Issued in Jamaica, New York on November 17, 1999.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 99–30501 Filed 11–22–99; 8:45 am]

BILLING CODE 4910–13–M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 34 and 35

Concept Release Concerning Over-the-Counter Derivatives

AGENCY: Commodity Futures Trading Commission.

ACTION: Concept release; withdrawal.

SUMMARY: On May 12, 1998, the Commission issued a concept release reexamining its approach to the over-the-counter derivatives market. The Commission has decided to withdraw the concept release.

FOR FURTHER INFORMATION CONTACT: Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street, NW, Washington, DC 20581, (202) 418–5100.

SUPPLEMENTARY INFORMATION: The Commodity Futures Trading Commission issued a concept release concerning over-the-counter derivatives on May 12, 1998 (63 FR 26114). In light of the comments received, the Commission has determined to withdraw the concept release from further consideration.

Issued in Washington, DC on November 17, 1999 by the Commission.

Jean A. Webb,

Secretary of the Commission.

Concurring Remarks of Commissioner Spears Withdrawal of Concept Release on Over-the-Counter Derivatives

The Commission's May 1998 Concept Release on Over-the-Counter Derivatives has been widely perceived, both within the derivatives industry and among other financial regulators, as indicating an intent to expand the Commission's regulatory reach with respect to OTC derivatives. In view of that perception and any legal uncertainty it may have created, I agree to withdrawal of the Concept Release. However, as one of the Commissioners who signed off on issuing the Concept Release, I also wish to make clear my intent in originally approving publication of that document.

The Concept Release was published in May of 1998. At that time, five years had passed since the last major Commission action involving OTC derivatives (the 1993 swaps, hybrids and energy exemptions). As noted in the Release's preamble, the OTC derivatives market had experienced a number of significant changes during that five-year period. In light of those changes, I viewed the Release strictly as an appropriate information gathering document. Thus, as stated in the preamble, the Release was published in hopes that the comments received would ''* * * constitute an important source of relevant data and analysis that [would] assist [the Commission] in determining whether its current regulatory approach continues to be appropriate or requires modification.'' [1] More importantly, the preamble also clearly states:

> The Commission has *no preconceived result in mind.* The Commission is open both to evidence in support of easing current restrictions and evidence indicating a need for additional safeguards. The Commission also welcomes comment on the extent to which certain matters are being or can be adequately addressed through self-regulation * * *[2] [emphasis supplied]

Concurring Remarks of Commissioner Erickson

I concur with the Commission's decision to withdraw the Concept Release on Over-the-Counter Derivatives because, in my view, the document has been rendered moot by subsequent events. The Commission published the Concept Release in May 1998, it asked the public to comment on a number of questions, and the public did so. No rules or orders were proposed and nothing related to the Concept Release currently is pending before the Commission. Moreover, representatives of the four federal financial regulators that comprise the President's Working Group on Financial Markets stated that they would use the comments received by the Commission to inform their study of OTC derivatives. I assume the public comments assisted the Working Group in preparing its report, which was issued on November 9, 1999.

I am concerned, however, about the potential precedent established by today's Commission action for future Commission actions, future Commissions, and, more broadly, for other federal agencies. I have reviewed 31 comment letters submitted to the Commission in response to the Concept Release and have examined related testimony given by various interested parties before several House and Senate committees. I am struck by the fact that despite the opposition the release provoked in some segments of the industry and among other regulators, nothing I saw cast any doubt on the substantive validity of the questions themselves. In fact, it seems to me that the Concept Release framed many of the issues we are currently discussing and, I believe, sparked the current dialogue regarding whether our existing regulatory structure fits today's financial markets.

I am not willing to concede that it was wrong for the Commission to ask questions about the application of its existing regulations in an evolving market. In fact, I believe it is our duty as an agency to constantly examine and re-examine the vitality and effectiveness of our regulatory scheme, and we should not be expected to defer to anyone else in fulfilling this duty. I am troubled that on a going-forward basis, the Commission may feel obliged to delegate to others its judgment about what kinds of questions are acceptable to ask about its own regulations.

Nonetheless, I am hopeful that through today's action this Commission will rededicate itself to addressing the derivatives industry issues unique to our time.

[FR Doc. 99–30513 Filed 11–22–99; 8:45 am]

BILLING CODE 6351–01–M

[1] 63 FR 26114, May 12, 1998.

[2] *Id.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0511]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Availability of New Data and Information and Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to January 24, 2000, the comment period for the proposal to require the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices and juice products (the juice HACCP proposal) that published in the **Federal Register** of April 24, 1998 (63 FR 20450). The agency is reopening the comment period for the juice

HACCP proposal in order to receive comment and other information on four specific issues: internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; application and measurement of the 5-log reduction standard; current methods used by juice processors to monitor the application of heat treatment to juice; and certain economic matters related to juice regulation. FDA is also announcing the availability of new data and other information about the safe processing of juice and juice products, and is requesting comment on the new data and other information.

DATES: Written comments must be received by January 24, 2000.

ADDRESSES: Submit written comments and requests for single copies of the transcripts to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5023.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 24, 1998 (63 FR 20450), FDA proposed regulations to ensure the safe and sanitary processing of fruit and vegetable juices. In addition, in the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final rule requiring that juice products not specifically processed to destroy harmful bacteria (i.e., processed to achieve a 5–log (105) reduction in the most resistant pathogen of public health significance) bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product (the warning statement rule). The compliance date for the warning statement rule was September 8, 1998, for apple juice and apple cider; the compliance date for juices other than apple juice or apple cider was November 5, 1998.

Interested persons were initially given until July 8, 1998, to comment on the HACCP proposal. On July 8, 1998 (63 FR 37057), in response to requests, the HACCP proposal comment period was extended to August 7, 1998. FDA subsequently reopened the comment period on December 17, 1998 (63 FR 69579) until January 19, 1999, to receive comments on data and other information that were presented at or developed as a result of two technical scientific workshops sponsored by FDA regarding implementation of the agency's warning statement requirement for fruit and vegetable juices and juice products and to receive comments and other information regarding the application of the 5–log pathogen reduction standard.

As noted, in the HACCP proposal, FDA proposed to require that juice processors include in their HACCP plans control measures that will produce at least a 5-log reduction in the pertinent pathogen. The agency did not propose a specific intervention technology (e.g., pasteurization), but instead proposed a flexible 5-log performance standard that theoretically could be met through cumulative steps and, at least for some fruit (e.g., oranges), through surface treatments. In the preamble to the proposed rule, FDA stated that pathogens are not reasonably likely to be present in the interior of sound whole oranges or other citrus fruits, and further, that the acidic nature of citrus fruits may further inactivate any pathogens that may be present (63 FR 20450 at 20478). In the proposal, FDA noted that steps such as culling, washing, brushing, and sanitizing the surface of fruit, followed by extraction that minimized contact with the peel, could be used cumulatively to attain the 5-log reduction, as long as processors could validate the reduction under their HACCP systems.

Comments to the proposed rule, as well as new information available to FDA, have questioned the assumption that pathogens are not likely to be found in the interior of citrus fruit and have further suggested that surface treatment of fruit alone may not be adequate to ensure the safety of juice. In addition, FDA has undertaken research that suggests that, under certain conditions, pathogens could be internalized into citrus fruit and could survive once inside the fruit (Ref. 1). Specifically, the FDA studies show that the temperature differential between warm citrus fruit and cool wash water containing dye causes uptake of the dye into the fruit (Ref. 2). FDA believes that this dye study suggests that pathogens could likewise be drawn into the fruit through the stem scar or imperceptible cracks and holes if warm fruit is washed in cold water during preprocessing or possibly while the fruit is on the tree during a heavy rain storm. These susceptible fruits appear to be intact and would not necessarily be culled out and thus, could be processed into juice.

FDA has also reviewed the published literature and certain unpublished information relevant to pathogen infiltration and survival in produce and has summarized this information in a background document (Ref. 3). This information, in addition to data gathered by FDA (Ref. 1), suggests that there is potential for internalization of pathogens in apparently intact fruit. Based on this information, FDA has concerns that citrus fruit may not be impervious to penetration by pathogens, as was originally assumed in the proposed HACCP rule and the final labeling rule.

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture will soon announce a 3-day meeting (December 8 through 10, 1999) of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF); during days one and two of that meeting, NACMCF will focus on juice safety. FDA intends to provide the members of NACMCF with a copy of the summary document, Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables, as well as a report of the results of the recent FDA studies concerning the internalization and survival of microorganisms in citrus, Preliminary Studies on the Potential for Infiltration, Growth and Survival of *Salmonella enterica* serovar Hartford and *Escherichia coli* O157:H7 within Oranges, for their consideration prior to the December meeting. At the December meeting, FDA will be asking NACMCF to consider performance criteria for fresh juice, and specifically, to make recommendations about the efficacy of surface treatments in ensuring the safety of citrus juices.

II. Request for Comments

In order for FDA to make sound decisions regarding the application of HACCP principles to the processing of juice, the agency should have before it the most complete administrative record possible. To that end, FDA is requesting additional comment in four separate areas: (1) Internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; (2) application and measurement of the 5-log reduction standard; (3) current methods used by juice processors to monitor the application of heat treatment to juice; and (4) certain economic matters related to juice regulation. In addition, FDA is requesting comment on the new data and other information being added to the administrative record of this rulemaking.

First, concerning internalization and survival of pathogens, FDA is requesting comment, and supporting data or other information, on the following questions:

(1) One assumption underlying the HACCP proposal is that there is no

internalization of pathogens in citrus fruit. Is this assumption valid?

(2) Is internalization of pathogens into citrus fruit theoretically possible?

(3) If internationalization of pathogens into citrus fruit is theoretically possible, is such internalization likely to result in a public health risk?

(4) If internalization does occur and it results in a public health risk, are there techniques to assure that internalization of pathogens does not occur? What are they?

Second, comments to the proposed HACCP rule requested that FDA clarify at what point in the production process a processor should begin to measure attainment of the 5–log pathogen reduction. In light of the new data and information on pathogen internalization and survival, FDA's current view is that for any juice made from fruit for which there is a potential for pathogens to be internalized, measurement of the 5–log reduction must begin where preventive treatment has intimate contact with pathogens. This means that the 5–log reduction must be achieved after the juice has been extracted. Accordingly, in terms of the application of the 5–log reduction, FDA requests comment on the following:

(1) FDA's current view is that the 5-log pathogen reduction must begin where the preventative treatment has intimate contact with the pathogens. FDA is particularly interested in any data or other information about scientifically validated procedures for a 5–log reduction that address FDA's concerns about pathogen internalization and that begin earlier in the process than the juice expression step.

(2) The ability of processors to achieve the desired level of public health protection if processors: (a) Use cumulative steps that are separated in time or location, or (b) do not package product immediately after attaining the 5–log reduction.

(3) For firms producing fresh juice, the costs and economic feasibility of achieving a 5-log pathogen reduction using the approach reflected in FDA's current thinking.

(4) The benefits to processors of using this enhanced 5-log pathogen reduction approach in terms of improved shelf-life or other any benefit.

Third, FDA is aware that the majority of juice processors already apply some sort of heat treatment to the juice that they produce. Under a HACCP system, the application of heat is a critical control point (CCP) in terms of controlling microbiological hazards. FDA requests comments that describe the monitoring methods that juice processors currently use to assure that the heat treatment is adequately delivered so as to control pathogens.

Fourth, FDA also specifically requests comment on several economic issues, as follows:

(1) The agency is aware that some consumers prefer to consume raw (i.e., unprocessed) juice. FDA requests comment from these consumers concerning how much they would be willing to pay for a gallon of raw juice. FDA also requests information from raw juice processors on the percent of annual profit that firms derive from the sale of raw juice.

(2) The agency developed a preliminary regulatory impact analysis and a small entity analysis that estimate benefits and costs associated with the HACCP proposal. These analyses were published in the **Federal Register** of May 1, 1998 (63 FR 24254). FDA requests comment on impacts, costs, and benefits on businesses with fewer than 500 employees.

(3) FDA requests comment on the ways in which processors that have already implemented HACCP have done so in a manner that is different from the provisions of the proposed rule.

Finally, as noted above, FDA has prepared a summary of certain data and information regarding internalization and survival of pathogens in produce. The agency has also prepared reports of the agency's recent research. FDA is announcing the availability of the following: (1) Two documents summarizing new data on internalization and survival of microorganisms in citrus (Refs. 1 and 2); and (2) a review of published and unpublished information on internalization and survival of microorganisms in fruits and vegetables (Ref. 3). FDA is also announcing the availability for public comment of the transcripts from a July 15 to 16, 1999, FDA-sponsored technical scientific workshop on apple cider.

To be considered, written comments must be received by January 24, 2000, by the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Walderhaug, M. O., S. Edelson-Mammel, A. DeJesus, B. S. Eblen, A. J. Miller, and R. L. Buchanan. ''Preliminary Studies on the Potential for Infiltration, Growth and Survival of *Salmonella enterica* Serovar Hartford and *Escherichia coli* O157:H7 Within Oranges.'' U.S. Food and Drug Administration, November 8, 1999.

2. Merker, R., S. Edelson-Mammel, V. Davis, R. L. Buchanan. ''Preliminary Experiments on the Effect of Temperature Differences on Dye Uptake by Oranges and Grapefruit. U.S. Food and Drug Administration, November 4, 1999.

3. Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables, U.S. Food and Drug Administration, November 3, 1999.

Dated: November 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30525 Filed 11–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 70, 71 and 90

Proposed Program Policy Letter on Samples Used To Determine the Respirable Dust Level When Quartz Is Present

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for comments.

SUMMARY: The Mine Safety and Health Administration (MSHA) requests comments on a draft Program Policy Letter (PPL) regarding the samples that are used to determine the reduced respirable coal mine dust standard when more than 5.0 percent of quartz is present in the mine atmosphere. Under the PPL, the samples used to determine a reduced standard would be MSHA samples exclusively rather than a combination of MSHA and mine operator samples. MSHA is publishing this Notice to afford an opportunity for interested persons to comment on the draft PPL before it is issued.

DATES: Submit comments on or before December 23, 1999.

ADDRESSES: Send comments on the proposed policy—

(1) By mail to MSHA, Office of Standards, Regulations, and Variances, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203;

(2) By facsimile to MSHA, Office of Standards, Regulations, and Variances, 703–235–5551; or

(3) By electronic mail to comments@msha.gov. If possible, please