NFPA
The Food Safety People

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July 21, 2003

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0434; Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent; 68 FR 19766; April 22, 2003

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

NFPA submits the following comments on the proposed action referenced above.

Initial Observation

As noted in the preamble, two earlier withdrawal notices had removed 89 of 115 documents, and 9 of 10 documents, respectively. If the 84 documents addressed in the current notice are removed, the total list will be some 182 separate rulemakings that were terminated due to agency inaction. While there may be valid reasons for such action, the agency should better inform the public on how it intends to handle the issues addressed in the documents that it proposes to withdraw because companies are using the guidance provided in the published documents.

NFPA recommends the agency provide a notation in Table 1 for each item addressed in these comments indicating as appropriate – (1) already completed (with appropriate reference), (2) agency plans to institute new proceedings (with

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timetable), (3) agency plans to withdraw the item unless Citizen Petition filed to continue action, (4) agency plans to withdraw the item - preamble statements reflect current agency position, (5) agency plans to withdraw the proposal – preamble statements reflect current agency position and recognize additional uses for the food additive are permissible at GMP levels, (6) other information as appropriate. Clearly FDA must have made one of these assessments for each proposed action in order to include the proposal in the notice. Although this should have been provided in the initial proposal, inclusion in any final rule will clarify for all parties what future action, if any, can be expected for each item.

An example of a proposal the agency could identify as being deleted because subsequent agency action (including issuance of guidance documents or inclusion of provisions in related regulations, which have obviated the need to complete the proposed action) is the "Common or Usual Names for Nonstandardized Foods; Diluted Fruit or Vegetable Juice; 84N-0389" listed in Table 1, which was overtaken by the Nutrition Labeling and Education Act amendments to the Food, Drug, and Cosmetic Act with final regulations now codified at 21 CFR §101.30 and 102.33.

The generic note on possible future action provided by FDA in the preamble without identifying specific items is not adequate for those preparing comments on specific items.

Because a significant period of time has elapsed since these proposals were issued, the proposals may not be available to all interested parties. FDA should have made these documents available on the FDA web site for easy access to all interested parties.

General Comments - Future Agency Action

The agency is proposing to withdraw 84 proposals. In the preamble to the proposal FDA notes that withdrawal of these proposals does not preclude the agency from reinstituting proceedings to issue rules concerning the issues addressed in the proposals listed in Table 1. NFPA supports that position as being within the mandate of the agency and requests specific information on future agency intentions on each of the items addressed in these comments. FDA is not providing adequate justification for withdrawal or providing sufficient information to parties that continue to have interest in the particular action.

The agency suggests that if one wants any of these items to proceed one must re-submit a new Citizen Petition. This means that one must commit additional resources with no sense of the Agency's view to the action as originally proposed. Given the withdrawal proposed the interested public may conclude the Agency will again take no action.

The agency further states, "that for some proposals, the agency has plans to institute new proceedings." However, the agency fails to identify those items for which it plans to institute new proceedings. Such clarification should have been included in the document to assist those responding to the proposal. Without such information we can only assume that those issues in which we have an interest in seeing retained are not on the "institute new proceedings" list and respond accordingly.

FDA has also indicated that, in some instances, preambles to proposed rules that the Agency intends to withdraw may reflect its current views on the subject. Indeed, in some instances FDA may have signaled that voluntary compliance with a proposed rule was acceptable and may result in the exercise of Agency enforcement discretion. For example, at the time of the original publication of proposed rules to include a metric declaration of net contents (58 FR 29716, May 21, 1993 and 58 FR 67444, December 21, 1993), FDA advised informally that it would not object if industry elected to follow the proposed rules and change labels accordingly. Continued guidance from FDA is needed, specifically with respect to these proposals, since they would implement 1992 self-executing amendments to the Fair Packaging and Labeling Act, as well as amend current regulations under the Agency's rulemaking authority. Regarding these metric net contents proposals, it will be difficult for the regulated industry to parse which elements of the proposed rules reflect self-executing aspects of the statutory amendments and which reflect FDA's rulemaking initiative. Such understanding is critical, considering that the mere act of withdrawing proposals might cause some in industry to believe they must then change their labels. In general, withdrawing proposed rules will create confusion in the industry without a clear signal from FDA as to which proposals continue to reflect Agency thinking.

For example, in this docket the agency proposes to withdraw the 1996 proposal to revoke the standard of identity for low fat and non-fat yogurt (Docket No. 95P-0250; November 9, 1995; 60 FR 56541). On July 3, 2003 (68 FR 39873), the agency issued an advance notice of proposed rulemaking requesting comments on a February 18, 2000, petition from the National Yogurt Association to revoke the standards of identity for low fat (§131.203) and non-fat yogurt (§131.206) and to include the provisions of these standards in the standard for yogurt (§131.200). Is this action an example of the "institute new proceedings" that the agency was referring to in the proposal to withdraw? If so, which other documents proposed to be withdrawn are being considered for future work and what is the basis for that decision?

The agency should clearly identify those items scheduled for instituting new proceedings in any final rule withdrawing the proposals together with a time table and priority rating (i.e., when will the item appear as an "A" or "B" in the CFSAN Priority list).

GRAS Proposals

With respect to the proposed withdrawal of certain proposed GRAS affirmations noted in the proposed action, NFPA seeks clarification on each GRAS notice concerning FDA's position with respect to continued use of the ingredient. Does the preamble to each proposal continue to reflect the agency's current position? Has the agency taken into consideration the effect this action may have on U.S. international trade and/or on positions FDA may advocate at the international level (Codex Alimentarius, World Trade Organization).

NFPA must oppose this action unless FDA can provide assurance that the agency will continue to permit the use of these food ingredients as detailed in the preamble statements to the proposed rulemakings referenced in the document. Further, the Agency should recognize that additional uses not proposed in such rulemaking may be appropriate based on changes in food processing technologies that have occurred since the proposals were published, and that this action will not compromise the ability of the agency to actively support continued use of these additives at the international level including the Codex Alimentarius and its committees as well as in any trade disputes that may arise including action at the World Trade Organization (WTO). The FDA proposal affects the following GRAS food ingredients: Sorbic Acid and its salts; Butylated Hydroxytoluene; Brown and Yellow Mustard; Gelatin; Cellulose Derivatives; Tocopherols and Derivatives; Phosphates; Biotin; Lard and Lard oil; Glycerin; Sodium and Zinc Dithionite; Hydrochloric Acid; Magnesium, Potassium, Sodium, and Zinc Gluconate and Gluconic Acid; Caffeine; Protein Hydrolysates and Enzymatically Hydrolyzed Animal Protein; Zinc Salts; Regenerated Collagen; Ascorbic Acid and its Na and Ca salts, Erythorbic Acid and its Na salt, and Ascorbyl Palmitate; Unmodified and Acid-Modified Starches; and Shellac and Shellac Wax.

NFPA urges FDA to indicate which, if any, of these GRAS affirmations proposals are withdrawn because the use of the substance may be the subject of an acceptable GRAS notice.

Standards of Identity

With respect to proposed amendments to standards of identity, NFPA has specific comments on two proposals.

Pineapple Juice

FDA proposes to withdraw a proposal to amend the standard of identity for canned pineapple juice. The proposal, in response to a Citizen Petition from the Pineapple Growers Association of Hawaii, included two items: first, to permit the addition of pineapple juice from concentrate to pineapple juice to increase the brix level and second, to provide for the use of nutritive carbohydrate sweeteners. On

July 20, 1987, NFPA filed comments supporting both proposed amendments to the standard (copy attached).

The standard has since been amended to provide for the use of nutritive carbohydrate sweeteners as proposed in the document.

> 146.185 (a) Identity (1) "...It may be sweetened with any safe and suitable dry nutritive carbohydrate sweetener. However, if the pineapple juice is prepared from concentrate, such sweeteners in liquid form, also may be used..."

Therefore the second item in the proposed action has been completed.

NFPA continues to support amendment of the standard to provide for the addition of pineapple concentrate to increase the brix level of pineapple juice as provided for in the proposal. FDA already provides for the addition of concentrated fruit or vegetable juice to a 100 percent fruit or vegetable juice of the same species for all juices not subject to a standard of identity in 21 CFR §102.33 (g)(2) that states:

> "(g)(2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate..."

FDA should either proceed with the pineapple juice rulemaking to incorporate this amendment into the pineapple juice standard of identity or publish a notice as a policy statement, such as a notice in the preamble to the final rule withdrawing the proposed rulemaking, that 21 CFR §102.33(g)(2) applies to all fruit or vegetable juices including those fruit or vegetable juices subject to a standard of identity. We suggest it is preferable for the agency to consider this amendment to be a technical correction to bring the standard in line with what is permissible for all other juices and to amend the standard accordingly.

Canned Pineapple

FDA proposes to withdraw the proposal to amend the standard of identity for canned pineapple to provide for "whole" as an additional style of pack with "whole" defined as "Consisting of whole fruit peeled and cored into a reasonably symmetrical pineapple cylinder (unit) with both ends cut perpendicular to the cylinder axis." The action was initiated in response to a petition from the Pineapple Growers Association of Hawaii.

On May 22, 1989, NFPA filed comments supporting the amendment to include "whole" in the standard of identity for canned pineapple, noted that this style was

provided for in the Codex Alimentarius standard for Canned Pineapple, and requested the definition be revised as follows:

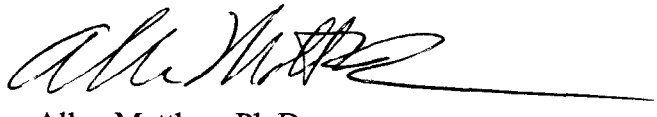
> "Whole. The maximum radial axis of the cylinder does not exceed the minimum radial axis of the cylinder by more than 10mm (0.39 inch). The cylinder may be cracked but not broken into separate pieces."

A copy of the comment is attached.

At that time the agency had issued two temporary marketing permits for firms to pack the product. We understand that if the agency withdraws this proposed rulemaking any temporary marketing permit issued under this proposal would be dropped and the product could no longer be packed. We request the agency complete this rulemaking as requested by NFPA in 1989 or provide that such product would be considered as a nonstandardized food not subject to the standard of identity provided it is otherwise properly labeled (refrigerated whole peeled/cored pineapple is currently marketed in the U.S.).

Thank you for providing this opportunity to comment on the proposed action.

Sincerely,



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July 20, 1987

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

Re: Pineapple Juice; Proposal to Amend U.S. Standards of Identity and Quality; Docket No. 86P-0338.

Dear Sir:

The National Food Processors Association (NFPA) is a scientifically and technically based trade association that represents nearly 600 companies including most of the major food processing companies in the U.S. About 450 of our member companies pack processed-prepared fruits, vegetables, meats, poultry, fish and specialty products (formulated and dairy) including canned, frozen, refrigerated, aseptic, dehydrated, pickled, and other preserved food items. Other members manufacture packaging and processing equipment, or provide supplies and services to the food processing industry.

NFPA, on behalf of its member who pack pineapple juice, supports the proposal to amend the standards of identity and quality for pineapple juice (21 CFR 146.185).

The proposal would amend the standards of identity and quality for pineapple juice by permitting the adjustment of the pineapple juice soluble solids content by the addition of concentrated pineapple juice in such quantity that the added concentrate does not contribute more than 15 percent of the total pineapple juice soluble solids to the finished food, providing for concentrated pineapple juice as an optional ingredient of pineapple juice, and replacing the word "sugars" with "nutritive carbohydrate sweeteners."

Thank you for providing this opportunity to comment.

Sincerely,

Allen W. Matthys, Ph.D.

AWM/erb

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May 22, 1989

Dockets Management Branch
(HFA - 305)
FOOD & DRUG ADMINISTRATION
5600 Fishers Lane, Room 4-62
Rockville, Maryland 20857

RE: Docket No. 88P-0224
Canned Pineapple; Proposal to Amend Standards of Identity and Quality.

Dear Sir:

The National Food Processors Association (NFPA) is a scientifically and technically based trade association that represents nearly 600 companies including most of the major food processing companies in the U.S. About 450 of our member companies pack processed-prepared fruits, vegetables, meats, poultry, fish and specialty products (formulated and dairy) including canned, frozen, refrigerated, aseptic, dehydrated, pickled, and other preserved food items. Other members manufacture packaging and processing equipment, or provide supplies and services to the food processing industry.

The NFPA, on behalf of its members who pack canned pineapple offers the following comments on the proposal to amend the standard of identity and quality for canned pineapple (21 CFR, Part 145.180).

The NFPA supports the FDA proposal to amend the standard of identity for canned pineapple at 145.180(a)(2)(xii) to include the style "whole" which is defined as "consisting of whole fruit peeled and cored into a reasonably symmetrical pineapple cylinder (unit) with both ends cut perpendicular to the cylinder axis." The new style of pack is included in the Codex Alimentarius standard for canned pineapple and has been successfully test marketed in the U.S. under two temporary marketing permits. We believe the addition of the "whole" pineapple as an optional style for canned pineapple would be in the interest of consumers because consumers have demonstrated interest in and acceptance of, this style of the fruit.

Under 145.180(b)(1)(ii)(i) the agency proposes that for whole style "the maximum diameter of the cylinder exceeds the minimum diameter of the cylinder by not more than 10 millimeters (3/8 inch). ..." NFPA objects to this proposed quality definition and supports the quality definition as contained in petition submitted by the Pineapple Growers Association of Hawaii. We suggest the proposed section be amended to read as follows:

> "(b)(1)(ii)(i) Whole. The maximum radial axis of the cylinder does not exceed the minimum radial axis of the cylinder by more than 10mm (0.39 inch). The cylinder may be cracked but not broken into separate pieces."

The purpose of the requirement is to provide for uniformity in the ring cut surface dimension and the centering of the core hole produced during the core removal operation for the "whole" style of pack. This can be accomplished by defining the maximum variation in the radial axis but not by defining the variations in the diameter of the entire unit. The latter will measure the outer variations but will not detect an off-center or irregular coring operation.

Thank you for providing this opportunity to comment.

Sincerely

Allen Matthys

Allen Matthys, Ph.D