

Reducing and Phasing Out the Use of Antibiotics and Hormone Growth Promoters in Canadian Agriculture

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April 2009

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Table of Contents

1. Introduction: Why Canada should consider reducing and phasing out the use of antibiotics and hormone growth promoters	1
2. Implementing a ban or reduction in the use of hormones and antibiotics for animal husbandry in Canada	3
Timing.....	3
Rationale and education	4
Cultural factors	4
Economics and international trade	5
An extended information/consultation process	5
3. The Role of Canadian Government Agencies	5
4. Recommendations	6
Appendix: Restricting Antibiotic and Hormone Growth Promoters in the European Union: Swedish and Danish Experiences	8
1. Background	8
2. The Swedish Ban on Antibiotics.....	9
3. The Danish Ban on Antibiotics.....	11
4. The Financial Impacts of the Bans.....	12
5. Regulation in the European Union	13
EU Ban on Antibiotics as Growth Promoters.....	13
EU Ban on Hormones as Growth Promoters.....	14

1. Introduction: Why Canada should consider reducing and phasing out the use of antibiotics and hormone growth promoters

In 2006, the Canadian Institute for Environmental Law and Policy published a report entitled *There Is No “Away” – Pharmaceuticals, Personal Care Products, and Endocrine-Disrupting Substances: Emerging Contaminants Detected in Water*. As the title suggests, that report described new types of contaminants, along with potential environmental and health effects related to those substances that are now being detected in water through improvements in testing capability.

The report also noted that during the last few decades there has been a dramatic increase in the quantities of drugs used annually in human and veterinary medicine and animal husbandry. The rise in use of drugs in animals is mainly due to the routine employment of hormones for growth promotion, and of antibiotics for growth promotion, increased feed efficiency and prophylaxis in flocks and herds, especially in intensive livestock operations. For example, regular sub-therapeutic doses of antibiotics can accelerate growth in some farm animal species, and in North America antibiotics are incorporated for this purpose in commercial animal feed. Included as one of CIELAP’s eleven recommendations in that report was the following:

Phase out the use of antibiotics and of hormones as animal growth promoters and review the use of preventive antibiotics in animal feed for eventual phase out. Immediately prohibit human use classes of antibiotics for growth promotion and routine prophylactic uses in poultry and livestock operations.¹

Both human health and ecological concerns are at the core of this recommendation.

First, it should be understood that pharmaceutical products given to animals (including humans) do not disappear but instead, some percentage of the active ingredients and/or metabolites (which may also be active) are excreted in urine and feces (typically, 25% - 75% of antibiotics, for example). For growth-promoting hormones and antibiotics, manure handling, including spreading on fields, can result in run-off that carries these compounds and the bacteria exposed to them to surface water or even to underground aquifers. Human exposure from these farming practices can also, of course, be related to handling animals directly or ingesting animal products.

For hormones and hormone-mimicking substances, there are many concerns about the effects on the endocrine systems of people and other animals, including serious impacts on reproduction in aquatic species, feminization in many species, and speculation about links to breast and testicular cancers in humans.

For antibiotics, a major problem is the emergence of strains of bacterial pathogens that are resistant to antibiotic use. When antibiotics are used to combat human illness, bacterial resistance can make such treatment ineffective, and previously easy-to-treat illnesses can become serious and even life-threatening. The ongoing exposure of bacteria in animals to antibiotics is one of the ways in which antibiotic resistance (sometimes called antimicrobial resistance or AMR) is created. A more detailed examination of all these topics is included in CIELAP’s earlier report.

Some Pharmaceuticals Used and Prohibited in Canada in Animal Husbandry²

Beef Cattle - Allowed are ear implants of growth hormones; and antibiotics for control of illness induced by an unnatural (grain-based) diet.

Dairy Cows - In 1999, Canada restricted use of bovine growth hormone for increased milk production; the U.S. has no such restrictions. In Canada, dairy cows are rarely given drugs for any reason other than treatment of illness.

Poultry - Antibiotics are used for growth promotion, disease prevention and treatment; growth hormones are prohibited.

Pigs - Antibiotics are used for growth promotion, disease prevention and treatment; growth hormones are prohibited.

Approximately 10 of the 100 or so antibiotics in commercial use for animals can be used in animal feed without a veterinary prescription in Canada.

CIELAP's recommendation is not an outlier in this discussion. The European Union (EU) and some of its members, notably Sweden and Denmark, have been moving in this direction since the 1990s, with increasing restrictions on pharmaceuticals used in rearing farm animals. Beginning on January 1, 2006, the EU instituted a total ban on hormone and antibiotic use in animal husbandry for purposes of growth promotion, though antibiotics used for therapeutic reasons, with various restrictions, have continued to be permitted. Other countries, for example Australia and New Zealand, have also instituted new restrictions. In Canada, one recommendation from Health Canada's *2002 Report of the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health* was to

[e]valuate antimicrobials for growth promotion or feed efficiency using sound risk analysis principles and rapidly phase out antimicrobial claims not fulfilling the following criteria:

- demonstrably effective;
- involving products rarely if ever used in human therapy; and
- not likely to impair the efficacy of any other prescribed antimicrobial for human infections through the development of resistant strains.³

It appears that this important recommendation has still not been fully implemented nearly 7 years later.

This present report discusses implementing the CIELAP recommendation for a Canadian phase-out in light of both the European experiences and other factors specific to Canada's situation, and makes a number of recommendations concerning an appropriate approach for moving forward. It references CIELAP's report, *Restricting Antibiotics and Hormone Growth Promoters in the European Union: Swedish and Danish Experience*, which was prepared as a background research piece for this project, and is included as the appendix to this report.

2. Implementing a ban or reduction in the use of hormones and antibiotics for animal husbandry in Canada

There are at least five major factors that need attention if CIELAP's recommendation is to be implemented. These are:

- (1) Timing
- (2) The rationale and education about it
- (3) Cultural factors
- (4) Economics and international trade
- (5) An extended information/consultation process.

We do not identify all specific agencies that should be involved here, but the assumption is that the restrictions are federal (Health Canada, and in particular the Veterinary Drugs Directorate), and that federal agencies are the main actors in such an initiative.

Timing

In the EU, the progression from partial restrictions in a few countries to a comprehensive EU-wide ban on growth promoters, along with limitations on antibiotics for veterinary therapeutic and prophylactic use, did not happen overnight; it took some 20 years. In part, this was because evidence of harm and harm reduction, particularly with respect to AMR pathogens, necessarily took time to accumulate. As well, however, this slow pace was because of the need to overcome opposition by farmers, who were concerned about the effects of economic competition from other countries, and who also needed time to adapt their production methods.

In Canada in 2009, the situation is somewhat different from that in Europe 10 years ago. There is now considerable evidence about potential risks from AMR and endocrine-disrupting substances (EDSs, which include hormones) and the documented reduction of AMR risk in the EU has demonstrated the wisdom of taking a precautionary approach.

Since there are differing cultural factors and economic conditions, discussed below, Canadian farmers will have some obstacles to overcome that were not as strongly present in the Scandinavian countries and the EU. Consequently, a time period for adjustment will need to be allowed to bring in some new restrictions. However, the lack of new regulatory initiatives in Canada despite increasing concern about AMR for over a decade gives the matter urgency. At this point, CIELAP would recommend the following actions:

- An immediate ban on classes of antibiotics used therapeutically in humans, when used for growth promotion and prophylaxis in livestock;⁴
- An immediate review of the extent to which classes of antibiotics used therapeutically in humans are also used therapeutically to treat animal illnesses, with a rapid phase-in of appropriate restrictions; and

- A longer phased-in approach for other restrictions directed at other antibiotics and at hormones, where additional restrictions are needed or recommended based on the results of risk assessments and of adaptation issues.

Rationale and education

Without a widespread understanding of the rationale for implementing restrictions on these agents, there will be strong political resistance to the process. Two distinct but complementary education programs are required to communicate the rationale:

- One intensive program should be aimed at farm organizations and farmers themselves, and would provide details about AMR and the need to minimize AMR; this includes highlighting the European experience of phasing out antibiotic use as a feed additive (see CIELAP's research in the appendix to this report on the success of those bans). As well, though the evidence related to adverse effects on human health may not be clear, the wisdom of a precautionary approach to harm reduction from exposure to growth hormones and other endocrine-disrupting substances (EDSs) should be presented
- In the second program, consumers would be given similar information, oriented toward support for Canadian farmers making these changes to promote human and ecological health.

As discussed below, additional information programs will be needed as part of the overall process.

Cultural factors

Many EU countries have had a strong history of embracing values and related political or institutional developments that have provided a cultural context of support for restricting the use of drugs in animal husbandry. These interests have included organic and biodynamic farming methods;⁵ the production of local, traditional, and artisanal food (e.g., the Slow Food movement, which began in Italy);⁶ the heritage value of agricultural landscapes;⁷ and animal welfare initiatives.⁸ Political and consumer support from these movements was a factor in the EU's ban (see the discussion in the appendix to this report, *Restricting Antibiotics and Hormone Growth Promoters in the European Union: Swedish and Danish Experience*). In particular, political support of economic incentives for farming practices that promote ecological goals and landscape values made change easier. Consumer support for food production that fosters animal welfare and uses organic methods was also valuable.

Similar movements also exist in Canada, though these may have been somewhat slower to gain momentum. Groups and individuals with these interests, along with environmental and health-related organizations, should play a role in providing ideas, information, and political support for the proposed restrictions.

Economics and international trade

Farmers in Canada have been squeezed economically for decades. Farming families today are almost always dependent on some off-farm income.⁹ Consequently, the economic effects of these restrictions must be carefully evaluated. In terms of straightforward production costs, these impacts are not necessarily negative and may be positive, as some EU experience indicates. However, other aspects of Canadian farm economics, such as market structures and trade implications, must be considered. The degree of integration with U.S. markets and their requirements (and lack thereof) are of special concern. It is worth noting, though, that previously integrated U.S./Canada beef production was disrupted by American interests after the recent Canadian “mad cow” outbreak. As well, the U.S. and Canada each adopted a different approach in regulating recombinant bovine growth hormone use in dairy cows.¹⁰

Potential economic benefits through expanded market opportunities should not be overlooked, either. Canada’s new Organic Products Regulations are scheduled to come into force on June 30, 2009, and according to the accompanying Regulatory Impact Analysis Statement published in the *Canada Gazette*, an important reason for this regulatory initiative was to allow Canadian products to be marketed in the EU, which requires standards comparable to its own requirements.¹¹

An extended information/consultation process

Probably the single most important factor to be considered is the quality of the consultation process preceding any new regulations on this matter. It should go without saying that the timeliness, inclusiveness, and willingness to listen that should be part of a serious consultation process are absolutely essential for success.

3. The Role of Canadian Government Agencies

A country-wide ban or additional restrictions in Canada on the use of growth hormones and antibiotics as growth promoters and prophylactic and therapeutic agents for animals, and the importation of meat treated with these agents, would come about as a result of action taken by Health Canada’s Veterinary Drugs Directorate. Specifically, changes to the regulations under the *Food and Drugs Act* would be the main vehicle for action.

Other actors that could be directly involved would include advisory committees that currently exist or might be revived, such as Health Canada’s Expert Advisory Committee on AMR Risk Assessment, or the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health. Similarly, Health Canada’s Office of Consumer and Public Involvement or others with expertise in that field should clearly be involved in the design and oversight of public consultations and education on these issues.

As well, Canada’s *Feeds Act* and its regulations, under the authority of the Canadian Food Inspection Agency, pertain to ensuring that there are appropriate use and safety warnings about

the pharmaceutical agents in animal feed, and relevant provisions of the Act and regulations may need to be updated.

Provincial government departments also may have particular provincial perspectives on these matters, including education and direct involvement with farmers, and should be involved.

4. Recommendations

Major effort, both inside and outside government agencies, will be needed to implement CIELAP's recommendation to ban and further restrict antibiotic and hormone growth promoters and prophylactic use of antibiotics in animal husbandry. The following are general recommendations for action:

1. Health Canada, through its Veterinary Drugs Directorate, should take steps to implement an immediate ban on the use of antibiotics as animal growth promoters and enhancers of animal feed efficiency, where those classes of antibiotics are of high importance for human therapeutic use.
2. Similarly, these classes of drugs should undergo immediate review and possible restriction for therapeutic uses in animals.
3. Hormones and antibiotics used for animal growth promotion should also be phased out entirely within 6 years (2015), with priorities determined by risk assessment and practical economic considerations.
4. In this initiative, well-designed, inclusive consultation with farmers, consumers, environmental and health professionals, provincial agencies, and many other interested individuals and organizations is of paramount importance. These consultations should commence in the near future and take place over the 6-year period of phasing out the use of hormones and antibiotics for growth promotion. Information programs, dialogue, and exploration of economic and trade implications should be supported by government.
5. Economic incentives should be developed to support changes to farming practices that assist farmers making a transition away from drug use in animal husbandry and at the same time enhancing animal welfare and/or ecological services such as habitat preservation or improvement.

¹ S. Holtz, Canadian Institute for Environmental Law and Policy, *There is No "Away": Pharmaceuticals, Personal Care Products, and Endocrine-Disrupting Substances: Emerging Contaminants Detected in Water*, 2006 at 41: http://www.cielap.org/pub/pub_noaway.php

² For further information, see S. Holtz, Canadian Institute for Environmental Law and Policy, *There is No "Away": Pharmaceuticals, Personal Care Products, and Endocrine-Disrupting Substances: Emerging Contaminants Detected in Water*, 2006 at 8-10: http://www.cielap.org/pub/pub_noaway.php

³ Health Canada, Report of the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health, *Uses of Antimicrobials in Food Animals in Canada: Impact on Resistance and Human*

Health, June 2002 at 91: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/pubs/amr-ram_final_report-rapport_06-27-eng.pdf

- ⁴ Technical discussions of AMR in Canada place antibiotics into four categories based on their importance as being the only, or one of several alternative preferred drugs for treatment of serious human disease; Class I drugs are of very high importance, with limited or no alternatives; Class II are of high importance, with some alternatives; Class III are of medium and Class IV of low importance. The only current Class I drug approved for animal use is virginiamycin, a streptogramin, which is not used in humans; there are several Class II drugs, including penicillin, in use. It should be noted that, although there is a relatively limited number of drugs available for animal use without a veterinary prescription, veterinarians can prescribe other human use drugs, and farmers can import drugs for “own use” without a prescription.
- ⁵ Foundation Ecology & Agriculture and Research Institute of Organic Agriculture, *Organic Farming in Europe: Recent Developments and Future Prospects*, 2002: http://ew.eea.europa.eu/agriculture/organic/Europe/of_in_europe
- ⁶ S. Kapoor, *Slow Food*, BBC Food Matters website, 2009: http://www.bbc.co.uk/food/food_matters/slowfood.shtml
- ⁷ European Commission Joint Research Centre – Institute for Environment and Sustainability, *European Landscapes: The IRENA Project*: <http://ies.jrc.ec.europa.eu/irena-project>
- ⁸ European Commission Food Safety website, Animal Welfare – Introduction: http://ec.europa.eu/food/animal/welfare/index_en.htm
- ⁹ D. Sparling, Canada Farm Income and Farm Structure 1999-2004, 2006 at 2: <http://www.rural-gc.agr.ca/pol/consult/miss/pdf/a30.pdf>
- ¹⁰ Health Canada Drugs and Health Products website, *Questions and Answers – Hormonal Growth Promoters*: http://www.hc-sc.gc.ca/dhp-mps/vet/faq/growth_hormones_promoters_croissance_hormonaux_stimulateurs-eng.php
- ¹¹ Organic Products Regulations, SOR/2006-338, under the *Canada Agricultural Products Act*, Regulatory Impact Analysis Statement, *Canada Gazette*, February 14, 2009: <http://gazette.gc.ca/rp-pr/p1/2009/2009-02-14/html/reg1-eng.html>

Appendix: Restricting Antibiotic and Hormone Growth Promoters in the European Union: Swedish and Danish Experiences

1. Background

Antibiotic and hormonal growth promoters (AHGPs) have been used in feed for livestock production for more than 50 years. In 1951, the U.S. Food and Drug Administration (FDA) approved antibiotics for use as feed additives for farm animals.¹ This was a response to studies observing that residual tetracycline in feed made chickens grow faster.² Since then, the use of AHGPs has become commonplace in livestock production around the world.

Antibiotic (also referred to as antimicrobials)³ and hormonal growth promoters are pharmaceuticals routinely given to farm animals for the purposes of disease prevention and growth promotion, rather than therapeutic purposes. A 2003 study by the Union of Concerned Scientists estimated that farm animals (including pigs, cows and chickens) are given 70% of the antibiotics produced in the United States.⁴ CIELAP's 2006 report, *There is No "Away": Pharmaceuticals, Personal Care Products, and Endocrine-Disrupting Substances: Emerging Contaminants Detected in Water*, noted that

[i]n the United States, about 25 million pounds of antibiotics and related drugs are administered to animals for non-therapeutic purposes, more than eight times the 3 million pounds used to treat human disease. This non-therapeutic use of antibiotics has increased one and a half times between 1985 and 2001.⁵

Hormones are also widely used to promote growth in cattle, administered through feed or ear implants, although they are not permitted to be given to hogs or poultry in Canada or the United States. Two thirds of U.S. beef cattle intended for American consumers receive growth hormones, and the six growth-promoting hormones approved for use in Canada are widely used in Canadian commercial beef production. While recombinant bovine growth hormone may be given to American dairy cows to increase their milk production, it has been banned for use in Canadian dairy cows since 1999.⁶

When AHGPs are given to farm animals, a percentage of their active ingredients are excreted in urine and feces; in the case of antibiotics, this may be 25% to 75% of the active ingredients.⁷ These pharmaceutical ingredients may then be carried in the runoff from manure spread on farm fields or treatment facilities for livestock waste.⁸

A growing body of evidence suggests the potential for environmental and human health impacts from AHGPs. There are concerns that hormones and hormone-mimicking substances may have impacts on the endocrine systems of people and other animals, including serious effects on reproduction in aquatic species, feminization in many species, and links to breast and testicular cancers in humans. The overuse of antibiotics results in the development of strains of bacterial pathogens resistant to antibiotics.⁹

One of the recommendations in CIELAP's 2006 report responded to concerns about the environmental and human health impacts of AHGPs, urging governments to:

[p]hase out the use of antibiotics and of hormones as animal growth promoters and review the use of preventive antibiotics in animal feed for eventual phase out. Immediately prohibit human use classes of antibiotics for growth promotion and routine prophylactic uses in poultry and livestock operations.¹⁰

Over the past several decades a number of European states, including Sweden and Denmark, have expressed concerns about the use of antibiotics and hormones in livestock production and responded to scientific evidence against the practice. The influence of these jurisdictions has led the European Union (EU) to implement a series of bans on specific AHGPs, followed by a complete ban on the use of all AHGPs as growth promoting agents in food animals that began in 2006. These bans applied the precautionary principle and were put in place to reduce risks to both humans and animals. They were intended to return antibiotics to their original role as therapeutics rather than growth agents, eliminating cross-resistance to medically important human drugs, and improving animal welfare.

AHGPs have been found to be less efficient where there are high animal hygiene or health and management standards in place. In other words, AHGPs perform best when conditions are worst, such as in crowded cattle feedlots. It has been shown in both Sweden and Denmark that if there is less overcrowding of livestock and infection control techniques are used, the economic advantages of using growth promoters may be eliminated.¹¹

This paper explores the context for and experience of bans on antibiotic and hormonal growth promoters within the EU, with a specific focus on the Swedish and Danish experiences. The purpose of this paper is to: describe how, why and when the bans came about in Sweden, Denmark and the EU; demonstrate the benefits and negative implications of the bans, including economic impacts; and highlight the factors that made the bans possible.

2. The Swedish Ban on Antibiotics

The focus of bans in Sweden has been on antibiotics for growth promotion, rather than hormones. In 1986 Sweden banned all use of antibiotics for the purposes of growth promotion.¹² Sweden was among the first countries to implement the recommendations of the United Kingdom's 1969 Swann Commission, which recommended restricting the use of antibiotics and prohibiting specific drugs in animal feed.¹³ In particular, the Swann Committee cautioned that antibiotics used for therapy should not be given to food animals.¹⁴

Sweden's 1986 *Feedstuffs Act* (also referred to as the *New Feed Act*)¹⁵ restricted the use of antimicrobials in food animals to veterinary use only, and required a prescription for veterinary use.¹⁶ As a result, antibiotics could only be given in therapeutic doses to treat disease, eliminating their use as growth agents.

Sweden has been monitoring the use of antimicrobials in animals since 1980,¹⁷ and the state of resistance to antibiotics beginning in 2000.¹⁸ Statistics show that Sweden's total annual usage of

antimicrobials in 2004 was about 65% lower than it had been prior to the 1986 ban. As of 2004, penicillin for treating individual animals was responsible for approximately 47% of the antibiotics consumed.¹⁹ (It is important to note that the Swedish statistics include the use of all antibiotics for both food animals and companion animals.)

Some literature indicates that there were no negative clinical effects reported for slaughter pigs, specialized beef and turkeys following implementation of the ban.²⁰ Others have suggested that thousands of pigs and chickens likely died as a result of the ban, although they have also observed that “the problems encountered by adopting the Swedish model have been justified by the outcome. Sweden has shown the rest of the world that it is possible to have modern farming without the use of antibiotics as growth promoters.”²¹

There were concerns that the ban was implemented too quickly, particularly with respect to chickens, and that producers were not given sufficient time to adjust to the restrictions on antibiotics as growth promoters. Before the 1986 ban, it had been common practice in Sweden to use avoparcin and later virginiamycin to prevent necrotic enteritis, a common illness in broiler chickens. When Sweden banned both of these antibiotics, problems with necrotic enteritis were expected and experienced. For example, during the first year, 90% of broiler chickens were continuously treated with double the dose of virginiamycin than they had received prior to the ban. Eventually an alternative to the use of virginiamycin was developed.²²

Animal food producers changed their practices to adjust to the ban on antibiotics for growth promotion. Industry players, producers, the feed industry and veterinarians showed that many other factors, including the construction and climate of stables, hygiene, management, and feed, particularly overriding recommended levels of protein, could also contribute to outbreaks of enteritis. As one response to these findings, Swedish producers and the feed industry developed feed that was richer in fibre and supplemented with enzymes. Initial outbreaks of necrotic enteritis were controlled through research projects and cooperation between producers, the feed industry and veterinarians. Over the period from 1995 to 2001, the amount of antibiotics used to prevent or treat outbreaks of necrotic enteritis in broiler chickens has been negligible.²³

Sweden also created a system for producers of broilers to receive an incentive for good animal management and care. Under this system, the best growers were able to breed higher populations or densities of broilers without risk to animal welfare.²⁴ The farms that were most successful in adapting to the antibiotics ban were those that were better managed and used tightly controlled systems such as all-in-all-out production.²⁵ In all-in-all-out systems, entire flocks of broiler chickens or herds of fattening pigs are moved together out of rearing units, allowing them to be completely disinfected before new stock arrives in order to reduce the transfer of bacteria to new animals.²⁶

The Swedish ban on antibiotics for growth promotion has been successful in part because of strong support from both farmers and consumers. Even in 1981, prior to the introduction of the ban in Sweden, farmers there used antibiotics sparingly and under the control of veterinarians, and the Federation of Swedish Farmers was open to ending the use of antibiotic growth promoters to ensure the confidence of consumers and the prevention of antibiotic-resistant bacteria.²⁷ In fact, this Federation requested a voluntary ban in 1985, one year before the legal

ban was instituted.²⁸ The ban on antibiotics as growth promoters was consistent with broader concerns in Sweden about animal welfare. In 1988, Sweden enacted the strict Animal Welfare Act²⁹ to require high standards in agricultural production methods in order to prevent unnecessary suffering or diseases in animals. This reflected the understanding in Sweden that animals that are healthy and not stressed will be more profitable.³⁰

3. The Danish Ban on Antibiotics

Denmark introduced its first antibiotic ban in May 1995 when it banned the use of avoparcin in the country.³¹ This followed the release of a 1993 report that linked the emergence of the antibiotic-resistant bacteria – *vanA* vancomycin-resistant *Enterococcus faecium* (VREF) – to the administration of avoparcin as a growth promoter in food animals.³² Subsequent findings in Germany and Denmark confirmed the relationship between VREF and the use of avoparcin. In spite of the 1995 avoparcin ban, the total use of antimicrobials for growth promotion continued to increase until January 1998 when Denmark banned a second growth promoter, virginiamycin.³³ Following this, in February 1998, the cattle and broiler chicken industries in Denmark voluntarily ended the use of all antimicrobial growth promoters. This was a response to consumer concerns about the possibility of a public health risk from using antimicrobials. The swine industry also voluntarily ended the use of antimicrobial growth promoters in pigs over 35 kg at this time.³⁴

Denmark also introduced the Danish Integrated Antimicrobial Resistance Monitoring and Research Program (DANMAP) in 1995, making it the first country to establish “systematic and continuous monitoring of antimicrobial agent consumption and resistance in animals, food, and humans.”³⁵ Over the period that the Danish bans have been in place, DANMAP has provided scientific data and helped to evaluate the impacts of the bans and guide further regulation.³⁶ Similar programs have since been implemented in other countries, such as Canada (the Canadian Integrated Program for Antimicrobial Resistance Surveillance, CIPARS)³⁷ and the US (National Antimicrobial Resistance Monitoring System, NARMS).³⁸

As with Sweden, Denmark’s bans on the use of antibiotics as growth promoters have been viewed as beneficial overall. A World Health Organization (WHO) report found that Denmark’s program has been effective in reducing the total amount of antimicrobials administered to food animals and has reduced antimicrobial resistance in significant reservoirs of food animals, consequently reducing threats to public health from antibiotic resistance.³⁹ In Denmark,

the negative impacts of antimicrobial growth promoter termination are largely attributable to their disease prophylaxis (i.e. disease prevention) properties, with no effect on growth in broilers and only a small effect on growth in pigs. In pigs, where most antimicrobials were used in Denmark, antimicrobial growth promoter termination was associated with a reduction in growth rate and an increase in mortality and diarrhoea in weaners, but these changes were not detectable in finishers.⁴⁰

Because of these problems with post-weaning diarrhoea, there was increased use of antimicrobials for therapy among weaner pigs. However, this increase did not lead to a significant rise in antimicrobial resistance among *E. coli*.⁴¹

DANMAP data showed that the 1995 ban on avoparcin lowered the occurrence of VREF found in both broiler chickens and pigs. By 2005, less than 3% of the *E. faecium* isolates from broiler chickens were resistant to vancomycin, down substantially from approximately 80% before the ban was in place. While there was not a substantial change in the occurrence of VREF in pigs initially, evidence suggested that its persistence related to the continued use of macrolides such as tylosin for growth promotion, which eventually decreased as of 1998.⁴²

The conclusion of the WHO report was that “under conditions similar to those found in Denmark, the use of antimicrobials for the sole purpose of growth promotion can be discontinued.”⁴³ The conditions for livestock production in Denmark referred to in the report include closed housing, good biosecurity, available veterinary services, relatively good health of pigs and broilers and a high level of infrastructure. In addition to these factors, Denmark’s pig industry consists of a governing cooperative and includes farmers as co-owners of slaughterhouses, which facilitated voluntary action on antimicrobial growth promoters across the country. The report noted that other countries may need a longer period for full implementation perhaps supported by regulatory action in order to implement a similar program.⁴⁴

4. The Financial Impacts of the Bans

Following Sweden’s 1986 ban on antibiotics as growth promoters, the net increase in cost to consumers was estimated to be approximately US\$0.12 +/- \$0.06/kg for retail meat (SEK⁴⁵ 8.10/US \$). About half of this increased cost was attributed to the ban on antibiotics while the other half was thought to be due to the animal welfare legislation introduced in 1988.⁴⁶

Some factors present in Sweden assisted the industry with the financial transition to the ban on antibiotic growth promoters. For example,

Swedish pork producers control most of the packing sector and through their union could negotiate with both the government and with consumer groups. One outcome of this structure is that the Swedish producers and consumers could (and did) negotiate a compensation for pork producers to offset the additional expense associated with the ban.⁴⁷

This type of compensation would be difficult to replicate in a more competitive market such as the United States or Canada. Although consumers in North America would eventually pay an additional cost, this would probably occur after several years due to the fact that some producers would have reduced production or been forced out of business.⁴⁸

Sweden’s “trace-back” system also helped Swedish pork producers to retain a competitive edge despite the implementation of the ban. This innovative system gives consumers the opportunity to trace each piece of meat they purchase back to the farm that produced it. Entering a code on an internet website provides the consumer with a picture of the producer of the pork and specific information about how it was raised. The capacity for consumers to identify better or sub-standard producers has allowed Swedish farmers to retain their market share and even capture price premiums in the UK market. Similar systems are now used in other EU countries as well. One study has indicated that US consumers would be willing to pay up to \$0.40/lb for such

system.⁴⁹ It has also been suggested that the trace-back system “has the potential to completely alter the structure of US and world pork markets.”⁵⁰

A 1996 study of the costs of animal production in Sweden (compared with Denmark before the antibiotics ban had been fully implemented there) confirmed that the costs of producing pigs was slightly higher in Sweden at that time, but also noted that the investment costs of improving the animal environment would become more profitable if an antibiotics ban were in place.⁵¹

In Denmark, the WHO has reported that, as of 2003,

[t]he net costs associated with productivity losses incurred by removing antimicrobial growth promoters from pig and poultry production were estimated at 7.75 DKK (1.04 €) per pig produced and no net cost for poultry. This translates into an increase in pig production costs of just over 1%. Some of these costs (e.g. increased therapeutic antimicrobials, reduced growth rate) have been measured and were not large, but others, especially some costs associated with modifications of the production systems, are difficult to measure and were not included in this report, although they may have been substantial for some producers.⁵²

The report estimated that pig production was about 1.4% per annum lower than expected while poultry production was 0.4% higher following implementation of the ban. In some cases, as with broiler chickens, savings in antibiotic growth promoter costs tended to offset any losses experienced in feed efficiency. However, the report also pointed out that additional costs to both production and the national economy may be at least somewhat offset by: increased consumer confidence in and demand for Danish poultry and pork free of antimicrobial growth promoters; and the human health benefits of ending the use of antibiotics for growth promotion.⁵³ Another report suggested that the ban did not have a direct effect on Denmark’s export market for pork, but in fact has given Denmark a competitive advantage in relation to consumer with concerns about the human health impacts of antibiotic use.⁵⁴

5. Regulation in the European Union

EU Ban on Antibiotics as Growth Promoters

Following the actions in European countries such as Sweden and Denmark, the Commission of the European Union banned the use of avoparcin as a growth promoter in all EU member states in 1997.⁵⁵

In May 1999, the EU Scientific Steering Committee released an opinion report on antimicrobial resistance which presented a number of recommendations, including the following:

Regarding the use of antimicrobials as growth promoting agents, the use of agents from classes which are or may be used in human or veterinary medicine (i.e., where there is a risk of selecting for cross-resistance to drugs used to treat bacterial infections) should be phased out as soon as possible and ultimately abolished. Efforts should also be made to replace those antimicrobials promoting growth with no known risk of influencing intestinal bacterial infections by non-antimicrobial alternatives. It is essential that these

actions are paralleled by the introduction of changes in animal husbandry practices which will maintain animal health and welfare during the phase-out process.⁵⁶

Following the release of this report, additional antibiotics were banned in the EU for growth promotion use in 1999: in July, tylosin, spiramycin, bacitracin and virginiamycin because they belonged to classes of antimicrobial drugs that are also used to treat humans; and in September, olaquinox and carbadox due to concerns about toxicity from occupational exposure.⁵⁷

A second opinion issued by the Scientific Steering Committee in 2001 reviewed the findings of a two-year antimicrobial resistance surveillance carried out on seven products, and literature on antimicrobial resistance that had been published after its first opinion paper. The Committee concluded that none of the new information contradicted the scientific basis for its 1999 opinion on the use of antimicrobial growth promoters that are also used as antibiotics for human or animal therapy.⁵⁸ The Committee urged the European Commission to act on its 1999 recommendations and specifically “to pay special attention to implications of antimicrobial resistance to environmental microbial ecology.”⁵⁹

In 2003, the EU adopted a regulation⁶⁰ on feed additives that placed a general prohibition on antibiotics as growth promoters. Although the EU had already banned antibiotics used in human medicine from being added to animal feed, the new regulation completed the ban on antibiotic growth promoters by prohibiting the use of four further substances: monensin sodium; salinomycin sodium; avilamycin; and flavophospholipol.⁶¹ The regulation phased out antibiotic feed additives beginning January 1, 2006.⁶²

EU Ban on Hormones as Growth Promoters

Denmark was among the first countries to ban the use of hormones for growth promotion in meat animals, banning them in 1963. Concern about growth-promoting hormones became widespread in Europe in 1977 after the discovery that a number of young boys in Italy had begun to develop breasts. Researchers suggested that estrogen in poultry or meat might have been related to the incident.⁶³

As of January 1, 1989, the EU introduced a prohibition on the use of thyrostatic, oestrogenic or gestagenic substances for growth promotion in meat production. The use of hormones such as oestradiol-17 β , testosterone, progesterone to promote growth is now prohibited both for domestic production within the EU and in imports from other countries of meat from animals treated with these hormones.⁶⁴ In making this prohibition, the EU put in place “a level of sanitary protection of accepting no or “zero” additional risk to human health from the residues in meat and meat products of these hormones when used for growth promotion purposes.”⁶⁵

This prohibition prompted an international trade dispute, with Canada and the United States contesting the ban. In 1997 a World Trade Organization (WTO) panel ruled that the EU prohibition was not consistent with the Agreement on the Application of Sanitary and Phytosanitary Measures. On appeal by the EU, the WTO appellate body reversed most of the initial panel’s decision, but upheld the finding that the prohibition did not comply with the requirement in the Agreement that measures should be based on a relevant assessment of the risks to human health.⁶⁶

In response to the appellate ruling, the EU undertook a new scientific assessment of the human health risks of hormone residues in beef. In April 1999, the Scientific Committee On Veterinary Measures Relating To Public Health provided its opinion on the assessment of six banned hormones. After reviewing scientific evidence, it concluded that

the issues of concern include neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity and carcinogenicity. In consideration of the recent concerns relating to the lack of understanding of critical developmental periods in human life as well as the uncertainties in the estimates of endogenous hormone production rates and metabolic clearance capacity, particularly in prepubertal children, no threshold level and therefore no [Acceptable Daily Intake] can be established for any of the 6 hormones.⁶⁷

The committee found that the ban should continue in Europe, and also noted that the highest rates of hormone-related cancer, including cancer of the breast, ovary, prostate, testes and colon, were found in North America where hormone-treated meat is consumed.⁶⁸

Following the release of the scientific review, the EU made some amendments to its legislation prohibiting the use of growth hormones in meat production, but continued the ban.⁶⁹ The amended EU Directive⁷⁰ confirmed the prohibition of hormones for growth promotion in farm animals and also severely reduced the circumstances in which oestradiol-17 β may be administered for other purposes to animals that produce food. Only three uses continue to be permissible, but on a transitional basis and under strict veterinary control.⁷¹

¹ Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology, Health, and the Environment Committee on Agricultural Biotechnology and U.S. National Research Council, *Animal Biotechnology: Science Based Concerns*, National Academies Press, 2002 at 23.

² L. Edqvist and K. Pedersen, "Antimicrobials as growth promoters: resistance to common sense," in *Late lessons from early warnings: the precautionary principle 1896-2000*. Environmental Issue Report No. 22, European Environment Agency, 2001 at 93-99:
http://reports.eea.europa.eu/environmental_issue_report_2001_22/en/Issue_Report_No_22.pdf

³ Antimicrobials refer to pharmaceuticals that kill or suppress microscopic organisms including bacteria, viruses and parasites, while antibiotics are the specific antimicrobial drugs that kill or suppress bacteria: Australian Government, National Health and Medical Research Council web site, *Antimicrobial (Antibiotic) Resistance*:
<http://www.nhmrc.gov.au/about/committees/expert/eagar/aar.htm>

⁴ See Sustainable Table website: www.sustainabletable.org/issues/antibiotics/

⁵ S. Holtz, Canadian Institute for Environmental Law and Policy, *There is No "Away": Pharmaceuticals, Personal Care Products, and Endocrine-Disrupting Substances: Emerging Contaminants Detected in Water*, 2006 at 9:
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- ⁹ *Ibid.* at 19-28.
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