



# The Soap and Detergent Association

October 12, 2004

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

**RE: Docket No. 2004N-0081- Interim Final Rule To Prohibit the Use of Certain Cattle Material, to Address the Potential Risk of Bovine Spongiform Encephalopathy (BSE), in Human Food, Including Dietary Supplements, and Cosmetics**

To Whom It May Concern,

The Soap and Detergent Association (SDA), founded in 1926, represents the formulators of soaps, detergents, household, industrial and institutional cleaning products as well as the suppliers of ingredients and packaging to the industry. In addition, it is the home of the domestic oleochemical industry on whose behalf SDA submits these comments.

SDA appreciates the opportunity to comment on the Interim Final Rule, FDA Docket No. 2004N-0081. To begin, the SDA appreciates the consideration given to the scientific evidence in support of the safety of tallow derivatives processed using the stipulated processes.

SDA presents two comments directed at strengthening or clarifying the exemption granted in the IFR for tallow derivatives.

### Tallow Derivative Processing Standards

SDA believes that the IFR would be strengthened by stipulating the minimum process conditions which must be applied for each of the processes stipulated in the IFR. SDA recommends adopting the conditions as specified by the European Commission's (EC) Scientific Steering Committee (SSC). The SSC recommendation is the raw tallow should be submitted to hydrolysis at  $> 200^{\circ}\text{C}$  for 2 hours and corresponding pressure, followed by either:

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- Transesterification or hydrolysis at at least 200°C and appropriate corresponding pressure for 20 minutes, followed by a purification to remove (insoluble) impurities (to obtain glycerol and fatty acids and esters); or
- To obtain glycerol and soap: Saponification with NaOH 12M, followed by a purification to remove (insoluble) impurities (to obtain glycerol and soap):
  - o Batch process: at 95°C for 3 hours; or:
  - o Continuous process: at 140°C 2 bars (2000 hPa) for 8 minutes or equivalent conditions,

### **Hexane Insoluble Matter Standard**

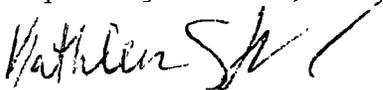
The traditional industrial standard for determining the level of insoluble protein is the American Oil Chemist Society (AOCS) method Ca 3a-46. SDA recommends that this method also be stipulated as a recognized test procedure. This method employs the use of Whatman GF/A filters with a 1.6 micron pore size with Kerosene/Petroleum ether solvents. The method currently endorsed by the IFR uses Corning "C" porosity filters with a 40-60 micron pore size with Hexane solvent. Minimal testing comparisons indicate the smaller filter size as prescribed by the AOCS method yields higher results, thereby producing more conservative total insoluble impurities (TII) levels.

### **Summary and Conclusions**

SDA and its member companies appreciate this opportunity to review and comment on the Interim Final Rule. Our comments reflect our continuing efforts to provide the most accurate technical data to date.

Please contact us at any time if you have any questions.

Respectfully submitted,



Kathleen Stanton  
Manager, Scientific Affairs

**The Soap and Detergent Association**

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**DATE:** October 15, 2004**TO:** [Click and type name]**FAX #:** 301.827.6870**FROM:** Kathleen Stanton**TEL #:** 202.662.2513**RE:** Docket No. 2004N-0081**PAGES:** 3 **URGENT** **For Review** **Please Comment** **Please Reply**

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**MESSAGE:**

Please accept our apologies if you have already received our comments. Upon looking through our records, it was unclear if these were received by the Administration via the eRulemaking Portal October 12, 2004. Thank you for considering our comments.

Kathleen Stanton  
Manager, Scientific Affairs