To Whom it May Concern:

United Fresh Produce Association (‘United’) appreciates the opportunity to provide comment on the first five chapters, and associated appendices, of draft guidance to aid in implementation of the Preventive Controls for Human Food rule.

Founded in 1904, the United Fresh Produce Association brings together companies across every segment of the fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. We empower industry leaders to shape sound government policy. We deliver the resources and expertise companies need to succeed in managing complex business and technical issues. We provide the training and development individuals need to advance their careers in produce. Through these endeavors, we unite our industry with a common purpose – to build long-term value for our members and grow produce consumption.

Fresh produce is a raw agricultural commodity (RAC) that fits within FDA’s definition of a ready-to-eat food. The absence of a kill step necessitates stringent food safety practices from farm to table. As an industry that has long implemented HACCP, it is very useful to see how food safety plans build upon HACCP principles. Table 1-1, comparing HACCP and food safety plans, is particularly helpful. Fresh produce companies have embraced the concept of Preventive Controls and recognizes the importance of strict adherence to GMPs. We commend FDA for drafting guidance to aid in the implementation of the Preventive Controls for Human Food rule.

Within fresh produce, recalls and outbreaks have demonstrated that an issue associated with a product type impacts all producers of that category, not just the firm associated with the issue. Thus, there is a vested interest in ensuring that the entirety of the produce industry understands how to implement strong, effective food safety programs.

We appreciate the effort associated with developing a guidance document of this magnitude that has applicability to a broad spectrum of FDA regulated food products. We commend the Agency for
providing clear information and for using examples. A workgroup comprised of food safety experts within the United Fresh membership deliberated various aspects of the draft guidance to develop comments on behalf of the association. As the guidance is finalized, United Fresh and our members would be happy to discuss specific issues with FDA to continue the alignment between FDA guidance and industry practice and limitations.

We focus our comments on 7 main areas, expanded upon below, and offer some additional specific suggestions for the document.

Key areas

1. Support for the concept that some foods may not have hazards requiring preventive controls.
2. Request for clarification on when regulatory violations need to be considered as hazards.
3. Suggestion that time/temperature control of fresh produce as a preventive control applies in only limited circumstances.
4. Suggestion that the use of antimicrobials in wash water may be described as process or sanitation preventive controls.
5. Request that the response to some results of environmental monitoring programs warrant corrections rather than corrective actions.
6. Recognition that fresh produce, and especially Raw Agricultural Products (RACs) have unique characteristics.
7. Request that the comment period be re-opened when all chapters of draft guidance have been published.

To expand upon these points:

1. **Not all foods have hazards requiring preventive controls.**

We appreciate FDA’s repeated recognition that some products may lack hazards that require a preventive control, and the acknowledgment of the role of cGMPs. In section 3.3.5 the agency appropriately recognizes the role that GMPs play in establishing a safe food production environment.

We find specific examples helpful so that industry and inspectors can use a common measure for determining the fine line between a cGMP and a preventive control. For example, Section 3.4.3 notes that “preventive controls for facility-related chemical hazards such as cleaning chemicals...are usually addressed through cGMPs.” This is reinforced in section 4.4. We look forward to seeing Chapter 10 because our members often question when sanitation is a cGMP and when it should be recognized as a Preventive Control. This is especially true of our packinghouse community, some of which fall under the Preventive Controls Rule while others are subject to the Produce Safety Rule (PSR). The PSR does not require the evaluation of hazards and determination of preventive controls. Rather, cleaning and sanitation requirements that are very similar to the GMPs in part 117 are required and deemed to be adequate. We hope that FDA will address the issue of regulatory alignment in forthcoming guidance.
In some cases the guidance seems to provide conflicting information on GMPs versus preventive controls. For example, in section 3.3 there seems to be inconsistency in the second paragraph, where FDA states that hazards such as viruses are generally controlled by cGMPs, but later, in the bullet related to People-related hazards, notes that worker hygiene and disease control sometimes control people-related hazards. It would be helpful to provide examples of when cGMPs do and do not address people-related hazards. We are not sure how a reader should interpret the inclusion of norovirus and parasites as a produce-associated hazards in Table 3-2 in light of the statement in this section that they should be controlled by adherence to GMPs and the Produce Safety Rule. We suggest clearer guidance that notes that the likelihood of contamination is low if supplying farms follow the Produce Safety Rule, so that this can be appropriately factored into the hazard evaluation, rather than implying that norovirus is a potential hazard and requires a supply chain control to confirm implementation of the Produce Safety Rule.

Similarly, section 3.4 on chemical hazards notes “chemical residues in a food are not always considered hazards...” however Table 3-6 lists several residues as hazards. While we recognize that each facility is different, and one facility might identify a hazard as needing a preventive control where another, because of the specifics of their operation, may appropriately rely on GMPs, we feel that additional examples would aid the industry in the criteria that help guide science based, consistent decision making.

2. Regulatory violations should not automatically be considered public health hazards

The guidance provides sometime conflicting information on what constitutes a hazard. In section 1.2, the draft guidance states that filth and regulatory violations may not be hazards, and United Fresh supports this perspective. However, later in the document there are examples of regulatory violations that FDA states are hazards. Within the fresh produce industry there is sometimes confusion of when pesticide residues constitute public health hazards, and we feel that some sections of the draft guidance perpetuate this confusion. For example, section 3 uses the term “adulterated” in a way that could be misconstrued by industry or regulators as meaning that the food safety plan needs to control these agents e.g., in Section 3.4.1.1., it states that “If pesticide residues are present ... the food is deemed adulterated”. Depending on the pesticide and level, this regulatory violation may or may not be a public health risk.

Similarly, in section 3.4.1.4 there is reference to the 2008 dioxin issue, which also was not a public health concern. The guidance document would be more useful if regulatory violations were either discussed in the context of how one can determine severity (or lack thereof), or omitted from the document, since it may confuse readers who should remain focused on food safety hazards that could adversely affect public health.

We offer an additional comment on section 3.4: the fourth paragraph discusses pre-market approval. Given FDA’s statements earlier in the document that regulatory violations do not necessarily correlate
with public health hazards, we question the value of this information. It is not clear how a PCQI would use this information.

United Fresh has a similar concern regarding FDA’s characterization of heavy metals. In section 3.4.1.3, FDA should note that another source of heavy metals is natural contamination of soil (e.g., due to volcanic activity); heavy metal contamination is not always anthropogenic in origin. This is suggested in section 4.6.3, which recognizes that soils may be naturally contaminated. However, different crops have differing abilities to uptake heavy metals. Therefore, in section 4.6.3 we believe it is appropriate to require that heavy metals in raw materials do not exceed a certain level (set based on safety) rather than suggesting that a supply chain program restrict farming in levels that may have higher levels of heavy metals in soils, if the crops grown in those soils do not accumulate heavy metals. Table 5-3 indicates an association between carrots and lead. We are not aware of public health issues associating carrots and lead that warrant inclusion of this pairing in this table. FDA reports that tested carrots fall below FDA’s tolerable intake levels http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm233520.htm

While excessive levels of heavy metals found in produce (as opposed to soil) may cause the product to be adulterated under Section 402 of the FD&C Act, situations in which the violative product is truly harmful to health are limited. The emphasis that the draft guidance places on heavy metals is not commensurate with the actual risk, at least as relevant to fresh produce.

3. **Time-temperature control is generally required for quality, not safety, of fresh produce, and should not be required for RACs**

The draft guidance suggests that time/temperature control is necessary to ensure produce safety. While the exact language states that this is recommended “in the absence of other barriers” we are concerned that inspectors, auditors, and others using the guidance will gloss over this qualifier and expect that fresh produce must be temperature controlled for safety. This is in conflict with the exemption in the Sanitary Transportation rule, where RACS do not require temperature control for safety.

We believe that the narrative that accompanies table 4-10, suggesting that refrigeration is required for all foods, including fresh produce, when water activity exceeds 0.85, is misleading. While FDA notes that another barrier can also be used to control growth, we are concerned that, as presented, refrigeration will be expected of foods unnecessarily. Just because a food has a high water activity, it does not mean it needs to be refrigerated. We encourage FDA to note this and similar examples so that it is clear that items like bananas do not need to be refrigerated.

The paragraph below Table 4-11 notes “bread spoils before it becomes hazardous”. Spoilage is a critical issue for fresh produce, and we hope that FDA will acknowledge this in guidance. Temperature control is relied upon for many produce items in order to maintain a quality product. Temperature, when used to control quality, should not be mistaken for a food safety process control. Based on Table 5-2 and
appendix Table 3-H, we are anxious to see chapter 7, where time/temperature control using fresh fruit salad as an example, is discussed.

Similarly, Appendix Table 3-C states that raw, RTE food products should not be exposed to conditions greater than 70F for more than 2 hours. The produce industry recognizes that fresh produce RACs that are covered under the Produce Safety Rule are considered RTE products. The vast majority of these products grow in environments that exceed 70F. The refrigeration parameters in the draft guidance could be interpreted to mean that bananas, avocados, whole tomatoes, and other items commonly stored at ambient temperature would need to be refrigerated. We do not believe this is FDA’s intent, and suggest that this table be revised or otherwise amended. We appreciate FDA’s attempt to simplify the hazard analysis and use of preventive controls, but believe that PCQIs should have adequate background and knowledge to evaluate hazards without reliance on this table. We are concerned that inspectors or auditors may use this table and expect a facility to be controlling hazards using a “one size fits all” approach. We support the paragraph on p 170 that begins “It is not possible to furnish recommendations for each pathogenic bacterium, process, type of food product, and temperature or combination of temperatures.” and suggest that this be emphasized rather than Table 3-C.

United Fresh recognizes that time-temperature controls are used in some fresh-cut products to prevent pathogen growth and toxin formation. However, we do not believe that science supports time-temperature controls for fresh produce RACs and we request that FDA clarify that the time-temperature recommendations that appear in final guidance do not pertain to fresh produce RACs.

4. Antimicrobials in wash water may be described as process or sanitation preventive controls

FDA has stated, and the FSPCA PCQI curriculum teaches, that risks need to be controlled regardless of the terminology that is used to describe that control within the food safety plan. Some United Fresh members consider the use of antimicrobials in wash water as a process preventive control while others consider it a sanitation preventive control. In either instance, the purpose is to prevent cross contamination via wash water. We request that FDA guidance explain that the use of antimicrobials in wash water can be considered either a process preventive control or a sanitation preventive control as long as the concentration of antimicrobial used is based on science (e.g., demonstrated efficacy at maintaining water of sanitary quality) and that the antimicrobial concentration is being maintained (i.e., through monitoring).

Specifically, section 3.3.4.3 references a chlorine wash as a process control for salad. We believe that since chlorine is addressing the issue of cross contamination on a product contact surface (water) rather than serving as a “kill step”, FDA could consider this a sanitation rather than a process control. We believe that all other elements of the control including parameters, monitoring, corrective actions, etc. should be in full force. Because the target of the antimicrobial is water, not the food, we encourage FDA to clarify that, if designated as a process preventive control, validation should focus on ensuring that the treated water remains effective at controlling cross contamination (e.g., that free chlorine levels are maintained). This approach is described as “option 2” or “option 3” (depending on setup) in a recent
5. Environmental monitoring program results often warrant corrections rather than corrective actions

Section 5.5.3 of the draft states that corrective actions should be taken "if you detect the presence of an environmental pathogen or appropriate indicator organism through your environmental monitoring activities." We recognize that the codified rule identifies that corrective actions are needed based on results from an environmental monitoring program. The formal process associated with taking a corrective action is well described in the draft guidance, but we do not feel that it is appropriate as a response to finding a positive in an environmental monitoring program. We believe that this is an example of where a "correction" rather than a corrective action should be taken if there is no risk to product safety (e.g., a positive test result in outer zones), and encourage FDA to use the guidance document to provide clarification to the final Preventive Controls rules regarding this topic.

Environmental monitoring should be encouraged, and a positive finding, while warranting appropriate action, could be viewed in a punitive fashion if a corrective action must be documented. It is unclear how one would document changes to prevent recurrence of the issue, especially when considering that transient positives are expected given the raw nature of fresh produce. We request that FDA clarify, in final guidance, that corrections can be taken in response to findings of an environmental monitoring program.

In addition, in section 5.5.3, FDA recommends documenting corrections, even though this is not required by the regulation. United Fresh supports this approach and believes the example given is appropriate. We suggest that this example and suggestion, if present in the final guidance, be incorporated in the FSPCA PC curriculum. The use of the phrase “we recommend” is a signal that inspectors may expect this practice, which is counter to the instruction provided in the FSPCA training curriculum regarding the circumstances under which corrections should be documented.

6. Fresh produce, and especially Raw Agricultural Products (RACs) have unique characteristics that require different considerations than processed foods

We recognize the difficulty in developing guidance that is applicable to as diverse a set of products and processes as are covered under the Preventive Controls Rule. Fresh produce, and especially Raw Agricultural Commodities (RACs) which, in certain situations, are handled in facilities covered by the Preventive Controls Rule, are inherently different from conventionally processed foods in that they are generally grown outside and lack a “kill” step. Members of the fresh produce community are well aware of the risks associated with these products. We are concerned that individuals who are not as familiar with the produce industry may mis-apply certain aspects of the guidance document that are relevant for conventionally processed foods but not applicable to produce, when evaluating fresh produce operations.
This is especially true for packinghouses, which, depending on where RACs are packed and an enterprise’s size, may fall under the Preventive Controls or Produce Safety Rule. Produce packinghouses are markedly different from manufactured foods because they do not materially or compositionally change produce as it is passed through a packinghouse. United Fresh and others in the produce industry continue to work with FDA to ensure that packinghouses are regulated on the basis of risk. However, until this issue is addressed it is important that guidance differentiate practices applicable to manufactured foods, especially those with a kill step, from practices that may be reasonably encountered in fresh produce packinghouses and other fresh produce facilities.

We suggest that FDA note, as applicable, where recommendations do not apply to RACs. We identify several instances below where we feel that the information related to RACs and in some cases fresh-cut produce could be subject to misinterpretation.

For example, in section 3.3.5.3.1 FDA states that facilities should be kept as dry as possible to limit opportunities for the growth of \textit{L. monocytogenes}. Many packing operations and fresh-cut facilities operate in wet environments as a part of the process. Water continues to be used at other points in the supply chain (e.g., the application of ice or use of misters) to keep produce hydrated to improve product quality. The presence of water in these facilities should not automatically be deemed hazardous if risks are being adequately controlled (e.g., through appropriate sanitation, use of water of sanitary quality, etc.).

Similarly, the concept of hygienic zoning (noted in section 4.4.2 and cross referenced with forthcoming chapter 10) may not always be relevant in facilities that lack a kill step. The produce industry employs methods to ensure that products move from dirtier to cleaner areas. While aligned with the spirit of hygienic zoning, there are not always clear lines that designate areas of higher and lower care. This is especially true in packing operations (and especially dry packing operations that lack a wash step). The risk of a dry packed product does not change as a result of sorting and grading. We request that FDA amend the guidance document to reflect that hygienic zoning is appropriately used when the risk of incoming and outgoing product is different (such as before and after a lethality step), which is not the case in many produce operations. It would be helpful for the guidance to include examples of how hygienic zoning can be employed by different subsets of the industry, including fresh produce.

United Fresh also has concerns with section 3.3.4.2.4. The draft guidance states, “\textit{ROP (reduced oxygen packaging) is used to prevent the growth of spoilage organisms, thereby extending the shelf life of the product. There are some other product quality benefits as well, such as reductions in rancidity, shrinkage, and color loss. However, ROP does not control the growth of all bacterial pathogens and can create a process-related biological hazard.” Within the produce industry, reduced oxygen/ modified atmosphere packaging is used for some products such as bagged leafy greens. However, this packaging is used primarily for the maintenance of product appearance by impacting the rate of leaf respiration. The draft guidance goes on to say “You should not use ROP unless barriers for \textit{C. botulinum} are present. These barriers include: a\textsubscript{w} below 0.93; pH below 4.6; salt above 10%; thermal processing in the final container;
and freezing with frozen storage and distribution." Fresh produce cannot employ any of these options, which suggests that ROP cannot be used for fresh produce.

To leave the language as it currently reads could imply to an inspector or auditor that a facility should have data that address the role of reduced oxygen/ modified atmosphere packaging in food safety of leafy greens or alternatively, a failure in ROP is a food safety concern. We do not feel this is appropriately risk based. The International Fresh-cut Produce Association (IFPA) published an in depth “Assessment of the risk of botulism contributed by modified atmosphere packaging of fresh-cut produce”. The science available at that time did not support a blanket statement about the risk of ROP with respect to fresh produce. Further, in the decades since the broad use of ROP in the fresh produce industry, there have been no reports of botulism associated with commercially available fresh produce packaged in ROP. We believe fresh produce processors should be encouraged to evaluate their products and processes as they relate to the risk of C. botulinum and other pathogens, but should not assume that ROP presents an automatic risk.

There are other parts of the guidance that seem to mis-convey risks associated with fresh produce. For example, in table 3-2 United Fresh does not believe it is appropriate to include the association of L. monocytogenes with RACS as a result of poor or ineffective process controls since RACS generally lack a process control except for the use of antimicrobials in wash water (which, as stated above can also be viewed as a sanitation preventive control). L. monocytogenes is not generally the target of this control (which prevents bacterial pathogen cross contamination - generally associated with the growing environment- in a more general way).

United Fresh is also concerned that the diversity within fresh produce is not accurately reflected in Appendix 1. By associating hazards with broad food categories (e.g., fresh-cut vegetables), does FDA expect that all hazard analyses for all products in this category will include these hazards as part of the analysis? Such generalizations, without references or more specific information, could result in the unnecessary inclusion of hazards in a hazard analysis that distract facilities from focusing on hazards of highest risk.

It is our understanding that inspectors will be preparing their own hazard analyses before conducting inspections. We are concerned that they may rely on these tables without understanding the variability within the categories. For example, Table 2H indicates mycotoxins as a potential hazard for fresh cut fruits when in actuality this is only a potential issue for one specific product and one specific mycotoxin. Additionally, there seem to be inconsistencies across categories. For example, why are S. aureus and Giardia lamblia indicated as potential hazards for fresh-cut vegetables but not fresh-cut fruits (Table 1-H)? Including references that can be used by readers to assess how the hazards relate to their products, and allow readers to assess risk, is recommended.

7. Guidance recommendations can be better assessed when all chapters are available
We request that the FDA consider re-opening the comment period when all draft chapters are available for public review, since our view of the first 5 chapters may be influenced by the content in subsequent chapters. Many chapters within the published draft guidance relate to forthcoming chapters. We appreciate the careful consideration FDA has given to the contents of the complete guidance document, as indicated in the table of contents. We also appreciate the time and resources required to develop a comprehensive document. United Fresh members anxiously await additional guidance, and do not wish to delay the process. However, given the complexity of the rule and the strong role that guidance will play in implementation, we feel that it’s important that guidance provide clear, accurate information that is based on science.

In addition to these main areas, we also offer suggestions for your consideration.

In section 1.4.2 it would be helpful to identify preventive controls that are not monitored. In Appendix 2, the templates suggest that only supply chain controls would not be expected to have a monitoring component.

In section 1.4.5, FDA states that validation can be used to show that the food safety plan as a whole is effective. We would appreciate clarification or examples from FDA showing the situations in which this is appropriate, and how it should be done, that would be different from verification.

Section 2.4 example question 6: we believe the inclusion of thermometers as an option to control for physical hazards is an error.

Section 2.4.2.2.1: we recommend that the relevance of outbreaks and recalls, especially if they are decades old or in other parts of the world be carefully considered. Given that supply chains, production practices and other risk factors vary over time, we urge FDA to recommend that PCQIs seek to understand how the cause of outbreaks and recalls may be used to help identify and evaluate hazards. We would not want inspectors to mistakenly assume that because an issue once occurred, that the hazard must be included in the hazard analysis.

2.4.2.2.3: we suggest using the formal name of the USDA micro modeling program so that readers can easily search for it.

2.4.2.4: we question the inclusion of *E. coli* O157:H7 as an example of an environmental pathogen. We fear that inspectors may expect to see this pathogen included in the hazard analysis of the post-process environment. The codified rule and preamble appropriately focus on *L. monocytogenes* and *Salmonella*, while also indicating that facilities may also identify other environmental pathogens of concern. We
believe this language is appropriate, and that including *E. coli* O157:H7 in this section of guidance will add unnecessary confusion and result in wasted resources.

2.4.2.4: the bullet that references intended or reasonably foreseeable use should be divided into two bullets. The concept of use should be separate from issues related to post process contamination.

3.3.4.2: it may be useful to note that while controlling pathogen growth is important, there are several pathogens that have a low infectious dose whereby growth may not be required to cause illness.

3.3.4.2.2: here and in other parts of the document (e.g., 4.3.2.1), FDA uses statements such as “long times are required”. It would be helpful to have a more quantitative measure, or range, to better understand what FDA means by “long times”.

3.3.5.3.2- science supports a focus on *Salmonella* as an environmental pathogen of concern in a “dry” operation, we would like more explicit guidance from FDA on their expectation that “dry” facilities also test for *Listeria*.

Table 3-8. since the focus is on hazards, we suggest adding a column to the table that describes the public health impact of each of these hazards.

3.4.2.1.1 the discussion of wheat as a big 8 allergen should be limited to wheat allergen. We suggest that the last two sentences about gluten be moved to section 3.4.2.2 related to food intolerance or food disorder so as to not confuse the issues, since there is a threshold associated with “gluten free” labels, whereas there is no threshold associated with the big 8 allergens to date.

4.3.1.1 discusses the use of heat treatment. Within the text, as well as in Tables 3-D and 3-E, FDA suggests that a 6 log reduction of vegetative pathogens is required. We seek FDA’s explanation on this measure, given that juice HACCP requires a 5 log reduction, and FDA guidance for some nut processing suggests that processes achieve a 5 log reduction. Through risk assessments, the almond community determined that a 4 log reduction of *Salmonella* provided appropriate public health protection. We recognize that FDA includes, in the description of Table 3-D, that lesser reductions may be possible based on scientific study, but are concerned that users of the guidance, including inspectors, may have an unrealistic expectation of processing conditions and that in some cases extensive processing will adversely impact quality. Within the fresh produce industry there is no “kill step” making it even more challenging to defend a process that does not produce a 6 log reduction in pathogens but instead serves to limit cross contamination via water.

4.3.1.2- the 5th paragraph describes HPP equipment as “costly”. We believe this is a subjective term and one that is not appropriate in an FDA guidance document.

4.3.1.3- we don’t believe pathogens such as *Listeria* should be characterized as “recently emerged”. The reference is nearly 20 years old, and perhaps this statement was appropriate when the paper was published but we suggest that the language in the guidance document be revised.
4.3.2.1- while noting that some pathogens such as *L. monocytogenes* can grow at near freezing temperatures is accurate, in order to maintain consistency with the data presented in Tables 3-C, we suggest the qualifier, “albeit slowly” to describe growth rate and impress upon readers that refrigeration still serves to limit growth of psychrotrophic pathogens.

This section also references the U.S. Food Code. While useful as a reference, we are aware of instances where inspectors, even pre-FSMA, have cited facilities based on Food Code requirements. Because the Food Code does not apply to FDA registered facilities, we hope that the Agency will train inspectors to evaluate the scientific justification within each food safety plan, rather than hold facilities to Food Code recommendations if they do not apply. This is of particular concern when FDA contracts with state inspectors, who may be more accustomed to regulating retail and foodservice establishments based on the Food Code.

Tables 4-12, 4-13 and 4-14 are redundant with Table 4-10.

Form 2-A. We request that FDA provide rationale on the inclusion of shelf life in this form. We recognize that this information is not required as per the regulation, but such documentation is suggested by the Agency and in the FSPCA curriculum. However, we do not understand how this aids in an evaluation of food safety hazards. Rather, we suggest that this form include the clear identification of allergens (in product and/or in the facility). We believe that this will be more helpful during the hazard analysis.

Form 2-D. We appreciate and support FDA’s suggestion that it is appropriate to reference an SOP within the food safety plan. This will help reduce duplication of information and will help industry leverage existing documents.

Form 2-I. To the best of our knowledge, this form is not available through FSPCA, but we believe it is valuable and suggest that it be included as a downloadable Word document through the FSPCA.

Table 3-B. Since this table refers to *internal* product temperature, we caution the Agency against asserting that “foods…under ordinary circumstances, will be safe”. The internal product temperature may be very different from the surface temperature. If the surface temperature is much warmer, the product may be unsafe even if the internal temperature is cold. It is also not clear how a reader would use this information. Given the complexity of many supply chains, one facility may not have visibility into the holding time and temperatures of other supply chain members, such that it is impossible to calculate cumulative exposure time. It would also be helpful to understand what pathogen levels are expected after the time/temperature combinations are exceeded that would render a product unsafe. What constitutes a “potentially hazardous condition”?

Table 3-D. We believe this table is taken from the seafood HACCP guidance. In that guidance document, there are additional footnotes that should be included here to help the reader better understand how to use this table.
Finally, we recognize that the first 5 chapters of the draft guidance relate to the subsequent chapters, as indicated by the cross-referencing within the draft guidance. We request that the FDA consider re-opening the comment period when all draft chapters are available for public review, since our view of the first 5 chapters may be influenced by the content in subsequent chapters.

Again, we appreciate the opportunity to offer comment, and would be pleased to meet with the Agency to discuss any of our comments.

Sincerely,

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