



**Statement by Robert P. Martin, Senior Officer
The Pew Environment Group
July 13, 2009
United States House of Representatives Committee on Rules

Hearing on H.R. 1549,
Preservation of Antibiotics for Medical Treatment Act**

Good afternoon Madame Chair and members of the Rules Committee. My name is Robert P. Martin and I am a senior officer at The Pew Environment Group. Prior to my current position at The Pew Environment Group, I was the Executive Director of the Pew Commission on Industrial Farm Animal Production (PCIFAP). I appreciate the opportunity to appear today.

The Pew Commission on Industrial Farm Animal Production was an independent commission funded by a grant from The Pew Charitable Trusts to the Johns Hopkins Bloomberg School of Public Health to investigate the problems associated with industrial farm animal production (IFAP) operations and to make recommendations to solve them. Fifteen Commissioners with diverse backgrounds began meeting in March of 2006 to start their evidence-based review of the problems caused by IFAP. I am attaching a list of the Commissioners with my statement.

Over the next two years, the Commission conducted 11 meetings and received thousands of pages of material submitted by a wide range of stakeholders and interested parties, including the animal agriculture industry. Two public hearings were held to hear from the general public with an interest in IFAP issues. Approximately 400 people attended those hearings. Eight technical

reports were commissioned from leading academics to provide information in the Commission's areas of interest. In addition, more than 170 peer-reviewed, independent academic studies were reviewed. The Commissioners themselves brought expertise in animal agriculture, public health, animal health, medicine, ethics, and rural sociology to the discussion. In addition, the Commission visited broiler, hog, dairy, egg, and swine IFAP operations, as well as a large cattle feedlot.

The Commission's findings make it clear that the present system of producing food animals in the United States is not sustainable and presents an unacceptable level of risk to public health, damage to the environment, as well as unnecessary harm to the animals we raise for food. In addition, the current system of industrial food animal production is detrimental to rural communities.

The Commission released its full report on April 29, 2008, that included 24 primary recommendations. The Commission was so concerned about the indiscriminate use of antibiotics in food animal production, and the potential threat to public health, that five of those recommendations deal with antibiotic use. The top two public health recommendations call for the end on the non-therapeutic use of antibiotics in food animal production and set strict definitions for their use. Those recommendations follow.

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 non-therapeutic (i.e. growth promoting) use in food animals¹ (see PCIFAP definition of "non-therapeutic").

¹ The PCIFAP defines non-therapeutic as any use of antimicrobials in food animals in the absence of clinical disease or known (documented) disease exposure; i.e. any use of the drug as a food or water additive for **growth**

- b. Immediately ban any new approvals of antimicrobials for non-therapeutic uses in food animals² and retroactively investigate antimicrobials previously approved.
- c. Strengthen recommendations in FDA Guidance #152 which requires the FDA determine that the drug is safe and effective for its intended use in the animal prior to approving an antimicrobial for a new animal drug application.
- d. To facilitate reduction in IFAP use of antibiotics and educate producers on how to raise food animals without using non-therapeutic antibiotics, the USDA's extension service should be tasked to create and expand programs that teach producers the husbandry methods and best practices necessary to maintain the high level of efficiency and productivity they enjoy today.

Background

In 1986 Sweden banned the use of antibiotics in food animal production except for therapeutic purposes and Denmark followed suit in 1998. A WHO (2002) report on the ban in Denmark found that “the termination of antimicrobial growth promoters in Denmark has dramatically reduced the food animal reservoir of enterococci resistant to these growth promoters, and therefore reduced a reservoir of genetic determinants (resistance genes) that encode antimicrobial resistance to several clinically important antimicrobial agents in humans.” The report also determined that the overall health of the animals (mainly swine) was not affected and the cost to producers was not significant. Effective January 1, 2006, the European Union also banned the use of growth-promoting antibiotics (Meatnews.com, 2005).

promotion, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other “routine” use as non-therapeutic.

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promotion, feed efficiency, weight gain, disease prevention in the absence of documented exposure or any other “routine” use as non-therapeutic.

In 1998, the National Academy of Sciences (NAS) Institute of Medicine (IOM) noted that antibiotic-resistant bacteria increase U.S. health care costs by a minimum of \$4 billion to \$5 billion annually (IOM, 1998). A year later, the NAS estimated that eliminating the use of antimicrobials as feed additives would cost each American consumer less than \$5 to \$10 per year, significantly less than the additional health care costs attributable to antimicrobial resistance (NAS, 1999). In 2005, Tufts University estimated that antibiotic resistant infections added \$50 billion annually to the cost of health care in the United States. In a 2007 analysis of the literature, another study found that a hospital stay was \$6,000 to \$10,000 more expensive for a person infected with a resistant bacterium as opposed to an antibiotic-susceptible infection (Cosgrove *et al*, 2005). The American Medical Association, American Public Health Association, National Association of County and City Health Officials, and National Campaign for Sustainable Agriculture are among the more than 300 organizations representing health, consumer, agricultural, environmental, humane, and other interests supporting enactment of legislation to phase out non-therapeutic use in farm animals of medically important antibiotics and calling for an immediate ban on antibiotics vital to human health.

The Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA) amends the Federal Food, Drug, and Cosmetic Act to withdraw approvals for feed-additive use of seven specific classes of antibiotics³—penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides—each of which contains antibiotics also used in human medicine (2009a). PAMTA provides for the automatic and immediate restriction of any other antibiotic used only in animals if the drug becomes important in human medicine, unless FDA determines that such use will not contribute to the development of resistance in

³ Fluoroquinolones are approved in animals only for therapeutic use (not for non-therapeutic use), and thus are not covered under PAMTA.

microbes that have the potential to affect humans. FDA Guidance #152 defines an antibiotic as potentially important in human medicine if FDA issues an Investigational New Drug determination or receives a New Drug Application for the compound (2009a).

Most antibiotics currently used in animal production systems for non-therapeutic purposes were approved before the Food and Drug Administration (FDA) began giving in-depth consideration to resistance during the drug approval process. The FDA has not established a schedule for reviewing existing approvals, although Guidance #152 notes the importance of doing so. Specifically, Guidance #152 sets forth the responsibility of the FDA Center for Veterinary Medicine (CVM), which is charged with regulating antimicrobials approved for use in animals: “prior to approving an antimicrobial new animal drug application, FDA must determine that the drug is safe and effective for its intended use in the animal. The Agency must also determine that the antimicrobial new animal drug intended for use in food-producing animals is safe with regard to human health (FDA-CVM, 2003).” The Guidance also says that “the FDA believes that human exposure through the ingestion of antimicrobial-resistant bacteria from animal-derived foods represents the most significant pathway for human exposure to bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals.” However, it goes on to warn that the “FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, the guidance describes the Agency’s current thinking on the topic and should be viewed only as guidance, unless specific regulatory or statutory requirements are cited. The use of the word ‘should’ in Agency guidance means that something is suggested or recommended, but not required” (FDA-CVM, 2003).

The Commission believes that the “recommendations” in Guidance #152 should be made legally enforceable and applied retroactively to previously approved antimicrobials. Additional funding for FDA is required to achieve this recommendation. If any reviews of antibiotic use under Guidance #152 have been conducted by the Center for Veterinary Medicine, the results of the review should be released immediately.

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

- a. The Commission defines as *non-therapeutic*⁴ any use of antimicrobials in food animals in the absence of microbial disease or known (documented) microbial disease exposure; thus, any use of the drug as an additive for growth promotion, feed efficiency, weight gain, routine disease prevention in the absence of documented exposure, or other routine purpose is considered non-therapeutic.⁵
- b. The Commission defines as *therapeutic* the use of antimicrobials in food animals with diagnosed microbial disease.
- c. The Commission defines as *prophylactic* the use of antimicrobials in healthy animals in advance of an expected exposure to an infectious agent or after such an exposure but before onset of laboratory-confirmed clinical disease as determined by a licensed professional.

Background

In 2000 the WHO, United National Food and Agriculture Organization (FAO), and World Organization for Animal Health (OIE, *Fr.* Office International des Épizooties) agreed on definitions of antimicrobial use in animal agriculture based on a consensus (WHO 2000). Government agencies in the United States, including the USDA and FDA, govern aspects of

⁴ For the Commission’s recommendations, the members considered many definitions; a complete list of sources is in Appendix 1.

⁵ This definition is adapted from PAMTA 2007.

antimicrobial use in food animals but have varying definitions of such use. Consistent definitions should be adopted for the use of all U.S. oversight groups that estimate types of antimicrobial use and for the development of law and policy. The Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA) defines non-therapeutic use as “any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose (2009a).” If the bill becomes law, this will be the legal definition of non-therapeutic use for all executive agencies and therefore legally enforceable.

The Danish Experience

In 1998, Denmark banned the use of antibiotics as growth promoters. Now, after 11 years of data are available, an updated assessment of the impacts of that ban will be published in the Journal of the American Veterinary Medical Association (JAVMA) later this year. It is important to understand the results of the ban on antibiotics used for growth promotion in Denmark, presently the European nation with the largest swine production, to have an idea of what would happen in the United States if a ban were implemented.

The Danish study is titled, *Use of Antimicrobials in the Danish Swine Production, 1992-2007; The Meat of the matter and Lesson Learned*. The primary author of the study, Dr. Frank Aarestrup of the National Food Institute of the Technical University in Denmark, has met recently with United States producers at a conference at Kansas State University to discuss the findings of his team.

- The United States leads the world in the use of antibiotics in food animal production, whether you use estimates from the Animal Health Institute or the Union of Concerned Scientists, according to Dr. Aarestrup. (Figure 1)
- Once the growth promotion ban was instituted in 1998, therapeutic use rose slightly from 1999 until 2003, but has leveled off since 2003. However, the total amount of antibiotics used post-ban is less than half the amount used in 1992 and the lower than the total amount used each year from 1992 to 1999. (Figure 2)
- Mortality in weaners increased for a brief time post ban and weight gain declined in the same period. However, according to a conversation I had with the study's author, mortality rates declined and weight gain recovered once production practices were improved, including better ventilation in the barns, more space provided for the animals, and more frequent cleaning of the barns. (Figures 3 and 4)
- The numbers of piglets per sow increased post-ban. (Figure 5)
- Mortality in finisher pigs increased slightly post-ban but declined significantly in 2006 and 2007 following improvement in production practices such as improved ventilation in barns and improved waste handling and barn cleaning; growth of finishers remained steady post-ban, with the daily gain on finisher pigs increasing post-ban. (Figure 6)

General conclusions from the Danish Study

- Total antimicrobial consumption in swine has been reduced from 100 mg /kg to 49 mg/kg from 1992 to 2008.
- Limited (if any) long term effect on overall productivity.
- Decrease in antimicrobial resistance has followed reduced use.

The Pew Commission on Industrial Farm Animal Production made our recommendations in an effort to stem the advance of antibiotic resistance. It has been shown that antibiotics once rendered ineffective due to overuse can become effective again once that overuse is stopped. It is important to note that the Pew Commission never advocated ending all antibiotic use in food

animal production. Such a recommendation would be irresponsible. We did seek to maintain the effectiveness of antibiotics to treat sick animals by limiting the routine use.

Madame Chair, I commend you for introducing this important legislation and for conducting this hearing today. The increase in bacterial antibiotic resistance, and the inappropriate use in food animal production, is a serious—if silent—threat to our public health.

Thank you.

Figure 1
Dr. Frank M. Aarestrup, Director
National Food Institute
Technical University of Denmark

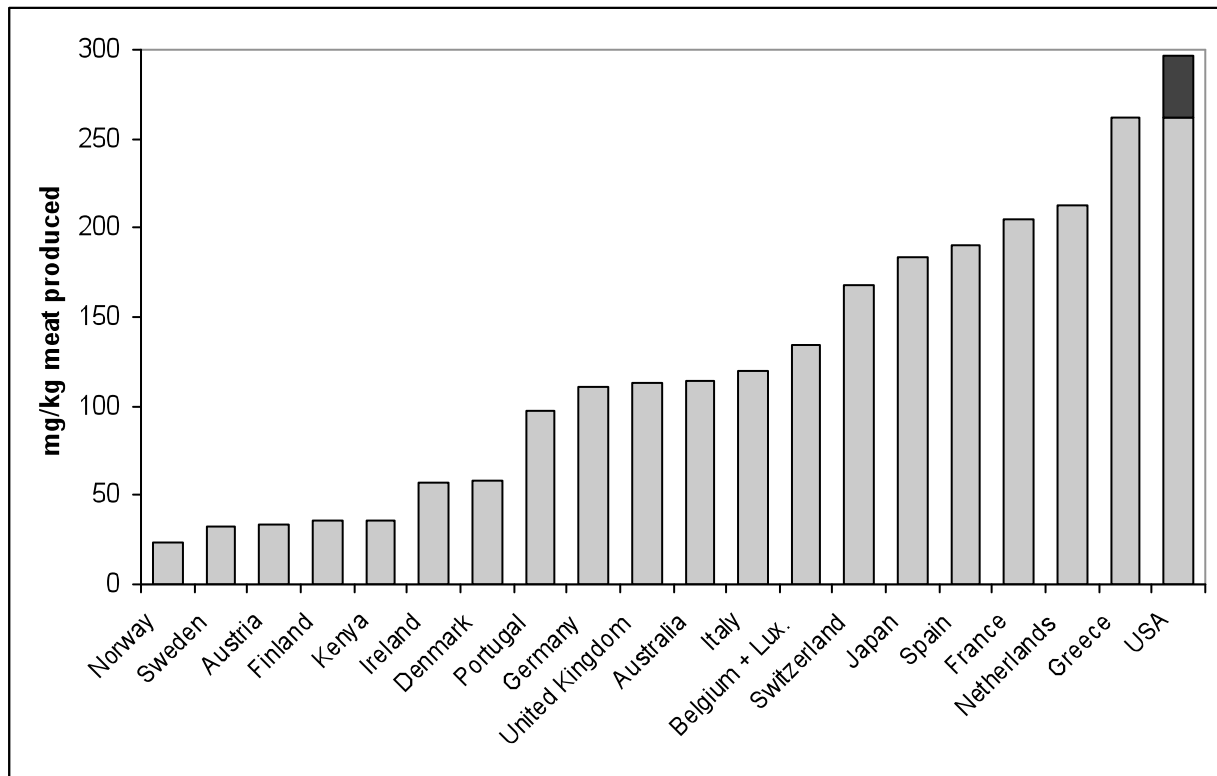
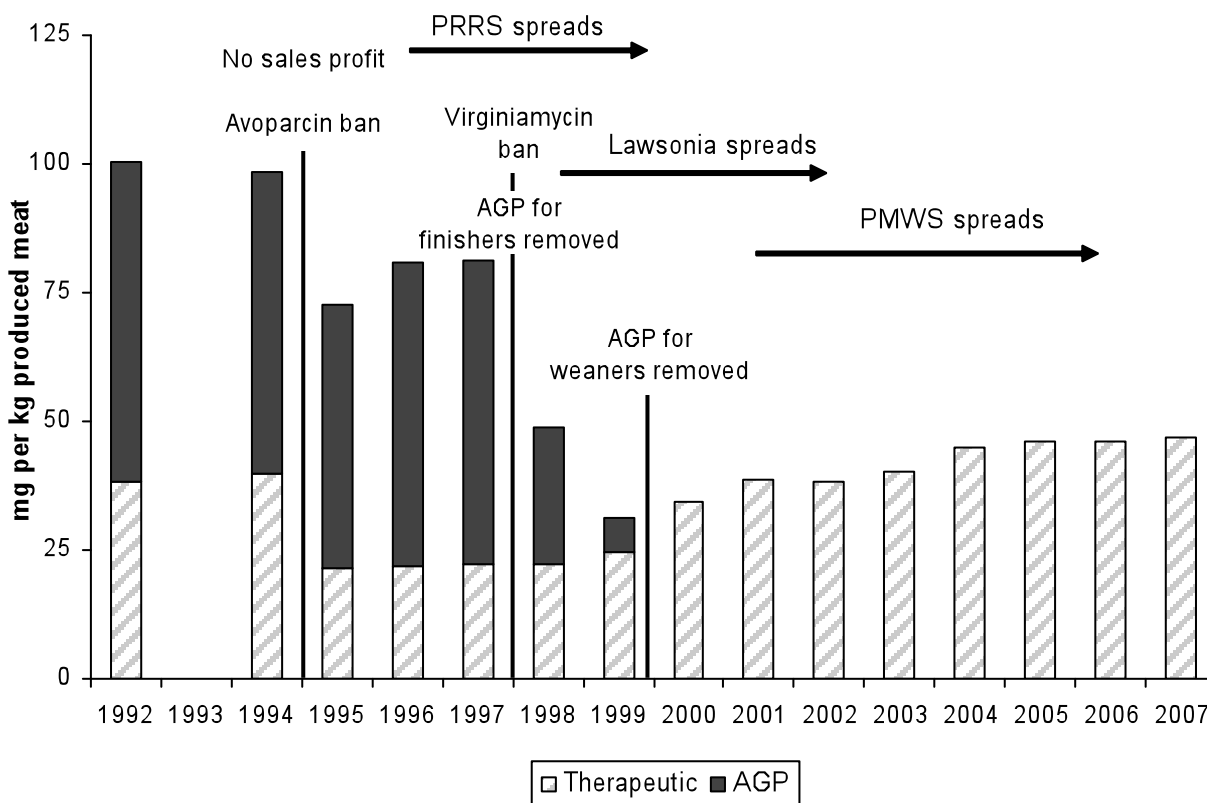


Figure 2
 Dr. Frank M. Aarestrup, Director
 National Food Institute
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Board (Callesen, 2002).

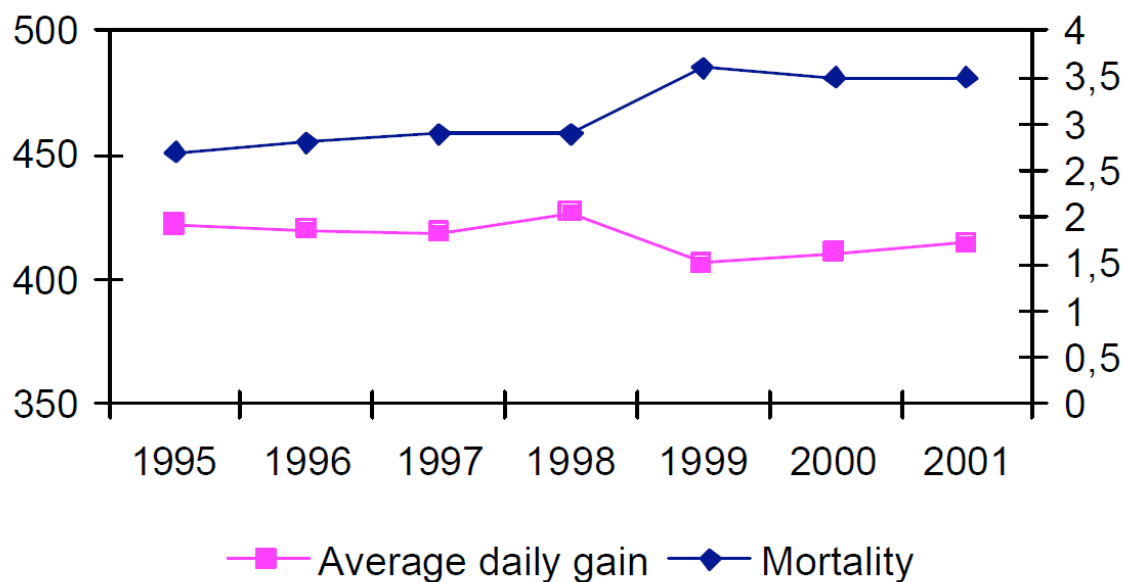


Figure 32. Productivity in Weaners: Danish Pork Board (Callesen, 2002).

Figure 4
 Dr. Frank M. Aarestrup, Director
 National Food Institute
 Technical University of Denmark

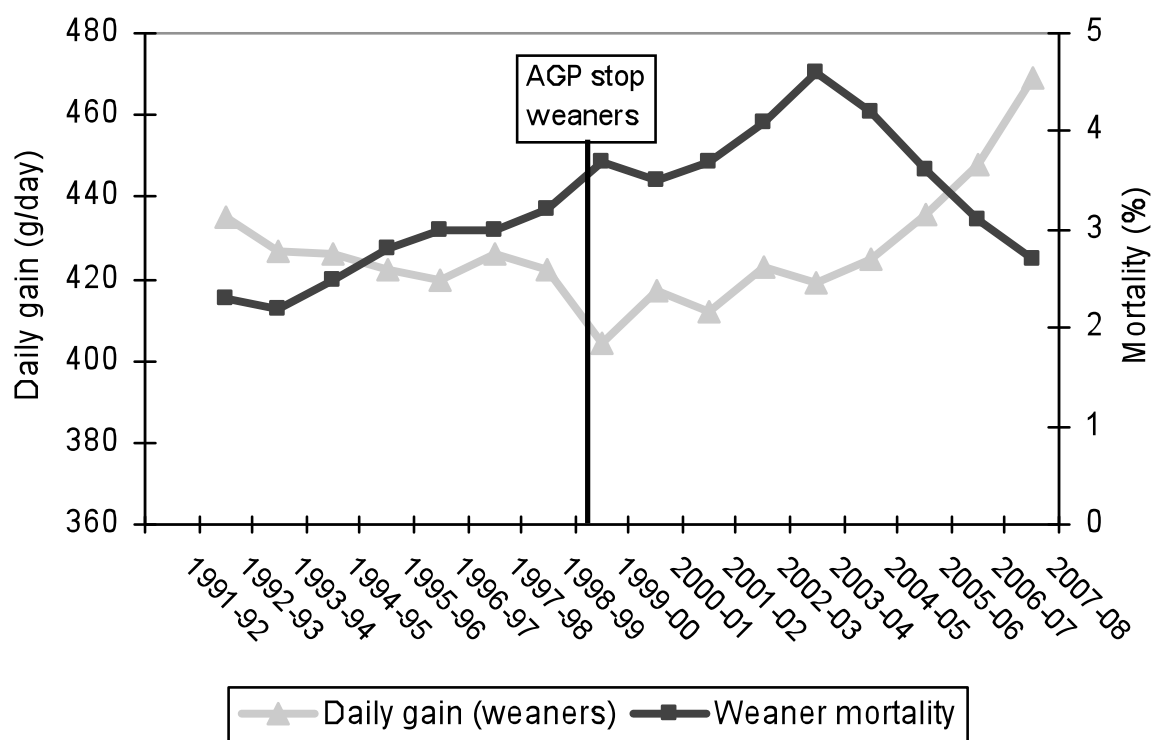


Figure 5
Dr. Frank M. Aarestrup, Director
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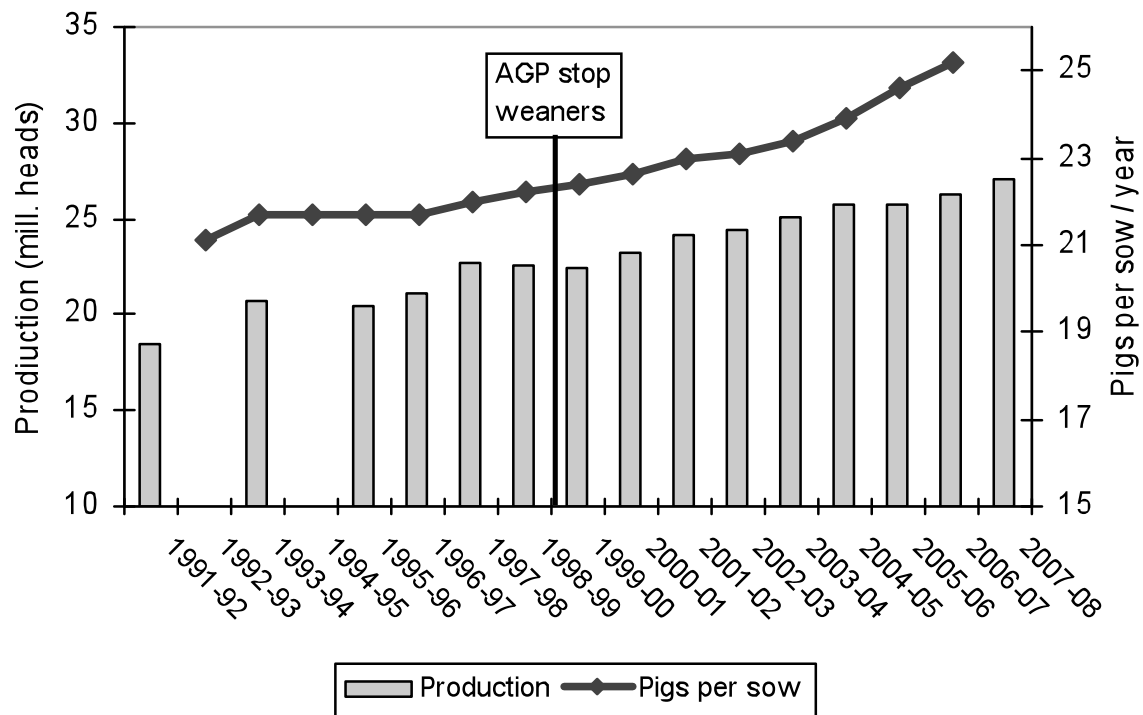
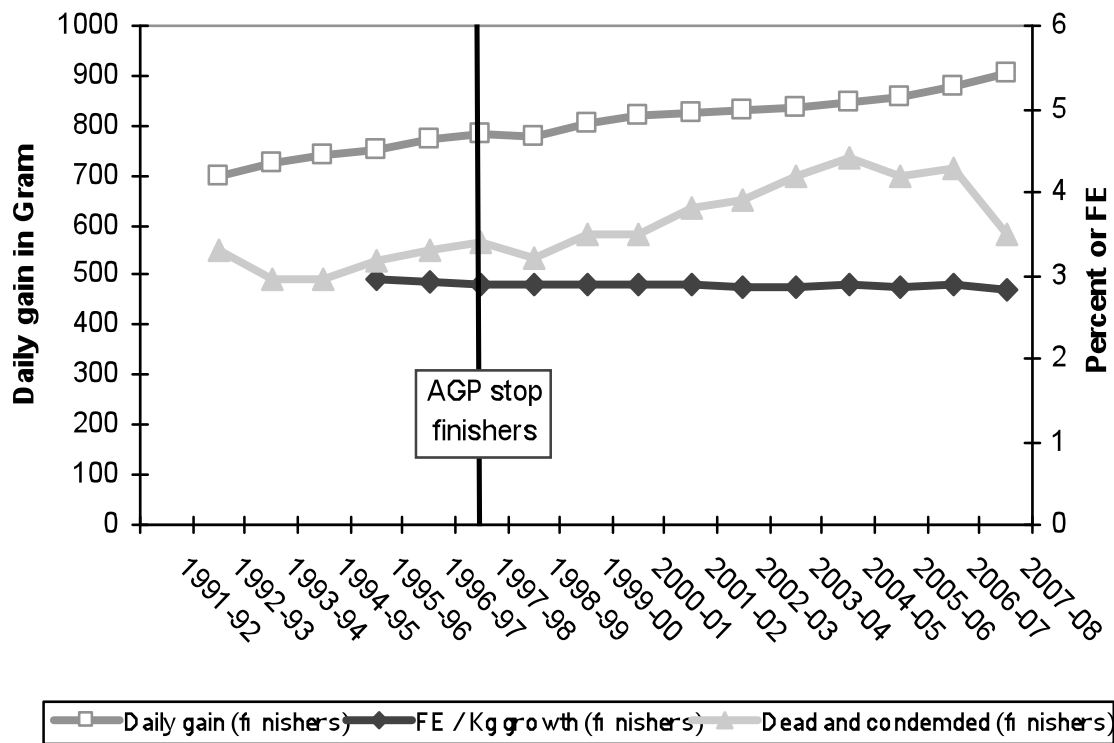


Figure 6
 Dr. Frank M. Aarestrup, Director
 National Food Institute
 Technical University of Denmark





PEW COMMISSION ON INDUSTRIAL FARM ANIMAL PRODUCTION

The Pew Commission on Industrial Farm Animal Production (PCFIAP) was a two-year study funded by The Pew Charitable Trusts through a grant to Johns Hopkins Bloomberg School of Public Health.

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