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# Ongoing lessons from Danish ‘experiments’

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The Danish pork industry has earned a reputation as an international leader in pork production and marketing. Among pork exporting nations, Denmark is widely perceived as a quality supplier, and trends in Danish industry are closely monitored by all nations aspiring to compete in the international marketplace for pork. During the 1990’s two initiatives involving the Danish pork industry drew more than the usual international attention. These were the Danish National *Salmonella* control and surveillance program implemented in 1995<sup>1</sup>, and regulatory changes related to the availability and use of antimicrobials in food animal production, most notably the banning of antimicrobials for use as growth promotants. Although Sweden had previously implemented programs to address these issues, they generated relatively minor interest. However Denmark’s status as a major meat exporting nation, and timing in relation to other international developments (e.g., HACCP/Pathogen Reduction Act in 1996 in the USA; increased WHO emphasis on antimicrobial resistance in the late 1990’s), made the Danish initiatives a focus of discussion. Both have been broadly promoted as models that should be implemented in other developed nations.<sup>2,3</sup> The Danish initiative to ban in-feed antimicrobial use for growth promotion catalyzed European regulations to ban growth promotants completely by 2006. In the USA, initial enthusiasm (or not) for these programs was predictably driven by established opinions among different sectors of the scientific and general community. However, the Danish penchant for detailed data collection and analysis provides an evolving resource for evaluating the outcomes of these interventions. As data continue to accumulate on the long-term impacts of these programs, assessment of the Danish experiments should be regularly updated, giving increasing weight to the body of evidence rather than to entrenched opinions and expectations.

## The Danish *Salmonella* Control Program for Swine

This program commenced in 1995 in response to a large outbreak of human salmonellosis associated with pork contaminated with *S. Infantis*.<sup>1</sup> Compared with the pre-existing Swedish *Salmonella* control program, the Danish program had several distinguishing features:

- It focused on control rather than elimination of *Salmonella*
- It employed serological rather than bacteriological testing (giving greater weight to specific serotypes of *Salmonella*)
- It targeted a small proportion of high risk herds for on-farm intervention, rather than all herds
- It gave less emphasis to controlling *Salmonella* in feed

In parallel with implementing the program, Danish and other European researchers have conducted considerable research to attempt to unravel the epidemiology of *Salmonella* and refine this approach to control.<sup>4,8</sup> A 2003 review of Danish *Salmonella* control programs reported positive outcomes for both poultry and swine, and estimated a benefit to cost ratio of 3 for the swine program.<sup>2</sup> However, this program included both preharvest (interventions on high risk farms) and post-farm (improved slaughter hygiene) components, and the relative importance of these respective elements was not determined. The considerable operating costs of this project (particularly the monthly testing of herd *Salmonella* seroprevalence) have prompted more detailed analysis of the contributions of the preharvest and post farm components of the program.<sup>9</sup> The authors concluded that apart from the first years of the project (1994-1998), the on-farm components made minimal contribution to reducing the incidence of positive carcasses or the numbers of human cases attributable to pork. Most of the benefits (but not the costs) attained from the program were attributed to improvements in slaughter hygiene. The evident explanation for this observation relates to the relative scope and efficacy of the on-farm and post farm interventions. The preharvest component has no impact on the vast majority of herds, as interventions are implemented only on a small minority of herds classified at high risk based on serological testing.<sup>1,4</sup> Moreover, although it is clear that the on-farm interventions have some impact on reducing prevalence within high risk herds, these effects are far from absolute. The large majority of herds classified as low risk (and not impacted by the preharvest interventions) still harbor *Salmonella* and indeed contribute the bulk of the *Salmonella* load entering the slaughtering facilities.<sup>9</sup> In contrast, the post-harvest interventions to re-

duce carcass contamination have broad scope (theoretically reducing risk across the entire industry) and have more direct impact on product safety by targeting contamination of product. Some recommendations from this analysis are:

- ‘Consider a limited or reduced investment in on-farm control; just enough to maintain the current infection status
- Carefully consider the significant variation and measurement error in the overall system being managed, to avoid short term overcorrection
- Remain open to new on-farm technologies that may make *Salmonella* control more cost-effective<sup>9</sup>

A series of ongoing studies of the costs and benefits of the Danish *Salmonella* Program in swine are scheduled for presentation at the 2005 SafePork conference in California. Notably, following their own assessments of the data, the Danish swine industry intends to target further control efforts for enteric foodborne pathogens entirely in the harvest and post-harvest sectors (Dahl J, personal communication, 2005). The long-term lesson emerging from the Danish experience appears to be that, in the absence of substantial advances in knowledge and technology for preharvest interventions, investment in preharvest control of *Salmonella* remains inefficient and resources are more effectively directed to control *Salmonella* contamination of pork in post-farm sectors of the pork supply chain.

## Antimicrobial use and resistance – more of the story!

The volume of literature generated in relation to the Danish and European bans on antimicrobial growth promotants is hard to keep pace with. It is self evident that competing costs and benefits are associated with the use of antimicrobials in food animal production, and opinions are polarized regarding their magnitudes (and associated uncertainty). Although the debate has concentrated on ‘non-therapeutic’ or ‘growth promotant’ (GP) use, I would argue that aggregate use is probably the most ecologically relevant measure. A typical stance of supporters of a GP ban is provided by Wegener (2003): ‘Routine use of antimicrobials in food-animals for growth promotion constitutes a serious public health problem, especially in the case where the same classes of antimicrobials are being used in humans. Growth promoter use creates a major food animal reservoir of resistant bacteria, with a potential for spread to humans by food intake or by animal contact. Recent experience from a number of European countries shows that the use of antimicrobials for growth promotion provides insignificant benefits to agriculture and that it can be terminated. Ending the use of antimicrobial growth promoters has led to reductions in the prevalence of resistant bacteria in food and food animals,

as well as in humans, in the countries where this has happened.’<sup>10</sup>

As an example from the other corner, I quote Philips et al., 2004: ‘The use of antibiotics in food animals selects for bacteria resistant to antibiotics used in humans, and these might spread via the food to humans and cause human infection, hence the banning of growth-promoters. The actual danger seems small, and there might be disadvantages to human and to animal health. The low dosages used for growth promotion are an unquantified hazard. Although some antibiotics are used both in animals and humans, most of the resistance problem in humans has arisen from human use. Resistance can be selected in food animals, and resistant bacteria can contaminate animal-derived food, but adequate cooking destroys them. How often they colonize the human gut, and transfer resistance genes is not known.’ ‘Even if resistant pathogens do reach man, the clinical consequences of resistance may be small.’<sup>11</sup>

Without attempting to dissect these opinions, instead I return to the Danish data as arguably the best source of understanding of what is happening, concentrating on 3 aspects – trends in antimicrobial use in food animal production; trends in antimicrobial resistance of *E.coli* in pigs; and regulation of veterinary activities in pig production in Denmark.

### Trends in antimicrobial use

The data illustrate that the lowest year for aggregate antimicrobial use occurred in 1999, prior to the banning of GP use in nurseries (Figure 1). The upward trend in therapeutic has clearly continued, and aggregate antimicrobial use in food animals again exceeds that of 1998. In comparison with 2003, in 2004 total antimicrobial use in pigs increased over 13% while production increased less than 3%. The increase was greatest in weaners (19%), compared with finishers (12%) and sows/suckling piglets (5%).<sup>12</sup> Anecdotal reports continue to support the view that removal of GP from finishing farms generally was not problematic in terms of animal health and production.<sup>13</sup> However, the marked and continuing increase in antimicrobial consumption in weaned pigs, despite substantial changes in production including increases in weaning age, raises further questions about the effect of the ban in this most vulnerable age-group of pigs. Ongoing problems with *Lawsonia intracellularis* infection have proven the most difficult challenge for veterinarians to manage.

### Trends in antimicrobial resistance of *E.coli* in pigs

One of the most contentious aspects of the antimicrobial debate is the public health threat posed by resistance determinants in commensal organisms of food animals (Figure 2). DANMAP has routinely monitored resistance in

Figure 1: Trends in antimicrobial use in humans and animals in Denmark, 1990 – 2004 (DANMAP, 2004)<sup>12</sup> (arrows indicate bans of growth promotants for finishers (F) and nursery (N))

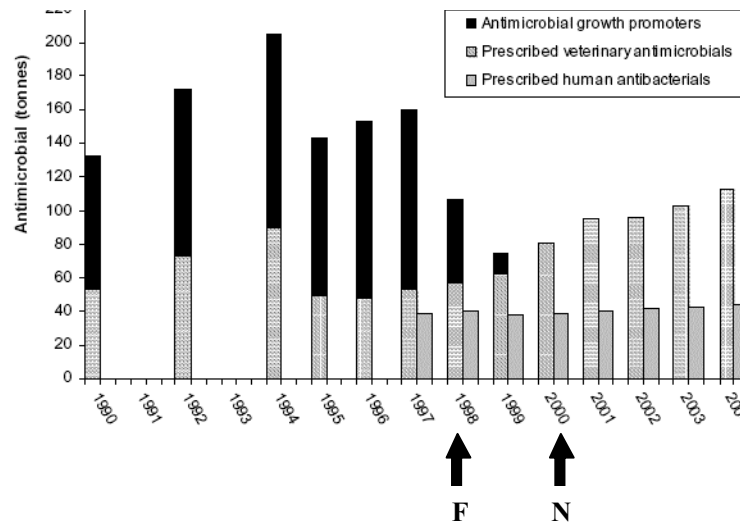
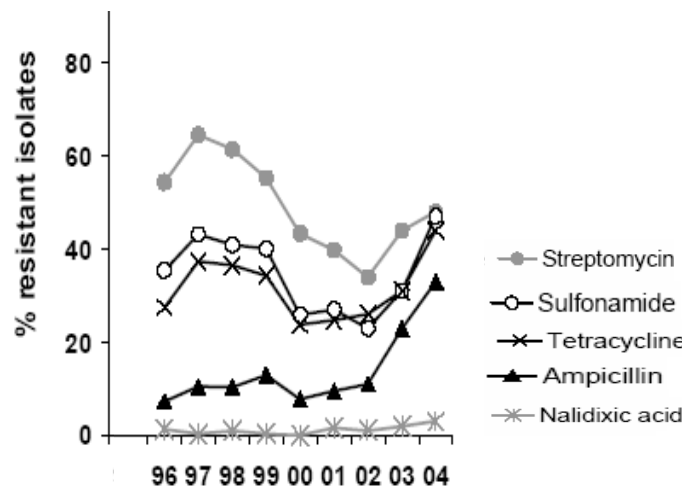


Figure 2: Trends in resistance to selected antimicrobials among *Escherichia coli* from pigs in Denmark (adapted from DANMAP, 2004)<sup>12</sup>



*E. coli* and enterococci isolated from food animals, and the data for *E. coli* are shown in Figure 2. Regardless of one's position on the magnitude of the public health threat posed by animal commensals as reservoirs of resistance genes, based on the 2004 DANMAP data it is hard to make a case that this reservoir has been materially reduced in swine *E. coli*, and particularly since the removal of GP from the nursery phase. On the contrary, resistance to all 5 antimicrobials, and particularly to ampicillin, has increased since 2000, in association with the increasing use of therapeutic antimicrobials in that period. So as the cloud of poorer animal health and welfare in nursery pigs seems to be growing darker, the silver lining of reducing the reservoir of resistance genes in swine populations is becoming harder to perceive.

### Veterinary oversight of pig production in Denmark

Wegener concluded that the use of GP provided 'insignificant benefits' to agriculture, a position endorsed by a WHO committee that reviewed the Danish data in November 2002.<sup>13</sup> However, the ongoing disease problems in weaned pigs (particularly ileitis) encountered following the 2000 GP ban (reflected in increasing therapeutic antimicrobial use), continues to raise questions about costs and benefits associated with the GP ban for weaned pigs. Without entering the murky waters of defining the point at which an increase in animal disease becomes 'significant', another question is how relevant the Danish data are to the North American industry.

While some may view the Danish GP bans to be worthy of replication without further analysis, for others the ex-

ternal validity of the Danish outcomes should not be ignored. Is the Danish GP experience informative for policy considerations in the USA; or with what confidence can the outcomes observed in Denmark (i.e. with animal health and production, resistance profiles in pathogens and commensals, and public health) be used to predict outcomes were the same interventions to be made in the USA? Rather than indulge in soothsaying, it is more useful to look at factors that might make the expectations different. With respect to animal health outcomes, I suggest that the most important, yet most overlooked, factor is the pre-existing regulatory structures governing veterinary prescribing in the respective countries. Assuming readers are familiar with US regulations, Danish regulations are described in Appendix 1,<sup>14</sup> with some selected passages are listed below

- The veterinarian may only hand out or prescribe antibiotics and chemotherapeutics for the farmer's continued treatment of diseased animals, except for adult cattle, for a maximum of 5 days.
- Farmers with herds of cattle or pigs may sign a voluntary contract for health consultancy with a named veterinarian. If such a contract has been agreed upon and has been registered by the regional veterinary officer, it is mandatory for the veterinarian to visit cattle herds at least 12 times a year, whereas 12 consultations a year, of which 6 must be farm visits, are mandatory for pig herds. The aim of such health consultancy is to improve the general health status of the herd, to decrease the risk of disease agents to cause disease, and to optimize the use of antibiotics to reduce the risk of developing bacterial resistance. On the above mentioned conditions the veterinarian may prescribe antibiotics and chemotherapeutics for the following 35 days for pigs and for calves less than one year old, if the necessity for further treatment has been established during a visit, if the reason for further treatment is described, and if initiatives have been agreed upon with the owner in order to solve the problem.<sup>14</sup>

Fully implemented after 1994, the regulations removed financial incentives for veterinarians to sell antimicrobials to farmers, and specifically mandated monthly 'herd health' visits to all production sites, thus minimizing the impact of the regulatory changes on the veterinary profession while aiming to motivate a more preventive actions. The noticeable drop in therapeutic usage in 1995 (Figure 1) is probably directly attributable to this change, but since the GP bans therapeutic usage has increased from a low point of 48 tons in 1996 to 101 tons in 2003.<sup>15</sup> This stipulation of regular herd health visits to underpin prescription of veterinary medicine was in place for about 3 to 5 years prior to the removal of GP from finishing or nursery pigs in Denmark. If one promotes the banning of

GP use in the USA based in part on the contention that the animal health impact of the GP bans in Denmark has been 'insignificant',<sup>10</sup> it is not prudent to ignore the fact the bans were imposed on swine populations following a period of more intensive veterinary oversight than exists in the current US industry. While the veterinary-client-patient relationship plays a central role in veterinary prescription drug use in the USA, it places much less stringent demands on veterinary oversight of production sites.

Finally, raising another point of interest to the wider veterinary profession, the Danish VETSTAT program also monitors antimicrobial use in companion animals.<sup>16</sup> An analysis of these data reported in the 2004 DANMAP report<sup>12</sup> points out that almost half of the total animal use of fluoroquinolones, and more than half that of cephalosporins, were used in companion animals. The authors discuss the implications of these data in the context of the relatively close contact between pets and owners, and suggest a need for more attention to be paid to companion animals as reservoirs of resistance.

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## Appendix 1: Danish Regulation of Veterinary Medicines: Distribution and use of veterinary medicine in Denmark, April 2003<sup>14</sup>

### Distribution

Danish legislation is designed to ensure that distribution of veterinary medicines takes place through authorized pharmacies. Since 1990, Danish veterinarians have no longer had the right to dispense.

Vitamins and certain ectoparasiticides and mineral complexes are non-prescriptive. Most other medicaments for veterinary use are prescription medicine.

All prescription-only medicine may be obtained only from a pharmacy or from a veterinarian. All veterinary products must be distributed to the veterinarian by a pharmacy. The veterinarian may hold stock of products obtained from a pharmacy and may on certain conditions supply products directly to the farmer, for the treatment of animals under his care. Feed mills which are subject to licensing and inspection can hold licensed premixes for the purpose of manufacturing medicated feed. Farmers may obtain medicated feed from feed mills on a veterinary prescription.

Veterinary vaccines may be distributed either by pharmacies or by the National Veterinary Institute.

Pet shops cannot sell veterinary drugs and wholesale distribution companies can only supply other wholesalers or pharmacies.

Some vitamins, iron complexes, and ectoparasitocidal medicaments are available from dealers having an authorization given by the Danish Medicines Agency to market these specific compounds.

Registration made by the veterinarian and by the pharmacy

Since mid-2000 it has been a requirement that any use or handing out of prescription-only drugs, including medicated feed, sera and vaccines, must be recorded by the veterinarian and reported to an official register called Vetstat. However there are exceptions for drugs used or handed out for treatment of horses and pet animals. Likewise, reporting to Vetstat is mandatory for pharmacies when handing out prescription-only drugs, and for feed-mills when handing out licensed food containing prescription-only drugs and coccidiostatics. For animal species used for agricultural production (except horses), reporting from the veterinarian includes information on the veterinarian responsible for the treatment, the drug prescribed, identification of the target herd, and the species (including age-group and disease-group) to be treated. For horses and pet animals reports are made only by the pharmacy.

Registrations made by the owner

Whenever a herd owner or his substitute uses registered drugs, recording is mandatory, regarding animals treated, drugs used, dates, reason for treatment, dosage and administration route, responsible person, and origin of drug (if not handed out by a veterinarian). Recording is not required for treatment with iron compounds, minerals or vitamin compounds for which no withdrawal period has been established. Registrations must be kept for 5 years.

### Restrictions

Veterinarians must use registered veterinary medical products for animals. If a registered product does not exist, a veterinarian may exceptionally for a single animal or for a small number of animals use, hand out or prescribe:

- a veterinary product registered for another species or for the same species but for another disease, or, if this does not exist,
- a registered medical product authorised for use against disease in man, or, if this does not exist,
- a compound prepared at a pharmacy after a prescription from a veterinarian (extemporaneous drug).

In accordance with EU-regulations a MRL (Maximum Residue Level) value must be established for the active substance of the drug used and for the animal species concerned.

Some substances may in general not be used. Thus stilbenes and thyreostatics and drugs containing those substances are totally prohibited. However thyreostatics may be used to treat cats or dogs with hyperthyroidism. The veterinarian must keep special registrations to show upon request from the regional Veterinary Officer.

Certain other substances are not allowed for animals used for production of meat or other products for human

consumption. Hormones and substances with hormone-like effect, including somatotropins are not allowed for use in production animals or fur animals for growth and yield promoting purposes.

Beta-agonists and substances with estrogenic, androgenic, and gestagenic effect are prohibited for use in production animals. However, in accordance with EU-regulations, registered drugs, with estrogenic, androgenic and gestagenic effect may be used in production animals for zootechnic or therapeutic purposes provided that a number of conditions are met. Likewise, beta-agonists and allyltrenbolone may be used in horses for specified therapeutic purposes.

Certain groups of medicaments are only permitted for treatment of animals provided that the treatment is performed by the veterinarian in person; no prescription or handing out is allowed. The below mentioned are such medicaments.

- Analgesics for injection including non-steroid anti-inflammatory drugs (NSAID) for injection.
- Anaesthetics for inhalation and injection.
- Euphoriant.
- Medicaments for injection containing Selenium.
- Direct-acting parasympathomimetics for injection.
- The following hormones and compounds with hormonal effect:
  - Adrenocorticotrophic hormones for injection.
  - Natural and synthetic adrenal cortex steroids for injection.
  - Beta-agonists for injection (beta-agonists for oral administration for therapeutic treatment of horses allowed under the responsibility of the veterinarian).
  - Oxytocine and analogous compounds for injection to enhance labour.
  - Progesterones and their derivatives for therapeutic and zootechnic use.
  - Prostaglandines and analogous compounds for injection.
  - Testosterones and derivatives hereof for therapeutic use (zootechnic use allowed only for fish under the responsibility of the veterinarian).
  - Estradiol 17 $\beta$  and derivatives hereof for therapeutic use and estrogens for zootechnic use.
- Fluoroquinolones for injection.
- Drugs registered for intravenous injection only (IV).

However, euphoriant may be handed out for peroral treatment of non-production animals. NSAIDs may be prescribed for clearly identified animals for use of until 5 days. In herds of calves or pigs with a voluntary contract for health consultancy, the veterinarian can prescribe NSAIDs for treating sick animals in the herd during the following 35 days. However, special requirements comparable to the requirements for prescribing antibiotics must be met.

#### Antibiotics

For antibiotics and chemotherapeutics some specific regulations are in force. Treatment of animals from which the products are used for human consumption may only take place, if the activity of the drugs is directed against existing diagnosed infections and aim at animal health. Veterinarians may only on special conditions supply or prescribe antibiotics and chemotherapeutics for use by the farmer, and the farmer must follow the advice and instructions given by the veterinarian. Instructions must be given in writing and must as a minimum comprise identification of target animals, diagnose, drug, dosage, clinical symptoms which must be present before treatment, withdrawal period, and administration route. The veterinarian may only hand out or prescribe antibiotics and chemotherapeutics for the farmer's continued treatment of diseased animals, except for adult cattle, for a maximum of 5 days.

Antibiotics or chemotherapeutics for use for not more than 35 days may be prescribed for poultry subject to public control, and for fur animals. For calves, lambs and kids less than 2 months old, antibiotic or chemotherapeutic tablets for not more than 35 days may be prescribed, if disease may be expected to spread in the herd. In any case, the prescribing veterinarian must make diagnosis during a farm visit.

Farmers with herds of cattle or pigs may sign a voluntary contract for health consultancy with a named veterinarian. If such a contract has been agreed upon and has been registered by the regional veterinary officer, it is mandatory for the veterinarian to visit cattle herds at least 12 times a year, whereas 12 consultations a year, of which 6 must be farm visits, are mandatory for pig herds. The aim of such health consultancy is to improve the general health status of the herd, to decrease the risk of disease agents to cause disease, and to optimize the use of antibiotics to reduce the risk of developing bacterial resistance. On the above mentioned conditions the veterinarian may prescribe antibiotics and chemotherapeutics for the following 35 days for pigs and for calves less than one year old, if the necessity for further treatment has been established during a visit, if the reason for further treatment is described, and if initiatives have been agreed upon with the owner in order to solve the problem. This must be re-

corded, together with the regular instructions for use of drugs handed out, as described above.

Furthermore, if a contract of health consultancy has been signed, antibiotics and chemotherapeutics may be prescribed or handed out to the owner for treatment of adult cattle for a 5-day period, or prescribed for one treatment of an infected mammary gland in dry cows. It is demanded, that the veterinarian in person has initiated the treatment.

Fluoroquinolones may only be used, handed out or prescribed for production animals for a maximum treatment period of 5 days, if it has been verified by laboratory examination that the agent causing disease is not sensitive to any other usable, permitted antibiotic or chemotherapeutic treatment. However, in case of acute disease, treatment with fluoroquinolones may be initiated before the result of the laboratory examination is known, but another drug must be used if the result shows other possibilities than fluoroquinolones. In any case of use of fluoroquinolones for production animals, the Regional Veterinary Officer must be informed within two weeks after termination of the treatment.

#### Withdrawal periods and control for residues

In all cases where antibiotics and chemotherapeutics or other drugs with a withdrawal period are administered to production animals - either by the veterinarian in person or by the farmer - the veterinarian must inform the farmer or his substitute about the withdrawal periods for the drugs used in order to avoid residues in meat from slaughter animals and in products (milk, eggs and honey) to be delivered for human consumption. Such information must be given verbally and in writing, and the veterinarian must keep a copy for at least 5 years.

Meat, poultry meat, milk and eggs from treated animals are not allowed to be used for human consumption during the fixed withdrawal time. If animals are delivered for emergency slaughter within the withdrawal period, the information regarding the withdrawal period, as described above, must accompany the animal to the slaughterhouse.

Danish provisions specifying the that it is prohibited to deliver animals for slaughter, or to deliver meat, milk, eggs, fish, honey or other animal products for consumption, if they contain residues of a drug in an amount which exceeds the MRL-value established in the valid EU-provisions, or if they contain residues from illegal treatment. Likewise it is prohibited to manufacture and or sell meat or products for human consumption, if they contain residues exceeding the MRL-values.

Suspected violations of the provisions described will be punished with an administrative fine or reported to the police.

As required in EU-provisions control for residues is performed in accordance with an annual residue plan. Furthermore, veterinarians and farmers are subject to control by the Regional Veterinary Officer.

