

# WORLD TRADE ORGANIZATION

G/SPS/N/USA/934

20 July 2004

(04-3115)

Committee on Sanitary and Phytosanitary Measures

Original: English

## NOTIFICATION

<b>1. Member to Agreement notifying:</b> <u>UNITED STATES</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> US Food and Drug Administration
<b>3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> Food for human consumption and cosmetics for use in the United States, except for meat, poultry and egg products that are exclusively regulated by the US Department of Agriculture
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> Trading partners who import human food or cosmetics into the United States
<b>5. Title, language and number of pages of the notified document:</b> Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle, Proposed Rule (11 pages, available in English)
<b>6. Description of content:</b> The Food and Drug Administration (FDA) is proposing to require 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. This is a companion rulemaking to FDA's interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics" (Federal Register, vol 69, pp. 42255-74; 14 July 2004). FDA is proposing recordkeeping requirements because records documenting the absence of prohibited cattle materials are needed by manufacturers and processors of human food and cosmetics that contain cattle material to ensure that these products do not contain prohibited cattle materials. In addition, such records are necessary to help FDA ensure compliance with the requirements of the interim final rule.
<b>7. Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input checked="" type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests
<b>8. International standard, guideline or recommendation:</b> <input type="checkbox"/> Codex Alimentarius Commission, <input type="checkbox"/> World Organization for Animal Health (OIE), <input type="checkbox"/> International Plant Protection Convention, <input checked="" type="checkbox"/> None <b>If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:</b>

<b>9. Relevant documents and language(s) in which these are available:</b>	Notice of Proposed Rulemaking in the Federal Register (FR), 69 FR 42274-42285 (available in English). It can be found at: <a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.pdf">http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.pdf</a> or <a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.htm">http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.htm</a>
<b>10. Proposed date of adoption:</b>	The date on which any rulemaking based on this proposal is finalized.
<b>11. Proposed date of entry into force:</b>	The Food and Drug Administration is proposing that any final rule based on this proposed rule be effective 30 days after issuance of that final rule.
<b>12. Final date for comments:</b>	Submit written or electronic comments by 13 August 2004  <b>Agency or authority designated to handle comments:</b> <input type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body:  Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, USA. It is possible to submit electronic comments to: <a href="http://www.fda.gov/dockets/ecomments">http://www.fda.gov/dockets/ecomments</a> . Submit comments by indicating DOCKET Number 2004N-0257 and Title "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle".
<b>13. Texts available from:</b>	<input type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body: US Enquiry Point, US Department of Agriculture, Stop 1027, Washington, DC 20250; Tel: (202) 720-0677; E-mail: <a href="mailto:fstsd@usda.gov">fstsd@usda.gov</a> . Complete text can also be found on the Internet at <a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.pdf">http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.pdf</a>