



October 8, 2004

251 O'Connor Ridge Blvd.
Suite 300
Irving, TX 75038

Docket No. 2004N-0081
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

Re: Docket No. 2004N-0081 (RIN 0910-AF47); Use of Materials Derived From Cattle in Human Food and Cosmetics.

Darling International Inc., as one of the largest independent rendering companies and processors of animal mortalities in the United States, appreciates the opportunity to submit the following comments in response to the above Notice, issued by the Food and Drug Administration (FDA) (Docket No. 2004N-0081).

Darling International Inc. is a member of the National Renderers Association (NRA) and the Animal Protein Producers Industry (APPI). We agree with comments to the aforementioned Interim Final Rule submitted separately by NRA and APPI.

Darling appreciates the science based approach the Agency has taken with respect to the use of tallow under this rule. We agree with the Agency's adoption of the International Office of Epizootics (OIE) decision that tallow with no more than 0.15% impurities is "protein-free" and safe with respect to bovine spongiform encephalopathy (BSE). However, Darling International Inc. has three primary concerns with respect to the Interim Final Rule.

- 1. Darling International Inc. encourages the FDA to accept the American Oil Chemist Society (AOCS) method (AOCS Official Method Ca 3a-46) for measuring impurities in tallow.**

Tallow is traded on the domestic and international markets according to objective trading standards developed and administered by the American Fats and Oils Association (AFOA). Standardized methods of analysis that have been peer reviewed, accepted and published by the American Oil Chemist Society (AOCS) must be used to determine if a load of tallow meets the stated specifications. Maximum insoluble impurities are one such specification and may be reported separately or collectively with moisture and unsaponifiable materials (MIU). The insoluble impurities specified by the AFOA and

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the hexane insoluble matter cited by the FDA both appear to measure the same non-glyceridic materials.

The AOCS method is current and accepted by the scientific community according to the peer review process. To the best of our knowledge, all commercial laboratories that service the fats and oils industry use the AOCS Official Method Ca 3a-46 to quantitate insoluble impurities. No commercial laboratories of which we are aware have ever used the method specified by the Agency for measuring hexane insoluble matter. Further, the laboratories we have contacted have been reluctant to adopt the method from the 5th edition Food Chemicals Codex.

Compared to the Food Chemicals Codex method, the AOCS Official Method is markedly less expensive to run (\$150 to \$275 compared with \$8 to \$10 per sample), requires 93% less total solvent, has 30-times lower solvent related disposal costs, does not require specialized equipment or supplies, is standardized under AOCS and is an industry standard. We understand that the Agency is concerned by the lower sample volume used in the AOCS Official Method. However, the filter apparatus used in AOCS Official Method Ca 3a-46 will detect smaller diameter particulate matter, making the AOCS method more sensitive than the Food Chemical Codex method.

The FDA has stated that methods other than the Food Chemical Codex method may be used if they are equivalent in accuracy, precision and sensitivity. It is difficult to demonstrate such equivalency without good data describing the typical variation (among samples and among laboratories) associated with the Food Chemical Codex method. Such data is not discussed in the procedure. Without statistics such as these, it is difficult to determine if the same results (statistically) are obtained when comparing two different methods.

2. Darling International Inc. requests clarification whether or not tallow derivatives must be derived from tallow that is either free of specified risk materials (SRM) or tallow containing not more than 0.15% impurities or whether such derivatives may be derived from tallow that meets neither criterion.

In its present form, the rule can be interpreted to exclude tallow derived from SRM and tallow with greater than 0.15% impurities or allow such tallow to be used as feedstock for tallow derivatives. We believe that tallow derivatives undergo sufficient processing such that it does not pose a risk of transmitting the BSE agent to humans. Therefore, such derivatives can safely be obtained from tallow extracted from any tissues or tallow with greater than 0.15% insoluble impurities.

The preamble to the rule (Section M. Tallow and Tallow Derivatives) supports our view. In this section, the Agency states: “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. In addition, the OIE also recommends that derivatives of protein-free tallow be freely traded among countries because they pose insignificant BSE risk to animals [Ref. 48]. Because we believe tallow has negligible risk of transmitting BSE, and tallow derivatives undergo additional processing, we do not believe tallow derivatives pose a risk of transmitting the agent that causes BSE to humans. (Emphasis added.)” However, the ambiguous

use of tallow throughout the Interim Final Rule is confusing and makes a clear interpretation difficult.

3. **Darling International Inc. requests clarification on the record keeping requirements described in the Proposed Rule (Docket No. 2004N-0257), which was also published by the FDA on July 14, 2004 as a companion rulemaking to the Interim Final Rule Use of Materials Derived From Cattle in Human Food and Cosmetics.**

It is our understanding from our discussions with the FDA, that it is the Agency's position that the record-keeping responsibilities under both the Interim Final Rule and the Proposed Rule were placed **only** on the manufacturer of the human food or cosmetic, and that ingredient suppliers, such as Darling International Inc. had no responsibilities for record-keeping under either the Interim Final Rule or the Proposed Rule. Darling requests that the FDA clarify this issue by clearly stating this position when the Agency issues its final version of these rules.

In summary, Darling International Inc. encourages the Agency to insure that these and other new regulations are based on sound science. Current science: (1) supports adoption of the AOCS method for measuring insoluble impurities in tallow, (2) suggests that tallow derivatives are safe and can be derived from either tallow extracted from any bovine tissue or tallow with greater than 0.15% impurities and (3) record keeping responsibilities associated with this Interim Final Rule and the companion Proposed Rule should be placed only on the manufacturer of the human food or cosmetic.

Respectfully,
Darling International Inc.



C. Ross Hamilton, Ph. D.
Director Government Affairs & Technology

Cc.: Tom Cook, President
National Renderers Association