

2030 Dow Center

By E-Mail and Overnight Courier

August 6, 2004

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

Re: Comments of The Dow Chemical Company on FDA's Notice of Proposed Rulemaking on "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle", Docket No. 2004N-0257

Dear Sir or Madam:

The Dow Chemical Company ("Dow") welcomes the opportunity to comment on FDA's proposed recordkeeping rule published at 69 Fed. Reg. 42275 (July 14, 2004). 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.

1. FDA Should Clarify That the Final Recordkeeping Rule Will Not Apply to Tallow Derivatives.

Dow supports FDA's determination to exclude tallow derivatives from the scope of the interim final rule, published at 69 Fed. Reg. 42256 (July 14, 2004), and from the scope of the proposed rule. The interim final rule explicitly excludes tallow derivatives. The preamble to the proposed rule refers to "tallow derivatives (exempt from this proposed rulemaking)", 69 Fed. Reg. at 42279.

Nevertheless, the text of the proposed rule could be read to apply to tallow derivatives. Proposed § 189.5(c)(1) reads (emphasis added):

Manufacturers and processors of human food that is manufactured from, processed with, or otherwise contains, **material from cattle** must establish and maintain records sufficient to demonstrate that the food is not manufactured from, processed with, or does not contain, prohibited cattle materials.

Similarly, proposed § 700.27(c)(1) reads (emphasis added):

Manufacturers and processors of a cosmetic that is manufactured from, processed with, or otherwise contains, **material from cattle** that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the food is not manufactured from, processed with, or does not contain, prohibited cattle materials.

Tallow derivatives can be characterized as “material from cattle”, since they are derived from tallow, which is derived from cattle. As a result, the proposed rules could be interpreted to apply to tallow derivatives.

FDA should clarify that tallow derivatives would not be subject to the final rule. This can be accomplished through amending the text of each provision to refer to “material from cattle (other than tallow derivatives)”. Alternatively, FDA could make a clarifying statement in the preamble to the final rule. For enduring clarity, however, Dow recommends amending the text of the final rule provisions.

2. FDA Should Clarify That Tallow Derivatives Are Exempt Even If Derived From Tallow Containing More Than 0.15 Percent Hexane-Insoluble Impurities.

Due to the definition of “tallow” in the interim final rule, FDA should clarify that the final recordkeeping rule does not apply to tallow derivatives derived from any kind of tallow.

The interim final rule contains the following definitions of “tallow” and “tallow derivatives” at 21 CFR §§ 189.5(a)(6) and (7) and 700.27(a)(6) and (7), 69 Fed. Reg. at 42273-74 (emphasis added):

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. **Tallow must be free of prohibited cattle material or must contain not more than 0.15 percent hexane-insoluble impurities**

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

The highlighted language constitutes the criteria set by the interim final rule to exclude tallow from the category of “prohibited cattle materials”. It is not actually part of the definition of “tallow”. In other words, tallow is “tallow” even if it does not meet those criteria and thus is not exempt from the category of “prohibited cattle materials”.

Accordingly, where the definition of “tallow derivative” refers to derivation from “tallow”, we understand FDA to mean that the term includes a tallow derivative derived

from any tallow, including tallow that contains more than 0.15 percent hexane-insoluble impurities. This interpretation is supported by the interim rule's definition of "prohibited cattle materials", §§ 189.5(a)(1) and 700.27(a)(1), 69 Fed. Reg. at 42274, 42275:

Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.

There FDA limited the exclusion for tallow, but did not limit the exclusion for tallow derivatives. The preamble provided the reasoning for not limiting tallow derivatives to tallow that is not a "prohibited cattle material", 69 Fed. Reg. at 422601:

Tallow derivatives are produced by subjecting tallow to chemical processes (hydrolysis, trans-esterification, and saponification) that involve high temperature and pressure. The TSEAC considered tallow derivatives in 1998 (Ref. 50) and determined that the rigorous conditions of manufacture are sufficient to further reduce the BSE risk in tallow derivatives Because . . . tallow derivatives undergo additional processing, we do not believe that tallow derivatives pose a risk of transmitting the agent that causes BSE to humans.

Thus, FDA determined that the various processes for making tallow derivatives are themselves sufficient to address satisfactorily the BSE transmission risk (i.e., even if the source tallow were to contain infectious material, the process of making tallow derivatives would destroy that material).

Nonetheless, there may remain some confusion in the proposed rule as to whether the exemption for tallow derivatives is limited to those derivatives made from tallow containing no more than 0.15 percent hexane-insoluble impurities, since the definition "tallow" includes that restriction. Accordingly, FDA should clarify that tallow derivatives would be exempt from the final recordkeeping rule regardless of the status of the source tallow.

Sincerely,

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