



The Dow Chemical Company

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2030 Dow Center

October 3, 2005

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

Re: Docket No. 2004N-0081: Use of Materials Derived From Cattle in Human Food and Cosmetics

Dear Sir or Madam:

The Dow Chemical Company ("Dow") welcomes the opportunity to comment on FDA's interim final rule and request for comments published at 70 Fed. Reg. 53063 (Sept. 7, 2005). Dow is a global manufacturer of chemicals and plastics. Among other things, Dow purchases tallow derivatives for use in manufacturing a variety of products subject to FDA jurisdiction. Dow recommends that FDA revise the definition of "prohibited cattle materials" to further clarify that the term does not apply to tallow derivatives, even if the tallow derivatives were derived from tallow containing more than 0.15 percent insoluble impurities.

Dow welcomes FDA's clarification in the preamble that tallow derivatives are not prohibited cattle materials regardless of the level of hexane-insoluble impurities in the tallow from which the tallow derivatives were derived. Dow had submitted comments requesting clarification on this issue. Apparently others did so also. The preamble explains (70 Fed. Reg. at 53065-66):

C. Clarification of the Classification of Tallow Derivatives

The interim final rule defines tallow and tallow derivatives and states that prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.

1. Comments Received

Several comments requested that we clarify whether the tallow used as starting material for the tallow derivatives has to contain no more than 0.15 percent insoluble impurities in order for the tallow derivatives not to be included in the definition of "prohibited cattle materials."

2. Response to Comments

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The exemption of tallow derivatives from the definition of “prohibited cattle materials” does not depend on the source tallow for the derivatives. For the reasons discussed in the preamble to the interim final rule, tallow derivatives present a negligible risk of transmitting the agent that causes BSE regardless of the source tallow. Therefore, all tallow derivatives are exempt from the ban on the use of prohibited cattle materials in human food and cosmetics.

Nevertheless, Dow remains concerned that the text of the definition of “prohibited cattle materials” in 21 CFR §§ 189.5(a)(1) and 700.27(a)(1) could be read to infer that for tallow derivatives to be excluded from that term, the tallow from which they were derived had to have no more than 0.15 percent insoluble impurities. The fact that several commenters raised this issue indicates that the potential for confusion exists based on the regulatory language itself. That definition reads:

Prohibited cattle materials means specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS)(Beef). Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products.

To remove this potential confusion, Dow recommends that FDA revise the last sentence of that definition to read as follows (emphasis added):

Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives (**regardless of the source of tallow**), hides and hide-derived products, and milk and milk products.

Sincerely,



Mark Duvall
Managing Counsel
The Dow Chemical Company
Telephone: (989) 638-4980
Fax: (989) 638-9636
E-mail: mnduvall@dow.com