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Waste Reduction by Waste Reduction, Inc.

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Cotton Annex
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Washington, DC 20250-3700

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Gordon I. Kaye

Sir:

We have carefully reviewed the Interim final rule and many of the comments received in relation to it since it was promulgated on 12 January. Although we can sympathize with the many small farmers/producers who have expressed their concerns about slaughtering their own non-ambulatory animals for family or custom use, and with the several Japanese specialty meat product producers who are concerned with a culturally-centered use of a particular byproduct, we must express support for even the quite limited actions taken in the Interim Final Rule to protect the health and safety of the American public and the safety of our food supply.

We strongly believe that basic and legitimate food safety and public health concerns require the establishment of a comprehensive, uniform, enforceable process for the removal and destruction of potentially infectious byproducts from the marketplace. The Interim Final Rule, as published, does not accomplish such a process, and we strongly support modifications that will improve this rule in important respects.

First, the rule only requires the removal of Specified Risk Material ("SRM") from cattle over thirty months of age. This requirement stops short of accepted and established SRM removal provisions which have been in place for years in other countries. Frankly, the 30 month requirement causes several problems:

1. It assumes that active prions are not, or cannot be present in animals below 30 months. This has been shown to be false.
2. It would require a dual-slaughtering system for the first time, one for over 30 month animals, and one for younger animals.
3. It would require implementation of admittedly arbitrary and imperfect methods of determining animal age, before the animal can be assigned to the "over 30" or "under 30" slaughtering and preparation procedure.

Thus, the 30-month threshold poses not only food safety and public health problems; it further causes inefficiencies and increases the possibility of mistakes in the animal slaughtering operations seeking to comply with this restriction.

There is little question that Specified Risk Material (SRM), which we believe has been properly defined in the Interim Final Rule, poses significant risk of human exposure to

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the BSE prion. Thus, it is critical to the efficacy of the rule that this material be destroyed in a manner that will prevent it from entering either the human *or animal* food supply in the US or in our export trade.

While the Interim Final Rule requires the removal of the SRM from the animals and its destruction, the rule does not specify how the SRM destruction must be accomplished nor how the USDA or the meat consuming public can be assured that appropriate measures are taken by the slaughterers and meat processors to ensure that 1) the procedures used to remove and handle SRM actually remove any residual potential prion-containing material from material destined for human food products, and that 2) once removed, the material is consistently treated in a manner that will not result in residual prions or disease agents being introduced into the environment. Rather, it merely asks that individual meat packers and handlers submit a plan as to how they will safely dispose of the material. This requirement virtually guarantees that prion inactivation standards will vary from one meatpacker to another, and that no uniform, comprehensive regulatory framework could be expected to result from application of the rule as now written.

It is well known that the infectivity of the BSE prion is extremely difficult to inactivate. Studies in both the US and Europe have clearly demonstrated that none of the conventional methods of disposal, (i.e., rendering, landfill, even incineration [except in closely controlled and regulated circumstances]), can reliably destroy the infectivity of BSE contaminated brain and spinal cord tissue. The required rendering method for BSE contaminated or suspect material in the EU can, under even the best laboratory-controlled conditions, reduce BSE infectivity by a factor of 10^2 to 10^3 (although some US renderers claim a maximum reduction of only 10^1). Meat and bone meal produced by such rendering in Europe is still considered infectious and must subsequently be destroyed under EU regulation by processing methods approved for the processing and disposal of Category 1 material.

While it is *assumed* that incineration at very high temperatures (>800°C) destroys the infectivity (although scrapie infectivity has been shown to resist 600°C for 15 minutes in several well-controlled laboratory studies; [Ref. 1]), no controlled studies of the efficacy of incineration in the reduction of BSE infectivity have been undertaken using actual commercial scale equipment. Further, very few available incinerators exist that might be used to achieve the necessary temperatures for sufficient time, nor are they able to handle whole animal carcasses or large amounts of fresh tissue with adequate residence time and agitation to assure that all biologic material is destroyed.

The only method that has been proven to be completely effective under controlled conditions in both numerous laboratory studies and in simulated commercial conditions using commercial equipment and standard procedures is alkaline hydrolysis of all

protein-containing animal tissue suspected to contain prions at elevated temperature (References 2-7). [1]

Based on the previously cited laboratory studies, the USDA-APHIS Emergency Services chose to use a large ***WR²*** Model 100-96-series Tissue Digestor to destroy 2 flocks of sheep seized in Vermont in 2001 suspected of harboring a TSE that was not scrapie and was suspect for BSE because the sheep had been fed contaminated meat and bone meal before they were imported from Belgium. Under the USDA's rules promulgated for a carcass disposal cost reimbursement program for ranchers for disposal of farmed deer and elk suspected of being infected with Chronic Wasting Disease (CWD; another prion disease closely related to BSE) only incineration and digestion by alkaline hydrolysis are approved as methods qualifying the ranchers for reimbursement (9CFRChapter 1 - Docket No. 01-068-1; please cross reference to our comments on that rulemaking, which, for convenience, are attached hereto.). Further, the large scale CWD elimination programs in both Colorado and Wisconsin use commercially available alkaline hydrolysis systems at elevated temperature to dispose of tons of infected and suspect deer and elk carcasses and heads daily. Further, based on the EU-SSC Opinion and Report (Reference 7), the European Union has recently promulgated regulations under which alkaline hydrolysis at elevated temperature is approved as a disposal method for *BSE contaminated meat byproducts and all other Category 1 materials* as defined in EU regulations (SANCO/2153/2003 Rev. 13).[1]

It is our strong belief that treatment and disposal of SRM should take place in a manner where separation from the slaughtering of animals or animal material destined for the food chain is assured. Further, we must be prepared for the eventuality that additional SRM from animals younger than 30 months, will be banned from the food chain and

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[1] A significant source of information upon which the EU-SSC Opinion and Report (Reference 7) was based is an internal draft report to the UK Department of Environment, Food, and Rural Affairs (DEFRA) summarizing the results of a validation study of alkaline hydrolysis at elevated temperature under simulated commercial condition using a commercially available ***WR²*** Model 100-Lab-30 Tissue Digestor. As reported to DEFRA, the protocols for this study were designed to examine the system under *"the worst possible conditions"* and that was precisely what was achieved. In this instance, sheep brains inside sheep skulls were doped with mouse-passaged 301V BSE agent, the prion shown to be most resistant to any inactivation process, and the heads were then wrapped in polyethylene bags and frozen at -70°C.

The frozen heads were subsequently loaded into the Digestor along with fresh mutton, including meat, bone, and fat to simulate a whole carcass, and digested for 3 hours with either 1 M NaOH or 1 M KOH, or for 6 hours with 1 M NaOH. Aliquots of the resultant hydrolysate were neutralized and diluted to 1+4, 1+9, and 1+49 prior to intracranial injection in naïve VM mice (the strain of mouse least resistant to BSE infection). The mice were maintained and observed for between 502 and 509 days prior to sacrifice and examination of the brain tissue. Only one mouse, that one in the 1+49 dilution set of the KOH-treated head, showed any clinical signs and was sacrificed at 438 days. Three other mice in this dilution set showed histologic signs when sacrificed at 509 days, as did one mouse in the 1+49 set of the 3 hour NaOH-treated head sacrificed at 505 days. NO MICE IN ANY OF THE MORE CONCENTRATED INJECTION SETS, NOR IN THE 6 HOUR NaOH TREATED HEAD OR A SUSPENSION OF THE BONE SHADOWS REMAINING FROM ANY OF THE DIGESTIONS (the calcium phosphate remnants of bones and teeth) SHOWED ANY CLINICAL OF NEUROPATHOHISTOLOGIC SIGNS OF INFECTION. Even under such conditions, conditions that would never obtain in a commercial situation, i.e., wrapping in polyethylene (which has a melting point of nearly 133°C) and freezing at -70°C, there was greater reduction in infectivity than achieved with any other tested method and complete elimination of infectivity at six hours even with the barriers imposed by the protocol. Given the facts that the unfrozen meat in the 3 hour digestions would have consumed a considerable portion of the alkali even before the polyethylene was dissolved and the head defrosted, and thus even exposed to the alkali, one could conclude as well from these studies that alkaline hydrolysis at elevated temperatures is even more effective than presumed in the initial planning process as the doped brain tissue was probably exposed for less that 1.5 hours in the 3 hour digestions.

destroyed, and the likelihood that SRM from animals younger than 30 months will also be banned from pet and other animal foods.

We must also emphasize our own strong belief that **no treated byproducts from either over 30 month animals or under 30 month animals should be allowed to enter ANY animal feed,** whether for livestock production or pet food use. The latter poses a particularly serious potential human health hazard because of the number of poor Americans whose primary source of dietary protein is derived from canned pet food. This dietary debacle was the principal reason for banning the use of pentobarbital-euthanized animals from pet food use; allowing SRM from even cattle less than 30 months to be used in pet food would create an even greater potential danger to human health and safety.

Requiring the destruction of SRM, while removing it from one potential secondary market (i.e., the protein market), does not, however, destroy its economic value. We must bear in mind that in eliminating one major market for rendered material, an effort must be made to assist the rendering and cattle industries to retrieve some of the market value of a significant portion of their output. If the government were to require separate and specific rendering facilities, some possibly regionally located and available to small producers, **using prescribed destruction methods for SRM**, the recovery of the economic value of the SRM could be facilitated by encouraging, even initially subsidizing, the development of alternative uses for the destroyed SRM. The hydrolysate from alkaline hydrolysis is an even better feedstock for anaerobic digestion methane gas (biogas) production than the traditional porcine manure that is used in these plants and, in a properly designed facility, could significantly contribute to creating an energy self-sufficient alkaline hydrolysis-anaerobic digestion facility. Also, the fat fraction that can be removed from SRM and subsequently hydrolyzed in approved alkaline hydrolysis systems can be safely resold for a number of uses and applications including bio-diesel production. Further, the amino acids, small peptides, and sugars in the hydrolysate make an excellent liquid or dry fertilizer that, because all proteins are destroyed in the process, can be considered safe for application to soils or crops. Finally, the mineral ash of the bones and teeth, resulting from the process, are excellent prion-free material that can be used as a stabilized (time released) and environmentally compatible phosphorous source for gardening (bone meal) and for addition to the liquid portion of the fertilizer resulting from the process. Traditional rendering companies using alkaline hydrolysis systems for destruction of SRM might thus continue to recover value from these byproducts in the form of energy for their own use and export into the grid, in the form of recovered derivatives of the fat fraction, and in the form of liquid or dried fertilizer for recycling of the valuable nutrients contained in the hydrolysate. As simple a procedure as mixing the liquid hydrolysate produced in the alkaline hydrolysis process with a cellulose-rich material such as sawdust, wood chips, peat, straw, bedding, leaves, paper or cardboard waste would also produce a dry fertilizer suitable for commercial and consumer use.

In summary:

We agree that the SRM listed in the Draft Final Regulations 9CFR301,309 for cattle over 30 months old must be destroyed and prevented from entering ***any*** human or animal food chain.

We believe that prescribed SRM from animals younger than 30 months must also be prohibited from entering any human or animal food chain.

We agree that no downer animals, except, perhaps those with limb injuries only, should be allowed to enter the food chain. While those with limb injuries could be omitted, the question arises as to the integrity of those making the "limb injury" determination, if this could truly be controlled. That is a question that must be addressed by regulatory authorities closer to the compliance issues in the meat producing industry. Would this be a loophole for many producers to slip marginal animals through?

We believe that the USDA must prescribe and supervise the method(s) of destruction of SRM and not leave those choices solely to the producers, slaughterers, or processors.

We believe that alkaline hydrolysis at elevated temperature is the most effective and environmentally responsible method of destroying the potential infectivity of BSE contaminated or suspect material. Unlike incineration, it is the most easily scaled system, the system most likely to produce an economically and environmentally useful product from the destruction of SRM, and the only system that has been proven at commercial scale to both destroy infectivity and easily dispose of multiple large animals. Further, and obviously, alkaline hydrolysis does not pose the air emission and other significant environmental hazards inherent in incineration.

We believe that the meatpacking and rendering industries must be integrated into the SRM disposal system and must be encouraged and possibly initially assisted to modernize, select the most effective destruction process (es), and develop secondary products and markets for the material produced from the destruction of SRM.

Respectfully submitted,

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Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species

Re: Docket No. 01-068-1

As the developers of the alkaline hydrolysis (alkaline digestion) process for disposal of biologic waste described in several places in the proposed rule, it is incumbent on WR² to comment on several aspects of this proposed rulemaking. We begin by commending the author(s) of the Federal Register notice for presenting a thorough and well organized background section, appropriately putting the problem of BSE entry and transmission in the US into the context of the worldwide BSE problem as well as presenting the possible relationship and parallel control problems of other prion diseases currently present in the US livestock industry, namely scrapie in sheep and goats and chronic wasting disease (CWD) in both domestic and wild deer and elk, the latter in a growing geographic distribution.

WR² believes that the specific control problem posed in the proposed rule must also be examined in a broader context that must include:

· mode of entry of animal diseases into the US,

· control of possible disease spread among animals destined for routine slaughter if the disease were to appear in the US naturally or sporadically, and

· control of animal disease outbreaks that might be natural epidemics or the result of agricultural bioterrorism,

all of which are within the purview of APHIS and are being addressed in various contexts by APHIS and by

working groups and consortia created by APHIS to examine these problems.

Efficacy of Disposal Methods for Downer Cattle and Dead Stock

The proposed rulemaking correctly evaluates the efficacy of the various methods for disposal of down cattle and dead stock and ranks them by efficacy. It has been clearly demonstrated in both laboratory level experiments and by analyzing the soil surrounding BSE carcasses buried on farms in the UK and Ireland that infectivity remains undiminished at the sites of burial of diseased tissue. Further evidence of this phenomenon has been demonstrated world-wide by recontamination of animals with related prion diseases where long abandoned contaminated sites were repopulated.

In the case of CWD, infectivity apparently remains in the soil where diseased animals have been housed even after removal of a significant layer of topsoil and attempts at cleaning the area have been undertaken, sometimes as much as several years to over a decade after removal of the diseased stock and contaminated soil.

As noted in the proposed rulemaking, there is also no evidence that composting destroys the infectivity of BSE prions, especially as the normal temperatures achieved in composting are significantly below those achieved in autoclaving or rendering, both of which have been demonstrated to be unable to destroy totally the infectivity of the BSE prions.

The proposed rulemaking also correctly presents the efficacy of rendering by current US methods as ranging only from a log-1 to a log-3 reduction in infectivity. This is consistent with published studies from the UK in which rendering efficacy was evaluated under well-controlled conditions and shown, at best, to be able to achieve a log-3 to log 3.5 reduction in infectivity.

While it is assumed that high temperature incineration (i.e., greater than 1000°C in the primary chamber) will destroy prion infectivity, this has not, to our knowledge, yet been demonstrated in well-controlled studies. It has been demonstrated that prion infectivity will survive 600°C for up to 15 minutes, conditions more stringent that those found in most incinerators currently in routine use.

To date, the only disposal method that has been shown to completely eliminate prion infectivity in both brain homogenates and whole animal tissues is alkaline hydrolysis at elevated temperature.

This has been thoroughly demonstrated at laboratory level in every one of the world's leading prion research laboratories and at temperatures as low as 100°C, and at a small-scale commercial level in a "worst-case" validation study at the Institute for Animal Health, University of Edinburgh. Even under certain, "worst case conditions" in that latter study, namely a prion load contained in brain tissue within a sheep skull bagged in polyethylene and frozen to -70°C, a level of infectivity reduction greater than that achieved by any other method was demonstrated (log-4.5 reduction) in a three hour digestion cycle at 150°C and complete elimination of infectivity was demonstrated in the same material at 6 hours.

It is evident and increasingly well-accepted that no routine processing of downer cattle, dead stock, offal, or specified risk material removed at slaughter would ever include wrapping and storing the material under those "worst case conditions" and that routine alkaline hydrolysis for 3 hours at 150°C would effectively destroy all infectivity. Validation studies have been started to demonstrate the efficacy of alkaline hydrolysis to eliminate prion infectivity at lower temperature for longer time periods, specifically ~100°C for times ranging from 16-24 hrs. In these studies, both western blot analysis of the hydrolyzate and intracranial injection bioassay studies will be used to evaluate prion destruction. While the bioassay results may not be available for 18-24 months after intracranial injection of naive mice, the western blot analyses of the hydrolyzate are expected to provide results relatively quickly.

In conclusion, if efficacy, i.e., complete elimination of infectivity or potential infectivity is the guiding criterion in a making a decision about method of destruction, alkaline hydrolysis at elevated temperature is the only method that is currently proven to meet that criterion.

Entry of Animal Diseases into the US in the Course of Normal Animal Importation

The responsibility for control of animal importation and reduction or elimination of the risk of importation of animal diseases also rests with APHIS and constitutes a very significant prevention method for eliminating the risk of BSE entry into the US cattle herds. Under normal circumstances, imported animals would pass through one of the Animal Import Centers (AIC) maintained by APHIS at key ports of entry and animals would be examined, their

histories reviewed, and they would be quarantined for appropriate periods before release from the AIC. These animal import centers are in the process of being modernized and upgraded to allow them to perform their important functions more efficiently. In addition, WR² is currently consulting with APHIS and USDA-PPQ on methods to improve the management of all waste from international airplane flights and from ships reaching the US from foreign ports to suggest means to prevent the escape of potentially infectious material from the point of entry.

A good example of how well this system works is seen in a review of the importation, quarantining, monitoring, and ultimate destruction of three flocks of Belgian sheep imported into Vermont several years ago in an attempt to improve and expand the breadth of the cheese industry there. The imported sheep were known to have been fed potentially BSE-contaminated meat and bone meal feed supplements before export from Belgium and were, therefore, carefully examined, restricted to three farms, and routinely monitored for signs of any TSE infections. Any downer animals or dead stock were carefully examined, including neurohistopathologic examination of brain tissue as well as western blot assay for infectious prion proteins and a small number of animals were randomly sacrificed each year for similar examination.

When evidence of a TSE infection appeared in several (4) sheep in the summer of 2000, and test data suggested that the TSE in question was not sheep scrapie and could not be shown not to be BSE without further study, the sheep were ordered to be seized and destroyed. After several months of overcoming opposition and court actions, the sheep were seized by USDA and transported to the USDA facility at Ames, Iowa where they were euthanized, brain and other tissue collected for study, and the carcasses destroyed by alkaline hydrolysis at elevated temperature in a WR² Model 100-96-68 Tissue Digestor purchased by APHIS for the purpose. It is our understanding that the analysis of the brain and other tissue from these animals is still ongoing but that additional cases of TSE may have been identified in the tissues from the euthanized animals.

We have included this lengthy discussion of the Vermont sheep as an example of how the placement of alkaline hydrolysis Tissue Digestors of various sizes at key USDA facilities, as well as at state veterinary diagnostic laboratories would be able to contribute to the early and effective control of the beginnings of an outbreak of BSE or other TSE. As TSE are not communicable in the ordinary sense, it would be practical to bring the initial limited numbers of animals to sites of disposal.

However, as is discussed later in these comments, the availability of WR² mobile alkaline hydrolysis systems that could be brought to the site of a disease outbreak will also serve an important role in the containment of any BSE or other TSE outbreak and the process of purchasing and distributing these units has already been begun by APHIS as part of its Emergency Programs response preparations.

Control of Possible Disease Spread Among Animals Destined for Routine Slaughter if BSE Were to Appear in the US Naturally or Sporadically

If BSE were to be introduced into the US by any method that somehow bypassed the stringent import controls, or were still insufficiently established as an evident infection in an animal or animals that were imported and passed inspection, but subsequently developed the disease, the current ban on the feeding of ruminant derived feedstocks to other ruminants, as described in the proposed rulemaking, could prove to be sufficient to prevent spread of the disease, but there is some risk that poor carcass disposal techniques would compromise this sufficiency. In addition, the relative distribution of cattle raised for slaughter as beef versus cattle slaughtered after their useful life as milk producers is very different in the US than in the UK, Ireland, and other European countries. Many, many more cattle are raised for beef in the US and nearly all cattle slaughtered for beef are slaughtered before they reach 24 months of age, the earliest age at which signs of BSE infection have been detected in infected cattle in Europe.

However, if the disease were to appear in the US, there would be a significant public perception problem to be dealt with and there would without doubt be demands for instituting many of the controls currently in place in the UK, Ireland, and the rest of the EU, namely removal and destruction of specified risk material (SRM [heads, vertebral columns, intestines, spleen, and other offal]) and possibly even an over thirty month cull.

If, as we believe, alkaline hydrolysis continues to be the only completely effective and practical method for disposing of this suspect material, these measures would create the need for many Tissue Digestors at meat processing plants or rendering plants and it is likely that alkaline hydrolysis of SRM and offal would become part of the routine processing system at slaughtering plants.

The requirement for a sufficiently high volume of these devices for SRM disposal would surely result is

significantly reduced production and capital purchasing costs of these machines.

To accommodate this development would take alkaline hydrolysis process development in two different directions, both of which have already been explored and one of which has been effected. Digestion of SRM and offal is, clearly, easier than digestion of whole carcasses, which would be the normal pathway for downer cattle and dead stock. Therefore, it is most likely that shorter cycles at 150°C could be used for this material, allowing increased throughput each day. This would certainly be necessary and practical at large meat processing plants, and would even further reduce per pound processing and disposal costs. Remember, however, that there are also many small meat slaughtering and packing operations in the US that would be faced with the same disposal problems. Because of lower waste volumes, they would need and benefit from a practical but even less costly method than the Tissue Digestors operating at elevated temperature and pressure (150°C and 65 psig for 3 hrs).

To satisfy this requirement, WR² has already developed a line of Tissue Digestors (some of which are labeled WR² Agri-Lyzers™) that operate at ~100°C and at atmospheric pressure for extended time periods up to 24 hrs. One or more such units, which are priced at a small fraction of the cost of high temperature/high pressure Tissue Digestors with comparable waste capacities per cycle could easily meet the needs of such small processors. This is why WR² is undertaking immediate efficacy testing of the lower temperature process and devices, so that they are ready and certified to meet this need should it arise.

Control of Animal Disease Outbreaks that Might be the Result of Agricultural Bioterrorism or Natural Epidemics

The introduction of BSE into the US as a means of bioterrorism seems very unlikely as it is very impractical. Significant amounts of deliberately mislabeled and contaminated meat and bone meal feed stock (MBM) would have to be introduced where animals are fed or numerous cattle would have to receive intracranial injections of relatively virulent strains of BSE prions and those animals would then have to get into the food chain for additional cattle, or would have to be improperly disposed of in a manner that risked spread of TSE infection to other exposed animals.

The only likelihood of need for large-scale destruction of BSE suspect cattle would be if a significant number of infected cattle were found in a particular herd and the whole herd was ordered destroyed. Another TSE, such as CWD, could also affect a large enough number of deer and elk that mass elimination of a significant portion of the wild population (as is currently being attempted in Wisconsin) or of a captive herd were ordered. However, even in these conditions, carefully controlled and monitored transport of animals or carcasses to a central location for digestion by alkaline hydrolysis at elevated temperature and pressure would be practical. However, the use of mobile Digestor units that could be brought together at a remote site if necessary would add to the safety and effectiveness of any elimination program.

The more likely scenario for large numbers of infected animals to have to be destroyed in situ would be a "natural" or bioterrorist-caused outbreak of some more common and more contagious infectious agent such as bovine tuberculosis, foot and mouth disease, brucellosis, or anthrax. Under this scenario, large numbers of animals in a single geographic area or several widely separated geographic areas would likely be involved. As discussed in several recent APHIS and state-sponsored seminars of this subject, ordinary incinerators large enough to deal with the numbers of animals would not be able to be brought to the site. As in many large-scale animal disposal situations the recent past, air curtain burners could be effective but could be potentially polluting and would demand a constant and reliable source of wood fuel, something not likely to be found on the Great Plains where much of the cattle raising in the US takes place. As recently discussed at one of these seminars, the combination of a fleet of high temperature/high pressure mobile Tissue Digestors brought together from various states and, even, from Federal facilities (4000 lb and 8000 lb capacity Tissue Digestors) combined with a larger fleet of 3000 lb capacity Agri-Lyzers towed behind pickup trucks and mobilized from state and county transportation departments, animal control departments, and environmental control departments, and even from individual farmers, farm cooperatives, and feedlots could quickly bring to bear on the problem a very large disposal capacity that would provide assured destruction of any infectious agent.

Economic Considerations: Capital Costs, Per Pound Operating Costs, and Recycling Revenues

As correctly noted in the proposed rulemaking, economic considerations will have a very significant impact on what method or methods are selected for control of BSE pathways involving downer cattle and dead stock, and of other TSE and non-TSE infections in agricultural animal populations. These considerations must take into account initial capital costs, operating costs, and recovery of costs through sale of byproduct or end product.

The Proposed Rule Docket mentions the cost factor of alkaline hydrolysis with a premature statement that such

devices are "relatively expensive." As a new technology with less than 100 installations worldwide (with the installation rate growing at a rate of nearly 600% per year), alkaline hydrolysis Tissue Digestor manufacturing has not yet benefited from the significant cost reductions that will accompany high volume requirements for these machines. As several animal carcass destruction applications are beginning to now standardize on alkaline hydrolysis as the method of choice, including for both TSE and non-TSE biological tissue destruction, it is reasonable to anticipate that any decision to select this method for deployment at a significant number of sites will result in both capital and operating cost reductions for long-term deployment and use of the alkaline hydrolysis process.

Further, as knowledge grows regarding the cost-offsets to be gained by recycling of the hydrolyzate (or liquid residue) from alkaline hydrolysis for biogas production or for use as fertilizer or fertilizer feedstocks, the net operating cost per pound of waste material processed with alkaline hydrolysis, which is already attractively low, will be even lower.

Both fixed-base incinerators and large Tissue Digestors currently have relatively high capital costs for initial installation, although Digestors cost only between 25% and 33% of large pathologic incinerators of comparable capacity that operate at the high temperatures currently assumed to destroy prion infectivity; in addition, Tissue Digestors produce no particulate air emissions.

The long term ownership and operating costs of the two systems are radically different, with pathologic incinerators that reach appropriate temperatures estimated to operate at 50 to 75 cents per pound of carcass because of the low fuel value of whole carcasses and the current high prices of fuel oil and natural gas. While certain types of field burning devices and cement kilns may operate at high temperatures and lower costs than pathologic incinerators, the latter are not always near enough to sites of animal loss for practical use and the former, as noted above, require large amounts of wood fuel that is not always conveniently available at sites of animal loss and, also, generally need considerable operator intervention to keep the system going and to try to assure that all the tissue is burned. Fixed-base Tissue Digestors operate at 2 ½ to 6 cents per pound of waste processed based primarily on the cost of the alkali solution that is used in the system (which varies depending on the volumes in which it can be purchased and stored on site). Wherever the alkali material can be stored on site in significant volume, operating costs are at the lower end of this range. Energy costs for fixed-base Digestors are minimal as they are heated only to 100°C to 150°C degrees (as opposed to the need to heat to over 1,000°C in an incinerator) and fixed-base Digestors are normally heated by already existing building steam sources and the energy cost is merely that needed to bring the steam from condensate pressure (zero PSIG) to operating (heating) pressure (<75 PSIG). Mobile high temperature/high pressure Tissue Digestors are slightly more expensive, operating in the range of 4 to 8 cents per pound. But this is still significantly less than the operating costs of incineration. They are slightly more costly to operate than fixed-base Tissue Digestors or because they must use diesel fuel or propane to generate their own steam and electricity on the trailer on which the Digestor is mounted. Trailer-mounted Agri-Lyzers are also designed to be self-sufficient for heating and electricity, with propane or diesel heating of the alkali solution with an in-tank burner and a diesel or propane power generator to provide electricity for control systems, pumps, etc. Also, because of the materials from which they are built, both fixed-base Digestor installations and mobile operations have a much greater life expectancy that comparable oxidative systems (burners, incinerators) and much lower maintenance costs.

The proposed rulemaking provides a great deal of information on the economic aspects of rendering and makes much of the changes in the rendering industry and the costs associated with rendering now that the value of MBM has be radically reduced by the ruminant feed ban and, while not mentioned in the rulemaking, the depression in the hide market. The rulemaking describes the end product of Tissue Digestors as "innocuous liquid waste and some calcium phosphate." The liquid waste is suitable for release to a sanitary sewer but while that is the easiest method of disposal it may not be the most cost-effective, because it eliminates the significant economic and environmental benefits of recycling.

The undiluted liquid hydrolyzate is about a 6% solution of amino acids, small peptides, sugars, soaps and electrolytes. It is an excellent fertilizer (if KOH is the alkali used) and can be directly land applied to fallow fields and was recently approved by the State of Illinois for field spraying (with dilution) on growing corn or soybean crops. If mixed with peat moss or other cellulosic materials (sawdust, wood chips, ground corn husks) it is absorbed into the dry material and can be packaged and sold as a solid fertilizer. It is an excellent compost additive providing a form of supercharging carbon. Similarly, the sterile calcium phosphate residue from bones and teeth can be added to any of the fertilizer compositions or dried and used as bone meal for bulbs and roses. Perhaps the most valuable use of the hydrolyzate, however, especially for fixed base units (or mobile units from which the hydrolyzate can be collected in tanker trucks) is as a feedstock for anaerobic fermentation (anaerobic digestion) waste treatment systems in which biogas (methane) is generated that can be used to heat water,

produce steam, and generate electricity for the plant using the Tissue Digestor system and from which the spent microbial biomass and residue can be used as a fertilizer

ENTEC, an Austrian manufacturer of anaerobic digestion system for farm waste and sewage treatment with over 100 current installations in Europe, the Middle East, and Asia has studied the use of the hydrolyzate from a demonstration WR² Tissue Digestor that has been operating in the UK and Ireland for the past year as a feedstock for its anaerobic digestion systems. ENTEC has concluded that the hydrolyzate is about 1.75 times as good as the best material it has previously used as feedstock (usually pig manure) and has several current proposals before large protein (beef, poultry) processors in the UK, Ireland, and the US for combined systems involving alkaline hydrolysis (AH) and anaerobic digestion (AD). Their analyses show that the combined systems would produce enough methane (or biogas) to operate the meat processing plant (producing heat, steam, and electricity) as well as both the hydrolysis and anaerobic digestion systems and still have enough capacity left over to sell electricity into the local grid. The process water used and generated in the two systems is ultimately collected by distillation and recycled and the small amount of biomass remaining at the end of the anaerobic digestion process is available as fertilizer or, if dried, as fuel cake for another hydrocarbon burning system.

Finally, WR² must comment on, and set forth the facts related to the statement on page 2707 that ..."most State laws do not yet recognize or recommend it (i.e., alkaline hydrolysis Tissue Digestion™) as a means of dead stock disposal."

The fact is that every state in which a Tissue Digestor has been installed has either specifically approved its use for animal carcass destruction (if state law/regulations required such specific approval), or many states have approved Tissue Digestors by rule based upon the fact that the conditions of Tissue Digestor operation exceed those of an autoclave or other sterilization device, or because the performance standards exceed those of STAATT 1 and STAATT 2.

Some of WR²'s primary customers are States, themselves, and some have used funds provided by APHIS for the purchase of Tissue Digestors. States that currently operate Tissue Digestors, have Tissue Digestors at sites awaiting final facility construction, or have Tissue Digestors on order include Florida, Pennsylvania, Illinois, Texas, Wisconsin, Minnesota, Colorado, and California. Ohio will join this list soon, as will other states. Most significantly, Tissue Digestors have been approved at every venue at which approval was sought for their use for human pathologic waste and regulated medical waste, the definition of which often includes the phrase "capable of causing disease in humans or animals."

End Note:

WR², as a knowledgeable participant in the battle against animal diseases, is pleased to provide these comments, and to express its appreciation to USDA-APHIS for its truly professional and dedicated leadership in providing effective first lines of defense to our country against biologic hazards affecting animals and our national and international food supplies.

We are pleased to offer our ongoing assistance as choices are made in the deployment of strategies and policies by APHIS in the coming weeks and months.

Respectfully submitted:

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and

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