

# WORLD TRADE ORGANIZATION

G/SPS/N/USA/645  
17 October 2002

(02-5668)

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> Food and Drug Administration – FDA
<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> Fruit and vegetable juices
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> Trading partners
<b>5. Title, language and number of pages of the notified document:</b> Draft Guidance for Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices, (20 pages, available in English)
<b>6. Description of content:</b> FDA has issued a draft guidance entitled "Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices", to assist processors in developing appropriate control measures to prevent contamination by harmful microorganisms, e.g. salmonella, of certain juices and juice concentrates during bulk transport. This guidance addresses an issue raised in a petition from industry asking that FDA revise a provision in the recently enacted juice HACCP regulation that requires all juice processors to treat juice in the facility where the final packaging occurs. FDA included this provision in the regulation because it was concerned with the potential for the contamination of juice by harmful microorganisms during bulk transport. Under the guidance, FDA is exercising enforcement discretion to allow processors an alternative means by which to address the safety of juice during transport.
<b>7. Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input 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"/> Office International des Epizooties, <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 availability in 67 FR 62488 and "Draft Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices" (available in English)

<b>10. Proposed date of adoption:</b> This guidance is applicable upon issuance of the final guidance.
<b>11. Proposed date of entry into force:</b> This guidance is applicable upon issuance of the final guidance.
<b>12. Final date for comments:</b> Submit written or electronic objections by 6 December 2002. <b>Agency or authority designated to handle comments:</b> Food and Drug Administration <input type="checkbox"/> <b>National notification authority,</b> <input type="checkbox"/> <b>National enquiry point, or address, fax number and E-mail address (if available) of other body:</b> 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, U.S.A. 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 No. 02P-0009 and Title Draft Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices; Availability
<b>13. Texts available from:</b> <input checked="" type="checkbox"/> <b>National notification authority,</b> <input checked="" type="checkbox"/> <b>National enquiry point, or address, fax number and E-mail address (if available) of other body:</b>  United States SPS Enquiry Point / Notification Point Mr. William Janis U.S. Department of Agriculture Stop 1027 Washington, DC 20250 Tel: (202) 720-9047 Fax: (202) 720-0677 E-mail: <a href="mailto:William.janis2@usda.gov">William.janis2@usda.gov</a>  Complete text can be also be found on the Internet <a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/100702d.htm">http://www.fda.gov/OHRMS/DOCKETS/98fr/100702d.htm</a> by looking under DOCKET No. 02P-0009 and at <a href="http://www.cfsan.fda.gov/~dms/juicgui4.html">http://www.cfsan.fda.gov/~dms/juicgui4.html</a>