International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

November 11, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 02D-0333 - Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition

To the Dockets Management Branch

The International Dairy Foods Association and its constituent organizations, the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA) have a combined membership of 600 dairy processors who produce eighty-five percent of all dairy products. Almost 200 of these same members' process and package 10% of all juice drinks and 30% of the total orange juice made from concentrate in the United States. Many of these products are regulated under 21 CFR 120, Food and Drug Administration's Juice Hazard Analysis Critical Control Point (HACCP) regulation. IDFA has been preparing its members to comply with the Juice HACCP regulation through an intensive training program of short courses since April, 2001 as well as a number of individual company juice HACCP training programs. IDFA supports FDA's issuance of additional guidance providing more details and clarifying FDA's views regarding implementation of the Juice HACCP regulation and provides the following comments on that guidance.

In general, IDFA is concerned that the Hazards and Controls Guide arbitrarily deals with some potential hazards, requiring very prescriptive control measures without making clear scientific basis for identifying the hazards or controls. Processors will incur significant additional costs to comply with recommendations in the Hazard and Controls Guide that were not factored into the cost/benefit analysis in the original Juice HACCP regulation. Moreover, IDFA believes these extra costs will not result in significantly improving product safety.

Because the juice HACCP regulation does not clearly address the use of voluntary prerequisite programs to reduce the likelihood of occurrence of potential hazards, IDFA concludes that FDA has interpreted the Hazard and Controls Guide to mean all hazards must be addressed by the mandatory Sanitation Standard Operating Procedures (SSOPs) or at a Critical Control Point (CCP). IDFA believes this approach is forced and does not recognize the important and

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necessary role that prerequisite programs play in laying the foundation for a solid HACCP program, whether it applies to juices or any other food product. If a processor's hazard analysis finds that a prerequisite adequately reduces the likelihood of occurrence of a hazard, then FDA should accept this and treat that prerequisite under the juice HACCP regulation in the same manner as the mandatory SSOPs.

The Hazards Guide does not address potential hazards in a scientific manner consistent with normal operating practices in the juice beverage industry. The prerequisite programs, mandatory SSOPs and the hazard analysis should dictate whether the likelihood of a potential hazard is adequately reduced or whether a control measure is required, for example:

a. Section IV. C.1.2 & 4.2, V.D.1.0 & 1.1, 1.2, Table 1, Table 2, VII.A.2.0, VII.B.1.0, Patulin: The Hazard Guide treats patulin as a hazard that needs to be controlled (1.1, third paragraph) by stating that patulin is a hazard reasonably likely to occur. However, IDFA is not aware of scientific literature or epidemiological studies that support that approach. Testing for patulin (IV.D.1.2), as recommended in the Hazard Guide to verify the CCP is problematic since only a limited number of laboratories have the capability and those that do take 24 to 36 hours to report results, very slow for determining process control. Current industry practice utilizes good agricultural practices, storage and processing conditions, and processor supplier control programs to achieve an acceptable reduction in the likelihood of occurrence of patulin, as a result the Hazard Guide should recognize that the likelihood of patulin's occurrence can be dealt with through the SSOP on adulteration or a supplier control prerequisite program.

b. Section IV.C.1.23, FD&C Yellow No.6: IDFA is aware of scientific information supporting the classification of Yellow No. 5 as a food intolerant substance, but cannot find any scientific basis for including Yellow No. 6. It should be removed from the list in the Hazards Guide and dealt with like any other ingredient, through labeling and appropriate levels of use.

c. Section IV.C.1.31 & E.1.1, Table 1, Glass Fragments: FDA's recall data, morbidity and mortality data from the Centers for Disease Control and other reports indicate that the practices of the bottling industry do not present public health problems associated with glass fragments, though under HACCP they should be considered a potential hazard. The Hazard Guide should provide guidance that recognizes glass fragments are a potential hazard that is not reasonably likely to occur and therefore can be addressed under the SSOP on adulteration. Supplier control, handling and cleaning of the glass containers, visual inspections, and bottle storage after filling can reduce the likelihood of occurrence to an acceptable level. Thus the hazard guides should not mandate a CCP control program for glass containers used for juices.

d. Section IV.C.1.32 & E.1.2, Table 1, Table 2, VII.A.2.0, 3.0, 4.0, Table 7, Metal Fragments: The same arguments apply to metal fragments. Metal fragments should be considered a potential hazard and the Hazard Guide should provide guidance that

recognizes the SSOP on adulteration can address this hazard. Pre-operational inspections, equipment maintenance programs, visual inspection of processing equipment, and responding to consumer complaints together can reduce the likelihood of occurrence to an acceptable level making it unnecessary for the hazard guide to mandate a CCP control program for metal fragments in juices.

3. Section V.C.1.1 & C.5.2 *Cryptosporidium parvum*: The Hazard Guide assumes that water supplies used in processing apple juices can become contaminated with *cryptosporidium parvum* and cites a National Food Processor Association study as a reference for a 5-log reduction of common juice pathogens. This study did not address *c. parvum*. However, the hazard guide recommends doubling the study's recommended pasteurization time to 6 seconds to provide a 5-log reduction for *c. parvum* without any substantiating information. IDFA is not aware of any scientific studies that have established a "Z" value for *c. parvum*, preventing a sound scientific calculation or extrapolation to establish an effective time and temperature relationship for eliminating the organism. Farther scientific work is necessary, IDFA believes, before the hazard guide can support increased pasteurization criteria to achieve a 5-log reduction in *c. parvum*.

4. Section IV.C.3.3 & 3.4, Table 1, Allergen Control: Section 120.8 (c) of the Juice HACCP regulations states: *"Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Section 120.6, they are not required to be included in the HACCP plan."* Conversely, the Hazard Guide conveys a strong bias in favor of control via a CCP: *"We recommend that you control such hazards under your HACCP plan, and not under your SSOPs . . ."*

Dairy plants have historically run juices and dairy products on the same equipment, either processing the juices first or conducting enhanced rinsing or complete cleaning if processing juices after dairy products. As a result, the dairy industry has a history of preventing milk proteins from entering juices. IDFA believes that as long as the mandatory SSOP is effective and adequate records are available documenting the SSOP, the potential hazard of milk residues in the juice is not "reasonably likely to occur." The hazard guide's recommendation to inspect visually each piece of equipment prior to startup (Section VII.C) is not practical since many pieces of equipment and product pipelines are not easily disassembled. Additionally, to occasionally swab food contact surfaces between milk product and juice beverage runs would be more effective than conducting allergen tests of already bottled juice beverages. Finally, the use of allergen test kits to make a determination of effectiveness of the cleaning procedures is dependent upon the performance and reliability of the test kit. But IDFA is not aware that FDA has evaluated the claims of allergen test kit manufacturers to provide sufficient confidence upon which to base important safety decisions regarding allergens.

IDFA recommends that the Hazard Guide present these sections in a more balanced fashion, as in the juice HACCP regulation. The proof of effectiveness of a processors control system should be determined during an FDA audit, not based on assumptions about "reasonably likely to occur."

5. Section IV.C.5.31, Table 7, Pasteurization Equipment: Traditional HTST systems used in the dairy industry and juice industry for achieving a 5-log reduction in pathogens utilize a temperature recorder and controller to establish a record on an almost continuous basis so that product is diverted if the temperature falls below the critical limit. However, the most commonly used positive displacement pumps or variable speed centrifugal pumps have no visual point of reference to evaluate flow rate, making it virtually impossible to obtain meaningful information regarding the flow rate or timing of the pasteurization unit during production. In addition, timing or flow rate does not fit the definition of a critical limit for those systems without magnetic flow meters. IDFA recommends that the juice Hazard Guide utilize the HTST pasteurization model established by the NCIMS HACCP Committee, using only temperature as a critical limit and deal with the flow rate or timing of a traditional HTST system as part of calibration under verification of a properly functioning pasteurization unit.

6. Table 2. The table asks the processor to answer the questions about whether any potential hazards are significant without providing any guidance as to how to evaluate "significant." Decisions regarding potential hazards should be made according to the likelihood of them occurring or whether they are "reasonably likely to occur" as explained in Section IV.C.3.1 & 3.2 of the draft Hazards and Controls Guide. Without guidance, processors will be forced into subjective and challengeable decisions. Also, while there are many formats currently for hazard analysis tables, it is important that the format assist the HACCP team in sorting out the potential hazards, their likelihood of occurrence, and control measures, if needed. A much simpler format and decision tree are attached for your review and consideration.

7. Highlights Section, note under definition for Verification, Section III.B.3.0: Section 120.13 of the HACCP regulation recommends training for a number of activities required of the processor, but also recognizes experience. The draft Hazards and Controls Guide, in a number of other locations, uses the term "trained individual" without also referencing experience as an equally acceptable alternative. This could be misunderstood by readers and should be handled as presented in the original juice HACCP regulation or as in Section B.2.0 of the Hazard Guide. The real proof of a processor's ability to comply with the regulation should be based on the outcome of an FDA audit, not on how much training employees received.

IDFA would also like to take this opportunity to make a few general comments on the Juice HACCP Regulator Training document and the training session FDA held October 30. In some instance, this training establishes new policies on minimum acceptable requirements that IDFA believes should be removed from the document and issued as guidance to the industry.

1. General, Interviewing Employees: Many processors have an employee policy that limits access to production employees to reduce disruption during production. This document should acknowledge that and recommend FDA investigators work with plant management to arrange times for interviews with specific employees.

2. Chapters 3 and 4, Performing Your Own Hazard Analysis: The recommendation for an FDA investigator to conduct his or her own hazard analysis will be very time consuming, if done

properly. The investigator must know and understand the plant layout, processing steps, ingredients, and potential hazards. All three of which can be unique to a particular processing location. IDFA understands that this recommendation is based on the seafood HACCP, but that program does not require a processor to have a written hazard analysis, making sense for the FDA investigator to develop one. This is not the case under the juice HACCP regulation. The processor must have a written hazard analysis so there is no need for the FDA investigator to develop his or her own. Moreover, the processor's hazard analysis and HACCP plan are the documents that the FDA investigator should be auditing against, not the investigator's own hazard analysis.

3. Chapter 10, Records Falsification: Uncharacteristically regular, unusually constant, or unusually neat are arbitrary falsification indicators and they may in fact reflect very good records systems. This section needs to have more practical suggestions, less subjective and easier to measure.

4. Chapter 11, Daily Monitoring:

a. The frequency of every 4 hours for determination of the SSOP on safety of water, condition and cleanliness of the food contact surfaces and prevention of cross contamination is arbitrary and not based on actual need or processing conditions. This arbitrary timeframe should be deleted for a more general explanation.
b. The monitoring of employee health conditions daily, before the start of production, is not practical. During the start of production, only a few of the production workers are usually present. This mandatory SSOP should be monitored and documented by employee training, company policies and production supervisor oversight, not a daily "cuts, sneezing and cough" inspection.
c. The requirement of a daily pest control monitoring record may not be practical. The real proof of an effective plant pest control program is to review the records and evaluate the conditions of the plant, not require a daily record.
d. The example "Daily Sanitation Report" includes a column for "4 Hour Time" and "8 Hour Time". This may create an expectation in the mind of the FDA investigator to demand 4 and 8 hour records, when there is no reason to use a particular frequency. We strongly encourage a removal of these arbitrary timeframes that do not provide any more certainty regarding monitoring of mandatory SSOPs.

5. The October 30 training for FDA investigators was generally very good in IDFA's opinion. A few answers were overly prescriptive or utilized seafood HACCP guidance, and thus were not consistent with the juice HACCP regulation or with current HACCP philosophy. Examples include,

a. The requirement that a processor have records that the product side of a plate heat exchanger in the HTST cooling section be at a higher pressure than on the cooling media side is not a requirement in the Juice HACCP regulation or in any nationally recognized milk pasteurization system. IDFA is not aware of data that shows this is a public health problem.

b. The illustration of an investigator tracking pasteurizer seal numbers through the records system may lead trainees to require all seals be numbered. This is not commonly done in the industry or required. This segment of the video training should be modified or qualified in training material.
c. The illustration of an investigator tracking operational limits through the records system may lead trainees to expect processors to use operating limits instead of critical limits as a measure of CCP control. This could result in confusion by a trainee and should be modified or qualified in training material.

In summary, the dairy industry looks forward to cooperating with FDA as enforcement of the juice HACCP regulation begins. We encourage redrafting and issuance of the guidance documents as soon as possible so the industry can properly implement the juice HACCP regulation without delay. IDFA hopes FDA current HACCP philosophy and its practical application will be incorporated into FDA's enforcement plans and the training of field investigators so the industry is not limited to past approaches that may have become outdated and limited in their effectiveness. The regulation of any HACCP program must place the responsibility for a safe food supply on the shoulders of the processing industry and minimize or eliminate arbitrary performance standards that do not have a scientific basis.

With best personal regards, I am

Sincerely,

Greg Frazier
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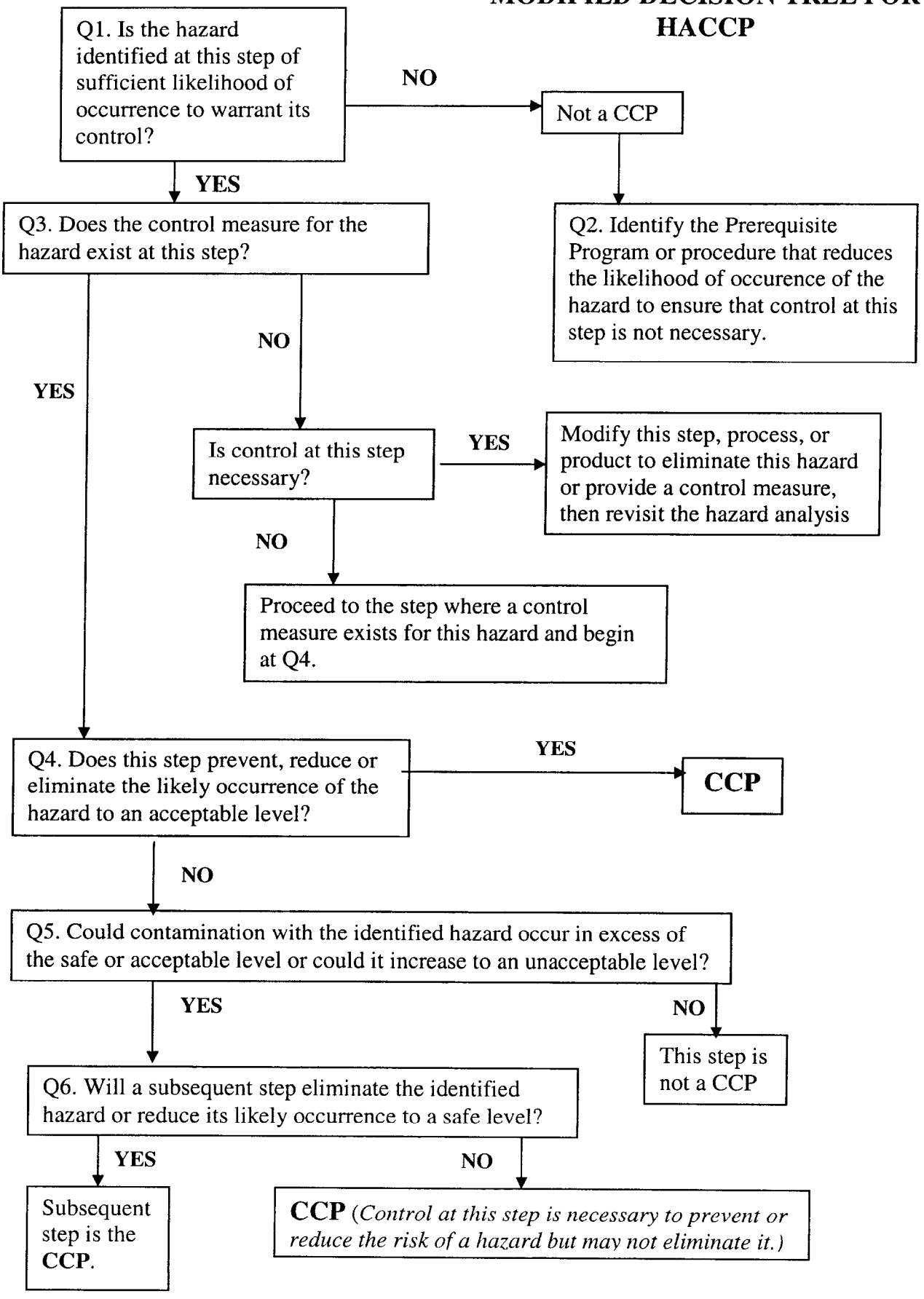
MODIFIED DECISION TREE FOR HACCP



Process Step/ Ingredient or Input	*Identify the specific Potential Hazard* • Biological (B) • Chemical (C) • Physical (P)	Q1. Is the hazard identified at this step of sufficient likelihood of occurrence to warrant its control? • If "yes", then proceed to Q3 • If "no", stop and document at Q2	Q2. Identify the Prerequisite Program or procedure that reduces the likelihood of occurrence of the hazard to ensure that control at this step is not necessary.	Q3 – Q6. Does a control measure exist at this step to prevent, reduce or eliminate the likely occurrence of a hazard to an acceptable level? If "yes", document as a CCP If "no", indicate where this will happen.