



Waste Reduction by Waste Reduction, Inc.

Comments on FDA Proposed Rulemaking - Docket No. 2002N-0273

From a public health standpoint, we are surprised and concerned that the FDA would consider disposal of the brain and spinal cord of cattle over 30 months of age, the material it considers the highest risk SRM, through landfill or incineration (page 44). It has been well demonstrated that there is no reduction in potential infectivity of BSE contaminated material sent to landfill. Incineration of animal material is an extremely inefficient process; animal tissues do not make good fuel being 65% to 70% water. Further, without specifying the conditions of temperature, residence time, and agitation, there is no control over the efficiency of the proposed incineration. The work of Paul Brown at NIH has clearly shown that the infectivity of prions (in that case 256K scrapie agent) could survive a temperature of 600°C for 15 minutes, conditions virtually never reached in routine incinerators. Alkaline hydrolysis at elevated temperature* has been demonstrated to destroy infectivity even of the most virulent strain of BSE. i.e., 301V mouse –passaged BSE, and has been included in EU legislation as a disposal method for all Category 1 material, including known BSE-contaminated material.

We agree strongly with FDA's concerns about cross contamination, not only between ruminant feed processing lines and SRM destruction lines but also between clean ruminant feed made from fresh animal and plant material and ruminant feed contaminated with chicken droppings, non-ruminant feed that could contain SRM, blood, and other waste products. While the infectious dose quoted in Reference 13, 0.01gram of brain tissue from a BSE infected animal, is frightening enough, a report that appeared after the publication of the proposed rulemaking suggests that the actual infectious dose may be as little as one-tenth that amount. While these possible routes of infection of cattle are of serious concern, a potentially more direct route of infection of *humans* has not been adequately considered or discussed in connection with the banning of SRM from animal feed. It is an unfortunate fact in this country that many poor people derive their major protein intake from the eating of pet foods. Thus, the possible inclusion of SRM in those products could pose a direct threat to human health. The eating of pet foods by poor people was one of the primary reasons for the banning from pet foods of material derived from animals euthanized with barbiturates. SRMs included in pet food could pose a similar significant threat.

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We are also uncomfortable with the elimination of the small intestine of cattle younger than 30 months of age as SRM. Absorption in the small intestine is the primary route of infection for the prions that cause Bovine Spongiform Encephalopathy and it has been demonstrated that these

agents can localize and reproduce in the lymph nodes of the intestine before they travel to the central nervous system. For that reason, we believe that the small intestine of all cattle, or, at least, the terminal ileum of all cattle, even those younger than 30 months of age, should be designated as SRM and removed from the human and animal food chains. While we realize that this would significantly increase the amount of SRM that needed to be destroyed, we also believe that the necessary infrastructure for that destruction, using scaled-up versions of current alkaline hydrolysis technology, could rapidly be deployed either as fixed-base plants or as large-scale mobile systems. While some of the numbers quoted in the discussion section of the proposed rulemaking for the amount of SRM to be generated seem very large, efficient use of as few as 100 alkaline hydrolysis systems capable of processing 20,000 pounds per cycle and as few as only three cycles per day could process the 2 billion pounds per year reported on page 25 of the proposed rulemaking.

We must also question the cost estimates for disposal made by ERG. No specific estimate for any of the proposed disposal methods is presented; rather, a lump sum “low-end” estimate is given with no relation to any method. We do not know how they derived any figures on the cost of alkaline hydrolysis for their analysis as they did not contact us or, to the best of our knowledge, any of the sites currently using large volume Tissue Digestors™. Operating costs for these Digestors (not including labor and amortization of capital equipment) range between \$2.5 per 100 lbs and \$4 per 100 lbs, far less than the \$12 average cited. Further, considering that the ERG survey had to have been made some months before the publication of the proposed rulemaking, it could not have taken into account the dramatic increase in natural gas costs to fuel the proposed incinerator disposal pathway. Thus, even the apparently high estimates presented that must include this as, perhaps, the primary disposal pathway are probably much too low under present circumstances.

In summary, although we accept that the proposed rulemaking may be an improvement over the present unregulated situation with regard to the use of SRM in animal feeds, we do not believe it is inclusive enough nor goes far enough. We believe the original proposal from FDA would provide significantly greater protection of public health than the currently proposed regulation.

* In the spirit of full disclosure, it must be noted that WR² is the developer of the Alkaline Hydrolysis Process and the manufacturer of Tissue Digestors™ for the use of the Process.