

TAB B

transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. The preamble to the interim final rule describes the background and justification for the ^{ban} ~~prohibition~~ on prohibited cattle materials in human food and cosmetics.

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In this companion rulemaking, we are proposing that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. We believe that records documenting the absence of prohibited cattle materials in human food and cosmetics are critical for manufacturers, processors, and FDA to ensure compliance with the ^{ban} ~~prohibitions~~ on the use of prohibited cattle materials in the interim final rule. Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material. There is currently no way to test reliably for the presence of the bovine spongiform encephalopathy (BSE) agent or for the presence of prohibited cattle materials. Therefore, manufacturers and processors of human food and cosmetics must depend on records from the suppliers of cattle material to demonstrate that the supplier's cattle material does not contain prohibited cattle materials.

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Through these records, manufacturers and processors of human food and cosmetics can ensure that prohibited cattle materials are not included in their products. The agency believes that recordkeeping and records access

affirm their compliance with the relevant recordkeeping requirements in this proposed rule at the time of entry into the United States and provide required records if requested.

3. Costs and Benefits of the Proposed Rule

This proposed rule would require manufacturers and processors of FDA-regulated human food and cosmetics manufactured from, processed with, or otherwise containing, cattle material to maintain records demonstrating that prohibited cattle materials are not used in their products. This proposed rule would require that the manufacturer or processor retain records for 2 years after using the cattle material in food or cosmetics. Records must be kept at the manufacturing or processing establishment or another reasonably accessible location. Manufacturers and processors must provide FDA with access to the required records for inspection and copying.

a. *Costs of proposed rule, ~~industry profile~~* FDA used establishment data from the FDA Small Business Model (which includes information on all establishments in a manufacturing sector regardless of size) (Ref. 1) to determine the number of food manufacturers and processors that will need to comply with the proposed recordkeeping requirements. The model contains information on the number of establishments in certain food producing sectors but does not have information on specific ingredients used by the food establishments in making products. Data from the model indicates that 181 establishments produce spreads, 127 establishments produce flavoring extracts, 40 establishments produce canned soups and stews, 625 establishments produce nonchocolate candy, 88 establishments produce yogurt, and 451 establishments produce ice cream. FDA cannot verify that all of these establishments actually use cattle materials that fall under the jurisdiction of

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