Thirdly, the drug sponsor must submit as part of the microbial safety portion of the human food safety submission, a qualitative risk assessment and proposed conditions of use, following the FDA’s Center for Veterinary Medicine Guidance for Industry #152, “Evaluating the Safety of

Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.” <http://www.fda.gov/cvm/Documents/fguide152.pdf>.

GFI #152 is provided as one way to address the risk to human health due to antimicrobial resistant food borne bacteria originating in antimicrobial-treated food animals. This was a priority action item in the U.S. Public Health Action Plan that the federal government and other stakeholders worked together over several years to draft and finally implement in October, 2003. This guidance document follows the OIE risk assessment outline (see Risk Assessment section). Briefly, an initial Hazard Identification establishes a possible causal pathway whereby the use of a particular class of antimicrobial can select for resistant bacteria that may be present on meats and could result in negative human treatment failures. If a pathway is identified, a qualitative assessment is undertaken. A release assessment (on-farm resistance selection), an exposure assessment (meat consumption and contamination levels), and a consequence assessment (importance of the antimicrobial class to human medicine) is then undertaken. An integration of these three components results in an overall risk estimate. Based on the risk assessments, products are put into a low, medium or high risk category. Corresponding risk management strategies can be applied. One of the risk management steps can be a Veterinary Medicine Advisory Committee (VMAC) review of the application and risk management plans (FDA Veterinarian, September/October 2004). Two product subclasses have been reviewed by the CVM’s Veterinary Medicine Advisory Committee, held in a public forum, and CVM has indicated that other sponsor applications have satisfied the requirements for microbial safety, thus leading to product approvals.

The first layer of protection conferred by the drug approval process is the key to ensuring that only efficacious products that are manufactured according to quality standards and are safe for humans are approved.

## LAYER 2: POST APPROVAL REVIEW

Antimicrobials that have been approved by the FDA and have met all safety and efficacy requirements are continually monitored to determine whether they remain safe and effective for their label indications. Adverse reaction reports are reviewed on an annual basis taking into account the extent of use of the product. As will be discussed later antimicrobial resistance is also monitored in animals that become ill, in meat samples obtained from slaughter houses, in retail meats, and in humans. FDA has also undertaken a re-evaluation of existing antimicrobial products intended for use in feed using risk analysis principles to determine whether the product should remain on the market, be withdrawn entirely, or the label be modified in some way to maintain public health.

### **Risk Analysis**

Government Agencies often rely on Risk analysis to address questions regarding public health and safety. Risk Analysis is comprised of three components; risk assessment, risk management and risk communication. Risk assessment provides insight into the frequency and severity of the risk, risk management provides options as to what to do about the hazard occurring, and, risk communication is what the risk managers convey to the public and stakeholders about the risk and the actions taken to address it. Risk assessment has been used to evaluate several food safety issues, such as *Salmonella enteritidis* in eggs (<http://www.foodsafety.gov/~dms/lmr2-toc.html>) or *Listeria monocytogenes* in ready-to-eat foods ([http://www.fsis.usda.gov/oppde/rdad/FRPubs/04-034N/Executive\\_Summary.pdf](http://www.fsis.usda.gov/oppde/rdad/FRPubs/04-034N/Executive_Summary.pdf)). More recently, the process of risk analysis has been applied to antimicrobial resistant food borne bacteria.

The OIE convened an *ad hoc* panel that outlined a general approach on the process to be used ([http://www.oie.int/eng/normes/mcode/en\\_chapitre\\_3.9.4.htm](http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm)). In general, it established the need to conduct a Hazard Identification, then if a causal pathway is identified that requires further study, first a qualitative, and, then if needed, a semi-quantitative or quantitative risk assessment should be undertaken. The component parts of the risk assessment include release, exposure, consequence, and, risk estimate. Risk management actions are then proposed. Risk communication is done throughout the entire process.

The value of utilizing a risk assessment process is that it allows stakeholders to provide inputs into an iterative process that seeks to provide information for all the necessary links along the causal pathway and is open to inclusion of new data. A qualitative risk assessment, such as that outlined under the Center for Veterinary Medicine's Guidance document #152 will usually be done by acquisition of information from the literature and does not generally employ mathematical evaluations to evaluate relative risk (e.g. risk estimates might range from low to high). A quantitative risk assessment employs a mathematical model, sometimes done as a Monte Carlo simulation, using stochastic data (or assumed values) which provide a numerical estimate of risk. Either method will allow the identification of key points along the pathway to be considered for risk management interventions. Quantitative risk assessment is generally viewed as preferable to qualitative because it is less subjective.

To illustrate the feasibility of risk assessment applied to antimicrobial resistant bacteria of food animal origin, several examples of evaluations of approved animal antimicrobials are provided. One of the first risk assessments to be done was for the use of fluoroquinolones in beef cattle and the human health risk associated with fluoroquinolone resistant *Campylobacter* in ground beef. (4) Using available data, a semi-quantitative model was used to derive an overall risk estimate, noting appropriate data gaps and assumptions. The study estimated adverse clinical outcomes could occur in a small percentage of people who consumed improperly cooked beef and provided suggestions for minimizing the risk. A risk assessment was conducted by FDA/CVM on the use of fluoroquinolones in poultry to estimate any potential human health harm. The findings of this risk assessment led to the removal of enrofloxacin for the treatment of airsacculitis in poultry based on an estimated increase in the number of fluoroquinolone-resistant *Campylobacter* infections in humans. (5)

A later study conducted indicated that carcasses from slaughtered birds with airsacculitis were more likely to be contaminated with *E. coli* and *Salmonella* which could lead to an overall greater number of food borne infections regardless of their antimicrobial resistance profile. (6) A follow up risk assessment conducted by utilizing this information concluded that "withdrawing animal antimicrobials can cause far more human illness-days than it would prevent: the estimated human BENEFIT:RISK health ratio for human health impacts of continued animal antimicrobial use exceeds 1,000:1 in many cases." (7) The model developed by Cox and Popken strongly suggested that regulatory agencies should consider the benefits of an antimicrobial in addition to the risks, prior to taking action in removing a product from the marketplace. A study on an in-feed antimicrobial, virginiamycin, evaluated the potential for human glycopeptide resistant *E. faecium* to acquire streptogramin resistance and cause adverse clinical outcomes in patients. (8) A unique feature of this evaluation is that it also calculated the human health benefits from the use of the product in chickens and found that benefits far exceeded any potential risk. A multi-species, multi-formulation deterministic risk assessment of two macrolide antimicrobials followed the general outline of Guidance 152. The risk estimation of this study showed a differential numerical risk for *Campylobacter* for each commodity. (9)

The value of conducting the exercise of risk analysis has brought many new aspects of the complexity of the antimicrobial resistance issue to light. For example, the need to establish a possible causal pathway, which can then be assessed for the probability of occurrence, has required thoughtful consideration of the sequence of events that must occur for the antimicrobial resistant bacteria to flow along the food chain. Knowing which links to act upon would allow the

most effective interventions to be implemented. This process utilizes surveillance data, integrated with responsible use guidelines, to ensure that appropriate and proportionate risk management strategies are implemented.

Going forward, improved risk assessments can be enhanced with the use of simulation models using stochastic distributions based on real-world data. Collaborative work to better acquire data on human clinical treatment outcomes will be of value to properly assess the ultimate risk.

### LAYER 3: FOOD SAFETY MONITORING PROGRAMS

There are a number of government and corporately sponsored monitoring programs in place that have been established to watch over the food supply for consumers in the USA. Different federal agencies have separate, but related, responsibilities for monitoring and/or regulating various aspects of food safety and the different commodities such as meat, poultry, fish, vegetables, and fruits. Monitoring programs in place can sample for and document contamination/adulteration of meat and poultry for chemical residues such as drugs (including antimicrobials) and pesticides. Separate programs test meat and poultry at slaughter establishments for food borne disease causing bacteria under the USDA's pathogen reduction initiative. The USDA, FDA, and CDC participate in a program to test for antimicrobial resistant food borne bacteria in meat and poultry and from human food borne disease patients. This information is important for tracking potential human health impacts resulting from the use of antimicrobials in food animal agriculture.

The purpose of this section is to focus on those programs that not only monitor meat and poultry products for food borne disease pathogens but also for antimicrobial resistance and antimicrobial usage. These monitoring programs complement each other and are an integral basis of the safest meat and poultry food supplies in the world. Note that the USDA Animal and Plant Health Inspection Service also conducts the National Animal Health Monitoring System (NAHMS) which collects microbiological data on individual livestock or poultry animal sectors annually, and includes some antimicrobial usage data ([www.aphis.usda.gov/vs/ceah/ncahs/nahms](http://www.aphis.usda.gov/vs/ceah/ncahs/nahms)).

Key agencies and programs to be discussed include: 1) The FSIS HACCP and Pathogen Reduction regulations, 2) The USDA ,FDA, CDC National Antimicrobial Resistance Monitoring System (NARMS), and related programs, 3) other antimicrobial resistance testing programs, and 3) Independent antimicrobial usage surveys.

### MICROBIAL TESTING OF RAW MEAT AND POULTRY

The Food Safety and Inspection Service (FSIS) is the public health agency in the USDA responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe and wholesome ([http://www.fsis.usda.gov/About\\_FSIS/index.asp](http://www.fsis.usda.gov/About_FSIS/index.asp)).

On July 25, 1996, the U.S. Department of Agriculture published the *Final Rule on Pathogen Reduction: Hazard Analysis and Critical Control Point (PR/HACCP) Systems*. (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf>). The principal focus of this rule, which complements existing food safety laws and regulations, is to reduce both the pathogenic organisms on meat and poultry products and the incidence of food borne illness associated with these products. FSIS uses baseline studies to determine the nationwide prevalence of pathogens and other microorganisms in raw meat and poultry products. Baseline studies are also used to measure the number (levels) of organisms, identify national trends in pathogen levels, assess the performance of pathogen reduction initiatives, evaluate potential indicator organisms, and take into account regional variations, seasonality, and other critical factors related to the prevalence of pathogens in meat and poultry products. Baseline studies

provide important data for risk assessments supporting regulatory initiatives. For instance, FSIS uses baseline studies to establish performance standards for meat and poultry, mandated in the HACCP regulation, which play a significant role in ensuring continued sanitary operations in meat and poultry establishments. These standards establish a maximum allowable prevalence of *Salmonella* bacteria in carcasses of all major food producing species and are used to determine whether or not further interventions are necessary in the processing plant. FSIS reports from the *Salmonella* testing program are released on an annual basis. Isolates from this testing are also used to support the animal portion of the National Antimicrobial Resistance Monitoring program which is discussed below.

## NATIONAL ANTIMICROBIAL RESISTANCE MONITORING SYSTEM

The National Antimicrobial Resistance Monitoring System (NARMS) is a multi-agency program comprised of the USDA, CDC, and FDA. The FDA is the coordinating agency ([http://www.fda.gov/cvm/narms\\_pg.html](http://www.fda.gov/cvm/narms_pg.html)) for monitoring resistance in isolates associated with animals, while the CDC coordinates the collection and study of isolates from humans. The program was initiated in the mid-1990s due to public health concerns associated with the use of antimicrobials in food producing animals. As a post-marketing activity, the antimicrobial susceptibilities of enteric microorganisms have been monitored from isolates collected annually from federally inspected (USDA-FSIS) slaughter and processing facilities (representing healthy market animal sets), from diagnostic specimens from clinics (from ill, dead and/or therapeutically treated veterinary lab source animals), and other miscellaneous animal sources as part of the USDA animal arm of NARMS centered at the USDA Agricultural Research Service laboratories in Athens, Georgia ([http://www.ars.usda.gov/main/site\\_main.htm?modecode=66120508](http://www.ars.usda.gov/main/site_main.htm?modecode=66120508)) as well as from retail meats by the FDA/CVM ([http://www.fda.gov/cvm/narms\\_pg.html](http://www.fda.gov/cvm/narms_pg.html)).

The human arm of NARMS has been based at the Food Borne and Diarrheal Diseases Branch of the National Center for Infectious Diseases at the Centers for Disease Control & Prevention (CDC), and utilizes FoodNet and other nation-wide sources of human isolates ([www.cdc.gov/narms](http://www.cdc.gov/narms)). The animal and human branches were recently supplemented in 2002 by the FDA Center for Veterinary Medicine's Office of Research (Laurel, MD) initiative in testing retail meat samples, intended to represent a later step in the food chain from farm to consumer. Non-Typhi *Salmonella* was selected as the sentinel organism among all programs. Additional organisms including *Escherichia coli*, *Campylobacter*, *Enterococcus*, *Salmonella Typhi*, *Listeria*, *Vibrio*, and *Shigella* from humans are also tested by CDC.

The objectives of NARMS are:

1. To provide descriptive data on the extent and temporal trends of antimicrobial susceptibility in *Salmonella* and other enteric organisms from the human and animal populations;
2. Facilitate the identification of resistance in humans and animals as it arises;
3. Provide timely information to veterinarians and physicians;
4. Prolong the lifespan of approved drugs by promoting the prudent and judicious use of antimicrobials; and,
5. Identifying areas for more detailed investigation.

NARMS annual reports, with data summaries are available from each program. To date, seven years' worth of data representing over 50,000 animal and 11,000 human *Salmonella* isolates have been reported. Human isolates tested against most drug classes potentially related to animal usage, have shown stable or declining trend patterns through report years 2004. (10)

The majority of MDR (multiple drug resistant) types such as *Salmonella Typhimurium* DT104 have shown stable or declining prevalence in both food animal and human sectors since 1996. The importance of public health surveillance has been seen in the identification of rare or new clonal resistance types among human animal-origin bacteria. While antimicrobial selective pressure is one factor, other factors such as climate, transmissibility, management practices, commingling and transport to slaughter, can contribute to dissemination and colonization of food animals with particular bacterial populations, including drug resistant subtypes. Thus, the tracking of specific serotypes and serotype prevalence is an important part all NARMS branches, in addition to resistance/susceptibility testing. The 10 to 15 most prevalent serotypes of *Salmonella* spp. are reported annually in addition to the detailed resistance patterns.

The NARMS has been described as a post-market surveillance program for animal antimicrobials. Data from NARMS has been applied by drug sponsors as part of data submissions seeking approval of new drugs. For older and already-marketed drugs, NARMS provides data on temporal resistance patterns. More recently, improvements in NARMS sampling, scope, reporting and future directions have been recommended by expert review boards in 2006. NARMS and related programs remain key parts of the comprehensive *Public Health Action Plan to Combat Antimicrobial Resistance* (<http://www.cdc.gov/drugresistance/actionplan/html/index.htm>). NARMS and related programs are supported by a broad base of consumer, industry, and government organizations and appear to be valuable tools in informing all stakeholders on the state of resistance in key microorganisms of concern.

A new program within USDA-APHIS called the Collaboration on Animal Health and Food Safety Epidemiology (CAHFSE) has been started to supplement the passive NARMS and NAHMS programs with a more real-time, active surveillance approach ([www.aphis.usda.gov/cahfse](http://www.aphis.usda.gov/cahfse)). The stated mission of this surveillance effort is (1) to enhance overall understanding of bacteria that pose a food-safety risk by monitoring these bacteria on-farm and in-plant over time, and (2) to provide a means to routinely monitor critical diseases in food-animal production. A particular emphasis of CAHFSE is to address issues related to bacteria that are resistant to antimicrobials. Swine is the first species studied as part of the CAHFSE program. The new program utilizes confidentially collected on-farm data through surveys, including details on antimicrobial usage types and amounts. The intent is to collect comprehensive, specific information which may potentially relate farm practices to microbiological patterns. VetNet is a program of the ARS, and is the animal arm of PulseNet, the National Molecular Subtyping Network for Food borne Disease Surveillance. PulseNet links the CDC, FDA, and USDA/VetNet's DNA fingerprinting databases. This system is intended to track potential origins of bacterial isolates causing illness in humans.

## SENTRY AND OTHER SURVEILLANCE PROGRAMS

The SENTRY Antimicrobial Surveillance Program was initiated in 1997 and represents the most comprehensive human surveillance program in place worldwide ([www.jmilabs.com](http://www.jmilabs.com)). The SENTRY Program collects consecutive isolates from clinically documented infections in more than 80 medical centers worldwide. The isolates are collected according to the type of infection (objectives) and susceptibility tested in a central microbiology laboratory by reference broth microdilution methods according to CLSI guidelines. The Program also incorporates molecular typing (ribotyping and PFGE) and resistance mechanism analysis of selected isolates. Extensive and sophisticated databases allow the program to report on relevant resistance patterns and identify problem areas to physicians and public health authorities. Principal investigators of SENTRY and related programs publish results in numerous scientific journals and at meetings on the latest trends in human antimicrobial resistance.

Of the over two million hospital-acquired infections per year in the United States, the resistant organisms of greatest risk for poor patient therapeutic outcomes are:

1. Methicillin-resistant *S. aureus*
2. Enterococci resistant to vancomycin
3. *E. coli* and *Klebsiella* spp. resistant to third-generation cephalosporins;
4. All pathogens having fluoroquinolone resistance
5. Multi-drug resistant *P. aeruginosa* and *Acinetobacter* spp.

Since previous worldwide constraints on the animal uses of avoparcin (a vancomycin analog), and limits on the uses of fluoroquinolones have long been in place in the E.U., U.S., and elsewhere, few of the above mentioned pathogens can be said to link directly to the usage of animal antimicrobials. Estimates by the human medical community of the contribution of animal use to resistant human infections support this contention. (2)

Rates of resistance among SENTRY monitored institutions vary widely, but notable increases in resistance among the five listed nosocomial organisms have invariably been driven by use of antimicrobials in humans as well as other factors such as absence or declines in public health infrastructure and local infection control practices.

Additional programs exist worldwide, including several country-sponsored programs which regularly report on data findings from both animal and human sources. Examples of this include CIPARS (Canada, <http://www.phac-aspc.gc.ca/cipars-picra/index.html>), MARAN (Netherlands, [www.cidc-lelystad.nl/docs/MARAN-2002-web.pdf](http://www.cidc-lelystad.nl/docs/MARAN-2002-web.pdf)), SVARM and SWEDRES (Sweden, [www.strama.se](http://www.strama.se), [www.sva.se](http://www.sva.se)), DANMAP (Denmark, [www.dfvf.dk](http://www.dfvf.dk)), Germ-Vet (Germany) and MAFF (U.K., <http://archive.food.gov.uk/maff/archive/inf/newsrel/fsa/fsa1699.htm> ). Industry-sponsored projects to evaluate antimicrobial resistance in abattoirs and farms have additionally been completed (CEESA). Efforts to compare broader results of worldwide resistance data bases and to evaluate trends have been made, such as the GAARD and MYSTIC programs. (11) Most of these surveys have not highlighted any direct animal-human connections in their respective countries, although differences between countries may reflect differences in animal types and rearing methods, including differences in antimicrobial usage patterns.

## ANTIMICROBIAL USE DATA

Availability of accurate data on the total quantities of antimicrobials used in animal agriculture has been a key topic of controversy in the debate on the impact of animal use on human health. Until recently, there was little information on the actual amounts of antimicrobials produced and used in animal populations. For that matter, there was little interest in quantities produced and used in human medicine although human use data was more accessible from pharmacy and hospital records. With the concerns for increasing resistance to available antimicrobials and fewer new antimicrobials being developed by the pharmaceutical industry this information has become of greater interest.

FDA does require by law all companies with approved antimicrobial products to report on the units sold of each finished product on the yearly anniversary of the approval, as is required of all other animal drugs. (12) However, this information is for the purpose of comparing the number of reported adverse drug events (ADE ) with the amount of product used in order to better understand the significance of ADE . Finished product contains the active ingredient and a number of formulation components. Several years ago estimates of the quantities of antimicrobial compounds produced annually appeared in government publications and the popular press. These estimates came from extrapolation of old information released by the US International Trade Commission which suggested that up 50 million pounds of human and animal antimicrobials were produced annually. However, more recent data suggests that this



number may have included a whole range of antibacterial, antifungal and antiviral chemicals in addition to those pharmaceutical agents that are of human or animal medical importance. The Animal Health Institute (AHI), the industry trade association, is a source of antimicrobial use data. AHI since 1998 has been compiling information on the amount in pounds of antimicrobial drugs sold by AHI member companies. AHI estimates that its members produce about 85% of all antimicrobials used in animals.

AHI asks members to provide active ingredient quantities for major classes of antimicrobial compounds on a yearly basis and to also estimate the percentage of these compounds sold strictly for use as growth promoters. The AHI numbers represent quantities produced and sold by manufacturers. AHI reports quantities for several major classes of antimicrobials and aggregates active ingredients produced by only one or two companies to another antimicrobial category to protect proprietary information. In 2006, AHI members reported 26.4 million pounds of antimicrobials were sold for all uses in food producing, companion (including horses), and exotic species. (13)

In addition, the estimated percentage use of these antimicrobials for strictly growth promotion or feed efficiency is estimated at only 4.5% of the total used with nearly 96% being used for therapeutic purposes as defined by the AVMA.

The Union of Concerned Scientists (UCS) published a report in 2001 called *Logging It: Estimates of Antimicrobial Abuse in Livestock* (14). This report suggests that 24.5 million pounds of antimicrobials are used in livestock and poultry alone for on-therapeutic use. The methodology for the estimates relied on using USDA statistics ([www.nass.usda.gov](http://www.nass.usda.gov)) for the number of livestock and poultry that could theoretically receive an antimicrobial and then multiplying these numbers by estimated average doses for FDA approved antimicrobials. The authors used the publicly available list of FDA approved antimicrobials to arrive at usage levels of each class of active ingredient. However, this method of analysis overestimates use in animals, because: 1) not all FDA approved products are concurrently used in animal production; and, 2) some products are not or never were marketed.

Information on the total use of antimicrobials in human medicine is not readily available, either. Proprietary marketing information services compile information on sales of antimicrobial products to hospitals and pharmacies but this data is not publicly available. It is likely that the total volumes of antimicrobials produced for human use is less than that produced for animal use simply because of the much larger animal populations in the United States compared with the number of humans. Furthermore, comparison to human use is not possible due to different indications, use, weights, etc., to mention only a few. USDA reports animal populations of about 160 million cattle and hogs, 130 million dogs and cats, and 8.5 billion chickens and turkeys in comparison to about 300 million people. That means there are 30 times more farm and companion animals than humans in the US. Another way of examining the data on antimicrobial use in food animals is discussed in a paper by Barber published in 2001. (15) The author estimates that *the biomass of food-producing animals in the United States is more than 5 times that of humans, dogs, and cats. Therefore, on average, a unit of human and pet biomass in the United States uses at least 10 times more antimicrobial per year than does a unit of food-animal biomass.* Another important consideration in comparing usage is that a substantial percentage of the total quantity of antimicrobials used in animal health are drugs that have no relationship or relevance to antimicrobials used in human medicine. AHI reports that of the 26.4 million total pounds in 2006, 11.2 million pounds, or 42%, were compounds not used at all in human medicine. Furthermore these drugs are not known to cross select for resistance to any human antimicrobial. UCS reports that 45% of their total estimated on-therapeutic antimicrobial use of 24.5 million pounds are drugs currently not used to treat human diseases.

## LAYER 4: RESPONSIBLE USE

The AVMA, species-specific veterinary groups, and feed and producer groups have all worked with government agencies including FDA to produce guidelines for safe and judicious use of antimicrobials based on several principles for use in managing infectious diseases. The Judicious Use Principles are designed to minimize the need for antimicrobial use, but when needed, to use them properly, and to evaluate the outcome of the use (<http://www.avma.org/scienact/jtua/default.asp>).

These guidelines are used as the basis for producer education programs and represent an important effort on the part of the animal agriculture community to ensure that antimicrobials are used properly. Many producers have used these guidelines to create standard operating procedures for antimicrobial use on the farm. For example the National Pork Board has instituted the Take Care - Use Antimicrobials Responsibly Program ([www.npb.org](http://www.npb.org)). Take Care is based on five principles to guide antimicrobial use in pig production. It has been endorsed and adopted by numerous large and small producers.

Extra label drug use is also controlled at the Federal level with the advent of the Animal Medicinal Drug Use Clarification Act (AMDUCA) which establishes criteria for when a veterinarian may use an antimicrobial or other animal drug outside of label directions. The AVMA has created a decision algorithm to help in the decision-making process (<http://www.avma.org/reference/amduca/amduca2.asp>). This serves the purpose of affording the ability of the veterinarian to treat a disease that may not be currently approved on a product label while assuring that food safety is maintained. It should be noted that antimicrobials added to feed are strictly regulated as far as their use and cannot be administered outside of label directions even by a veterinarian.

The Veterinary Antimicrobial Decision Support System (VADS, [www.vads.org](http://www.vads.org)) provides veterinarians with a database of pharmacology and microbiology data to enable better decisions to be made on use of antimicrobials.

Another program in place to guide safe drug use is the Food Animal Residue Avoidance Databank (FARAD). FARAD is a National Food Safety Project administered through the U.S. Department of Agriculture Cooperative State Research, Education, and Extension Service. FARAD is a computer-based decision support system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminate residue problems ([www.farad.org](http://www.farad.org)). Although the FARAD databank does not address issues relative to food borne pathogens or antimicrobial resistance in the food supply, it is an important resource for the animal agriculture industry regarding drug metabolism and elimination and provides valuable information that helps keep the food supply safe and free from drug and chemical residues. Violative residues might also be an indicator of inappropriate use, for example.

More recently the Centers for Disease Control and Prevention began the *Get Smart* Program aimed at judicious use of antimicrobial in both humans and animals ([http://www.cdc.gov/narms/get\\_smart.htm](http://www.cdc.gov/narms/get_smart.htm)). In particular the program encourages the more appropriate use of antimicrobials in treating respiratory tract infections in humans where nearly 75% of all antimicrobials are prescribed. In animals the program is aimed at reducing the emergence of resistant food borne pathogens that could be transferred to people via food or environmental sources. *Get Smart: Know When Antimicrobials Work on the Farm* will have five major areas of activity:

1. Distribute current practices and educational materials.
2. Fund sites and provide technical assistance to develop, implement, and evaluate local campaigns.
3. Support development and testing of veterinary medical curricula for students.

4. Fund a national advertising campaign promoting the appropriate use of antimicrobials.
5. Develop an efficient and accurate means of measuring antimicrobial use in a local campaign.

All of these programs represent efforts that have been specifically designed to improve animal drug use to maximize their effectiveness in controlling and treating animal disease while taking account of the need to safeguard public health and safety. Judicious use represents another barrier to the resistant food borne pathogens from affecting human health.

#### LAYER 5: PATHOGEN REDUCTION IN FOOD PROCESSING PLANTS

FSIS implemented the HACCP/Pathogen Reduction so called mega-reg in all slaughter and processing plants over the last 10 years beginning with larger plants and finally bringing all federally inspected plants on-line. The regulation requires a new paradigm in the production of meat and poultry which focuses on controlling the processes of producing safe food products. Each plant must have an approved HACCP plan in place which identifies the potential physical, chemical or microbiological hazards with the production of the particular meat or poultry product, the critical control points which must be monitored to insure that occurrence of potential hazards in finished product are minimized and certain tests that will be performed to determine compliance with the plan.

In the case of slaughter plants, keeping fecal contamination to a minimum is essential to reducing food borne pathogens. The regulation requires that steps be taken to remove fecal contaminants through trimming, washing or other means. Effectiveness of these methods is determined through daily coliform counts from carcasses. As a final measure, *Salmonella* testing is performed to determine compliance with certain performance standards as discussed previously in this paper. Food processing companies have engaged numerous new technologies aimed at reducing the occurrence of pathogens on raw product. Beef plants have used extensive carcass trimming in addition to carcass vacuuming techniques to remove feces. Steam sterilization of entire beef carcasses has been instrumental in reducing pathogen contamination to near zero in many plants. Antimicrobial washes and use of antibacterial agents such as bacteriocins have also been tried. With poultry, liberal use of antimicrobial treatments such as chlorine, ozone, and ultraviolet light exposure in the chill tanks, coupled with other technologies have helped reduce carcass pathogen loads. Maintaining evisceration equipment in good working order contributes to the reduction of breakage of carcass GI tracts and subsequent contamination of the meat with the caecal contents and has reduced the spread of bacteria within the poultry plant environment.

Efforts to reduce overall food contamination and food borne illness has a direct effect on reducing antimicrobial resistant bacteria in meat and poultry since resistant bacteria are a small subset of the total bacterial load on carcasses. Interventions at slaughter and processing such as carcass washes, steam sterilization, ozone in the chill water, and other actions taken under HACCP are equally effective in reducing antimicrobial resistant bacteria as well as antimicrobial susceptible food borne pathogens. (16)

FSIS also requires safe handling and cooking instructions on all raw meat and poultry products produced from inspected establishments. These labels have been, for all practical purposes, extended to products prepared at retail establishments, such as fresh ground beef. The instructions provide a specific warning to consumers that raw meat and poultry could contain harmful bacteria and further provides explicit directions on proper handling and cooking of the product.

Recent findings indicate that FSIS meat inspection activities performed since the inception of the HACCP rules are making a difference. The recent Morbidity and Mortality Weekly Report

(MMWR) titled Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food ---10 States, United States, 2005 published by the Centers for Disease Control and Prevention (CDC), reports that food borne disease is on the decline since 1996

([http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5514a2.htm?s\\_cid=mm5514a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5514a2.htm?s_cid=mm5514a2_e)).

The Foodborne Diseases Active Surveillance Network (FoodNet) of CDC Emerging Infections Program collects data from 10 U.S. states regarding diseases caused by enteric pathogens transmitted commonly through food. FoodNet quantifies and monitors the incidence of these infections by conducting active, population-based surveillance for laboratory-confirmed illness. This report describes preliminary surveillance data for 2005 and compares them with baseline data from the period 1996-1998.

Incidence of infections caused by *Campylobacter*, *Listeria*, *Salmonella*, Shiga toxin producing *Escherichia coli* O157 (STEC O157), *Shigella*, and *Yersinia* has declined, and *Campylobacter* and *Listeria* incidence are approaching levels targeted by national health objectives. The estimated incidence of infection with *Yersinia* decreased 49% (CI = 36%--59%), *Shigella* decreased 43% (CI = 18%--60%), *Listeria* decreased 32% (CI = 16%--45%), *Campylobacter* decreased 30% (CI = 25%--35%), STEC O157 decreased 29% (CI = 12%--42%), and *Salmonella* decreased 9% (CI = 2%--15%). However, most of those declines occurred before 2005, and *Vibrio* infections have increased, indicating that further measures are needed to prevent food borne illness. CDC most recent update of its report on food borne disease incidence demonstrates that the Healthy People 2010 goals have been achieved for *E. coli* O157:H7 infections and nearly been achieved for campylobacteriosis and listeriosis already ([http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5514a2.htm?s\\_cid=mm5514a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5514a2.htm?s_cid=mm5514a2_e)).

These results must be considered a major success for scientifically validated and carefully implemented governmental programs. Only *Salmonella* infections are not below current expectation and this appears to be due to a small number of processors who have not demonstrated process control under HACCP to date. Specific industry led initiatives have also helped to mitigate human food borne infections. For example, based upon a risk assessment, egg quality assurance programs were implemented that have now substantially reduced the rate of *S. enteritidis* infections transmitted via table eggs. Similarly, using risk assessment models to determine the most effective intervention points, post processing lethality treatments have reduced the rate of *E. coli* O157:H7 attributed to ground beef. Additional intense focus by FSIS on HACCP compliance and process control will undoubtedly further reduce the potential for food borne infections, especially *Salmonella* transmission in the future.

## CONCLUSIONS

Because of concerns for potential adverse impacts on human health of antimicrobial use in animals, additional safeguards and layers of protection have been put in place over the last 10 years to complement the rigorous regulatory system mandated by Federal law. These actions have been implemented along the farm to table food continuum, from production through food inspection and processing, and final preparation by the consumer.

Each step is important in ensuring that a safe food supply is maintained with harmful pathogens including antimicrobial resistant pathogens minimized. To begin with, antimicrobials are approved only after meeting the regulatory requirements that ensure safety under the conditions of use. When the product is used, it is under the supervision of a veterinarian according to Judicious Use Guidelines within a herd/flock health management plan to increase the likelihood that only healthy animals enter the food chain. During slaughter/processing, hygienic measures are employed with HACCP plans to guide handling of foods of animal origin. Appropriate handling, transportation and storage from the plant to retail markets are observed. Good kitchen hygiene/cooking practices serve as a final safeguard prior to consumption.

However, should a break in the chain occur, the physician who prescribes an antimicrobial for a consumer with a food borne disease, will have several therapeutic treatment options available and can base the choice on laboratory susceptibility test results. Throughout the food chain, NARMS and other monitoring programs serve to collect data on-farm, at retail and from sick persons to look for trends in bacterial species or resistance traits that require closer study and possible intervention. Thus, each of the layers of protection can help to minimize and contain antimicrobial resistant food borne bacteria as envisioned in the US Public Health Action Plan.

While foods of animal origin will always remain a possible source of human infection for antimicrobial resistant infections, published material provides information that there are significant non-food routes for transmission for organisms typically considered to be primarily food borne, and that some non-traditional routes of transmission need to be considered. Recent genome sequencing studies provide substantive information supporting that non-animal environmental sources are a significant reservoir for human *Campylobacter* infections. (17) On the other hand; recent PulseNet data provide PFGE genotyping evidence that indeed some outbreak infections are associated with animal derived foods. Barber provides an interesting perspective that contests the widely made assumption that infection flow is unidirectional and from animal to man. (15) It is certain that some zoonotic animal infections are the result of human fecal contamination. New information in the area of risk analysis for the first time defines public health benefits that are derived from the use of animal antimicrobials. In their role for preventing and treating animal disease, antimicrobials may play a role in reducing the transmission of zoonotic pathogens.

In short, the complexity of environmental recycling from animal to man and man to animal is only beginning to be understood. The old paradigms are changing as foods of animal origin come under more intense scrutiny and regulatory programs evolve to provide continually improving surveillance and protection for the consumer.

## FUTURE DIRECTIONS

Clearly the layers of protection between the use of antimicrobials in food animals and human food borne disease treatment are now in place and will be maintained, if not strengthened. Continued support for monitoring of bacterial pathogens and resistance will come from both regulatory authorities and the industry. More defined antimicrobial resistance monitoring at the farm level through programs such as CAHFSE tied to specific antimicrobial use will help elucidate the true contribution of drug use to resistance selection and transfer through food. Improvements to NARMS, such as coordinated reporting and representative sampling should also be supported.

In the future, the risks will be further elucidated and reduced by facilitation of more quantitative risk assessments to guide proportionate risk management interventions, as well as support tools to Judicious Use Guidelines, such as the Veterinary Antimicrobial Diagnostic System (VADS) and strengthening of diagnostic laboratory capability to improve diagnostics and susceptibility test reports to veterinarians. As well, improvements in HACCP programs and reduction of pathogen loads in the retail sector will further reduce the risk of foodborne pathogens causing human illness, whether or not they are resistant to antimicrobials..

More research on new antimicrobial agents will be engaged to search for innovative technologies to treat animal disease while minimizing the potential for impact on human medicine. Improved understanding and dialog with human healthcare providers as to what has been done, and what can be done together will be important to reduce the misunderstanding and misperceptions on the use of animal drugs in food animals.

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# **Panel: Responsible Antibiotic Use**

## **Antibiotics, Animal Agriculture, and the Deepening Health Crisis of Antibiotic Resistance**

**Richard Wood**  
Food Animal Concerns Trust

### **SUMMARY STATEMENT**

For the past six decades, antibiotic drugs have turned bacterial infections into treatable conditions, rather than the life-threatening scourges they once were. Today, however, the efficacy of many antibiotics is decreasing as more types of bacteria develop resistance to these valuable drugs. As the National Academy of Science's Institute of Medicine observed in 2003, "Clearly, a decrease in the inappropriate use of antimicrobials in human medicine alone is not enough. Substantial efforts must be made to decrease inappropriate overuse of antimicrobials in animals and agriculture as well." The Centers for Disease Control and Prevention (CDC) continues to identify antibiotic resistance as one of its top concerns for human health.

### **ANTIBIOTICS AND ANIMAL AGRICULTURE**

An estimated 70 percent of all antibiotics used in the United States are administered to swine, poultry, and beef cattle for non-therapeutic purposes (i.e., other than treating or controlling disease), and the majority of these drugs belong to classes of antibiotics used to treat human illnesses. There are two nominally distinct types of non-therapeutic uses in food animals: to induce slightly faster growth, and to prevent disease, however, the distinction between non-therapeutic uses is largely a matter of semantics as many antibiotics are approved for both growth promotion and disease prevention.

Resistant bacteria created by the non-therapeutic uses of antibiotics in agriculture most directly affect humans through contamination of meat products, but may also reach people via the environment, particularly waterways. Some two trillion pounds of animal waste is generated annually, much of it contaminated with resistant bacteria and undigested antibiotics. When the manure is stored or disposed of on farmland, both the bacteria and the antibiotics can run off into waterways and contaminate soil. One study detected resistant bacteria identical to those found on swine farms in groundwater more than 750 feet downstream from the farm.

### **LATEST REPORTS STRESS NEED FOR IMMEDIATE CHANGE**

In April 2008, the Pew Commission on Industrial Farm Animal Production released its final report including comprehensive recommendations on how to mitigate the environmental, economic, social, and public health impacts of industrial animal production. Their highest priority public health recommendation is the banning of non-therapeutic uses of antibiotics in food animal production.

The Union of Concerned Scientists (UCS) also released a report on the costs—economic, environmental, and health—of industrial animal farms in April of 2008. In the report, UCS stresses that one of the main "hidden" costs from the excessive use of antibiotics in animal production is the development of antibiotic resistant bacteria and harder-to-treat human infections.



Finally, conventional wisdom in the past had methicillin-resistant *Staphylococcus aureus* (MRSA) pegged as an opportunistic infection occurring mainly in hospitals. Recently published scientific research coming out of the Netherlands, Canada, and the United States has found that animal production facilities serve as a reservoir of MRSA bacteria. The published studies in *Veterinary Microbiology* and preliminary results in the U.S. identify industrial animal farms as a community source of MRSA. This development demonstrates the need for the United States government to start systematic testing of its livestock for MRSA as well as determining if livestock strains of MRSA are present in U.S. hospitals.

These recent reports illustrate the depths of the problem with industrial animal production and the steps necessary to avert what may become a public health disaster—a return to the pre-antibiotic era. Policymakers, producers, and consumers are urged to support steps to immediately reduce antibiotic use in food animals.

## **Panel: Responsible Antibiotic Use**

### **Responsible Use of Antimicrobials**

**Thomas J. Burkgren,**  
American Association of Swine Veterinarians

Antimicrobials are an important tool for food animal veterinarians to use in protecting the health and well-being of animals. For more than 50 years, antimicrobials have been used in animals to treat, prevent and control infectious bacterial diseases. Antimicrobials have also been successfully used to improve feed efficiency and weight gain. Overall, antimicrobials are an important part of any management system that ensures the health and well-being of animals. As an important tool, it is imperative that they are used in a responsible manner.

The responsible use of antimicrobials is a shared societal responsibility amongst those who prescribe and use antimicrobials. Physicians and their patients, as well as veterinarians and their clients, are responsible for responsible use. Swine veterinarians and pork producers share concerns with other health professionals and the public over the use of antimicrobials and possible risks to both human and animal health. Differences of opinions have arisen, however, in how to mitigate these risks. The issue of antimicrobial resistance is complex and solutions must be carefully considered for effectiveness and for unintended consequences. Therefore it is essential that veterinarians and swine producers give thought and effort towards the responsible use of antimicrobials.

There are several synonyms for responsible, including prudent, proper, appropriate, and judicious. All are similar in meaning and are used interchangeably within the discussion of antimicrobial use and the desire to protect human and animal health. It is important to note from the start that responsible use does not equate to no use or even reduced use of antimicrobials. Responsible use is more aptly described as decreasing overuse and misuse of antimicrobials.

Antimicrobial use in swine production includes treatment and prevention of bacterial diseases and improvement of nutritional efficiency. Antimicrobials are an important tool in the good management of animal health, but are not the only tool. Their responsible use in swine clearly benefits animal health and well-being as well as food safety and human health. The goals of responsible use efforts in swine production include the following:

1. Prevent violative antimicrobial residues in pork
2. Optimize the effectiveness of antimicrobials
3. Minimize the risk of antimicrobial resistance
4. Maintain availability of antimicrobials

The prevention of violative residues in pork has been recognized by veterinarians for decades; however it is often not included in the discussion of responsible use. It remains, however, a vital part of any responsible use effort on the farm. Determination of appropriate withdrawal times has been part of the animal drug approval process since the early days of use in food-producing animals. Veterinarians and producers are required to abide by the withdrawals set forth by the regulatory body responsible for the approval of the drug. Particular attention may need to be paid to withdrawal times if pork is exported to another country. The maximum residue limits (MRL's) may differ between countries. Over the years, violative residues in US pork have decreased to a barely perceptible level due to efforts of veterinarians, pork producers and programs such as the Pork Quality Assurance (PQA) program.

The maximization of efficacy of antimicrobials requires using the correct antimicrobial for the targeted bacteria. Identification of the targeted bacteria requires an accurate clinical diagnosis that is substantiated through diagnostic tests and clinical experience. After identification of the causative bacteria, an antimicrobial must be selected based on current pharmacological information and principles. Bacterial culture and susceptibility to antimicrobials are significant aids to selection of an antimicrobial. Veterinarians must also carefully consider past clinical outcomes and experience. The selected drug must be used at the correct dose (amount and frequency), treatment duration, and route of administration.

The minimization of development of bacterial resistance to antimicrobials is aimed at protecting both animal and human health. It is a commonly accepted fact that the use of antimicrobials will eventually result in the development or expression of antibiotic resistance in bacteria. This then reduces the effectiveness of that particular antimicrobial against the resistant bacteria. If either animals or humans are infected with those resistant bacteria, then health can be threatened. In order to minimize resistance development, veterinarians must treat with the correct antimicrobials only when it is beneficial to the animal. Once again the antimicrobial must be carefully selected and used at the correct dose and treatment duration. By reducing the misuse and overuse of antimicrobials, it is hoped that resistance development can be curtailed.

The availability of antimicrobials is important to veterinarians and producers. The veterinarian's oath includes "protection of animal health, the relief of animal suffering, the conservation of livestock resources." Antimicrobials are one of the key tools to accomplishing all three. Most if not all of the activist organizations advocating against the use of antimicrobials in food animals are in favor of broad bans and prohibitions. While simple in their construct, these actions will have severe unintended consequences on animal health and well-being. Responsible use of antimicrobials is part of the effort to maintain availability of an armamentarium of efficacious drugs.

Over the last ten years there has been numerous responsible use guidelines developed for animals and humans in many countries. In 1999, the American Association of Swine Veterinarians developed and published a document entitled "Basic Guidelines of Judicious Therapeutic Use of Antimicrobials in Pork Production." These guidelines (see Appendix A) are directed towards veterinarians. Since that time, these guidelines were revised in 2004. They have also been adapted for producers.

The AASV Responsible Use Guidelines concentrate on three general areas. First is the use of preventative strategies and alternatives to antimicrobials. Second is the role of the veterinarian in the decision-making on antimicrobial use. The last area is the actual use of antimicrobials. Together these three areas provide a foundation for reducing misuse and overuse of antimicrobials on the farm. These guidelines are limited, however, due to the lack of definitive knowledge of how antibiotics select for resistant bacteria under different use conditions. As this knowledge increases, veterinarians will be much better equipped to reduce the development of antimicrobial resistance. In the meantime, the following guidelines are the current official position of the American Association of Swine Veterinarians.

In 2005, the National Pork Board of the United States, in conjunction with the American Association of Swine Veterinarians, developed the Take Care – Use Antibiotics Responsibly™ program. This program is a proactive approach that provides producers and their veterinarians with specific principles and guidelines to minimize the risk of antimicrobial resistance. These assist in the evaluation of antimicrobial use on the farm. The five principles are:

1. Take appropriate steps to decrease the need for the application of antimicrobials.
2. Assess the advantages and disadvantages of all uses of antimicrobials.
3. Use antimicrobials only when they provide measurable benefits.

4. Complete the Pork Quality Assurance program and fully implement the management practices described for responsible use of animal health products into daily operations.
5. Follow the Take Care Responsible Use Guidelines.

The implementation of these principles on farms will complement any swine management system. While much of the principles are based on common sense, it is the application of the principles that will help achieve the goals of responsible use. Each of the five principles will be discussed in more detail below.

### **1. Take appropriate steps to decrease the need for the application of antimicrobials.**

A good herd health management program will decrease the need for antimicrobials. The use of preventative health practices such as biosecurity, hygiene, health monitoring, and vaccination play an important role in maintaining good health for swine. Management of herd genetics, nutrition, pig flow and environment can all play a role in better management. A routine review of all medication use on a farm can be an enlightening exercise for veterinarian and producer alike. Planning is also essential to the development of an effective health management program. The involvement of a veterinarian in the planning and decision-making is a fundamental part of the process.

### **2. Assess the advantages and disadvantages of all uses of antimicrobials.**

Considerations to include in any assessment of medication use include animal health and welfare, environmental, food safety and economic impact. The risk of potential development of antimicrobial resistance should also be considered. The use of alternative strategies should be judged for effectiveness. Examples might be changes made to ventilation rates in a building or the use of supportive therapy such as aspirin or electrolytes. Producers and veterinarians need to consider other management options before deciding to use antimicrobials.

Once the decision is made to use antimicrobials, then its use should be minimized by treating only for as long as needed for the desired clinical response. Careful calculation of the appropriate duration of therapy and dose (both amount and frequency) must be done. The use of antimicrobials in chronic, non-responsive cases is not recommended. Attention must be given to following the proper withdrawal times before marketing treated animals. Veterinarians can work closely with producers in developing treatment and prevention protocols. Regular reviews of medication use can identify management areas that may be in need of improvement. The routine use of antimicrobials should be discontinued when it is no longer needed.

### **3. Use antimicrobials only when they provide measurable benefits.**

Farms and pigs can differ in how they respond to the use of antimicrobials. Some of the measurable benefits of antimicrobial use include reduced mortality and morbidity, improved welfare, and improved nutritional efficiency. Producers need to consider the specific benefits that accrue from antimicrobial use on their farms. Clinical measures such as mortality and morbidity are fairly straight forward. On the other hand, nutritional efficiency can be more difficult to measure, especially in an on-farm setting.

The assessment of the measurable benefit of nutritional efficiency should have a foundation in science-based data. Research trials from similar farms can be used. Scientifically valid trials on your farm can provide an even better objective measure of the benefit that is specific to the farm. However, an improperly designed trial can provide misinformation that is not valid. Veterinarians and nutritionists can provide assistance in trial design.

**4. Complete the Pork Quality Assurance program and fully implement the management practices described for responsible use of animal health products into daily operations.**

In 1989, pork producers and veterinarians created the Pork Quality Assurance® Program (PQA). It was designed to assist pork producers meet consumer demands for quality and safety. It also assisted producers develop comprehensive management systems to attend to the health and welfare needs of animals. The proper use of animal health products are an important part of PQA, especially in the prevention of violative drug residues.

Accurate record-keeping of treatments is an essential part of any quality assurance program. Written records should include identification of treated animals, drug administered, route of administration, withdrawal time, name of person administering and name of prescribing veterinarian. Careful attention should be paid to the adherence to the withdrawal time and tracking of the identified animals.

**5. Follow the Take Care Responsible Use Guidelines**

**Guideline A** - *Use professional veterinary input as the basis for all medication decision-making.*

The first step to the use of veterinary input is the establishment of a veterinarian/client/patient relationship (VCPR). A VCPR includes the following:

1. Medical decisions about animals are made by the producer and the veterinarian.
2. Producers implement those decisions as agreed
3. The veterinarian must visit production facilities regularly enough to have sufficient knowledge of the animals and their keeping.
4. The veterinarian must be readily available for follow-up treatment/consultation.

Veterinarians and producers need to use the latest information on the use of antimicrobials. Attention must be paid to label instructions. If a drug is used in a manner not consistent with the label then care must be taken to ensure that no harm is done to the animal and that an appropriate withdrawal time is established.

**Guideline B** - *Antibiotics should be used for treatment only when there is an appropriate clinical diagnosis.*

Accuracy of diagnosis can be supported through observation of clinical signs, herd history, necropsy, and laboratory tests. Bacterial culture and sensitivity results will aid in the selection of antimicrobials to be used for prevention and therapy. Consideration can be given to other factors contributing to the expression of clinical symptoms. By understanding the role of these factors, the veterinarian and producer can work towards solutions that may not require the continued use of antimicrobials.

**Guideline C** - *Limit antimicrobial treatment to ill or at-risk animals, treating the fewest animals indicated.*

The decision to initiate treatment must be based on consideration of morbidity and mortality rates among the group of pigs. These will assist in the determination to use individual, group or herd treatments. Past treatments and results should also be considered. The use of antimicrobials as preventative therapy can be a very effective strategy that may even decrease

the amount of antimicrobials used and the time needed for administration. The responsible use of antimicrobials includes:

1. Using antimicrobials only when necessary,
2. Administering antimicrobials to the smallest number of animals feasible, and
3. Administering antimicrobials for the least amount of time necessary to alleviate clinical symptoms and prevent reoccurrence of the disease.

**Guideline D** – *Antimicrobials that are important in treating antimicrobial resistant infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification.*

Producers and veterinarians should carefully weigh the choice of antimicrobial to treat disease. Once again herd history of antimicrobial use and results can be useful. Culture and sensitivity should be part of the diagnostic plan. Treatment protocols can be developed to minimize development of resistance. It is wise to prepare a written treatment protocol and educate all animal caretakers in antimicrobial use.

**Guideline E** – *Mixing together medications may be counterproductive.*

Many products are not compatible when administered or mixed with other medications. This may result in changes to efficacy and withdrawal time. In addition, animal health and welfare may be threatened from tissue and systemic reactions to products. The mixing of medications should only be done with specific documented scientific information and rational justification.

**Guideline F** – *Minimize environmental exposure through proper handling and disposal of all animal health products, including antimicrobials.*

Adjustments should be made to all water medicators, waterers, and feeders to deliver the desired dosage and avoid spillage and waste. Outdated or unused medications should be handled appropriately and disposed of in a proper manner. Protocols for handling and disposal of medications should be written and documented. All persons handling medications should be trained on these protocols.

The duty for responsible antimicrobial use in swine production belongs to the producers and veterinarians entrusted with care for the pigs. No one is better positioned to know the keeping and care of the animals. This knowledge of animal health and welfare is balanced with concern over food safety and human health. Producing safe wholesome pork is a commitment not taken lightly. Producers and veterinarians realize that without shared concerns with consumers, the swine industry will be viewed as suspect and untrustworthy. Any such distrust might result in regulations and restrictions that are detrimental to animal health and welfare, perhaps even to human health. Therefore it behooves the entire swine industry to remain steadfast in the commitment to producer safe wholesome pork.

## **APPENDIX A**

### **Basic Guidelines of Judicious Therapeutic Use of Antimicrobials in *Pork Production*** (Approved by the AASV Board of Directors – October 2004)

Veterinarians agree to protect animal and public health when they pledge the Veterinarian's Oath. This oath is applicable today as it was when it was written many years ago. Swine practitioners are committed to "the use of scientific knowledge and skills for the benefit of

society". This commitment remains the core of veterinarians' efforts to achieve "the protection of animal health, the relief of animal suffering, the conservation of livestock resources, the promotion of public health, and the advancement of medical knowledge."

### **AASV Position Statement**

When a condition exists that threatens or impairs animal health and well being, it is essential that an accurate clinical diagnosis be obtained. Appropriate diagnostic techniques and clinical experience should substantiate a presumptive diagnosis. Once the decision is reached to use antimicrobials for therapy, veterinarians strive to optimize therapeutic efficacy, minimize resistance to antimicrobials, and protect public and animal health.

The American Association of Swine Veterinarians supports and is committed to the following objectives as developed by the American Veterinary Medical Association's Steering Committee on Judicious Therapeutic Antimicrobial Use:

1. Support development of a scientific knowledge base that provides the basis for judicious therapeutic antimicrobials use.
2. Support educational efforts that promote judicious therapeutic antimicrobials use.
3. Preserve therapeutic efficacy of antimicrobials.
4. Ensure current and future availability of veterinary antimicrobials.

### **Judicious Therapeutic Use of Antimicrobials Principles for Swine Veterinarians**

1. **Preventive strategies, such as appropriate husbandry and hygiene, routine health monitoring, and immunization, should be emphasized.**
  - A. Establish the definitive diagnosis.
  - B. Recognize the roles played by the following factors in the course of the disease(s):
    1. Genetics
      - a. Genetic sources
      - b. Genetic predisposition
    2. Nutrition
      - a. Water availability and quality
      - b. Protein
      - c. Energy
      - d. Micronutrients
    3. Housing
      - a. Air space per pig
      - b. Temperature extremes beyond the thermal comfort zone of swine
      - c. Meteorological conditions (e.g., seasonal patterns)
      - d. Ventilation
    4. Management
      - a. Stocking density
      - b. Appropriate biosecurity controls of animals and humans
      - c. Isolation and acclimatization of incoming breeding swine.

- d. Appropriate and timely use of cleaning, disinfection and drying of premises.
  - e. Depopulation/repopulation to eliminate a disease organism.
- 5. Health
  - a. Immune status of the animals
  - b. Herd dynamics and health status of the sow herd
  - c. Presence and importance of concurrent infections
  - d. Source of pigs (e.g., single source or multiple sources)
- 2. **Other therapeutic options should be considered prior to or in conjunction with antimicrobial therapy.**
  - A. Examples include acidification of feed or water, electrolyte therapy, supportive care (e.g., antipyretic therapy).
- 3. **Judicious use of antimicrobials, when under the direction of a veterinarian, should meet all requirements of a veterinarian-client-patient relationship.**
  - A. Antimicrobials represent a powerful therapeutic option. Specific guidelines on the use of prescription antimicrobials and the extralabel use of any antimicrobial must involve a VCPR. We believe that judicious use requires the oversight of a veterinarian at some point in the decision making process. (See **GLOSSARY** for the definition of VCPR as it appears in AMDUCA)
- 4. **Prescription, Veterinary Feed Directive, and extralabel use of antimicrobials must meet all the requirements of a valid veterinarian-client-patient relationship.**
  - A. The law prohibits extra label use of antimicrobials in the feed.
- 5. **Extralabel antimicrobial therapy must be prescribed only in accordance with the Animal Medicinal Drug Use Clarification Act amendments to the Food, Drug, and Cosmetic Act and its regulations.**
  - A. The following drugs are expressly prohibited for extralabel use in food animals: chloramphenicol, clenbuteral, diethylstilbestrol, dimetridazole, ipronidazole, other nitroimidazoles, furazolidone, nitrofurazone, sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine), fluoroquinolones, glycopeptides (e.g., vancomycin), and phenylbutazone in female dairy cattle 20 months of age or older. (Current as of October 7, 2004. Check for updates on the FDA web site at [www.fda.gov/cvm](http://www.fda.gov/cvm))
  - B. For more information on extralabel drug use, see the AMDUCA guidance brochure entitled *Extralabel Drug Use (ELDU)*, published by the AVMA.
- 6. **Veterinarians should work with those responsible for the care of animals to use antimicrobials judiciously regardless of the distribution system through which the antimicrobial was obtained.**
  - A. Judicious use requires the oversight of a veterinarian at some point in the decision making process.
  - B. Veterinarians are the primary source of information on the use of swine antimicrobials.



- C. Veterinarians must accurately communicate written, adequate directions to the client for antimicrobial use.
  - D. The Pork Quality Assurance (PQA) program of the National Pork Board provides a basis for the judicious use of antimicrobials.
  - E. The AASV recognizes the legal availability of antimicrobials obtained through over-the-counter (OTC) distribution channels.
  - F. The extra label uses of OTC antimicrobials fall within the regulatory constraints of the Animal Medicinal Drug Use Clarification Act and thus requires the oversight of a veterinarian.
7. **Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles.**
- A. Package inserts should be considered as sources of information for the practitioner.
  - B. Continuing education is an important component of maintaining and enhancing the veterinarian's pharmacological knowledge.
  - C. AASV supports the development of a veterinary antimicrobial decision system for swine to improve accuracy in the selection of therapeutics.
  - D. The compounding of antimicrobials should be avoided in those instances where there is a lack of supporting scientific pharmacological data.
  - E. Combinations that do not currently have FDA approval should not be used in the absence of supporting scientific pharmacological data.
  - F. Cost is not a factor when considering the use of compounded therapeutic antimicrobials.
  - G. For more information on compounding, see the FDA Compliance Policy Guide entitled *Compounding of Drugs for Use in Animals*.
8. **Antimicrobials considered important in treating refractory infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification. Consider using other antimicrobials for initial therapy.** (In this context, this principle takes into account development of resistance or cross-resistance to important antimicrobials).
9. **Utilize culture and susceptibility results to aid in the selection of antimicrobials when clinically relevant.**
- A. Clinical outcomes, history, and experience should also be used in the selection of antimicrobials.
  - B. Veterinarians should utilize appropriate references for proper procedures and accurate interpretation of susceptibility results, such as the NCCLS publication, *Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard*.

10. **Therapeutic antimicrobial use should be confined to appropriate clinical indications.**
  - A. An accurate diagnosis includes characterization of etiology.
  - B. Practitioners should strive to rule out parasitisms, mycotoxicoses, nutritional imbalances, and viral infections.
  - C. Secondary bacterial pathogens may require antimicrobial therapy.
11. **Therapeutic exposure to antimicrobials should be minimized by treating only for as long as needed for the desired clinical response.**
  - A. Therapeutic exposure involves both dose and duration.
  - B. Continued use of antimicrobials in chronic, non-responsive clinical cases should be discouraged.
  - C. Withdrawal times must always be considered during the selection of antimicrobials.
12. **Limit therapeutic antimicrobial treatment to ill or at risk animals, treating the fewest animals indicated.**
  - A. Consider group morbidity and mortality rates when deciding whether or not to initiate herd, group, or individual therapy.
  - B. Consider the herd health history for the therapeutic use of antimicrobials in the control and prevention of disease.
  - C. When these factors are appropriately considered, preventative therapy is a judicious use of antimicrobials.
13. **Minimize environmental contamination with antimicrobials whenever possible.**
  - A. Water medicators and feeders need to be properly adjusted to deliver the desired dose and to avoid spillage and waste.
14. **Accurate records of treatment and outcome should be used to evaluate therapeutic regimens.**
  - A. AASV recommends the use of treatment records such as those proposed by the Pork Quality Assurance (PQA) program of the National Pork Board.
  - B. Compliance to treatment regimens can be monitored by the review of pertinent records.
  - C. Accurate animal or group identification must be employed within a production system for effective residue avoidance.

## GLOSSARY

**Antibiotic**--a chemical substance produced by a microorganism which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms.

**Antimicrobial**--an agent that kills bacteria or suppresses their multiplication or growth. This includes antibiotics and synthetic agents. This excludes ionophores and arsenicals.

**Narrow Spectrum Antimicrobial**--an antimicrobial effective against a limited number of bacterial genera; often applied to an antimicrobial active against either Gram-positive or Gram-negative bacteria.

**Broad Spectrum Antimicrobial**--an antimicrobial effective against a large number of bacterial genera; generally describes antibiotics effective against both Gram-positive and Gram-negative bacteria.

**Antibiotic Resistance**--a property of bacteria that confers the capacity to inactivate or exclude antibiotics or a mechanism that blocks the inhibitory or killing effects of antibiotics.

**Extralabel**--Extralabel use means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

**Immunization**--the process of rendering a subject immune or of becoming immune, either by conventional vaccination or exposure.

**Monitoring**--monitoring includes periodic health surveillance of the population or individual animal examination.

**Therapeutic**--treatment, control, and prevention of bacterial disease.

**Veterinarian/Client/Patient Relationship (VCPR)** -- A VCPR exists when all of the following conditions have been met:

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
2. The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) are kept.
3. The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.

**Veterinary Feed Directive (VFD) Drug**--The VFD category of medicated feeds was created by the Animal Drug Availability Act of 1996 to provide an alternative to prescription status for certain therapeutic animal pharmaceuticals for use in feed. Any animal feed bearing or containing a VFD drug shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice.

# APPENDIX A

## Program and Speaker Contact Information

### Morning Moderator:

Richard Reynnells, National Program Leader  
Animal Production Systems  
USDA Cooperative State Research, Education, and Extension Service,  
Plant and Animal Systems  
800 9<sup>th</sup> Street, SW, Room 3140 Waterfront Centre  
Washington, DC 20250-2220  
T#: 202.401.5352  
F#: 202.401.6156  
Email: rreynnells@csrees.usda.gov

8:30 - 8:35

### **Welcome**

Richard Reynnells

8:35 - 8:45

### **Introductory Comments**

David R. Brubaker  
Organizational Dynamics  
University of Pennsylvania  
145 South Spruce Street  
Lititz, PA 17543  
T#: 717.627.0410  
F#: 717.627.1847  
email: PennsylvaniaB@aol.com

8:45 - 9:15

### **Regulatory Roles that Enhance Food Safety and Animal Welfare**

Jim Hodges, Executive Vice President  
American Meat Institute  
1150 Connecticut Ave., NW  
Washington DC 20036  
T#: 202.587.4231  
C#: 703.801.2015  
F#: 202.587.4300  
email: jhodges@meatami.com

9:15 - 9:45

### **European Rules and Regulations Related to Animal Welfare and Food Safety**

Ed Pajor, Director  
Center for Food Animal Welfare  
Department of Animal Sciences  
Lilly Hall, Purdue University  
915 W. State Street  
West Lafayette, IN 47906  
T#: 765.496.6665  
F#: 765.494.9346  
email: pajor@purdue.edu  
**E.A. Pajor**

9:45 - 10:00 **BREAK**

10:00 - 11:40 **Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety**

10:00 - 10:20 Paul Shapiro, Senior Director  
HSUS Factory Farming Campaign  
Humane Society of the United States  
2100 L Street NW  
Washington, DC 20037  
T#: 301.721.6432  
F#: 301.721.6414  
email: pshapiro@hsus.org

10:20 - 10:40 Marcos H. Rostagno  
Research Animal Scientist  
USDA-ARS-LBRU  
125 S. Russell St.  
West Lafayette, IN 47907  
T#: 765-496-7946 (Office)  
T#: 765-583-2187 (Lab)  
F#: 765-496-1993  
email: Marcos.Rostagno@ars.usda.gov  
rostagno@purdue.edu

10:40 - 11:00 Tony Pescatore  
Department of Animal and Food Sciences  
907 Garrigus Building  
University of Kentucky  
Lexington, KY 40546-0215  
T#: 859.257.7529  
F#: 859.257.2686  
email: apescato@uky.edu

11:00 - 11:20 Marie Wheatley, CEO  
American Humane  
63 Inverness Drive East  
Englewood, CO 80112  
T#: 303.925.9485 direct  
F#: 303.792.5333  
email: mariew@americanhumane.org

11:20 - 11:40 Discussion

11:40 - 12:45 **LUNCH**

**Afternoon Moderator:**

David R. Brubaker  
Organizational Dynamics  
University of Pennsylvania  
145 South Spruce Street  
Lititz, PA 17543  
T#: 717.627.0410  
F#: 717.627.1847  
email: PennsylvaniaB@aol.com

12:45 - 1:15

**Slaughter Facility Management**

Janet M. Riley, Senior Vice President  
Public Affairs and Professional Development  
American Meat Institute/Nat. Hot Dog & Sausage Council  
1150 Connecticut Ave., NW  
Washington DC 20036  
T#: 202.587.4245  
C#: 703.801.2238  
F#: 202.587.4300  
email: jriley@meatami.com

1:15 - 1:45

**Treatment of Sick and Injured Animals: Should They be Moved and If So, How?**

Jim Reynolds  
American Association of Bovine Practitioners  
1514 W. Kaweah Ave.  
Visalia, CA 93277-2327  
T#: 559.688.1731  
H#: 559.662.8923  
email: jreynold@vmtrc.ucdavis.edu

University of California  
Veterinary Medicine Teaching and Research Center  
18830 Road 112  
Tulare, CA 93274  
T#: 559.688.1731  
C#: 559.686.4231  
email: jreynold@vmtrc.ucdavis.edu

1:45 - 2:05

**Animal Care in the Dairy Industry**

Jamie Jonker  
National Milk Producers Federation  
2101 Wilson Blvd. Suite 400  
Arlington, VA 22201  
T#: 703.243.6111  
F#: 703.841.9328  
email: jjonker@nmpf.org

2:05 - 2:20

Discussion

2:20 - 2:40

**BREAK**

2:40 - 3:40

**Panel: Responsible Antibiotic Use**

2:40 - 3:00

Richard Carnevale  
Animal Health Institute  
1325 G Street NW, Suite 700  
Washington, DC 20005  
T#: 202.637.2440  
F#: 202.393.1667  
email: rcarnevale@ahi.org

3:00 - 3:20 Richard Wood, Executive Director  
Food Animal Concerns Trust  
P. O. Box 14599  
Chicago, IL 60614  
T#: 773.525.4952  
F#: 773.525.5226  
email: rrwood@fact.cc

3:20 - 3:40 Tom Burkgren, Executive Director  
American Association of Swine Veterinarians  
902 1<sup>st</sup> Avenue  
Perry, IA 50220  
T#: 515.465.5255  
F#: 515.465.3832  
email: Burkgren@aasv.org

Due to unavoidable conflict the presentation was made by:

Harry Snelson  
American Association of Swine Veterinarians  
P.O. Box 1291  
Burgaw, NC 28425  
T#: 910.221.5316  
F#: 910.221.5317  
Email: Snelson@aasv.org

3:40 - 4:00 Discussion



# APPENDIX B

## 2008 List of Co-Coordinator

David R. Brubaker  
Organizational Dynamics  
University of Pennsylvania  
145 South Spruce Street  
Lititz, PA 17543  
T#: 717.627.0410  
F#: 717.627.1847  
email: PennsylvaniaB@aol.com

Gail Golab, Director, Animal Welfare Division  
American Veterinary Medical Association  
1931 North Meacham Road, Suite 100  
Schaumburg, Illinois 60173-4360  
T#: 847.285.6618  
F#: 847.925.1329  
email: ggolab@avma.org

Ken Klippen, Poultry Industry Consultant  
Klippen and Associates  
P. O. Box 7156  
Audubon, PA 19407-7156  
T#: 610.415.1055  
Cell#: 484.744.3851  
F#:  
email: ken@klippenassociates.com

Marie Wheatley, President and CEO  
American Humane  
63 Inverness Drive East  
Englewood, CO 80112  
T#: 303.925.9485 direct  
F#: 303.792.5333  
Email: mariew@americanhumane.org

Richard Wood, Executive Director  
Food Animal Concerns Trust  
P. O. Box 14599  
Chicago, IL 60614  
T#: 773.525.4952  
F#: 773.525.5226  
email: rrwood@fact.cc

Richard Reynnells, NPL, Animal Production Systems  
USDA CSREES, PAS  
800 9<sup>th</sup> Street, SW, Room 3140 Waterfront Centre  
Washington, DC 20250-2220  
T#: 202.401.5352  
F#: 202.401.6156  
Email: rreynells@csrees.usda.gov

# APPENDIX C

## Power Point Presentations

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# European Policies, Research and Assessment Activities Related to Animal Welfare: Lessons for the US?

**E. A. Pajor**

Department of Animal Sciences  
Purdue University

Animal welfare policies and research in Europe and the implications for US Agriculture

Dr. Ed Pajor  
Director, Center for Animal Well-Being  
Department of Animal Sciences



## Acknowledgements

- Dr. Isabelle Veissier – INRA , FRANCE
- Dr. Janice Swanson – Michigan State University
- Dr. Joy Mench – University of California, Davis
- OIE
- UBC Animal Welfare Group

## Outline

- European activities
  - Legislation, Regulations, Standards
  - Quality Assurance Programs
  - Research Welfare Quality Project
- OIE – beyond Europe
- US activities
- Future direction

## Animal Welfare in Europe

- Citizens look to Government for leadership
- National Governments
- Supernational Institutions
  - Council of Europe
  - European Union
- Stipulates minimum requirements that need to be adopted by member states

## Council of Europe



- Founded 1949. Animal welfare 1960's
- 46 member states
- Committee of foreign ministers
- Parliamentary assembly – 315 representatives
- Issues both binding conventions and non-binding guidelines

## Council of Europe conventions for farm animals

- Protection of animals during international transport
- Protection of animals kept for farming purposes
- Protection of animals for Slaughter
  
- Conventions state minimum requirements which are fixed and need to be included in national laws
- Acceptance of conventions varies across Council of Europe



## European Union



- Formerly European Economic Community
- Different animal protection laws could impose unfair competition advantage
- Issue legislative text (directives)
- Directives based on reports of scientific experts

## General trend for EU Directives

- To increase space allowance per animal
- Permit social interactions
- More freedom of movement
- Provide enriched environments
- Feed animals consistent with physiological and behavioral needs
- Limit painful interventions

## EU directives



- Become national regulations
  
- New European rural policy (2007-2013)
- Direct payments to farmers will depend on following good farming practices that incorporate animal welfare legislation  
.....\$\$\$\$

## National Regulations

- Conforms to European regulations but may also define more stringent measures
  - Norway – castration by a vet using anesthetic
  - Other countries – no anesthetic required before 7 days of age
  
- In addition to laws certain countries may have Codes of Practice



## Quality Assurance Schemes

- Industry based
- Retailer “gate keeping device”
- Aimed at niche markets
- More strict than other regulations



## 3 types of Quality Assurance Schemes

- General quality
  - Animal welfare part but focus is on food safety, product quality and traceability,
  - welfare criteria meet basic legal requirements
- Animal Welfare
  - Surpass national legislation
  - Surpass standards in quality schemes
- Organic Schemes
  - Animal welfare included as part of a production philosophy which includes environmental and human health, food safety and food quality

## Animal Welfare Standards and the World Organization for Animal Health (OIE)

(Standards beyond Europe)



## The OIE



- World Organization for Animal Health
- Created in 1924 – 28 countries
- Standards to combat outbreak of animal diseases
- Still primary mission – 167 Member Countries
- OIE standards are the international reference in the field of animal diseases and zoonoses for WTO

## OIE

- Animal diseases linked to suffering and welfare
- 2002 receive mandate to provide leadership in developing standards in animal welfare
- OIE Terrestrial Animal Health code and Aquatic Animal Health Code
- Aim to produce standards in the area of animal welfare that could be used for international trade
- Use as foundation for legislation in countries that currently do not have legislation in animal welfare



## OIE

- Guidelines need to be science based
  - Different measures for health, affective states, behavioral responses
- 8 guiding principles for animal welfare
  - 5 freedoms

## 5 freedoms

- 1. Freedom from hunger and thirst
- 2. Freedom from discomfort
- 3. Freedom from pain, injury and disease
- 4. Freedom to express normal behavior
- 5. Freedom from fear and distress

## OIE



- Guidelines need to be science based
  - Different measures for health, affective states, behavioral responses
- 8 guiding principles for animal welfare
  - 5 freedoms
  - 3 R's (reduction, refinement, replacement)
  - Value assumptions are part of welfare
  - Animal based criteria rather than design criteria should be the basis for comparing standards

## Guideline criteria

- Resource based (design/input)
  - Space allowances, temperature ranges air quality, provision of food and water bio-security, inspection rates.
  - Easy to measure
  - Limited to specific breeds, established systems and problems
- Animal-based (performance/output) criteria
  - Survival rate, disease and injury, body condition, reaction to handlers, behavior
  - Better criteria as they reflect the influence of variables and handler experience
  - Difficult to measure

- 2005- Four sets of codes
  - Slaughter for human consumption
  - Land transport
  - Sea transport
  - Humane killing of animals of disease control purposes

## OIE Future Activities

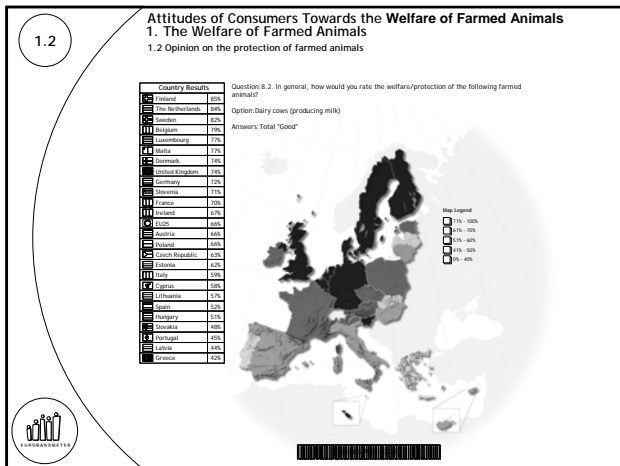
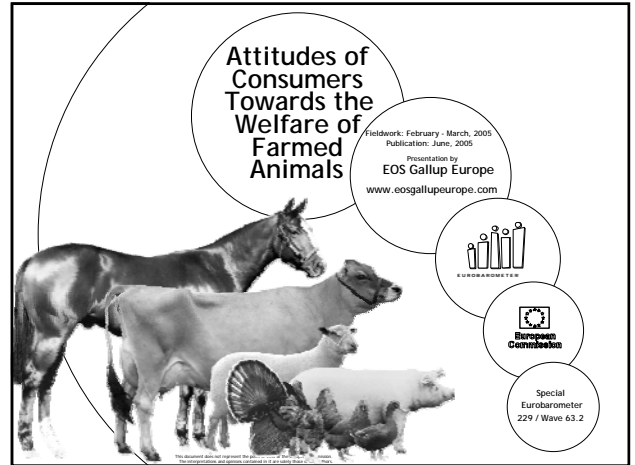


- Companion Animal Welfare – stray dogs
- Wild animal welfare – harvesting/culling
- Lab animal welfare
- **Terrestrial (Farm) Animal welfare**
  - **Housing and Production systems**
  - **Extremely challenging, diverse systems and priorities**
- October 2008, 2<sup>nd</sup> Animal Welfare Conference, Cairo

## Public Opinion in Europe: Eurobarometer

# Eurobarometer

- European commission
- Series of surveys on the attitudes of Europeans on a variety of topics



- Animal welfare is an important attribute of overall food quality (Eurobarometer, 2005)
- Reluctance to purchase animal friendly products due to a lack of transparent, reliable, understandable information about how animal products are produced

- ## Animal Welfare in Europe and Beyond
- Legislation, standards, guidelines, codes
  - Supernational, national, niche, local
  - Economics and Trade
  - Important to the Public
  - Part of the culture of agriculture

## Welfare Research in Europe: The welfare quality project

## Welfare Quality Project

- Largest piece of integrated research work carried out in Animal Welfare in Europe
- Expanded to include 5 Latin American Countries
- 44 institutes and universities
- 17 countries
- 17 million Euros



## Welfare Quality Goals

- To develop practical strategies, measures to improve animal welfare
- To develop a European standard for the assessment of animal welfare
- To integrate and interrelate the most appropriate specialist expertise in the multidisciplinary field of animal welfare in Europe



## Measures

- Clear, scientifically valid, address welfare concerns and allow clear communication
- 4 welfare criteria that capture public's description of animal welfare
- 12 welfare principles that should be covered in the measurement systems

Table 1: Welfare principles and criteria identified in Welfare Quality®

Welfare criteria	Welfare principles	Meaning
Good feeding	1. Absence of prolonged hunger	Animals should not suffer from prolonged hunger
	2. Absence of prolonged thirst	Animals should not suffer from prolonged thirst
	3. Comfort around resting	Animals should be comfortable, especially within their lying areas
Good housing	4. Thermal comfort	Animals should be in good thermal environment
	5. Ease of Movement	Animals should be able to moving around freely
Good health	6. Absence of injuries	Animals should not be physically injured
	7. Absence of disease	Animals should be free of disease
	8. Absence of pain induced by management procedures	Animals should not suffer from pain induced by inappropriate management
	9. Expression of social behaviours	Animals should be allowed to express natural, non-harmful, social behaviours.
Appropriate behaviour	10. Expression of other behaviours	Animals should have the possibility of expressing other intuitively desirable natural behaviours, such as exploration and play
	11. Good human-animal relationship	Good Human-animal relationships are beneficial to the welfare of animals
	12. Absence of general fear	Animals should not experience negative emotions such as fear, distress, frustration or apathy

<http://www.welfarequality.net>

## Welfare Quality Project

- Combined analyses of consumer/citizen perceptions and attitudes with existing knowledge from animal welfare science
- Recent publications

Welfare Quality  
Welfare Quality Reports No. 1

Welfare Quality  
Welfare Quality Reports No. 2

Farm Animal Welfare Concerns  
Consumers, Retailers and Producers

Attitudes of Consumers, Retailers and Producers to Farm Animal Welfare

edited by  
Joakim Rippe  
Mark Rose

edited by  
Lena Kjaerum  
Mark Rose  
Mark Rose



- On farm Assessment/Monitoring systems currently being piloted out for numerous species
- Emphasis on Animal based criteria
- Project will likely have significant impact on North American Agriculture

## Animal Welfare - USA

## Regulating Animal Welfare

- Voluntary (Guidelines) vs. Involuntary (laws)
- On farm – mostly voluntary but state bans on specific production systems are appearing



The check on the outside of the carton shows the care on the inside

## Quality Assurance Strategies

- Development, Implementation and audit of the guidelines/standards
- Private sector taking the lead
- Emphasis has been on engineering criteria

## Handling and Welfare Guidelines

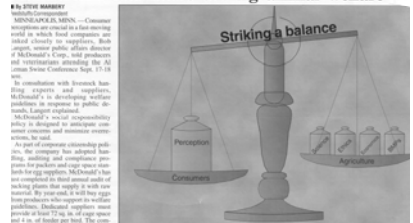
- American Meat Institute
- United Egg Producers
- McDonald's, BK, Wendy's & KFC
- Whole Foods
- Agricultural Animal Alliance
- Animal Welfare Institute
- Certified Humane
- Independent companies

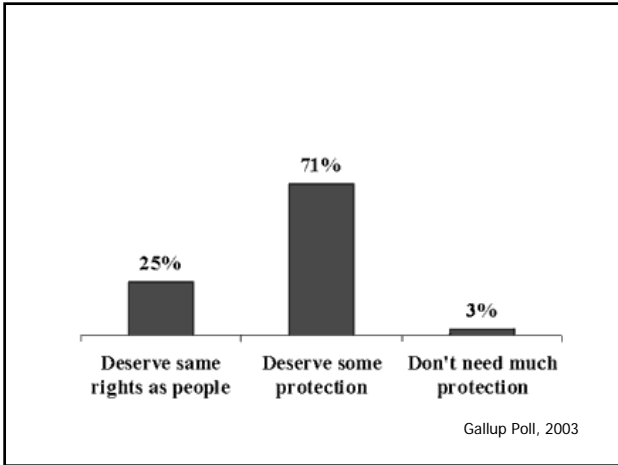


## Public Opinion

# Feedstuffs

THE WEEKLY NEWSPAPER FOR AGRIBUSINESS  
Mainstream consumers driving animal welfare





- ### American Farm Bureau Survey, 2007
- 95 percent of respondents agreed with the statement, "It is important to me that animals on farms are well cared for."
  - 68 percent think the government should take an active role in promoting the welfare of farm animals.
  - 75 percent would vote for a state law requiring producers to treat farm animals better.
  - 76 percent disagreed with the statement, "Low meat prices are more important than the well-being of farm animals."

- ## Animal Law
- Rapid growing area of law
  - 75 Law schools in the US now offer at least 1 course in animal law
  - Journal of Animal Law and Ethics (Penn)
  - Feb 24-24, 2007 National animal advocacy competition at Harvard Law School
  - Practices being banned on ballot initiatives

- ## Animal Welfare in the USA
- Legislation, standards, guidelines, codes
  - National, niche, local
  - Economics and Trade
  - Important to the Public
  - Becoming part of the culture of agriculture

## Improving Animal welfare?

- ## Standards
- US guidelines driven by retailers, producers
  - Market factors
  - Plethora of programs
    - Different standards
    - Difficult to understand
    - Assurance, enforcement varies with program

## Standards and the Public

- Concerns of consumers/citizens must be included in the process
- Need better/more information about public attitudes
- Dialogue with public/external critics necessary as they can influence animal welfare policy

## National Dialogue and Process about Farm Animal Welfare

- Set standards where sufficient science exist
- Develop and validate performance based standards of animal welfare
- Follow-up mechanism
- Increase and sustain dialogue among producers, scientists, veterinarians and other stakeholders
- Facilitate transparency and ethical consistency
- Provide incentives for producers to adopt and follow practices

## A useful model ?

- Eurobarometer
  - Attitudes of citizens and consumers
- Welfare Quality Project
- Standards and principles reflect scientific knowledge but are based on the public's shared values
- The US is not Europe but perhaps the time has come for science-based national standards that reflect US values and the unique challenges faced by US agriculture

## Farm Animal welfare


- Thank you
- [pajor@purdue.edu](mailto:pajor@purdue.edu)




# Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety

Paul Shapiro

Humane Society of the United States

  
THE HUMANE SOCIETY  
OF THE UNITED STATES

## Public Policy and Farm Animal Welfare




### Moving the Ball Forward for Farm Animals

  
THE HUMANE SOCIETY  
OF THE UNITED STATES


## Americans Believe Animals Deserve Legal Protection

- 50 state anti-cruelty codes
- 50 states ban dogfighting (All felony)
- 50 states ban cockfighting (37 felony; 13 misd.)



  
THE HUMANE SOCIETY  
OF THE UNITED STATES

## The Issue of Animal Consideration Has Already Been Settled



  
THE HUMANE SOCIETY  
OF THE UNITED STATES

## Does that Consideration Extend Toward Farm Animals?



**All Major Animal Welfare Groups Support Public Policies to Protect Farm Animals**

Logos of animal welfare organizations: farmsanctuary, WSPA, American Humane, ASPCA, PETA, Animal Welfare Institute, FACT, and RSPCA.



**Expectations by Americans**

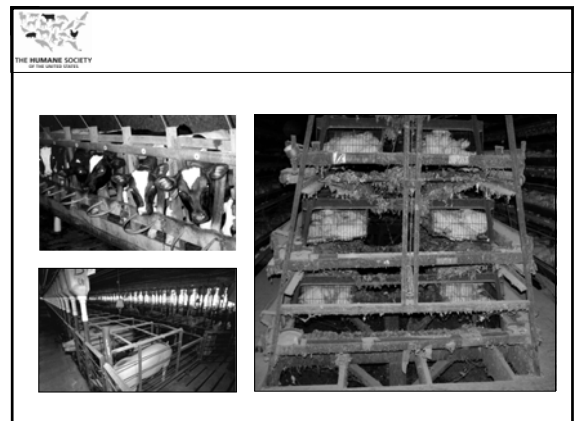
- 64% of Americans oppose gestation crates for sows.  
Oklahoma State Univ., funded by American Farm Bureau (2007)
- 75% of Americans would vote for a law in their state that would require farmers to treat their animals more humanely.  
Oklahoma State Univ., funded by American Farm Bureau (2007)
- 64% of Americans support passing strict laws concerning the treatment of farm animals.  
Gallup (2008)

**Other Findings from the 2007 American Farm Bureau-Funded Poll**

- 81% agree: Farm animals have roughly the same ability to feel pain and discomfort as humans.
- 76% disagree: Low meat prices are more important than the well-being of farm animals.
- 95% agree: It is important to me that animals on farms are well cared for.
- 68% agree: The government should take an active role in promoting farm animal welfare.
- 89% agree: Food companies that require farmers to treat their animals better are doing the right thing.
- 70% agree: Food companies that require farmers to treat their animals better, no matter what it costs farmers, are doing the right thing.


**How Much Protection Do Farm Animals Really Have?**

A hand holding a gavel, symbolizing law or justice.



THE HUMANE SOCIETY  
OF THE UNITED STATES


## Closing the Gap



THE HUMANE SOCIETY  
OF THE UNITED STATES

## Dr. Temple Grandin on Gestation Crates


“Gestation crates for pigs are a real problem.... Basically, you’re asking a sow to live in an airline seat.... I think it’s something that needs to be phased out.”



THE HUMANE SOCIETY  
OF THE UNITED STATES

## U.S. Crate Bans

- Gestation crates banned by Florida voters, 55% to 45% in 2002
- Gestation/veal crates banned by Arizona voters, 62% to 38% in 2006
- Gestation crates banned in Oregon in 2007
- Gestation/veal crates banned in Colorado in 2008




THE HUMANE SOCIETY  
OF THE UNITED STATES

## Pork Industry Giants Now Moving



THE HUMANE SOCIETY  
OF THE UNITED STATES

## Veal Industry Phasing Out Crates



“[Veal crates are] inhumane and archaic practices that do nothing more than subject a calf to stress, fear, physical harm and pain.”  
Randy Strauss, CEO of Strauss Veal

“recommends that the entire veal industry convert to the group housing methodology.”  
May 2007 Resolution, American Veal Association

Yes on Prop 2 - Mozilla Firefox

http://www.yesprop2.com

YES! ON PROP 2

JOIN the Campaign

WRITE TO PROP 21 | FACT SHEETS | EMPLOYERS | ABOUT THE OPPOSITION | PHOTOVIDEOS

Donate

Volunteer

Tell a Friend

Register to Vote

Supporter Tools

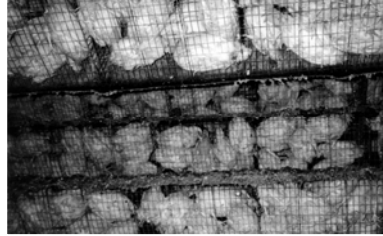
Vote YES! on Prop 2 ... to support family farmers



## Battery Cages Prevent Their Most Basic Behaviors



## Afforded Less Space Than a Sheet of Paper Per Hen



## An Alternative: Cage-Free Production



## The Science on Cage-Free Production

“Battery cages present inherent animal welfare problems, most notably by their small size and barren conditions. Hens are unable to engage in many of their natural behaviors and endure high levels of stress and frustration. Cage-free egg production, while not perfect, does not entail such inherent animal welfare disadvantages and is a very good step in the right direction for the egg industry.”

— Dr. Michael Appleby, Animal Welfare Policy Advisor  
World Society for the Protection of Animals



Prepared by Don Bell, Poultry Specialist (emeritus), University of California, Riverside

**Table A-4 Summary of Costs by System – Estimated for US**

System	Estimated Cost of Production (¢/doz)	Difference from cage (in ¢/doz)	Difference from cage in %
Cage	43.13	n/a	n/a
Free-range	71.53	+28.40	+65.8

\*This is *not* a conservative estimate. Other studies show 8-24% increase.

Source: Bell D. 2005. A review of recent publications on animal welfare issues for table egg laying hens. United Egg Producers Annual Meeting, October, p. 7.



## Potential production cost increase of battery cage ban...



Vote NO on California Proposition 2 | Vote NO on California Prop 2 - Mozilla Firefox

http://www.safeandhealthy.org

Californians for SAFE Food  
NO on Prop 2

"This outdoor access enhances the likelihood that such poultry will have direct contact with migratory and wild birds as well as other animals, substantially increasing the risk of Avian Influenza (AI), Exotic Newcastle Disease, and other diseases."  
- UNITED STATES ANIMAL HEALTH ASSOCIATION

Donate Frequently Asked Questions Campaign updates Resources

Vote NO on California Proposition 2

NO on Prop. 2 - Breaking News

September 14, 2009  
UNITE HERE Joins United Food and Commercial Workers Western States Council in Fight to Defeat Proposition 2: Leading Labor Unions Join Business Organizations and Teachers, Who Oppose Prop. 2 to Save Workers, Safe Consumer and Life!

September 11, 2009  
California State Firefighters' Association Opposes Prop. 2: Organization Representing More Than 25,000 California Firefighters Announces Opposition to

WHY OPPOSE PROPOSITION 2?  
Undermines animal welfare and food safety in California  
Threatens food safety and increases antibiotic resistance  
jeopardizes public health  
Eliminates fresh, safe and local eggs, forces a dependence on eggs from Mexico and

Sign-up TO JOIN THE COALITION  
Proposition 2 is a risky, dangerous, and costly measure banning almost all modern egg production in California.  
Vote NO on Prop. 2, it's the SAFE Food Initiative.  
Organization Opposition Sign-up Form  
Individual Contribution

THE HUMANE SOCIETY OF THE UNITED STATES

## What's Happened Elsewhere?

- UK: McDonald's *only* sells cage-free eggs now.
- UK: All Asda (Wal-Mart) brand eggs now cage-free.
- Switzerland imports of eggs dropped sharply after cage ban took effect.
- Austria: The major grocery chains now have cage-free only policies.



THE HUMANE SOCIETY OF THE UNITED STATES

## What's Happened in the U.S.?



THE HUMANE SOCIETY OF THE UNITED STATES

## What's Likely to Happen in the Wake of Prop 2's Passage?

"A California ballot initiative this fall concerning housing for hens, sows and veal calves is actually an initiative that will affect all of livestock and poultry production across the entire U.S., if not North America."

--Feedstuffs Editorial 6-9-08

37The California Majority Report // No on Prop 2 Campaign Funded by the Same Out-of-State Egg Producers that the Campaign Clai...

http://www.campaignreport.com/blogs/37the-california-majority-report-//no-on-prop-2-campaign-funded-by-the-same-out-of-state-egg-producers-that-the-campaign-clai...

September 16, 2009 @ 10:29 AM

One of the most repeated talking points by the No on Prop 2 campaign suggests that California's egg production will somehow collapse under a post-Prop 2 world. Here's how the No campaign explains it in a FAQ on their campaign page:

"The proposition wipes out Californians' access to locally grown, fresh eggs, and harms consumers by driving up prices at grocery stores and restaurants and creates a dependency on eggs shipped from other states and Mexico."

They also claim it will "wipe[ ] out almost all modern egg production in the state" who would do such a thing to our fair state? The widely-respected Humane Society of the United States of course, which is, according to the FAQ though not mentioned by name, a "well-funded, Washington, DC-based special interest group." Like the Deepwater Horizon Association and the AFP.

So that's the message. Prop 2, backed by out-of-state interests, will devastate California's egg industry. Surely out-of-state egg producers are lining up at the IRS to see Prop 2 passed then, since they anticipate a flood of new business as California's egg producers are put out of business, right? Confused, no?

"Between Iowa companies have made nearly a quarter of a million dollars in donations to "Californians for SAFE Food - No on Prop 2," a coalition organized to fight a ballot measure amending the state's health and safety code in relation to the confinement of livestock."

Oh, I'm confused. Riddle me this factory farmers: who would 13 Iowa egg producers dump a quarter million dollars into an opposition campaign to a California proposition that would increase Iowa egg producers' market share? If the No campaign's talking points were true, Iowa egg producers (along with donors from factory farms in Nebraska, Maine, Colorado, Utah,

THE HUMANE SOCIETY OF THE UNITED STATES

## Should Animals Raised for Food Really Be Unprotected?



Criminal      Legal?





THE HUMANE SOCIETY  
OF AMERICA

### **Ruth Harrison in 1964:**

"If one person is unkind to an animal it is considered to be cruelty, but where a lot of people are unkind to animals, especially in the name of commerce, the cruelty is condoned and, once large sums of money are at stake, will be defended to the last by otherwise intelligent people."



THE HUMANE SOCIETY  
OF AMERICA

Thank you.

[HumaneSociety.org](http://HumaneSociety.org)



# Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety

## Impact of Legislation on Animal Research

Marcos H. Rostagno

USDA, ARS, MWA, Livestock Behavior Research Unit

2008 Future Trends in Animal Agriculture Symposium  
September 17<sup>th</sup>, 2008

### Impact of Legislation on Animal Research

Marcos H. Rostagno, DVM, MPVM, PhD

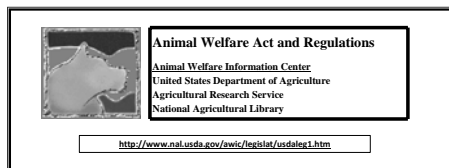
USDA – ARS – Livestock Behavior Research Unit  
West Lafayette, IN

[Marcos.Rostagno@ars.usda.gov](mailto:Marcos.Rostagno@ars.usda.gov)

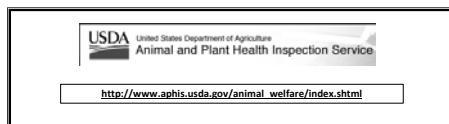


### Animal Welfare Act

- Signed into law in 1966.
- Only Federal law in the U.S. that regulates the treatment of animals in research, exhibition, transport, and by dealers.
- To regulate the care and use of animals in the laboratory.
- It has been amended four times: 1970, 1976, 1985, 1990.
- Enforced by the USDA, APHIS, Animal Care (AC).
  
- All other laws, policies, and guidelines refer to it as the minimum acceptable standard.



Animal Welfare Act and Regulations  
Animal Welfare Information Center  
United States Department of Agriculture  
Agricultural Research Service  
National Agricultural Library  
<http://www.nal.usda.gov/awic/legislat/usdalaw1.htm>



USDA United States Department of Agriculture  
Animal and Plant Health Inspection Service  
[http://www.aphis.usda.gov/animal\\_welfare/index.shtml](http://www.aphis.usda.gov/animal_welfare/index.shtml)

### Animal Welfare Act

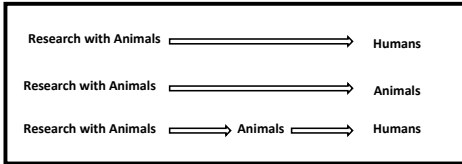
#### RESEARCH FACILITIES

- ☞ Responsibilities & Functions:
  - Attending Veterinarians
  - Institutional Official (IO)
  - Principal Investigator (PI)
  - Institutional Animal Care & Use Committee (IACUC)
- ☞ Regulation of Field Research
- ☞ Reports, Notifications and Recordkeeping
- ☞ Qualifications & Training Required for Research Personnel

# Animal Welfare & Research

## Ethical dilemma:

Scientific benefits x Animal distress



**Basic x Applied Research**



William Russell & Rex Burch (1959)  
"The Principles of Humane Experimental Technique"

## The 3 R's

**Refinement** - improvements in husbandry and procedures which minimize actual or potential pain and suffering/distress when the use of animals is unavoidable/required.

**Reduction** - methods which minimize animal use and enable scientists to obtain comparable levels of information

**Replacement** - methods which avoid or replace the use of animals (absolute and relative replacements).

# Finding Alternatives

- Alternative approaches and techniques
  - Development of "models"
    - *in vitro*
    - Complexity of biological systems/processes
    - ↳ Validity ???
  - Consequences (partially...):
    - Fragmentation
    - Multidisciplinarity / Interdisciplinarity
- ↳ **Intellectual & Creative Challenge!!!**



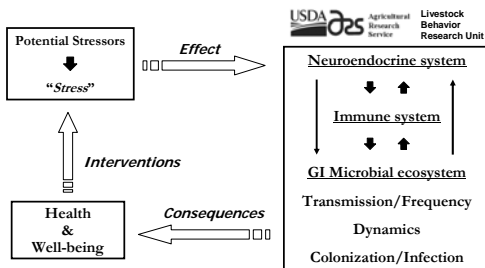
# Ecology and Epidemiology of Pathogens

Observational or descriptive studies

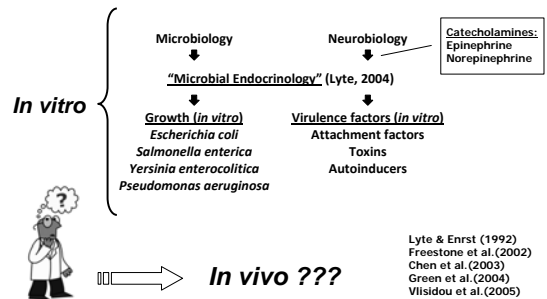
Non-invasive sampling (non-aggressive)



# Effect of Potential Stressors on the Gastrointestinal Microbial Ecosystem



# Potential Effect of Stress on Bacterial Pathogens



## Impact on Research

- ↓ number of animals used in research
- ↑ development and use of *in vitro* models
- ↑ bureaucracy (↑ time: planning - execution)
- ↑ control and accountability
- ↑ awareness and respect for the animals (animal care)
- ↑ quality of experiments (design, protocol)



Variability between  
research area, institution and country.



## Funding Animal Research

**National Institutes of Health (NIH)**  
(*Guide for the Care and Use of Laboratory Animals*)



Others following the same path...



## Publication of Animal-Based Research

Scientists often failed to report  
measures to minimize animal distress



***Not anymore!!!***

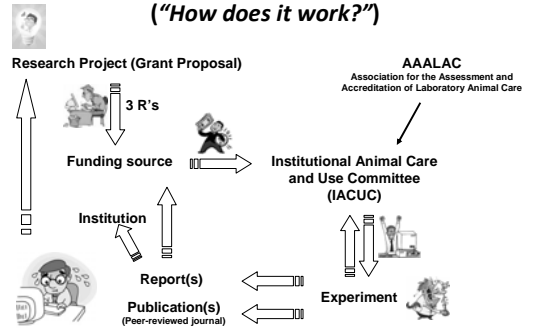
Scientific journals increasingly requiring  
reporting and justification



*Journals with high impact factor  
Helping to minimize variability...*

## Animal Welfare in Research

("How does it work?")



## Acknowledgements



USDA-ARS  
Livestock Behavior Research Unit

- Purdue University
- National Pork Board
- Technicians & Students

## Thank you!!!



Questions & Comments are very welcome!

# Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety

## The Pros and Cons of Animal Welfare Legislation

Tony Pescatore  
University of Kentucky

The Pros and Cons of  
Animal Welfare Legislation

Anthony Pescatore

**Well Being**  
The satisfaction of basic physical needs and encouragement of necessary behaviors

Physical Needs	Behaviors
<ul style="list-style-type: none"> <li>■ Food</li> <li>■ Water</li> <li>■ Shelter</li> <li>■ Health</li> <li>■ Safety</li> <li>■ Actual Existence</li> </ul>	<ul style="list-style-type: none"> <li>■ Feeding Behavior</li> <li>■ Drinking Behavior</li> <li>■ Social interaction</li> <li>■ Maintenance Behavior</li> <li>■ Sleep Behavior</li> <li>■ Response to predators</li> <li>■ Grooming Behavior</li> <li>■ Locomotion Behavior</li> <li>■ Sexual Behavior</li> <li>■ Maternal/Paternal Behavior</li> </ul>

There is no one system that can provide all the physical needs of the animal and all of the behaviors.

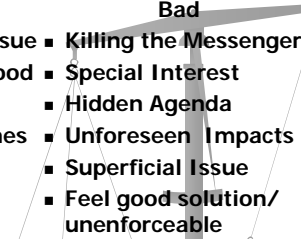
Where should animal welfare come from?

Individual, Third Party Customers End Users, State / Local Regulation, National Legislation

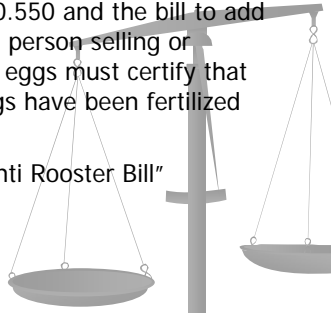
Industry /self regulated, Industry / Government Partnership (NPIP), National Regulation, State/Local Legislation

desirable ← → undesirable

## What makes a law good or bad

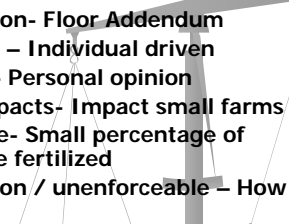
- | Good                            | Bad                                    |
|---------------------------------|--|
| ■ Discussion of Issue           | ■ Killing the Messenger                |
| ■ The Common Good               | ■ Special Interest                     |
| ■ Clear Agenda                  | ■ Hidden Agenda                        |
| ■ Defined Outcomes              | ■ Unforeseen Impacts                   |
| ■ Real Issue                    | ■ Superficial Issue                    |
| ■ Real Solution/<br>enforceable | ■ Feel good solution/<br>unenforceable |
- 

## Sample Legislature

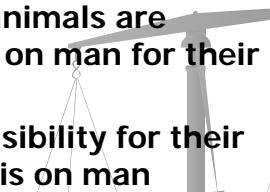
- Amend KRS 260.550 and the bill to add provision that a person selling or marketing shell eggs must certify that none of the eggs have been fertilized
- 

" Anti Rooster Bill"

Amend KRS 260.550 and the bill to add provision that a person selling or marketing shell eggs must certify that none of the eggs have been fertilized

- Lack of Discussion- Floor Addendum
  - Special Interest – Individual driven
  - Hidden Agenda- Personal opinion
  - Unforeseen Impacts- Impact small farms
  - Superficial Issue- Small percentage of eggs for sale are fertilized
  - Feel good solution / unenforceable – How do you know?
- 

## Man's relationship to animals

- Domestic animals are dependent on man for their existence
  - The responsibility for their well being is on man
- 

# Panel: Pro's and Con's of Using Legislation to Advance Views of Farm Animal Welfare and Food Safety

**Marie Belew Wheatley**  
American Humane Association



## **FUTURE TRENDS IN ANIMAL AGRICULTURE**

Pros and Cons of Using Legislation to Advance Views of Animal Welfare and Food Safety

September 17, 2008

**Presented by**  
**Marie Belew Wheatley**  
**President & CEO**

## **AMERICAN HUMANE**

- Founded in 1877
- Oldest humane organization dedicated to protecting both children and animals
- Began with efforts to improve welfare of farm animals
- Encourage humane behavior through education, advocacy, motivation

## **PROGRAMS**

- "No Animals Were Harmed"®
- Red Star Animal Emergency Services
- The Link
- Human-Animal Bond
- American Humane Certified™

## American Humane Certified™

- First and original certification program
- Legacy program
- Credible third party, independent audit
- Science-based standards for all species
- Independent Scientific Committee review
- Fastest growing, premier animal welfare label

## PROGRAM STRENGTHS

- Moderate, balanced reasonable policies
- Education, motivation, collaboration driven
- Agricultural friendly
- Positive partnership with agricultural alliances and producers
- Solution based, economically viable
- Best practices in good animal husbandry

## RATIONALE FOR LEGISLATION ACTION

- Egregious animal welfare abuse
- Need to affect national policy change
- Significant Legislative Examples
  - 28 Hour Rule for transportation of animals
  - Humane Methods of Slaughter Act

## POSITION ON USE OF LEGISLATION TO ADVANCE VIEWS

- Will address animal welfare, not food safety
- 60% of consumers believe that food safety is tied to animal welfare
- Favor regulation of food safety
- Concerned about excessive farm animal welfare legislation

## SOLUTION BASED

- Favor education, motivation, collaboration
- Demonstrate humane practices can increase productivity and efficiency
- Share knowledge, technology, best practices
- Partnership and collaboration
  - Economically viable and achievable
  - Embrace and adopt new humane practices

## SOLUTION-BASED ALTERNATIVES

- Work with national agriculture trade groups and producers
- Improve audit technology – three-tiered system
- Create markets for humanely labeled food choices



## COMMITTED

- Work collaboratively with agriculture
- Develop solutions with science community and animal specialists to welfare issues
- Research alternative welfare systems
- Support continued improvement of animal welfare
- Advocate voluntary participation by agriculture



**GOOD FOR ANIMALS**

**GOOD FOR BUSINESS**

**GOOD FOR PEOPLE**

# Slaughter Facility Management

**Janet M. Riley**  
American Meat Institute

## Ensuring Optimal Welfare in the Plant Setting

to the  
*2008 Future Trends in Animal Agriculture*

Janet M. Riley  
Senior Vice President  
Public Affairs and Professional Development



## History

- Humane Slaughter Act – 1958
- Humane Slaughter Act – 1978
- Emergence of Animal Rights Movement – 1980s
- 1991 *Recommended Animal Handling Guidelines for Meat Packers*
- 1996 – Grandin audits for USDA
- 1997 – Good Management Practices for Animal Handling & Stunning

## History

- 1997-98 – Reenergized committee with practical approach established
- 1999 – First Animal Handling Conference
- 2005 – Merged 1991 and 2005 documents into *Recommended Animal Handling Guidelines and Audit Guide, 2005*
- 2005 – Launched dedicated web site
- 2007 – Updated guidelines/audit

## Our Philosophy

- Optimal welfare is good for livestock – and good for business
- Ensuring animal welfare is ethically appropriate, but also offers distinct benefits
  - Quality
  - Worker safety
  - Employee morale

## Total System Approach

- Management commitment
- Design with the animal in mind
- Train employees
- Embrace best practices
- Think creatively
- Measure, measure, measure
- Recognize achievement
- Work collaboratively with your inspector
- Share good ideas/be non-competitive

## Management Commitment

- Worked hard to secure senior-level buy in
  - Do it because it's right...but communicate benefits back to management



## Design With the Animal in Mind

- Know your species!
- Animals have natural follow the leader instincts – use them
- Use circular designs/avoid sharp corners
- Understand impact of distractions
- Proper lighting

## Train Employees

- Annual Conference
- Training videos
- Web site
- Acknowledge those who are trained

## Embrace Best Practices

- Encourage use of industry recommended guidelines
- Strive to exceed federal rules

## Creative Thinking

- Some of the best ideas are the least expensive
  - "Cardboard and duct tape solutions"
  - Plastic trash bag drivers
- Showcase good ideas/simple changes

## Measure, Measure, Measure

- AMIF provides standard forms on public site
- AMI Board in 2005 recommended that third party animal welfare audits be conducted in plants at least annually
- Internal audits – once a week

## Recognize Achievement

- Travel to conference = reward
- Smart, innovative people become speakers
- Encourage plants to recognize conference attendees and welfare innovators within plant/corporation
- Special awards for 'above and beyond'

## CARING



## Share Good Ideas.. Be Non-Competitive

- Animal Welfare Committee meets at plant annually
  - Tour plant with Dr. Grandin
- Plants with problems can request phone, email or in-person assistance
- Members are expected to bring good ideas to conference

## animalhandling.org

Home Government Regulations Guidelines/Auditing Training/Animal Welfare Assistance

**Animal Welfare 101**

**Press Room**

**Photography**

**Frequently Asked Questions**

**Important Links**

**Contact Information**

ANIMALHANDLING.ORG IS SPONSORED BY THE U.S. MEAT INDUSTRY, WHICH IS COMMITTED TO INSURING OPTIMAL LIVESTOCK HANDLING IN ITS PLANTS. OPTIMAL HANDLING IS ETHICALLY APPROPRIATE, CREATES POSITIVE WORKPLACES AND ENSURES HIGHER QUALITY MEAT PRODUCTS.

THE PURPOSE OF THIS WEB SITE IS TWO-FOLD:

- TO PROVIDE INFORMATION TO MEMBERS OF THE MEAT INDUSTRY AND THEIR CUSTOMERS ABOUT GOVERNMENT REGULATIONS, VOLUNTARY GUIDELINES, TRAINING AND CUSTOMER REQUIREMENTS, AND
- TO SERVE AS A RESOURCE TO THE NEWS MEDIA AND THE PUBLIC ABOUT THE TREATMENT OF LIVESTOCK IN MEAT PROCESSING OPERATIONS.

**AMI**

The materials contained in this web site are not intended as safety advice to any party, but as guidelines. The contents displayed and linked to in any way represent advice for the humane meat industry. Please consult the safe handling, directions and labeling for meat and poultry products for accurate. For more information, please contact FSIS for details.

## animalhandling.org

Home Government Regulations Guidelines/Auditing Training/Animal Welfare Assistance

**GUIDELINES/AUDITING**

**Animal Welfare 101**

**Press Room**

**Photography**

**Frequently Asked Questions**

**Important Links**

**Contact Information**

Since 1991, the AMI Foundation has encouraged its members to subscribe to voluntary animal welfare guidelines and to embrace auditing programs – and they have done so. The meat industry was the first sector in animal agriculture to develop such guidelines and to begin self-audit programs.

Data collected by Colorado State University's Dr. Temple Grandin for the U.S. Department of Agriculture and major restaurant chains show that animal handling in the meat industry has improved dramatically. The data can be viewed at [www.grandin.com](http://www.grandin.com)

The AMI Foundation released its 2004 Animal Handling and Audit Guidelines in December 2004. These replace previous versions. The 2004 edition includes sample audit forms.

- To download the guidelines, click here.
- To download the cattle/sheep and sheep audits forms only, click here.

Many companies also retain third party expert auditors. American Meat Institute members who perform third party animal welfare audits include:

- Food ProTech
- Food Safety-Net Services Ltd.
- NSF
- Silliker
- Voight Consulting

**animalhandling.org**

Home Government Regulations Guidelines/Handling Training/Animal Welfare Assistance

**PHOTOGRAPHY**

Animal Welfare 101  
 Price Reason  
 Photography  
 Frequently Asked Questions  
 Important Links  
 Contact Information

ENSURING OPTIMAL LIVESTOCK HANDLING AND WELFARE REQUIRES A KEEN UNDERSTANDING OF LIVESTOCK BEHAVIOR.

**WHAT ARE THEIR NATURAL INSTINCTS?**

**WHAT CAUSES THEM STRESS?**

**HOW CAN STRESS BE REDUCED?**

FOODING PLANTS ARE DESIGNED WITH OPTIMAL WELFARE AS A GOAL. THE PHOTOS BELOW PROVIDE EXAMPLES OF THE MANY CONSIDERATIONS THAT GO INTO ANIMAL HANDLING IN THE MEAT INDUSTRY.

Please courtesy of South Grande, P.R.O.

Pigs come to feed and eliminate themselves.

Feed troughs are placed in the center of the pen.

Pigs are hesitant to walk on new floor. They will be easier to move if allowed to explore the new floor first.

Pigs walk side by side with unobstructed path between them.

**Also from Animalhandling.org**

Helmet Stickers

AMF offers helmet stickers for use in recognizing employees who have been trained in cattle and hog animal handling and stunning. These stickers are available for \$25 for 100 stickers, including shipping and handling. To order these stickers, [click here](#). Please specify either cattle or hog stickers.

AMF also offers two training videos: Good Animal Handling Practices for Beef Processors and Good Animal Handling Practices for Pork Processors. Using Dr. Temple Grandin as the lead instructor, these 15-minute videos facilitate in-plant training in the principles of good animal handling. The videos are available in both English and Spanish.

To download an order form, [click here](#).

**Animal Welfare Assistance**

Animal welfare assistance is available directly from AMF staff experts 24 hours a day, seven days a week. In addition, because animal welfare is treated as a non-competitive issue by AMF members, industry events are also available to assist others when problems occur. To utilize AMF's Animal Welfare Assistance Program, email or call Janet Hogg, 202/567-4245, or Lynn Monsonette, 202/567-4227. Be prepared to describe the nature of the problem and the nature of your operation. A staff member will respond to you promptly.

**Work Collaboratively With Your Inspector**

- Common goals
- Keep them informed
  - Training
  - New equipment
- Respect their knowledge, responsibilities

**Cameras in the Plant Setting**

- Video surveillance
- Video auditing

**The Net Effect – Grandin Data**

Captive bolt stunning of cattle -- percent stunned with one shot

	% of plant 1996	% of plants 2006
■ Excellent	18%	56%
■ Acceptable	18%	44%
■ Not acceptable	9%	0
■ Serious problem	55%	0

Source: [www.grandin.com](http://www.grandin.com)

**The Net Effect – Grandin Data**

Percentage of cattle vocalizing in beef plants

	% of plant 1996	% of plants 2006
■ Excellent	45	56
■ Acceptable	28	35
■ Not Acceptable	24	5
■ Serious Problem	5	0

Source: [www.grandin.com](http://www.grandin.com)

## **The Net Effect – Grandin Data**

- In 1996, “1 in 10 plants could not stun pigs properly”
- In 2006, 100 percent had excellent or acceptable stunning; no plant failed

Source: [www.grandin.com](http://www.grandin.com)

## **Sustained Vigilance Essential**

- We are not done – and never will be!
- Continued training
- Continued focus
- Small plant outreach
- Ongoing review/updating of guidelines
- PAACO Review
- Development of Livestock Transportation Audit

***Thank you!***

**Janet Riley**

**[jriley@meatami.com](mailto:jriley@meatami.com)**

**[www.animalhandling.org](http://www.animalhandling.org)**

**[www.meatami.com](http://www.meatami.com)**

# Treatment of Sick and Injured Animals: Should They be Moved and if So, How?

**Jim Reynolds**  
University of California  
American Association of Bovine Practitioners

## Future Trends in Animal Agriculture Symposium

### Treatment of Sick and Injured Animals: Should They be Moved and If So, How?

Jim Reynolds DVM, MPVM  
Veterinary Medicine Teaching and Research  
Center, Tulare, CA



## Sick and Injured Livestock

- Welfare and Food Safety Issues
- Distinguish between sick and disabled
- Sick
  - Farm diagnostic and treatment protocols
  - Mastitis, pneumonia, foot disease, infections, injury
- Disabled
  - Very sick, thin, weak, chronic disease
  - At risk of becoming nonambulatory
- Nonambulatory

## Sick and Injured Livestock

- Decision Tree:
- Diagnosis
  - Prognosis
  - Treatment
- Considerations:
- Welfare
  - Economic value
  - Likelihood of recovery
- On the Farm
  - Transportation
  - Market (Sales or auction barn)
  - Slaughter
    - Swine may develop porcine stress syndrome
    - Recoverable with rest

## Why are downed cattle an issue?

### Welfare:

- Pain and suffering

### Public Health:

- Downed animals may increase pathogen load at slaughter houses
  - N Engl J Med 1987 Mar 5;316(10):565-70
- USDA considers non-ambulatory cattle at high risk for BSE
- Therefore not allowed for USDA slaughter

## What are “Downed Cows” ?



- Non-ambulatory livestock
- "nonambulatory" means unable to stand and walk without assistance.
  - California Penal Code Section 599f
- Incidence rates estimated from 0.4 to 2.1% for dairy cattle

## What to do when a cow or calf becomes a downer

- 1) Physical examination
  - assess the distress, or suffering of the animal
  - diagnosis
- 2) Prognosis
- 3) Euthanize if suffering or prognosis poor
- 4) Treatment plan if recoverable



Work with your veterinarian to make a plan for your dairy

## Disabled or Nonambulatory Cattle can be Treated or Moved

- Move if necessary
- Do not drag on ground
- Use sled, sling or tractor buckets (carefully)



## What to do ...

- Bedding and shelter
  - Protect from environment and wildlife
  - Soft bedding
    - Dirt, sand, grass
- Food and water
  - Adult dairy cows need 20 to 40 gallons of water per day
  - Protect from other cattle



## What to do ...

### Physical examination

- assess the distress, or suffering of the animal
- make a diagnosis, if possible

- Check:
  - Temperature
    - Fever: possible infection, mastitis, metritis
  - Legs for fractures, injuries
  - Udder for mastitis
  - Palpate for pregnancy
  - Check for tumors

## What to do ...

### Make a Prognosis

- Determine the likely outcome of the cow
- Fractures: very poor
- If not likely to recover → euthanize
- If in distress and unable to relieve pain → euthanize





## Medical Treatment of Down Cattle

- 2 goals: 1) correct the cause  
2) minimize secondary nerve and muscle damage
- Compartmentalization (or Crush) syndrome
    - Weight of cow damages muscles and nerves
    - Research: 50% of cows down > 3 hours stayed down
  - Soft bedding to reduce pressure in large muscle masses

## Managing Crush Syndrome

- Slings or hip lifts
  - May help stand and walk
- Sternal recumbency
  - Can prop with hay bales
- Rolling side-to-side
  - Every 2 hours
- Water baths



## Medical Treatment of Down Cattle

- Pain and inflammation control
  - In the USA flunixin, aspirin, dexamethasone
- Treat initial condition
  - “4 M’s”: Milk fever, mastitis, metritis, musculoskeletal
- **Work with your veterinarian to make a treatment plan**

## Physical Treatment for Down Cows

Water baths

- Response/recovery mixed in trials
- Probably better response if used early after calving trauma
- Water must be kept at cow temperature



**Downcow.com**

## Float Tanks

UC Davis non-controlled trial with 70 cows:

- 46% overall recovery rate
- 78% recovery rate for cows with calving paralysis
- Cows down < 1 day averaged 3 days to stand
- Cows down 2 or more days averaged 5 days to stand

## Research on Nonambulatory Cattle:

Dr. John Maas, Dr. Carolyn Stull et al

“Determining the causes of disabled dairy cattle”

50 dairy cattle examined at a slaughter house, trace-back to farm



Research on down Cows: (Maas, Stull, et al)

Diagnosis	#Cows	#Condemned
Injury	19	1
Calving paralysis	12	3
Mastitis	6	3
Lymphosarcoma	5	4
Metritis	2	--
Other	5	--
Unknown	1	--

(pneumonia, gastroenteritis, LDA, septicemia)

Presented by Dr. C. Stull at Livestock Conservation Institute 1996 annual meeting

Research on down Cows:

Dr. John Maas, et al

Microbiology

0157:H7 0/20 cows

Salmonella 7/50 cows

6 fecal shedders

- 4 passed
- 1 condemned
- 1 unknown

1 septicemic (passed)



Dairy Welfare Audit Requirements

- Down cow plan
- Trained personnel
- Equipment to comfortably move animal
- Sheltered area
- Feed and Water
- Treatment plan
- Euthanasia program
- Verification that the above actually happens



Conclusions

On the Farm:

- Nonambulatory livestock can be treated humanely
- Outcome depends on diagnosis
- Must have equipment, trained personnel
- Rarely economical to treat nonambulatory cattle

At the Market (auction yard):

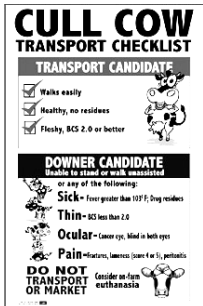
- Cannot continue through market chain
- Technically possible to humanely treat and move to hospital facility

At the slaughter facility:

- Cannot move into slaughter
- Technically possible to humanely treat and move to hospital facility


AVMA and AABP position statement on "Disabled Livestock"

If the animal is in extreme distress and the condition is obviously irreversible, the animal should be immediately euthanized or humanely slaughtered on the farm.




# Animal Care in the Dairy Industry

**Jamie S. Jonker**  
National Milk Producers Federation



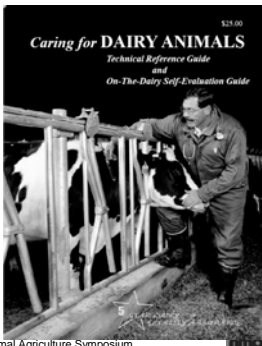
*Animal Care in the Dairy Industry*


*Jamie Jonker – Director, Regulatory Affairs  
National Milk Producers Federation*

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*Dairy Industry Animal Care Efforts*


- Caring for Dairy Animals
- Widespread use in industry
- Producer friendly




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*DQA Caring for Dairy Animals*

- Comprehensive set of dairy animal well-being guidelines
- Recommends best management practices based on the most current science
- Voluntary self-audit in a checklist format completed by producers
- Third party on-farm verification



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*DQA Caring for Dairy Animals*

- Joint effort of the Dairy Quality Assurance Center and National Milk Producers Federation
- Developed by scientific advisory board using the most current animal well-being research
- Endorsed by:
  - American Association of Bovine Practitioners (AABP)
  - Food Marketing Institute
  - National Council of Chain Restaurants
- Guidelines distributed widely in industry:
  - Dairy Farmers Dairy Nutritionists
  - Veterinarians Milk Cooperative Field Staff
  - Other Dairy Consultants



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## DQA Caring for Dairy Animals

### Reciprocal recognition with American Humane Certified program

*"Certification by American Humane Certified and DQA assures consumers they are buying high-quality dairy products that are from humanely treated animals."*

- Marie Belew Wheatley, President and CEO of American Humane (September 9, 2008)

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## DQA Caring for Dairy Animals 10 Tenets

1. Producer and Employee Attitudes including training employees and family members; emergency, weekend, and holiday care; monitoring the care provided to animals; and visitors
2. Evaluating Animal Health Care including establishing a herd health program; udder health; breeding; sanitation and waste management; hygiene and locomotion scoring; parasites; pest control; animal identification and health records; husbandry practices; and administration of medication
3. Environment for Dairy Animals including environmental temperature; monitoring air temperature, humidity, quality, and movement; heat stress; lighting; noise; animal activity; and stray voltage

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## DQA Caring for Dairy Animals 10 Tenets

4. Facilities Provided for Dairy Animals including floor space; bedding; flooring; mud; social environment; hospital facilities; breeding facilities; restraint facilities (gates and fences)
5. Dairy Nutritional Care including water and waterers; feed nutritional quality; feeders or feed bunks; feed storage; and sanitation of eating areas
6. Milking Procedures and Equipment including milking facility; milking equipment; and udder sanitation
7. Transporting and Handling Animals including animal handling; restraint equipment; loading and unloading; transportation factors; vehicles; in-transit care; and flight zone

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## DQA Caring for Dairy Animals 10 Tenets

8. Birth and Management of Calves including calving area; navel care; nutritional care of calves; marketing and transportation; and body condition scoring
9. Sick, Hospitalized, Nonambulatory, and Dead Animals including sick and injured animals; prevention of and care for nonambulatory animals; euthanasia; and dead animals and disposal
10. Annual Evaluation including self-evaluation; HACCP principle review; and Dairy Quality Assurance walk-through and verification

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## Culling and Transporting Dairy Cattle

- NMPF/DMI/AABP joint effort
- Top 10 culling and transportation decision list
- Distributed widely
  - All dairy producers through cooperatives, proprietary processors, and producer requests – Ad in Hoard's Dairyman
  - Livestock Marketing Association
  - American Association of Bovine Practitioners
  - others

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## Top 10 Culling & Transporting List

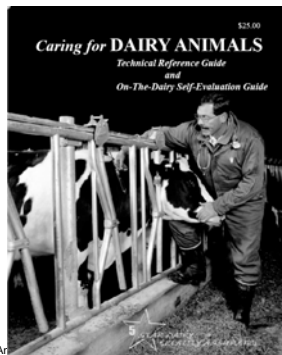
The infographic is divided into two columns. The left column is titled 'Top 10 Considerations for Culling and Transporting Dairy Animals to a Packing or Processing Facility' and the right column is titled 'Las 10 consideraciones más importantes para el descarte y transporte de animales lecheros a un matadero o planta procesadora'. Each column contains 10 numbered items with corresponding icons and brief descriptions.

## NMFF/DMI/DQA Center



- Future efforts
- Establish National Dairy Quality Assurance Program
- Adopt program to cooperative and producer needs

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## Questions?

*Jamie Jenker - Director, Regulatory Affairs  
National Milk Producers Federation*

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## Panel: Responsible Antibiotic Use


# Antimicrobial Use in Animals: Multiple Layers of Protection Safeguard Human Health Prepared by the Animal Health Institute

Richard Carnevale  
Animal Health Institute

**Responsible Antibiotic Use**  
2008 Future Trends in Animal Agriculture Symposium

Dr. Richard Carnevale  
Vice-President for Regulatory, Scientific and  
International Affairs  
Animal Health Institute


September 17, 2008 Washington, DC



**FDA approval**

- Responsible use of antibiotics or any animal medicines begins with using FDA approved products.
- The regulatory process for review and approval of new medicines is stringent, science-based, and protective of public health.
- The relationship between the sponsor and the regulator is professional and aimed at the same goal - availability of high quality safe and effective drugs.

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**Why do we need antibiotics?**

Antibiotics preserve our nation's safe and abundant food supply by:

- Disease treatment
- Disease control
- Disease prevention
- Health maintenance that increases productivity

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**Antibiotic Uses**


Efficacy

- Disease Treatment**  
Administration of an antimicrobial to an animal or group of animals which exhibit clinical disease
- Disease Prevention**  
Administration of an antimicrobial to exposed healthy animals considered to be at risk, but prior to expected onset of disease
- Disease Control**  
Administration of an antimicrobial to animals, usually a flock or herd, in which morbidity and/or mortality has exceeded baseline norms
- Growth, or Health Maintenance**  
Administration of an antimicrobial, usually as a feed additive, over a period of time to growing animals that results in improved performance, i.e. weight gain or feed conversion

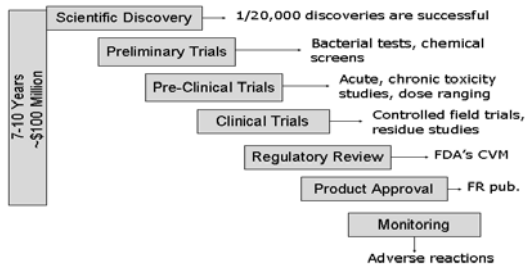
Therapeutic Uses -- AVMA, FDA, CODEX

Definitions from Clinical and Laboratory Standards Institute

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## Discovery, Approval and Post Approval

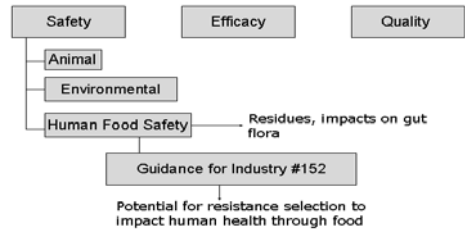


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## FDA Approval Process



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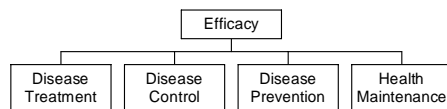
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## ANTIBIOTIC REGULATION AND USES

### STRINGENT REGULATORY CRITERIA

- Human Safety
- Animal Safety
- Environmental Safety
- Quality (manufacturing)
- Efficacy



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## ANTIBIOTIC USE IS STRICTLY REGULATED

"An antibiotic can only be used according to its approved label specifications; except as directed for therapeutic purposes under the supervision of a veterinarian as part of a valid veterinarian-client-patient relationship; but only for FDA approved animal and human drugs"

In feed, no extra-label use is allowed by law.



Injection



In water



In feed

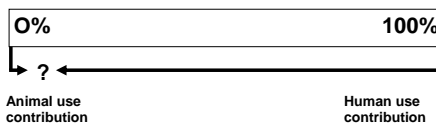
- |                             |                    |
|-----------------------------|--------------------|
| <b>Label specifications</b> | • Dosage           |
| • Species                   | • Usage directions |
| • Use within species        | • Cautions         |

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## RESISTANCE TRANSFER TO HUMANS

- Probability is the issue; not possibility!
- To what extent does the use of antibiotics used in food animals contribute to bacterial antibiotic resistance in humans?



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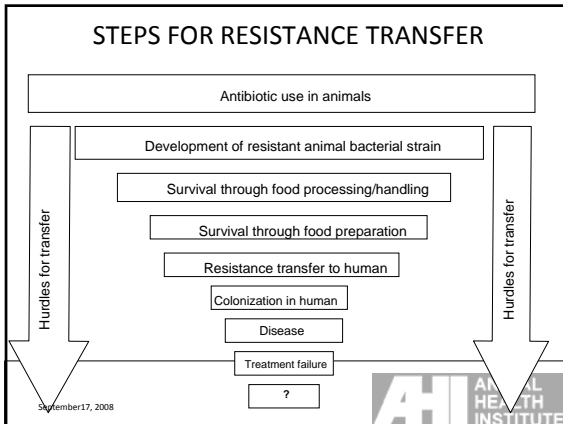
## Contribution of Animal Use to Human Resistance

- Majority of resistant infections in humans not associated with animals:
  - Respiratory tract infections - *Strep. pneumoniae*
  - Venereal diseases – *Neisseria gonorrhoea*
  - Nosocomial infections – *Vancomycin Resistant Enterococci (VRE)*, hospital strains of *MRSA*.
- Foodborne bacteria such as *Salmonella spp.* and *Campylobacter jejuni* are primary link.

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### FDA RISK ASSESSMENT

- Guidance document issued October 2002.
- Requires manufacturers to evaluate new and existing products based on qualitative risk assessment.
- Three components:
  - **Release assessment** ( how likely resistant bacteria will be selected by use of the drug)
  - **Exposure assessment** ( how likely people will consume resistant bacteria)
  - **Consequence assessment** ( importance of drug to human medicine)

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### US FDA CVM Guidance 152

Hazard Identification (Characterization)

↓ Qualitative Risk Assessment

**Release Assessment**  
Probability that resistant bacteria are present in the target animal as a consequence of drug use  
**Rank as Low, Medium, or High**

**Exposure Assessment**  
Probability for humans to ingest the resistant bacteria in question from the relevant food commodity  
**Rank as Low, Medium, or High**

**Consequence Assessment**  
Probability that human exposure to resistant bacteria results in an adverse human health consequence  
**Rank as Important, Highly Important, Critically Important**

**Overall Risk Estimate**  
Integration of Release, Exposure and Consequence Assessments Rank as Low, Medium, or High

**Risk Estimation**

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### Risk Management Steps in GFI #152

Approval conditions	Category 1 (High)	Category 2 (Medium)	Category 3 (Low)
Marketing Status <sup>1</sup>	Rx	Rx/VFD	Rx/VFD/OTC
Extra-label use (ELU)	ELU Restrictions	Restricted in some cases <sup>2</sup>	ELU permitted
Extent of use <sup>2</sup>	Low	Low, medium	Low, medium, high
Post-approval monitoring (e.g., NARMS)	Yes	Yes	In certain cases
Advisory committee review considered	Yes	In certain cases <sup>3</sup>	No

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### Managing Resistance

AVMA guidelines and quality assurance programs in animals for the prudent use of antibiotics :

- Veterinarians and other health care experts establish a herd-management plan to help prevent diseases.
- Veterinarian-client-patient relationships strengthened to ensure proper medications are used.
- Ensure safe storage of animal health products
- Share the safest techniques for administering animal health products

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### Managing Resistance

Prudent Use Guidelines cont...

- Follow label instructions or specific off-label directions from the veterinarian.
- Develop tips for efficient record keeping to track usage
- Perform drug residue tests to ensure that trace levels of a drug have cleared an animal's system before it is sold as food; and
- Educate all farm personnel who are involved with animal health care on proper drug use

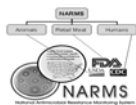
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## Managing Resistance

The Food and Drug Administration, the Centers for Disease Control and Prevention and the Department of Agriculture monitor levels of resistant foodborne pathogens in humans and animals:



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## What are we doing?

- AHI supports a strong science-based evaluation by FDA of the risks and benefits of antimicrobials.
- Risk assessment should be used to determine:
  - Rate of antibiotic resistance development
  - Transfer of antibiotic resistance through the food chain
  - Contribution of foodborne antibiotic resistant pathogens to antibiotic resistance disease in humans.
- AHI continues to support resources for NARMS and a new program (CAFHSE) under ARS, FSIS, and APHIS to examine antibiotic resistance and usage locally.

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## Examples of Risk Assessments

- Hurd, J.H. S.; S. Doores; D. Hayes; A. Mathew; J. Maurer; P. Silley; R. Singer; RN Jones. **Public Health Consequences of Macrolide use in Food Animals: A Semi-quantitative Risk Assessment.** *J. Food Protection* 2004; 67:980-992.
  - Examined the potential risks of using macrolide antibiotics (tylosin, tilmicosin) in selecting for resistant *Campylobacter* and *Enterococcus* bacteria that could cause resistant human illnesses.
  - Approximate annual probability of less than 1 in 10 million *Campylobacter*-derived and approximately 1 in 3 billion *E. faecium*-derived risk.

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## Examples of Risk Assessments

- Cox LA Jr, Popken DA. **Quantifying potential human health impacts of animal antimicrobial use: Enrofloxacin and macrolides in chickens.** *Risk Analysis* 2006;26(1):135-46.
  - Quantitative risk assessment of the likely human health impacts of continuing versus withdrawing use of fluoroquinolones and macrolides in production of broiler chickens in the United States
  - Suggests that withdrawing animal antibiotics can cause far more human illness-days than it would prevent because of increased illness rates in animals, microbial loads in servings from the affected animals, and hence human health risks.

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## Examples of Risk Assessments

- **Risk Assessment of Streptogramin Resistance in *Enterococcus faecium* Attributable to the Use of Streptogramins (virginiamycin) in Animals – FDA Center for Veterinary Medicine**  
[http://www.fda.gov/cvm/Documents/SREF\\_RA\\_FinalDraft.pdf](http://www.fda.gov/cvm/Documents/SREF_RA_FinalDraft.pdf)
- Definitive hazard could not be identified due to:
  - "...differences in the characteristics of resistant *E. faecium* isolated from animal and human sources, with respect to minimum inhibitory concentration (MIC) distributions and the presence of known resistance genes.

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## Streptogramin Risk Assessment

- Assuming a 10% attribution:
  - risk of acquiring resistant streptogramin-resistant *E. faecium* from a food pathway:
    - 6 to 120 chances in 100 million in one year for hospitalized patients
    - 0.7 to 14 chances in 100 million in one year for the general population
- Assuming a 100% attribution:
  - 60 to 1,200 chances in 100 million per person per year for hospitalized patients
  - 7 to 140 chances in 100 million per person per year for the general US population.

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# Panel: Responsible Antibiotic Use

## Antibiotics, Animal Agriculture, and the Deepening Health Crisis of Antibiotic Resistance

Richard Wood  
Food Animal Concerns Trust

### Responsible Antibiotic Use

The benefits of reducing antibiotic use in agriculture



Richard Wood

Executive Director, Food Animal Concerns Trust

### Keep Antibiotics Working

Coalition of 13 consumer, health, environmental, other NGOs

– 9 million total members

Mission

– End use of antibiotics important in human medicine as non-therapeutic feed additives



[www.KeepAntibioticsWorking.com](http://www.KeepAntibioticsWorking.com)

### Antibiotic resistance: an overview

- The inability to treat bacterial infections is a growing public health crisis
  - CDC: "a top concern"
  - Infants, elderly, immunosuppressed most vulnerable
  - Economic costs huge
- The more antibiotics are used, the worse the problem of antibiotic resistance
  - "The more you use 'em, the faster you lose 'em."



image credit: ImageVault

### Two Major Sources of Resistance



Use in human medicine



Use in animal agriculture

## Antibiotics in Human Medicine

- A major cause of antibiotic resistance in human pathogens
- Various efforts underway to promote more rational use of antibiotics by physicians and patients

## Antibiotics in Animal Agriculture

**Therapeutic Use:** Treat sick animals or those likely to get sick because of illness in the herd or flock

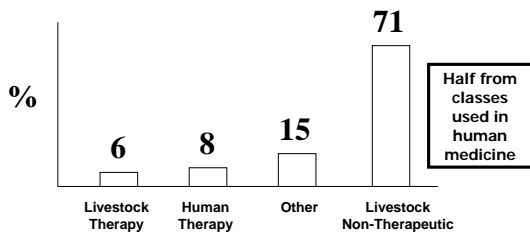


**Non-therapeutic Use:**

Generally added to feed, without a prescription and given on a routine basis

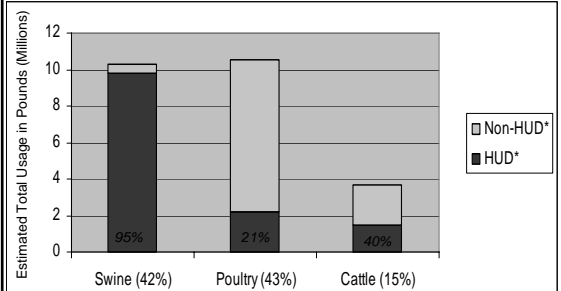
- Growth Promotion
- “Prophylaxis” – to prevent illness due to stress, transport, early weaning, overcrowding, etc.

## Estimated U.S. antimicrobial use



Source: Union of Concerned Scientists

## Non-Therapeutic Drug Use by Species



Source: UCS estimates

Species

\*HUD: Human Use Drug

## Medically important antibiotics used as non-therapeutic feed additives

Macrolides  
Penicillins  
Tetracyclines  
Streptogramins  
Aminoglycosides  
Lincosamides  
Sulfonamides

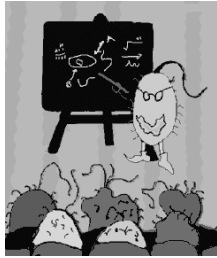


## Routes of Exposure



## Resistance transfer

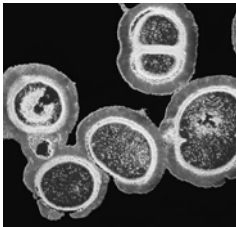
- Unlike higher organisms, bacteria can transfer genes to unrelated bacteria.
- Antibiotic resistance can spread quickly and widely among different types of bacteria.



## Multi-drug resistant cases decreasing?

- 1 in 5 human *Salmonella* infections resistant
- 1 in 5 *Campylobacter* infections resistant to Ciprofloxacin
- 2 in 5 resistant to tetracycline.
- Overall drops in resistance in human *Salmonella* track with drops in resistance in poultry isolates and documented reductions in antibiotic use by poultry producers.
- 3.4 million *Salmonella* and *Campylobacter* illnesses
- Cephalosporin resistance in *Salmonella* has risen from 0.2 to 3.4% in human isolates from 1996 to 2004

## Enter MRSA: A Dangerous New Bug



Methicillin-resistant *Staphylococcus aureus*

## MRSA cases tied to Dutch livestock

- Found in pigs, pig farmers, and their families.
- Located in areas with high concentrations of pigs and cows.
- Transmitted within hospitals and the community.



## MRSA cases tied to Dutch livestock

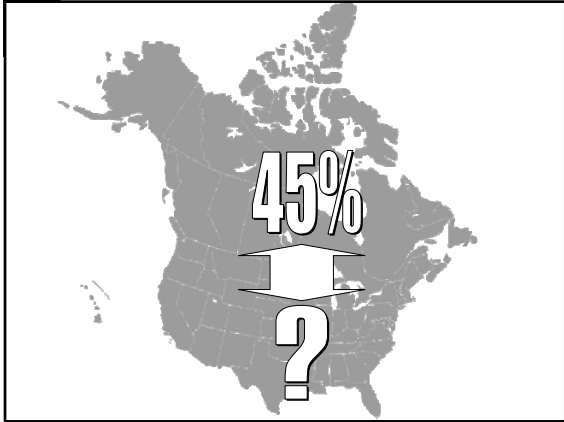


Pig strain of MRSA causes more than 20% of MRSA infections in the Netherlands

## MRSA found on Canadian farms



- 45% of pig farms
- 25% of pigs



### ST398 – How Prevalent in the US?

**APHIS**  
Veterinary Services  
Center for Laboratory and Research

**Info Sheet**

**Methicillin-resistant Staphylococcus aureus**  
A Growing Concern for Animal and Human Health

**Introduction**  
Methicillin-resistant Staphylococcus aureus (MRSA) is a multi-resistant pathogen. Having emerged first in hospitals, MRSA now occurs in many settings such as in the community, in long-term care facilities, and in animal health settings. Now MRSA is spreading to animal health settings.

**MRSA in Humans**  
If a person is a carrier of MRSA, they may have no symptoms and not know they are carrying it. However, MRSA can cause skin infections, abscesses, and other infections. MRSA can also cause more serious infections, such as pneumonia, bloodstream infections, and bone infections.

**MRSA in Animals**  
MRSA is carried by a host of animals ranging from wild to domestic. MRSA is found in the nasal passages and on the skin of many animals. MRSA is also found in the feces of many animals. MRSA is also found in the environment, such as in soil and water.

**MRSA in Food**  
MRSA is found in the meat of many animals. MRSA is also found in the milk of many animals. MRSA is also found in the eggs of many animals. MRSA is also found in the honey of many animals.

**VS**

**December 2011**

The evolution of MRSA and other drug-resistant pathogens has been linked to extensive antibiotic use in medicine and food animal production. MRSA strains have acquired resistance to the beta-lactam class of antibiotics, which includes penicillin and derivatives such as methicillin, oxacillin, and amoxicillin. Beta-lactam resistance is promoted by the mecA gene, which expresses a protein in the bacterial cell wall that has a weak affinity for beta-lactam antibiotics. Most MRSA

United States Department of Agriculture • Animal and Plant Health Inspection

### More action has been abroad and in the private sector

- 1999-2006: European Union phases out use of all antibiotics as growth promoters.
- June 2003: McDonald's adopts antibiotics policy.
- Dec. 2003: Bon Appétit adopts antibiotics policy.
- Aug. 2005 Compass Group USA adopts antibiotics policy

**Dinner is Drug-Free**  
Pressured by environmentalists, food chains are pushing suppliers to slash antibiotics use

### What is happening in Denmark?

- The goal to reduce a reservoir of antimicrobial resistant bacteria has been accomplished.
- The ban occurred with insignificant animal health impacts.
- Increased therapeutic treatment numbers due to increase in herd size & new disease pressures - PRRS and circoviruses.

**CDC** Department of Health and Human Services  
Centers for Disease Control and Prevention

**Scientists agree:**

*Limit the use of medically- important antibiotics in healthy farm animals*

### Commission on Industrial Farm Animal Ag

Antimicrobial Resistance Life-threatening bacteria are becoming more dangerous and drug resistant because of imprudent antibiotic use in humans as well as animals, yet the federal government response to protect the efficacy of these drugs has been limited.

Health experts are concerned about the approval of drugs from this class of medicines for animal use because they are one of the last defenses against many grave human infections.

## Commission Recommendations

Recommendation #1. Restrict the use of antimicrobials in food animal production to reduce the risk of antimicrobial resistance to medically important antibiotics.

- a. Phase out and ban use of antimicrobials for nontherapeutic
- b. Immediately ban any new approvals of antimicrobials for nontherapeutic uses in food animals and retroactively investigate antimicrobials previously approved.

Recommendation #2. Clarify antimicrobial definitions to provide clear estimates of use and facilitate clear policies on antimicrobial use.

## Needed Next Steps

- Federal policies to phase-out routine antibiotic use
- Implement data collection
- MRSA livestock & healthcare prevalence testing
- Research & Training to help farmers transition



## Thanks!



# Panel: Responsible Antibiotic Use

## Responsible Use of Antimicrobials

**Thomas J. Burkgren and Harry Snelson**  
American Association of Swine Veterinarians

### Responsible use of antibiotics

Tom Burkgren, DVM, MBA  
American Association of Swine Veterinarians

### Why does society care?

- Safe food
- Contamination of meat
  - Drug residues
  - Bacteria
- Antibiotic-resistant bacteria

### Antibiotic Resistance

- Complex issue
- Contentious issue
- Several stakeholders
- Proposed solutions
  - Voluntary
  - Regulatory
  - Legislative
- Unintended consequences of solutions

Responsible Use ≠ No Use



## Goals of Responsible Use

- Prevent violative drug residues
- Minimize the risk of antibiotic resistance
- Optimize the effectiveness of antibiotics
- Maintain the availability of antibiotics

## Responsible Use in Swine

- Pork Quality Assurance
- Judicious Use Guidelines
- Take Care – Use Antibiotics Responsibly

## Take Care – Use Antibiotics Responsibly™

- National Pork Board
- American Association of Swine Veterinarians

## Principles of Take Care – Use Antibiotics Responsibly™

- Decrease the need for antibiotics
- Assess all uses of antibiotics
- Use only if measurable benefits exist
- Implement management practices - Pork Quality Assurance
- Follow responsible use guidelines

## Responsible Use Guidelines

Use professional veterinary input as the basis for all medication decision-making

### Veterinary Input

- Valid veterinarian-client-patient relationship
- Latest information on antibiotic use
- Label instructions
- Withdrawal timing

Antibiotics should be used for treatment only when there is an appropriate clinical diagnosis

### Appropriate Clinical Diagnosis

- Clinical signs
- Herd history
- Necropsy
- Laboratory testing
  - Bacterial culture & sensitivity
  - Serology

Limit antibiotic treatment to ill or at-risk animals, treating the fewest animals indicated

### Treatment of ill or at-risk animals

- Morbidity & mortality
- Clinical history
- Individual or group treatment
- Preventative therapy
- Timing of therapy
- Responsible use

### Responsible Use

- Use antibiotics only when necessary
- Smallest number of animals feasible
- Least amount of time
  - Alleviate clinical symptoms
  - Prevent reoccurrence
- Balance with need to preserve animal health & welfare

Antibiotics that are important in treating antimicrobial-resistant infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification

Mixing together medications may be counterproductive

Minimize environmental exposure through proper handling and disposal of animal health products, including antibiotics

### Conclusion

- Shared responsibility for responsible use of antibiotics
- Heightened attention of the public
- Demonstration of concern through voluntary action
- Swine veterinarians & pork producers take the risk seriously



THANK YOU!

# NOTES