



ANIMAL WELFARE INSTITUTE

PO Box 3650 Washington, DC 20007-0150 www.awionline.org
telephone: (202) 337-2332 facsimile: (202) 338-9478

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98D-1146 - Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern

To Whom It May Concern:

On behalf of the Animal Welfare Institute (AWI) and its members, I am writing to strongly object to the draft guidance. It is inherently problematic to implement a system in which "drug sponsors" complete risk assessments on their own products and attempt to estimate such things as "probability of contamination on food product". Instead, we urge the FDA to ban growth promoting, non-therapeutic uses of antibiotics in agricultural production. A ban, in conjunction with better feeding practices and truly humane husbandry, is the only way to ensure the effectiveness of antibiotics to treat human and animal illness.

According to the Union of Concerned Scientists, an estimated 70% of all antibiotics in the U.S. are fed to pigs, poultry and beef cattle in factories. This growing reliance on and overuse of antibiotics is only inherent in the factory system where farm animals are routinely fed antibiotics to promote growth and compensate for stressful, unsanitary conditions. In factories, pigs are confined in coffin-like crates in which they cannot turn around, hens are cramped in cages so small they cannot stretch their wings and beef cattle are forced to stand ankle deep in their own waste. The routine feeding of antibiotics to animals on factory farms is speeding the development of dangerous antibiotic-resistant germs that cause hard-to-treat infections in both people and farm animals.

AWI has a program in which we work with humane, independent family farmers. Now over 250 farmers raise pigs in accordance with AWI's Humane Husbandry Standards which prohibit the routine use of subtherapeutic antibiotics to control or mask disease or promote growth. In addition, the standards also require animals be raised in humane environments, either on pasture or in bedded buildings, allowing them to express their natural repertoire of behaviors. A copy of the standards is enclosed. The success of this program and the increasing demand for products from animals not treated with antibiotics demonstrates that the routine, non-therapeutic use of antibiotics is simply not necessary

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and actually not preferred by a growing number of customers, when production environments are modified to promote the overall well-being of animals, including their emotional and psychological well-being. Furthermore, we draw your attention to those farmers in the Swedish pig industry who eliminated nontherapeutic antibiotic use successfully by maintaining high levels of hygiene and enriched environments compatible with pigs' behavioral and biological needs.

One additional point I would like to address is the claim recently made by representatives of the agricultural and pharmaceutical industries that Denmark's ban on growth promoting antibiotics in 1999 is responsible for health problems in farm animals. In reality Danish pig farms, despite being one tenth or less the size of the largest swine farms in the U.S., continue to use intensive confinement production techniques similar to those used by industrialized producers in the U.S. As demonstrated by the pig farmers that are part of AWI's humane husbandry program and the above mentioned Swedish pig farmers, producers who have been consistently successful in eliminating nontherapeutic antibiotic use have done so after reducing the intensity of production and incorporating animal welfare into husbandry and facilities. It is simply not possible to eliminate nontherapeutic antibiotic use without changing production facilities and management to support animal welfare first. For additional history on the use of antibiotics, please see pages 32-44 of the enclosed book, *The Price We Pay For Corporate Hogs*.

In conclusion, AWI strongly urges the FDA to prohibit the use of antimicrobial drugs for nontherapeutic and preventative uses as it has been demonstrated they are not necessary if animals are kept humanely.

Thank you for your consideration.

Sincerely,



Wendy Swann
Research Associate

Enclosures



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PO Box 3650 Washington, DC 20007-0150 www.awionline.org
telephone: (202) 337-2332 facsimile: (202) 338-9478

Diane Halverson, Program Director
Phone: 507-645-8434; Fax: 507-664-9448

ANIMAL WELFARE INSTITUTE HUMANE ON-FARM HUSBANDRY CRITERIA FOR PIGS

General Husbandry

Housing for animals shall be designed to allow the animal to behave naturally.

Housing shall be sufficiently spacious to allow all animals to lie down in full lateral recumbency at one time and to move freely.

Pigs are active, social animals by nature, and close confinement in crates is prohibited unless briefly required for vaccination, feeding, marking or veterinary procedures or in the rare event that a sow may savagely attack her piglets, and then only temporarily until the sow is calm.

Pigs shall have continuous access to pens bedded with straw or chopped corn stover, or pasture or dirt yards in which they can root, explore, play or build nests. Substitutes for straw and corn stover may be used only with the approval of the Animal Welfare Institute. Straw is the preferred bedding for farrowing sows and their nursing piglets.

Even when bedding is not needed for warmth, straw or other approved material shall be provided to hogs that do not have continuous access to pasture or dirt. The bedding shall be provided in quantities sufficient to give the hogs material in which to play, explore and root.

Pigs housed outdoors shall have continuous access to shelters that protect them from the heat, wind, cold or rain. Adequate straw shall be provided to keep pigs comfortable in cold weather. In the case of pigs loose-housed in groups in deep-bedded systems, there shall be sufficient amount of litter to create a deep litter bed in which composting can start and be sustained to provide warmth and destroy pathogens.

Type of Farm

Each farm shall be a family farm, that is, a farm on which an individual or family member (a) owns the hogs; (b) depends upon the farm for its livelihood; (c) participates in the daily physical labor to manage the hogs and the farm operation. This shall not prohibit networking among family farmers as long as all criteria listed herein are adhered to by every member of the network.

Practical Prohibitions and Requirements

New buildings shall be constructed with windows or openings that let in daylight.

The equipment and fittings in buildings and other premises that house pigs shall be so designed that they do not inflict injuries or entail risks to the health of the animals. The fittings and other equipment shall not prevent the animals from behaving naturally, nor unwarrantably limit their freedom of movement or otherwise cause them distress.

Persons who transport live animals shall attend to the animals and take the necessary steps to ensure that the animals are not injured or caused to suffer during loading, transport and unloading.

Hot prods or electric shocks shall not be used on the animals. "Boar bashing" shall be prohibited.

The animals' living quarters shall be cleaned by procedures that ensure satisfactory hygiene. The surfaces of deep litter beds shall be kept dry and be of good hygienic quality.

Pigs shall be given sufficient space to keep dunging and lying areas separate from eating areas.

The routine use of subtherapeutic antibiotics, hormones or sulfas to control or mask disease or promote growth is not permitted. The feeding of animal products to pigs is not allowed.

Animals shall have a feeding plan that will guarantee a sufficient, varied and well-balanced diet. Animals shall have access to their feed as long as is necessary for them to satisfy their feed requirements. Animals shall have free access to water.

In the event a pig suffers accidental injury on the farm, that animal shall receive individual treatment designed to minimize its pain and suffering. Ill or injured animals shall not be transported in the same compartment with healthy or uninjured animals.

If the injury is serious enough for the animal to be slaughtered it shall be euthanized on the farm.

Breeding animals

Skip-a-day feeding shall not be used in this program. All pigs shall be fed daily and the housing and distribution of feed shall be designed to minimize competition for food.

If nose-rings are used for pastured sows, the sows shall be supplied with straw or similar material which sows can easily manipulate to build nests. Only one nose-ring may be used per sow. Nose-ringing is only permitted if, by this practice, sows gain the freedom of living on pasture.

Weaning

On each farm weaning shall take place at a piglet weight or age that considers the health and welfare of both piglets and their mothers. This age/weight may vary, depending on the breed of the sow or gilt and level of milk production, her age and health, and the health of the individual piglets. The recommended weaning age is at least 6 weeks, but an earlier weaning date may be necessary, for example, if the mother is a gilt of a

breed with high milk production and nursing a large litter. Minimum age of pigs at weaning shall be 5 weeks.

Growing & Finishing Pigs

Pigs are highly intelligent animals with a strong instinct to root and explore. Their environment shall provide appropriate materials with which to fulfill these instinctive behaviors. A behaviorally appropriate and comfortable environment should eliminate the need for routine tail-docking and piglets shall not be tail docked. If tail-biting problems do arise, farmers shall make every effort to identify and eliminate the cause rather than resort to routine tail-docking.

Castration

If piglets are to be castrated, it must be done by the age of 2 weeks by a person proficient in the procedure.

Space Requirements

Space requirements for animals that are not free-ranging on pasture may vary according to the design of the indoor or indoor-outdoor housing system. The following minimum space requirements are based on Swedish experience, particularly experience with housing boars, pregnant sows and sows with litters in the Swedish Thorstensson and Ljungstrom versions of deep-straw-bedded pig housing. Farmers wanting to provide less space than that specified below must consult with the Animal Welfare Institute for review of housing design before deviations will be granted to farmers using the Animal Welfare Institute name in conjunction with their husbandry.

- 1) Boars: 64 square feet per individual (74 square feet if no separate dunging area is provided)
- 2) Sow and litter in pens:
 - pens with manure gutter - 54 square feet exclusive of gutter per sow and litter
 - pens without manure gutter - 64 square feet per sow and litter
- 3) Sow and litter in boxes:
 - 48 square feet per sow and litter
- 4) Sow and litter in group lactation housing:
 - 81 square feet per sow and litter
- 5) Gestating Sows (Individual housing in crates is prohibited; following requirements are for group housed sows.):
 - gestation and mating - 27 square feet per sow (exclusive of feeding area)
- 6) Weaned, Growing and Finishing Pigs: Space shall be provided to allow all pigs to lie down in full lateral recumbency at the same time. This minimum does not take account of other needs to move about and socialize and this minimum may need to be increased if new information warrants an increase.

General Principles

The Animal Welfare Institute will provide advice from veterinarians and experts in pig behavior when needed or requested.

Farmers in this program will be distinguished by a humane and conscientious attitude toward the animals in their care as well as by housing and husbandry standards which meet Animal Welfare Institute criteria.

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Recognizing that slight variations in the methods used to fulfill the above husbandry standards will exist, it is the goal of the Animal Welfare Institute that the highest level of husbandry is maintained at all times, with the possible exception of temporary deviations when unexpected circumstances arise that are not under the control of the farmer. A farmer's extended deviation from Animal Welfare Institute criteria shall be cause for withdrawal of permission to use the Animal Welfare Institute name in conjunction with that farmer's product.