Estrogen and progesterone data generated to support the human safety portion of Philips Roxane NADA and submitted to FDA demonstrated there are no differences between levels as demonstrated in Chem-Cast and Burdizzo castrated steers with regard to the hormones. Chem-Cast has also been declared as a GRAS item by FDA and has zero days tissue withdrawal with regard to slaughtering cattle having been treated with Chem-Cast.

When considering the safety of the animal being treated with Chem-Cast, Philips Roxane has demonstrated that 3.5 to 4.0 times the recommended label dose for calves weighing up to 150 pounds can be safely administered. However, at this time, only 2.5 times label recommended dose has been demonstrated to be safe for calves weighing 151 to 250 pounds. This lower safety margin for those higher weights occurred as a result of anticipating a lower dose requirement for actual castration than was demonstrated. Thus, a very wide margin of safety exists when using Chem-Cast as labeled.

It also has been demonstrated that Chem-Cast castration effects a more humane castration with reduced animal stress contributing to improved weight gains, lower grain to gain ratio and markedly reduced medical treatment days as compared to surgically and Burdizzo castrated calves for the four week period following castration. This stress data was generated by dividing 45 five-week-old calves into two groups that were then randomly subdivided into Surgical, Burdizzo and Chem-Cast treatment groups. All groups were treated on the same day, similarly housed and all nutrient consumption and medical treatments were regularly evaluated and recorded.

The Relationship of Environment to Respiratory Disease in the Dairy Calf

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Veterinarians have diagnosed enteric and pneumonic diseases in cattle for many decades. Causative organisms have been isolated on numerous occasions. Histopathological studies reveal typical lesions associated with specific organisms. Antibiotic sensitivities are conducted and treatment is now routinely instituted on the basis of sensitivity tests. Vaccines are produced against specific viruses and/or bacteria. Regimes for treatment have been offered. However, in spite of our best efforts as professionals many diseases continue practically unabated. Evidence for this conclusion is drawn from the yearly mortality rate in dairy calves of 8-25% in the United States (Agriculture Statistics 1980).

It is well accepted that infectious organisms and sometimes mildly or even non-infectious organisms cause disease. It is often very difficult for a veterinarian to draw a microbiological work picture that a client will understand. This is because it is human nature to believe what can be seen rather than believe what is unseen. It is often helpful in explaining the bacteriological process to clients to emphasize that 1 cm^3 of manure may contain up to 1 billion coliform organisms.

One of the major factors contributing to bacterial disease is sheer numbers of organisms or to put it another way, size of bacterial inoculum. A second bacteriological principle consists of virulence. An increase in virulence is achieved by serial passage of an organism through susceptible individuals. These two principles therefore play a great role in determining whether or not an animal does in fact sustain disease.

An animal's total defense mechanism consists of a number of parts. If sufficient numbers of organisms enter an animal's body, one or several of these defense mechanisms may be overwhelmed and disease can result. Further, environment is a stressor (Anderson, 1980). As a result of stress there is an elevation of endogenous steroids and the animal's defense mechanisms are thereby suppressed. This, in brief, explains the perpetuation process whereby clinical and sub-clinical disease becomes accentuated in undesirable confinement units regardless of species. A further observation is that it is important that as practitioners we become aware of when, how and under what circumstances vaccine studies are performed. If these studies are performed in undesirable environments, preventive medicine measures of the highest order are totally ineffective because of the overriding environmental effect (Anderson, 1980).

Calves which recover from severe enteric or respiratory diseases, depending on the causative organism, seldom achieve optimum growth rates (Anderson, 1976; Bates, 1976; Anderson & Bates, 1979). Many of these animals are stunted and are often inapparent carriers of disease. They exhibit no outward clinical signs and continue to serve as reservoirs diseminating disease organisms to non-immune animals which they contact.

When a calf contracts pneumonia and survives, if it is housed in an environment which perpetuates disease, a portion of the lung may be removed. That area of the lung will then be walled off. It will then fibrose (scar), and if the infection was severe enough, abscesses will form within the damaged lung tissue. In effect, this portion of the involved lung has been rendered nonfunctional. The net effect of this disease process may be moderate to severe. Limitations are, however, inevitably placed on total lung capacity. As a result the animal will never achieve its genetic potential, either in body size or, if it is a dairy animal, in milk production (Anderson, 1973; Anderson, 1976).

Artificial insemination has been used extensively for two decades. Embryo transfer has become commonplace. Cloning is now being studied; however, herd management has not kept pace with research. High quality genetics are resident in many herds. They become economically evident when diseases are controlled (Anderson, 1973).

Approximately 2% of the population of the United States produces the wealth of agricultural products which we enjoy. Agri-business is to be commended for its ability. Large, untapped areas of revenue, however, are being bypassed daily by producers because of chronically diseased animals. Applied field crop technology is relatively current. Applied animal housing and management technology is often either lacking or is 30 years or more behind modern techniques. Foreign countries visited, often show the same technological lag in epidemiological concepts seen in the U.S.

Animal flow patterns within a livestock operation are often disregarded in the interest of the economics of construction (Bates & Anderson, 1979). Errors are also made because a friend or neighbor may be regarded as the "all-knowing expert" in the field of building design and engineering. Livestock producers often do not understand that by preventing exposure of the newborn calf to older chronic recovered carrier animals respiratory disease can be markedly reduced. Aerosol contaminants are difficult to describe because they are not visible. As a result, the concept is disregarded by stockmen (Anderson, 1973; Anderson et al, 1978; Anderson & Bates, 1979). For many years the calving pen, if one was available, also served as a pen for other animals. This space may have evolved from the stall used as a bull pen. Because of artificial insemination, this enclosure was no longer used and it became available for storage of straw bales, for calf housing, or for maternity purposes.

The maternity pen for dairy cows is therefore often located in the same facility which houses the adult milking herd. As a result, the newborn calf is immediately exposed to all of the organisms which are being shed by the adults. This may occur as a result of an improperly designed ventilation system which conducts air from the older toward the younger animals. In addition, moisture migrates within a building from the warmer areas toward the colder areas. Aerosols are carried in this manner to the maturity pen or calf pens within a dairy barn. If the calf receives oral pathogenic and/or non-pathogenic bacteria in sufficient quantity, intestinal absorption of the necessary protective colostrum from the dam's first milk is inhibited or prevented. This is born out by studies conducted at the University of Minnesota since 1971 (Anderson). These have shown that calves born in the summer on a pasture, when cattle are usually dispersed over a larger area, exhibit adequate levels of colostrum. Gammaglobulin was present in adequate levels in over 90% of the calves tested. In winter, however, when calves are born in dirty, closed or poorly ventilated environments (West, 1970), less than 1/2 of the calves show evidence of having absorbed adequate colostrum (gammaglobulin). (Anderson).

Epidemiological and environmental evaluations indicate that the proper animal flow pattern on a dairy farm should be in the following order (Anderson, 1973; Anderson, 1976):

1. A clean cow enters a clean, disinfected maternity unit. This facility should be designed to allow for convenient manure removal. Each individual maternity pen should also be designed to be easily washed and disinfected between calvings. (There should be 1 maturity pen available per 25 cows in the herd).
2. A newborn calf should receive two quarts of clean colostrum which has been collected from all four quarters of the cow's clean udder. (The dairy cow produces varying levels of colostrum between quarters of her udder). One half of this amount (1 quart) should be given to the calf twice within 6 hours following birth.
3. A calf should be given necessary injections prescribed by the local veterinarian. These usually include vitamins, selenium (in deficient areas of the U.S.), injectable iron and any vaccine which is prescribed.
4. A plastic navel clip should be applied immediately following birth to prevent bacterial entrance and subsequent local navel and/or systemic infections.
5. The calf should then be dried off.
6. The calf is transported to a clean calf hutch which provides semi-isolation and it is maintained in this unit for a period of two months.
7. At the age of 6 weeks, the calf is weaned. The weaning process, from either whole milk, milk replacer or from fermented colostrum rations, is best achieved by feeding once a day either in the morning or in the evening for one week. The other feeding either morning or evening should consist of warm water which is placed in the milk pail to allow free access by the calf. During the course of this weaning period close observation should be paid to the total dry feed consumption which the calf is exhibiting to be sure that the calf is consuming an adequate grain ration by the time it is weaned. Growth rate should be 1 lb. per head per day or greater. Two weeks following weaning, at the age of 8 weeks, the calf is moved to a "super hutch". This unit is designed to house a maximum number of 8 calves which are exposed only

to each other and never to older cattle (Anderson, 1973). The 8 calves are housed in this "super hutch" for a period of 2 months. Two weeks prior to being removed from this structure each calf is vaccinated with intranasal IBR and PI-3 vaccine.

8. The calves by this time are 4 months of age and are then moved to a more labor efficient unit that houses older animals. The newly introduced group of calves in this unit should be separated from their older counterparts by a barrier wall. This wall is usually constructed of 1 x 6 inch oak or elm boards 7 feet (2.2 meters) high. The reason for its construction is to attempt to minimize the size of inoculum (numbers of organisms) transmitted from the older animals to younger recently introduced animals (Bates & Anderson, 1979).
9. In a mechanically ventilated environment, air flow should always be from the younger toward the older animals.
10. Naturally ventilated buildings have been found to work very well for housing dairy herd replacements. Air enters the building by a continuous row of tip out doors installed around the entire periphery of the building (Heinrichs, 1962). Exhaust air is conducted through an unobstructed open ridge in the "stack effect". Aerosol transmission is thereby reduced from pen to pen by an upward air movement. Due to the large volume of air removed from the naturally ventilated building, dilution of aerosols also plays a role in disease control.

This animal "flow pattern" was initiated in 1963 and has been refined and modified since that time. Data collected from DHIA records from herds on research programs illustrates the following results:

1. Death losses have consistently been reduced from 30 and 40% yearly to 1%.
2. Heifer replacements with genetic capability reared before the changes in these flow patterns produced milk at the rate of 40-50 lbs. (18-20 kg/head/day). On auscultation with a stethoscope, the same animals often exhibited signs of chronic lung disease. Lung damage may not always be of significant magnitude however to manifest changes in auscultated lung sounds. Pathology may only be evident when histopathological serial sections of the lung are studied in great detail.
3. Heifer replacements with genetic capability reared after the changes in flow pattern now routinely produce 70-90 lbs. (31-40 kg/milk/head/day) (Anderson).
4. Heifer replacements reared under this new system are now routinely giving birth to their first calf at 22-23 months of age (Anderson). Minnesota DHIA records indicate that the average age of heifer replacements at their first calving date is 29 months. A dairy producer sustains a $70.00 per month loss per head for every months past 24 months on the first calving date.
5. Steer calves reared under this new method of management can be regularly finished for slaughter at 1,050 to 1,150 lbs. (480-520 kg) in a period of 55-56 weeks of age. Increases in cash flow, with more than adequate numbers of replacement dairy animals is a distinct advantage. In addition, the resulting institution of the "closed herd concept" with no new animals being purchased, and no new pathogens being introduced, are all advantages of this program. Producers quickly realized the need for hygiene and sanitation after observing these beneficial results.

Prevention of exposure of the non-immune calf to older recovered carrier animals is necessary to allow expression of genetic potential. Concurrently, the individual animal's immune mechanism and immune status matures. As a result vaccination programs also become more effective under this new regime. Products used for immunization of animals are designed for use in healthy, normal animals properly housed and maintained which are thereby capable of producing a good immune response.

Postpartum uterine infections are also decreased markedly because of clean, isolated maternity facilities. Excessive numbers of organisms present in the environment are quickly taken into the cow's vagina during parturition (calving) and subsequently into the uterus. These organisms then produce postpartum metritis which often requires extensive treatment. In addition, because of chronic uterine infections, the herd calving intervals are increased, thereby reducing the total number of calves which a cow can produce during her lifetime.

A basic minimal exhaust of 4 air changes per hour via a negative pressure ventilation system should be maintained in winter for temperature and moisture control. The most important reason to maintain this air flow, however, is to remove and thereby dilute the suspended bacterial aerosol. No air, either cold or warm, should ever be recirculated within an animal housing unit. Recirculated air only serves to concentrate organisms. Increased capacity in the ventilation system is necessary during warmer weather. These capacities will range as high as 40 air changes per hour. The basic 4 air changes are supplied by a fan which is only switched and never stops unless the animals are removed from the building. The fans which supply the higher air capacities are controlled by thermostats. Proper air intake design is essential to satisfactory performance of any ventilation system (Bates and Anderson, 1979).

Spacial volume per animal housed must be considered. The volume for calves should be 200-250 ft^3 per animal. In tie-stall barns the accepted spatial volume per cow housed is 600 ft^3. Inadequate spatial volume concentrates the microflora and/or the aerosol in the environment thereby increasing the potential for disease.

Air intakes into the unit should never be located near exhaust fans from another unit.

Calf hutches should never be located near exhaust fans from other buildings. In addition, they should never be spaced closer together than 4 feet. Disease entities can be transmitted if calves are adjacent to each other.

Cats and dogs should **never** be allowed entry into the units housing maternity areas of any species. Cats carry and disseminate a variety of organisms from pasteurella to toxoplasma. In addition, cats should be discouraged from coming in contact with calves in hutches. Cats prefer drinking milk from calf pails and warming their feet on the back of a calf which is lying down. A small housing unit with an electric light bulb has proven successful to entice cats away from calf hutches.

Fly control is essential. It is best achieved by use of insecticide ear tags and residual types of fly spray. Bedding the calf hutches in summer with gravel discourages fly egg deposition due to lack of organic material. A small door extending the full width of the calf hutch at the rear of the unit near the ceiling is beneficial. This discourages flies from resting on the ceiling of the hutch at night during the summertime. It is absolutely essential however that this door be closed and sealed in the wintertime to prevent the calf hutch from turning into a "wind tunnel."

Bird control, especially starlings, is essential for disease prevention. They prefer both hutches and "super hutches" because of readily available feed and water. Feed dumped from pails or hutch feeders should be removed from the housing area to prevent bird congregation.

Through application of the basic disease control techniques innumerated inherited genetic capabilities can express themselves.

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Compatibility of Fenbendazole When Used Concomitantly with Other Products to Process Feeder Cattle

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Three studies were designed to evaluate the safety of Fenbendazole when administered concomitantly with a modified live vaccine, an organophosphate insecticide and a growth implant.

In one study 30 cattle most seronegative to IBR virus were vaccinated with an IBR modified live vaccine. Variables measured included serum antibody titers at 0 and 21 days. In a separate study 30 cattle were sprayed with an organophosphate insecticide-grubicide. Variables measured were blood and plasma cholinesterase activity at -2, 0, 1, 2, 7, 14 and 28 days.

In a third study 120 cattle received a zeranol ear implant. Weight gain and feed efficiency data were obtained every 28 days during the finishing period.

In each study 1/2 the cattle were drenched with fenbendazole suspension 10% (5mg/kg b.w.). Results were analyzed statistically.

No incompatibilities were observed indicating fenbendazole is safe when administered concomitantly with products used to process feeder cattle.