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January 9, 2002

Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

Dear Sir or Madam:

On behalf of the Florida Citrus Processors Association, the Florida Department of Citrus, and National Juice Products Association, I enclose for filing four (4) originals of a Citizen Petition. The petition seeks amendments to 21 CFR 120.24 as set forth in the petition itself.

We would appreciate being notified of the docket number as soon as one has been assigned to the enclosed petition.

Thank you for your assistance.

Respectfully,

Ansley Watson, Jr.

AWjr/a  
Enclosures

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02P.0009

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Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20857

## CITIZEN PETITION

Florida Citrus Processors Association, the Florida Department of Citrus, and National Juice Products Association jointly submit this petition to request that the Commissioner of Food and Drugs amend the provisions of 21 CFR 120.24 as hereinafter set forth. A description of each of the Petitioners is contained in Appendix F to this petition.

### A. Action Requested

1. Petitioners request that the Commissioner amend 21 CFR 120.24 (hereinafter, "Section 120.24" or the "regulation") to exempt, under certain conditions, concentrated and shelf-stable juices qualifying for the exemptions set forth in Section 120.24(a)(1) and (2) from the 5-log pathogen reduction requirement of the regulation. The current regulation, and the amendments thereto requested by this petition (shown in legislative style), are set forth in Appendix A hereto.

2. Petitioners request that initial effective date of Section 120.24, as it applies to concentrated and shelf-stable juice products which are (i) produced by processors exempt under Section 120.24(a)(1) or (2) and (ii) have been shipped and received in accordance with the requirements of Subpart A of 21 CFR Part 120 (including the SSOP set forth in 21 CFR 120.6(a)(5)), be stayed until such time as this petition has been disposed of by the Commissioner.

### B. Statement of Grounds

#### 1. Background

Section 120.24 was issued as a part of 21 CFR Part 120, and was published in its final form in the *Federal Register* for January 19, 2001 (66 FR 6137 *et seq.*). Part 120 will be referred to hereinafter as the "Juice HACCP Rule." As pertinent to this Citizen Petition, the Juice HACCP Rule has two basic types of requirements. Subpart A (Sections 120.1 through 120.14) generally requires all processors to have a written Hazard Analysis and Critical Control Points ("HACCP") plan, to verify and validate the plan from time to time, and to maintain certain records. Subpart B (primarily Section 120.24) requires processors, "[i]n order to meet the requirements of subpart A," to include in their HACCP plans control measures that will consistently produce, at a minimum, a 5 log (i.e.,  $10^5$ ) reduction, for a

period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the most resistant microorganism of public health significance that is likely to occur in the juice.

Section 120.24, as initially proposed by the Food and Drug Administration ("FDA"), was significantly different from the section as issued in its final form. Appendix B to this petition shows, in legislative style, the changes to the section (as initially proposed) that were made when the final Juice HACCP Rule was issued by FDA.

As indicated by the changes reflected in Appendix B, the regulation as finally issued purported to add exemptions from its 5-log pathogen reduction requirement for juice processors using either (i) a single thermal processing step sufficient to achieve shelf-stability of the juice or (ii) a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by Subpart A of the Juice HACCP Rule. However, these exemptions were made virtually meaningless for many processors by other changes, which require that a processor perform the 5-log pathogen reduction and final product packaging of all juice subject to the exemptions within a single production facility (hereinafter, the "single facility requirement").

## 2. The Proposed Amendments

The amendments to Section 120.24 sought by Petitioners are narrow in scope, and will not compromise the food safety objectives of the Juice HACCP Rule. Indeed, the proposed amendments recognize and embrace the value of HACCP principles and the requirements imposed upon processors (including Petitioners) by the provisions of Subpart A of the Juice HACCP Rule. By this petition, Petitioners seek no relief from the requirements of Subpart A of the rule.

Petitioners' proposed amendments would, among other things, lift the considerable financial burden imposed by current Section 120.24 on producers of juice products who purchase juice concentrates for storage or repackaging and sale in the form of juice concentrate. As currently written, the single facility requirement of the regulation dictates that the HACCP plans of such processors include a 5-log pathogen reduction *in addition to* the 5-log reduction performed by the same processor at a different plant, or by a different processor from which the juice was purchased. The purported rationale for the single facility requirement is indicated in the "Questions and Answers" relating to the Juice HACCP Rule, issued belatedly by FDA on August 31, 2001:

*46. If I produce a consumer frozen concentrate from a higher concentrated juice that comes from another location via tanker truck (whether or not under direct company control), do I need to redo the 5-log reduction?*

Yes. As discussed in response to question 40, the 5-log reduction must be

conducted in the same processing facility where final product packaging of the consumer concentrate occurs (§ 120.24(c)). Tanker trucks may be a source of contamination because it is particularly difficult to adequately sanitize them between shipments.

The amendments sought by Petitioners would exempt from the 5-log pathogen reduction requirement of the regulation concentrated and shelf-stable juices produced in a manner meeting the requirements for the exemptions set forth in 21 CFR 120.24(a)(1) or (2) and which are transferred in accordance with the HACCP principles set forth in Subpart A of the Juice HACCP Rule, including the sanitation standard operating procedure ("SSOP") set forth in Section 120.6(a)(5).

In adopting the final rule (and, in particular, Section 120.24), FDA provided in Section 120.24(a)(1) and (2) that processors of concentrated and shelf-stable juices are exempt from the 5-log pathogen reduction requirement of the regulation "because the processes for shelf-stable juices and concentrates are so rigorous that they exceed the minimum requirements for control of microbiological hazards." 66 FR 6145. Thus, FDA appears to be satisfied that -- when produced -- concentrated and shelf-stable juices are free of harmful pathogens. If these juices are packed in retail or food service packages in the same facility in which they are produced, no further treatment for pathogen reduction is required. However, if they are shipped to another facility for such packaging (whether the other facility is that of the same or a different processor), a 5-log pathogen reduction must be performed by the receiving facility. This requirement is not only burdensome, but assumes that the principles of HACCP imposed by the Juice HACCP Rule will not be effective to maintain the product in its pathogen-free state. This treatment of a historically "pathogen-free" product (even in the absence of HACCP plans which will now be required by the rule) is unwarranted, unsupported by the literature cited by FDA in support of the Juice HACCP Rule, and inconsistent with the agency's exemption of "retail establishments" from *all* of the rule's requirements.

The concentrated and shelf-stable juices contemplated by the exemptions in Section 120.24(a)(1) and (2) -- if transported from facility to facility in sealed and tamper-proof containers (such as drums, pails, tankers and other containers effectively cleaned and rendered free of pathogenic organisms) in accordance with SSOPs and HACCP plans -- should not reasonably be considered exposed to potential pathogen contamination during transport, particularly since they have never been associated with outbreaks of foodborne illness. The focus should be on the proper sanitation of tanker trucks and other containers, not on the fact that the products are moved from one facility to another. While FDA's response to Question 46 in the Questions and Answers previously referenced indicates that tanker trucks *may* be a source of contamination, there is no history whatsoever with respect to pathogen contamination of these products resulting from improperly sanitized tanker trucks. The disease outbreaks in which tank trucks were used for transportation of juice products had nothing to do with the sanitation of the tankers, but

arose from the handling of the products. Further, all were associated with un-pasteurized single-strength juices, not with the products exempted by Section 120.24(a)(1) or (2) of the regulation.

Petitioners acknowledge that proper risk assessment could possibly show that third party tanker cleaning services may not perform sufficient pathogen removal to prevent potential pathogen contamination of product later loaded into a tanker. However, this is clearly nothing more than another potential hazard to be addressed by a HACCP plan. Processors and shipping facilities have access to sanitizing chemicals, protocols, and sanitation evaluation technologies capable of ensuring the reduction of potential pathogenic organisms beyond any reasonable likelihood of significant risk.

An argument could also be made that it is possible for microfissures in the metallic surface of a tanker's internal lining to harbor pathogenic organisms, and that such fissures could "open" during transport of the product and result in pathogen contamination. However, it is highly unlikely that the level of pathogenic inoculum required to present a significant risk in finished products made from concentrate could exist in any such microfissure. Assuming 100 pathogenic organisms are required in a 240 ml serving to cause illness, the total pathogen load in a tanker of typical bulk citrus concentrate diluted to consumer level product and then reconstituted to single-strength juice would need to approximate between  $10^7$  and  $10^8$ .

Performing proper tanker sanitation "in house" under SSOPs and a properly designed HACCP plan is well within the capability of a typical processing plant.<sup>1</sup> Proper tanker sanitation and product transfer SSOPs (by both the shipping and receiving processors) will eliminate any necessity for the receiving processor to re-perform a 5-log pathogen reduction. The receiving processor's supplier agreements would impose, on the shipping processor, requirements for proper tanker (or other container) sanitation.

FDA's response to Question 50 (see Appendix C hereto) of the Questions and Answers issued on August 31, 2001, in which the potential for allergen cross-contamination is addressed, offers a precedent for utilizing a rigorous preventive sanitation method for container preparation. The principles which guided FDA's response to Question 50 logically extend to tanker and other container surfaces as well as processing equipment.<sup>2</sup> Petitioners' proposed amendments to Section 120.24 incorporate the same

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<sup>1</sup> It should be noted that such sanitation is required with respect to blending tanks and other product-transfer piping *within* a "single production facility" referenced in Section 120.24.

<sup>2</sup> See also Footnote 1, *supra*.

principles.

3. No History of Foodborne Illness

The preambles to the proposed (63 FR 20450-20451) and final (66 FR 6147) Juice HACCP Rules describe foodborne illnesses associated with consumption of juice products contaminated with harmful pathogens and occurring since the 1970s. The illnesses depicted were associated with un-pasteurized juices, and FDA concluded that the most significant hazards were associated with non heat-treated juices (66 FR 6146). *None of the literature cited in support of the proposal or adoption of the Juice HACCP Rule disclosed any incident of foodborne illness associated with concentrated or shelf-stable juice products.*

While FDA's concerns regarding tanker cleanliness may have some theoretical merit, those concerns are not substantiated by the literature relied upon by the agency for the proposal and adoption of the Juice HACCP Rule. Petitioners are, nevertheless, aware of five disease outbreaks pertaining to citrus concentrate, each of which is summarized in Appendix D to this petition. None of these incidents was traceable to the manufacture or shipment of juice concentrate. Rather, all were attributable to contamination or mishandling by end-product users (restaurants, cafeterias, etc.) or by a dairy that reconstituted the concentrate and packed single-strength juice.

Within the processed juice industry, the greatest burden of the 5-log pathogen reduction and single facility requirements of Section 120.24 is currently imposed on the segment of the industry with the most unblemished food safety history, while "fresh," un-pasteurized juices sold by "retail establishments" (as defined in the final rule) at farmer's markets, roadside stands or juice bars are not subject to *any* of the requirements of the Juice HACCP Rule (including the 5-log pathogen reduction requirement). The proposed amendments to Section 120.24 will lift from this historically safe segment of the industry an almost insurmountable burden, while having no detrimental effect on FDA's goals in adopting the Juice HACCP Rule.

4. Misplaced Reliance on Single Facility Requirement

Petitioners submit that the single facility requirement was the product of FDA's request to the National Advisory Committee on Microbiological Criteria for Foods ("NACMCF") regarding the application and measurement of the 5-log pathogen reduction requirement to citrus fruit. The NACMCF's response was based on its review of research and other information, and on three days of public meetings held December 8-10, 1999. As a result of the NACMCF's recommendations, FDA added, in Section 120.24(b), a limited exception, for citrus juice processors, to the requirement of that paragraph that all juice processors meet the requirements of paragraph (a) of the regulation through treatments that are applied directly to the juice. The limited exception permits citrus juice

processors to use treatments to fruit surfaces as part of the required 5-log pathogen reduction, provided that the 5-log reduction process begins after culling and cleaning (as defined in the Juice HACCP Rule) and the reduction is accomplished within a single production facility.

In the context of the NACMCF recommendations adopted by FDA, the "juice" which was discussed was generally un-pasteurized, and also single-strength (*i.e.*, it was *not* concentrated or shelf-stable juice as contemplated by the exemptions set forth in Section 120.24(a)(1) and (2)). 66 FR 6172. FDA's rationale for the single facility requirement is understandable in the context of single-strength juices which have not been processed via a single thermal processing step sufficient to achieve shelf-stability. However, it is weak at best in the context of shelf-stable and concentrated juices qualifying for the exemptions provided by Section 120.24(a)(1) and (2). While FDA correctly stated that there had been "several recent outbreaks" associated with microbially contaminated fresh juice in which "the evidence *suggests* that transportation *may* have played a role" (emphasis supplied), there is no evidence of any such outbreaks involving shelf-stable or concentrated juices qualifying for the referenced exemptions. 66 FR 6172.

Petitioners submit that FDA's conclusion that the single facility requirement -- developed in the context of juices other than those qualifying for the exemptions set forth in Section 120.24(a)(1) and (2) -- is unreasonable and unsupported by the evidence considered by the agency.

In its discussion of the single facility requirement, FDA stated (66 FR 6172):

Even within a single production facility, time between cumulative steps may provide an opportunity for growth or recontamination. Therefore, processors should include in their HACCP plans controls to protect against regrowth of pathogens between steps (e.g., limiting hold time and/or temperature) and to prevent recontamination of the juice during or after processing (e.g., aseptic handling between steps or between treatment and packaging).

This is exactly what Petitioners propose via the amendments sought herein. The Juice HACCP Rule places upon the juice processor the responsibility for performing an evaluation of potential microbiological, chemical and physical hazards associated with a particular product and process to determine what hazards are *reasonably likely to occur* and, if there are any such hazards, how they can best be controlled. All juice processors operating under HACCP principles (which the rule now requires) must utilize SSOPs, control points and/or critical control points to reduce to acceptable levels, prevent or eliminate the hazards associated with each specific product. The regulation's currently required re-application of a 5-log pathogen reduction to products qualifying for the exemptions set forth in Section 120.24(a)(1) and (2) -- products clearly unassociated with

any reasonable likelihood of pathogenic hazard occurrence -- is unnecessary.

5. FDA's Preliminary and Final Regulatory Impact Analyses Are Severely Flawed

With respect to products qualifying for the exemptions set forth in Section 120.24(a)(1) and (2), the Final Regulatory Impact Analysis which comprised a part of FDA's publication of the Juice HACCP Rule is flawed in terms of both the benefits which are calculated to flow from adoption of the rule and the costs which juice processors will incur to comply with the rule's requirements.

a. The PRIA. FDA's Preliminary Regulatory Impact Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products (the "PRIA") was published in the *Federal Register* for May 1, 1998 (63 FR 24253-24302) and, among other things, was directed to both the Juice HACCP Rule (as initially proposed on April 24, 1998), and another proposed rule which would require a warning and notice statement on the labels of un-pasteurized juice products which were not proposed to be covered by the proposed Juice HACCP Rule.<sup>3</sup> The PRIA purported to calculate the costs and benefits of the proposed rules, and did so prior to FDA's adding to Section 120.24 the single facility requirement. In calculating both the costs and the benefits, no distinction was made between, on the one hand, concentrated and shelf-stable juices and, on the other, other types or forms of juice.

The words "concentrate" and "concentrates" appear in the PRIA only five times, four in connection with documented instances of pesticide residues in various products, and one in connection with the coverage of the proposed HACCP and labeling rules. It is clear that, in making its analysis, FDA did not differentiate between juices qualifying for the exemptions set forth in Section 120.24(a)(1) and (2) -- which exemptions did not yet exist -- and other juices not covered by the exemptions.

In calculating the "quantitative estimates of health benefits" which would result from the proposed Juice HACCP Rule, FDA used a nine-step process, which is reproduced in summary fashion in Appendix E to this petition. In short (although the process is complicated), the total health benefits in dollars are determined by multiplying (a) the lost dollar value of utility losses for all combinations and levels of severity for specified durations for each of the most significant microbiological hazards which are reasonably likely to occur in juices, by (b) the reported cases associated with the identified hazards, multiplied by a factor to account for under reporting of illnesses associated with the hazards, by (c) the percentages of each type of hazard expected to be prevented by the 5-

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<sup>3</sup> Food Labeling: Warning and Notice Statement; Labeling of Juice Products, 63 FR 20486, April 24, 1998. The final version of this proposed rule was published in the *Federal Register* for July 8, 1998 (63 FR 37029-37056).

log reduction requirement. For all juices, the result of this exercise was an estimate of annual health benefits ranging from \$174 million to \$251 million (63 FR 24271).

Petitioners submit, however, that if the same exercise is conducted only with respect to juices qualifying for the exemptions set forth in Section 120.24(a)(1) and (2), as to which there have been *no reported cases*, the annual health benefits are zero because zero multiplied by any number is zero. With respect to these products, therefore, the proper point of beginning for the cost-benefit analysis is recognition that there are *no benefits*.

In estimating the costs to be incurred by processors to comply with the pathogen reduction requirements of the proposed Juice HACCP Rule, FDA in the PRIA "estimated the costs of purchasing special, low cost pasteurizers designed for low-volume applications that are suited to small businesses." 63 FR 24278. Although the agency recognized that the costs of pasteurization vary depending on numerous factors (including the capacity of the facility), it estimated the cost of a pasteurizer (including installation) to be between \$11,300 and \$26,700. 63 FR 24278. Further, FDA recognized that of the 1,070 processors it estimated would be covered by the Juice HACCP Rule, only a portion of them would need to initiate pasteurization. It clearly did not, however, anticipate that processors who currently had pasteurization equipment would be required to pasteurize concentrated juices qualifying for the exemption in Section 120.24(a)(2).<sup>4</sup> Because of the thermal concentration process used by these processors, only single-strength juices prepared from the concentrated products are pasteurized. The concentrate itself has typically never been pasteurized following its production, and the equipment used to pasteurize single-strength juices is not suitable for the pasteurization of concentrated products.

Petitioners are compiling information with respect to the cost of equipment which may be available to pasteurize concentrated products (as would currently be required as a result of the single facility requirement of Section 120.24) and will supplement this petition as soon as such information is available. However, preliminary estimates by one processor are that it will – if the amendments proposed herein are not adopted – be required to install five pasteurizers at an installed cost of \$700,000 each. Thus, if these

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<sup>4</sup> In discussing in the PRIA "other costs" related to processing for pathogen control, FDA stated (63 FR 24280):

... The pasteurization of juice causes changes in the characteristics of the products, primarily in terms of texture and taste. Some current consumers of *nonheat-treated juice* will bear the costs of losing a particular product as well as costs of searching for products with the characteristics they prefer the most. Thus, one cost of these regulations is the loss of "fresh" juice, that is, *juice that is not heat (or otherwise) processed*. . . . (emphasis supplied)

Clearly, the agency did not consider in the PRIA the costs associated with pasteurization of concentrated juices, which is required as a result of the single facility requirement of Section 120.24.

estimates are correct, the first year costs of a *single processor* to comply with the single facility requirement of Section 120.24 are almost 150% of the total first year costs of \$2,350,000 estimated by FDA in the PRIA for 120 plants. 63 FR 24280. In addition to the \$3,500,000 in first year costs, the single processor mentioned above estimates its recurring annual cost to operate the processors at \$3,000,000. The processor has indicated it would be unlikely that the five pasteurizers could be installed and operating in less than a year from the date they are ordered, and this estimated lead time assumes that not all processors requiring similar equipment to comply with the rule are ordering such equipment at the same time.

b. The Final Analysis. In publishing the final version of the Juice HACCP Rule, FDA purported to update the regulatory analysis published following the rule's proposal. While it recognized that all processors would be required to comply with the revised pathogen reduction requirement of the final version of Section 120.24, it continued to posit that not all processors would have to initiate pasteurization. In doing so, the agency stated:

Of the 2,300 processors covered by the HACCP rule, only a portion of these will need to initiate pasteurization. *In this final rule, processors of shelf-stable juice and juice concentrate will not need to incur additional costs for the control of pathogens.* FDA estimates that this new provision in the final rule applies to about 600 processors . . . . (emphasis supplied)

FDA's statement that these processors will not have to initiate pasteurization will be correct *only* if the amendments to Section 120.24 sought by this petition are adopted. Otherwise, as discussed in connection with the PRIA, *supra*, numerous processors who receive shelf-stable and concentrated juices produced in different plants (whether their own or a third party's) will be required to initiate pasteurization of concentrated juices at initial and continuing annual costs far exceeding FDA's estimates. These costs must be compared against *no* health benefits as a result of the pathogen reduction requirement of Section 120.24; that is, *zero times any number is still zero.*

Section 1 of Executive Order No. 12866 (September 30, 1993, 58 FR 51735) states, in part:

Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or *are made necessary by compelling public need*, such as material failures of private markets to protect or improve the health and safety of the public . . . . In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. . . . (emphasis supplied)

Petitioners submit that FDA's single facility requirement cannot pass muster under the requirement quoted above. The FDA's assessment of the costs and benefits associated with requiring re-application of a pathogen reduction to shelf-stable and concentrated juices simply because they were produced in a facility other than the one in which they are finally packaged is seriously flawed. It fails to recognize that there are no benefits which flow from the imposition of the requirement. It grossly underestimates the costs which will be incurred to achieve no benefits. These shortcomings will be remedied by adoption of the amendments sought by Petitioners herein.

6. Impact of the Current Single Facility Requirement

If processors are required to, in effect, re-pasteurize shelf-stable and concentrated juices as is currently required by the single facility requirement of Section 120.24, the process would create a severe negative impact on the flavor of the resulting product. Petitioners believe it is likely this negative impact on the resulting product's flavor will adversely affect consumer acceptance of the product. When coupled with the additional costs which processors will incur to comply with the current single facility requirement, this likely lack of consumer acceptance will simply result in the death of this segment of the juice industry -- the segment with an unblemished record of safety as it relates to pathogenic contamination.

7. Irreparable Harm

If the regulation is not amended as sought by this petition (and the regulation stayed pending the Commissioner's review and disposition of this petition), irreparable harm will result to re-processors of shelf-stable and concentrated juices. The single facility requirement of the regulation will require that they acquire equipment they do not currently possess -- at capital costs far exceeding those estimated by FDA -- for the purpose of re-pasteurizing incoming supplies of these products. This will add to the cost of their final products, and the added cost will be borne either by the processors or by consumers. Concentrated fruit juices and juices prepared from concentrate are extremely price-sensitive at both the wholesale and retail levels of distribution, and consumers have been shown to purchase less juice and/or seek out substitute beverages when prices increase.

Higher prices and deterioration in the quality of finished juice products will cost these processors both sales and customers. It is likely that, in the highly competitive juice market, these losses will not be recovered in the short term, if at all. Consumers who switch from fruit juice products to diluted juice substitutes or other types of beverages may well lose the nutritional benefits associated with one hundred percent juice products.

The additional costs to which these re-processors will be subjected in the event the amendments proposed herein by Petitioners are not promulgated by the Commissioner (and the regulation is not stayed pending rulemaking on the amendments) were not

anticipated by the Petitioners or by FDA in adopting the Juice HACCP Rule and the single facility requirement of Section 120.24. These re-processors first learned of the single facility requirement when the final Juice HACCP Rule was published in January 2001. See Appendix B. They had no opportunity to budget or plan for the large capital expenditures needed to comply with the new regulation. Tight margins for many juice processors can make "surprise" expenditures of the magnitude involved here particularly devastating. Many juice processors are highly leveraged, and lenders who require a processor to meet various financial tests can view changes in the regulatory environment as reasons to "call" loans.

The addition of the single facility requirement in the final version of Section 120.24 is exacerbated by FDA's delay in publishing the Questions and Answers relating to the entire Juice HACCP Rule. Published on August 31, 2001, this guidance left processors who are subject to the January 22, 2002 effective date with only five months to prepare. Preparation for compliance by that date has also been affected by the lack of a model HACCP training program for juice processors and a juice hazards guide.

Because virtually all of the retail frozen concentrated orange juice sold in the United States will be affected by non-compliance with the single facility requirement of the regulation, the companies that produce this product and its ingredients are subject to severe financial harm, including the possibility of bankruptcy. If the amendments to the regulation sought by petitioners are not adopted (and the requested stay granted promptly), it is likely that all shipments of frozen concentrated orange juice in the United States will cease on January 22, 2002.

#### 8. Conclusion

For the reasons set forth above, Petitioners submit that the amendments sought by this petition are in the public interest and in the interest of consumers, and should be promulgated by the Commissioner.

#### *C. Environmental Impact*

Pursuant to 21 CFR 25.30(j), promulgation by the Commissioner of the amendments to Section 120.24 proposed herein does not require the preparation of an environmental assessment or an environmental impact statement.

#### *D. Economic Impact*

Petitioners will submit a detailed statement regarding the economic impact of the action requested herein if requested by the Commissioner following review of this petition.

**E. Certification**

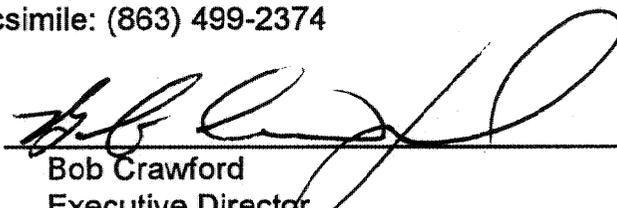
The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.

Respectfully submitted,

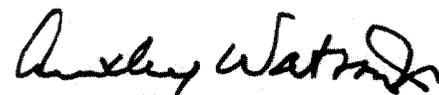
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PROPOSED AMENDMENTS TO SECTION 120.24

Sec. 120.24 Process Controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (i.e.,  $10^5$ ) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:

(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and

(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by Sec. 120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in Sec. 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors, except with respect to shelf-stable or concentrated juice products which (i) are received from processors exempt under paragraphs (a)(1) or (a)(2) above and (ii) have been shipped and received in accordance with the requirements of subpart A of this part (including the SSOP set forth in Sec. 120.6(a)(5)), shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices. ~~Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.~~

## SECTION 120.24 -- FINAL vs. PROPOSED RULES

## Sec. 120.24 Process Controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products, ~~except those subject to the requirements of part 113 or 114 of this chapter,~~ shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (i.e.,  $10^5$ ) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:

(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and

(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by Sec. 120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in Sec. 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices. Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.

## APPENDIX C

**50. *I am a dairy processor who also makes juice using my milk processing equipment. Should I be concerned about milk residues (allergenic proteins) being present in the juice? What are the controls to prevent possible allergen cross-contamination (cross-contact) in this situation, and should these controls be included in my HACCP Plan?***

Yes, when using milk processing equipment to process juice, cross-contact of milk protein into the juice is a concern. Allergens, such as milk, soy (soy milk), or egg (egg nog) should be considered chemical hazards that need to be addressed in your hazard analysis. Controls to prevent cross contact may include a rigorous sanitation regime in between a production run of milk products and a production of juice products. In addition to sanitation, production scheduling can have a large impact on minimizing cross-contact from shared equipment. Processors should try to schedule all non-allergen containing products first, followed by allergen containing products, with a full clean-up before again running a non-allergen product. Depending on the outcome of the hazard analysis, sanitation and production scheduling may be managed through SSOP's or as part of the HACCP plan.

**SUMMARY OF OUTBREAKS ASSOCIATED WITH CITRUS JUICE CONCENTRATES****1962**

St. Louis, MO. Twenty-four cases of Hepatitis A were traced to reconstituted orange juice handled by an asymptomatic employee in a hospital cafeteria.<sup>1</sup>

**1965**

University of California - Berkeley Football Game. 5,200 cases of gastroenteritis were traced to a frozen orange juice dessert product made from frozen concentrated orange juice. Contaminated water was suspected as the cause.<sup>2</sup>

**1989**

New York City Restaurant. Sixty-nine cases of typhoid fever (*Salmonella Typhi*) were traced to reconstituted orange juice handled by an asymptomatic restaurant employee.<sup>3</sup>

**1993**

Ohio school children. Twenty-three cases of gastroenteritis (vomiting). Frozen concentrated orange juice was reconstituted at school kitchen and held two weeks before serving. Ohio investigators report that the cause was "yeast or some other unknown toxicant." Centers for Disease Control web site cites "Rhodurula" (sic) as the suspected cause.<sup>4</sup>

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<sup>1</sup> Eisenstein, A.B., Aach, R.D., Jacobson, W and Goldman, A., An Epidemic of Infectious Hepatitis in a General Hospital, *Journal of the American Medical Association* 185:171 (1963).

<sup>2</sup> Anonymous, Report on Outbreak of Gastroenteritis from October 31 to November 5, 1965 following Pennsylvania State University vs. University of California, Berkeley Football Game at Memorial Stadium, Office of Environmental Health and Safety, Berkeley Campus, December 14, 1965; Tabershaw, R., Schmeizer, L. and Bruyn, H., Gastroenteritis from an Orange Juice Preparation, *Arch. Environ. Health* 15:72 (1967).

<sup>3</sup> Birkhead, G.S., Morse, D.L., Levine, W.C., Fudala, J.K., Kondracki, S.F., Chang, H.G., Shaydani, M., Novick, L. and Blake, P.A., Typhoid Fever at a Resort Hotel in New York: A Large Outbreak with an Unusual Vehicle, *Journal of Infectious Diseases* 167:1228 (1993).

<sup>4</sup> Hazard Analysis and Critical Control Point (HACCP): Procedures for the Safe and Sanitary Processing and Importing of Juice; Food Labeling: Warning Notice Statements; Labeling of Juice Products; Proposed Rules, 63 FR 20451 (1998).

1994

Alabama school children. Eighty-five cases of gastroenteritis (vomiting) traced to reconstituted orange juice in 4-oz. cartons which had been packaged at a dairy in Mobile, AL, and thermally abused during storage. The FDA Enforcement Report for April 20, 1994 states that the juice was "contaminated with yeast and *Bacillus Cereus* (sic)<sup>5</sup> and associated with an outbreak of foodborne illness."<sup>6</sup>

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<sup>5</sup> Petitioners believe it is unlikely the outbreak arose from *Bacillus cereus* due to the inability of this organism to grow at low pH. It more likely arose from yeast fermentation of the juice.

<sup>6</sup> Hazard Analysis and Critical Control Point (HACCP): Procedures for the Safe and Sanitary Processing and Importing of Juice; Food Labeling: Warning Notice Statements; Labeling of Juice Products; Proposed Rules, 63 FR 20451 (1998).

## APPENDIX E

### STEPS IN QUANTITATIVE ANALYSIS OF HEALTH BENEFITS

1. The most significant hazards in juice are described in terms of severity and duration;
2. The hazards are described in terms of resulting health effects and symptoms when they cause illness;
3. The health effects and symptoms are translated into consumer utility losses;
4. The utility losses are translated into values in terms of lost dollars (this gives the cost per case for every combination of level of severity and for the specified duration for each hazard);
5. The average annual number of reported cases associated with juice are distributed according to the percentages associated with each level of severity;
6. The factors used to account for under reporting of foodborne illness are estimated;
7. The reported cases are multiplied by the under reporting factors to get the estimated average annual number of cases;
8. The percentages of each type of hazard expected to be prevented by the proposal are listed; and
9. The total health benefits of the proposal are derived by multiplying numbers 4, 7, and 8. That is,  $TB = RC \times CF \times CR \times V$ , where

TB = total health benefits in dollars,

RC = number of reported cases,

CF = under reporting correction factor,

CR = percent of cases reduced,

V = dollar value per case averted (medical costs + value of pain and lost function).

## THE PETITIONERS

**Florida Citrus Processors Association** is a voluntary trade association with its headquarters in Winter Haven, Florida, and has 19 processor members. Its mission is to represent, communicate, protect and enhance the interests of its members and to promote the growth and welfare of the citrus industry. The organization was formed in 1931. The association serves its members by providing political, technical, and industry support. A primary responsibility is to provide a central point for gathering and publishing statistical information with regard to fruit usage, production volumes and movement, and inventories. A list of the Association's processor members is attached to this appendix.

**Florida Department of Citrus** is an executive agency of the State of Florida, authorized pursuant to Chapter 601, *Florida Statutes*, to regulate, market and conduct research related to citrus juice products. Specifically, Section 601.10, *Florida Statutes*, authorizes the FDOC to disseminate information of importance relating to citrus processors to interested persons and organizations, and to investigate and address the transportation problems affecting the Florida citrus industry.

**National Juice Products Association** is a trade association of juice and juice beverage processors incorporated in the State of Florida with its headquarters located in Tampa, Florida. Regular members of the association consist of 64 processor companies located throughout the United States, Canada, Europe, and South and Central America. Its regular members include major packers and distributors of a wide variety of fruit and vegetable juices, juice beverages and drinks. NJPA represents a significant majority of the juice and juice beverage processors in the United States. A list of the association's regular member companies is attached to this appendix.

## **Florida Citrus Processors Association**

Post Office Box 780 • Winter Haven, Florida 33882-0780 • 863/293-4171 • Fax: 863/293-4746

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Members 2001/02

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**A. Duda & Sons, Inc.**

LaBelle, Florida

**Cargill Citro Pure, Inc.**

Frostproof, Florida

**Citrosuco North America, Inc.**

Lake Wales, Florida

**Cutrale Citrus Juices, USA, Inc.**

Aubumdale, Florida

**Florida's Natural Growers**

Lake Wales, Florida

**Freshco, LTD.**

Fort Pierce, Florida

**Golden Gem Growers, Inc.**

Umatilla, Florida

**Holly Hill Fruit Products Co., Inc.**

Davenport, Florida

**Juice Bowl Products Inc.**

Lakeland, Florida

**Louis Dreyfus Citrus, Inc.**

Winter Garden, Florida

**Ocean Spray Cranberries, Inc.**

Vero Beach, Florida

**Parman Kendall Corporation**

Goulds, Florida

**Pasco Beverage Company, Inc.**

Dade City, Florida

**Peace River Citrus Products**

Fort Pierce, Florida

**Silver Springs Citrus**

Howey-in-the-Hills, Florida

**Southern Gardens Citrus Processing**

Clewiston, Florida

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**The Minute Maid Company,**  
**A Division of Coca Cola Co.**  
Apopka, Florida

**Tropicana Products, Inc.**  
Bradenton, Florida

**William G. Roe & Sons, Inc., DBA**  
**Blue Lake Citrus**  
Winter Haven, Florida



Headquarters: 400 N. Tampa Street/P. O. Box 1531/Tampa, Florida 33601/813-273-6572 Fax: 813-273-4396

## MEMBERSHIP LIST 2001-02

### REGULAR MEMBERS

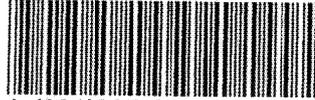
1. A. LASSONDE, INC.
2. AMERICAN FRUIT PROCESSORS
3. BASCITRUS AGRO INDUSTRIA
4. CANADAIGUA CONCENTRATES
5. CARGILL CITRO-AMERICA
6. CCPI/VALLEY FOODS
7. CITROFRUT, S.A.
8. CITROSOL, S.A. DE C.V.
9. CITROSUCO NORTH AMERICA
10. CITRUS BELLE, DIV. A. DUDA
11. CITRUS WORLD, INC.
12. CLEMENT PAPPAS & CO., INC.
13. CLIFFSTAR CORPORATION
14. CONFRUTTA, S.A.
15. COUNTRY PURE FOODS
16. CUTRALE CITRUS JUICES USA
17. DEL MONTE FOODS
18. DEL ORO, S.A.
19. DELANO GROWERS GRAPE
20. DINTER GMBH
21. DOLE PACKAGED FOODS
22. FLORIDA FLAVORS, INC.
23. FLAVORS FROM FLORIDA
24. GOLDEN GEM GROWERS, INC.
25. GIVADAUN ROURE
26. GREGORY PACKAGING INT'L
27. H.J. HEINZ COMPANY
28. JOHANNA FARMS, INC.
29. JUGOS DEL SUR, S.A.
30. JUGOS CONCENTRADOS
31. THE KROGER CO.
32. LE VIGNOBLE, S.A.
33. LOUIS DREYFUS CITRUS
34. MAUI PINEAPPLE
35. MCCAIN CITRUS, INC.
36. MINUTE MAID
37. NESTLE
38. OCEAN SPRAY CRANBERRIES
39. OLD ORCHARD BRANDS
40. OLYMPIC FOODS, INC.
41. ORFIVA, S.A.
42. PASCO BEVERAGES
43. PEACE RIVER CITRUS PROD.
44. PEPSICO, INC.
45. PITTRA -CAMERICAN
46. SAN JOAQUIN VALLEY
47. SILVER SPRINGS CITRUS COOP
48. SOCIEDAD COOPERATIVA
49. SOUTHERN GARDENS CITRUS
50. SUNDOR BRANDS, INC.
51. SUNKIST GROWERS, INC.
52. SUNPURE
53. SUN-RYPE
54. TECNOVIN DO BRASIL ICIE, LTDA
55. TEXAS CITRUS EXCHANGE
56. TICOFRUT, S.A.
57. TREE TOP, INC.
58. TROPICANA PRODUCTS, INC.
59. VENTURA COASTAL CORP.
60. VERY FINE PRODUCTS, INC.
61. VICENTE TRAPANI, S.A.
62. VIE DEL COMPANY
63. VITA-PAKT CITRUS PROD. CO.
64. WELCH'S

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Tammy G. Andis, Executive Secretary  
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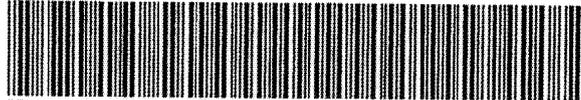
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Macfarlane Ferguson & McMulle SHIPPER'S FEDEX ACCOUNT NUMBER  
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Suite 2300  
Tampa, FL 33602



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