IDFA
International
Dairy Foods Association

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

RE: Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance: Appendix 1 [Docket No. FDA–2016–D–2343]

The International Dairy Foods Association (IDFA) appreciates the opportunity to provide comments on the Food and Drug Administration (FDA) draft guidance in Appendix 1 regarding the identification of known or reasonably foreseeable biological, chemical, and physical hazards in specific food categories to meet the requirements of the Hazard Analysis and Risk-Based Preventive Controls for Human Food final rule. We appreciate the many changes and improvements made to the first version of Appendix 1, which contains critically important guidance for our member companies. With that said, below we have provided additional comments and recommendations for future updates to specific sections in the latest draft version of Appendix 1.

IDFA represents the nation's dairy manufacturing and marketing industry, which supports more than 3.2 million jobs that generate $49 billion in direct wages and $794 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies and dairy companies and cooperatives to food retailers and suppliers. Together, our members represent most of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. More information about IDFA can be found at www.idfa.org.

IDFA Comments and Recommendations to Enhance Clarity, Scientific Accuracy and Utility of Appendix 1 Guidance

A1.1 – While we appreciate the update to the Purpose section in Appendix 1 to further explain and clarify the use of the phrases "known or reasonably foreseeable hazard" and "potential hazard" and that the agency treats them as synonyms, the repeated use of the phrase "known or reasonably foreseeable ('potential') hazard(s)" throughout the rest of the document makes

the document more difficult to read. To improve general readability, we suggest using the shorter phrase "potential hazard(s)" throughout the document, following this initial clarification. With that said it is important to note that food companies and experts may use these two phrases in slightly different ways and not as synonyms, as part of the continuum of the hazard analysis and identification process; we would recommend that in future updates to Appendix 1 FDA recognize this in the Purpose section. During the hazard analysis process, some companies may start with the universe of "all hazards," narrow that to a list of "potential hazards," and then, after further consideration of risk (severity, likelihood to occur, etc.) for a specific use of an ingredient/product, identify those that are known or reasonably foreseeable. We suggest FDA note that, for the purpose of this guidance, it is using the two phrases synonymously, but in practice, as part of the continuum of the hazard analysis process, there could be different degrees/types of questions applied in deciding what is a "potential hazard" versus a hazard that is "known or reasonably foreseeable."

A1.5.3 – We appreciate the clarification provided that the tables in Appendix I may not always apply to all food products in a given food subcategory.

A1.6.1.1 – We are concerned that the last/first paragraph of page 14/15 could be misleading. Appendix 1 does not address innate differences between organisms, such as heat and acid tolerance, ability to grow at refrigeration temperatures, or external factors that can favor one organism over another. For example, *E. coli* could be a much more resistant microorganism when compared to *Listeria monocytogenes* or Salmonella in food products that undergo high pressure processing. Focusing only on *Listeria monocytogenes* or Salmonella as potential hazards in this situation, and not also considering *E. coli* as a potential hazard could result in a process that may not be adequate. Although such considerations are emphasized in Chapters 2, 3 and elsewhere in the full Draft Guidance, it would be helpful to include a quick reference in this paragraph to remind companies about such approaches and considerations for ruling in/out the organisms listed in Appendix 1 as potential hazards for specific categories/subcategories of foods.

A1.6.1 – IDFA recommends that FDA consider including an explanation for why certain hazards were identified in each table in Appendix 1. We suggest the explanations be placed in as close proximity as possible to the relevant table, so end users are more likely to see the text. For example, FDA might consider moving the note relating to *Shigella* spp. under the "Fruits and Vegetables" food group.

A1.8.2 – The paragraph at the end of A1.8.2 emphasizes that it is just as important for a company to be able to thoroughly explain its rationale for a "No" conclusion for identifying a hazard as a "potential hazard" as it is for a company to explain its rationale for a "Yes" conclusion, and that companies should be prepared to answer such questions about their

hazard analysis. IDFA believes this important guidance to industry should be more prominently noted in Appendix 1 and would recommend that it be included in the Purpose section (A1.1).

Table 1E – Biological Hazards for Dairy –
1 – IDFA recommends that this table include other raw milk-based products. More specifically, we recommend including "raw milk products" as an additional category just below "raw milk." We suggest a footnote also be added, noting that this sub-category "Includes dairy products made from raw milk, except unpasteurized milk cheeses that are appropriately aged for 60 days or more."

2d – Cultured milk products – IDFA urges FDA to consider *B. cereus* a risk for uncontrolled or long and slow fermentations.[1]

3a – In addition to "Ice cream," IDFA recommends that "Ice cream and frozen yogurt mix" also be reflected in the table as types of fluid, soft serve mixes that would be stored refrigerated until frozen. This category should also include Pathogenic *E. coli*, *Salmonella spp.*, *L. mono.*, and *S. aureus* as potential hazards.

4a, 4b – IDFA does not agree that *S. aureus* is a risk for extra hard and hard cheeses. If the pH is <5.6, *S. aureus* will be outcompeted by the starter culture. Temperature is another factor, as *S. aureus* is not likely to produce toxin at aging temps <55°F in hard cheeses, although it may still grow.[2,3,4] FDA should consider adding a footnote to explain these points to users.

4d, 4e – Soft, ripened/unripened/fresh cheese – IDFA is concerned that the terminology used for these cheese categories does not align with the terminology used in the same cheese categories on the FDA's Food Traceability List (FTL); we believe this could result in confusion. For example, mozzarella would fall under one category/description in Appendix 1 and a different category/description on the FTL. Also, fresh mozzarella should be differentiated from low moisture, part skim (LMPS) mozzarella. Fresh mozzarella is a soft, unripened cheese (often just rennet/acid set, no cultures; moisture is around 60%), whereas LMPS mozzarella is a soft, ripened cheese (made with cultures; moisture usually < 50%). We urge FDA to align on

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[1] Ministry for Primary Industries. MPI Technical Paper No: 2016/58: Risk Profile: Bacillus cereus in Dairy Products. (2016) New Zealand Government. https://www.mpi.govt.nz/dmsdocument/14149-Risk-profile-Bacillus-Cereus-in-dairy-products

[2] International Commission on Microbiological Specifications for Foods. 1996. Microorganisms in Foods. 5. Characteristics of microbial pathogens. Blackie Academic & Professional, London.

[3] Halpin-Dohnalek, M.I. and Marth, E.H. 1989. Growth and Production of Enterotoxin A by Staphylococcus aureus in Cream. J. Dairy Science 72:2266-2275

[4] Leong, M.H., *et al*. 2014. Growth of *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, and *Staphylococcus aureus* on Cheese during Extended Storage at 25°C. J. Food Prot, Vol. 77, No. 8, Pages 1275–1288. doi:10.4315/0362-028X.JFP-14-047

terminology for the aforementioned cheese categories and make corrections to address inaccuracies with the manner in which mozzarella cheeses are being classified.

4e – Soft, unripened/fresh cheese – IDFA suggests that FDA consider including "goat cheese/Chèvre" as an example in the list of cheeses of this type, as this is a common type of cheese.

5a – As noted above for 4a and 4b, IDFA respectfully disagrees with *S. aureus* being considered a risk. We suggest that the agency consider adding a footnote noting that *S. aureus* can be a post-process contaminant and can grow rapidly in some cheeses with higher moisture and higher pH[5], but not for this category of hard cheeses.

5c – IDFA urges FDA to update this section to include pathogenic *E. coli*, *Salmonella spp*., *L. mono*, *S. aureus* as potential risks for pasteurized process cheese, given LACF cheese products are excluded. Research has shown that these pathogens can survive and/or grow with certain formulations.[6]

Table 2E – Chemical Hazards for Dairy –
Regarding raw milk for processing, IDFA urges FDA to include Aflatoxin M1 as a potential Mycotoxin hazard for consideration when conducting a hazard analysis.[7]

Regarding animal drug residues, as stated in amendments to IDFA's 2017 comments on the initial draft Appendix 1, we do not support inclusion of a hazard in a table in the guidance without evidence it is a known or reasonably foreseeable hazard for the food category. In this case, animal drug residues should only be included in a table for dairy products if these residues would be reasonably likely to be detected at levels deemed to be hazardous to human health. IDFA can say with certainty there is an extremely low likelihood of the occurrence of animal drug residues in most dairy products at such high levels based on the robust verification sampling and testing regularly performed by industry and regulatory authorities under the Grade "A" milk program. We recognize that dairy products made using non-Grade "A" (*i.e*., so-called "manufacturing grade") milk, which may not be subject to mandatory drug residue testing, could

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[5] Leong, M.H., *et al*. 2014. Growth of *Listeria monocytogenes, Salmonella* spp., *Escherichia coli* O157:H7, and *Staphylococcus aureus* on Cheese during Extended Storage at 25°C. J. Food Prot, Vol. 77, No. 8, Pages 1275–1288. doi:10.4315/0362-028X.JFP-14-047
[6] Glass, K.A., *et al*. Survival of Bacterial Pathogens in Pasteurized Process Cheese Slices Stored at 30°C. J Food Prot Vol. 61, No.3, 1998, Pages 290-294.
[7] Nikita Saha Turna, Felicia Wu, 2021. Aflatoxin M1 in milk: A global occurrence, intake, & exposure assessment, Trends in Food Science & Technology, Volume 110, Pages 183-192, https://doi.org/10.1016/j.tifs.2021.01.093.
(https://www.sciencedirect.com/science/article/pii/S0924224421000960)

be at a relatively higher risk as compared to Grade “A” milk; therefore, table 2e should only include such products. We again recommend that the FDA not include animal drug residues in the table as a potential hazard for all categories of dairy products, unless the agency is able to provide its rationale for doing so.

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Thank you, again, for the opportunity to comment on this draft guidance. IDFA’s recommended changes are intended to help improve the utility of this guidance for our industry sector, so please do not hesitate to contact us if you have any questions or need additional information.

Respectfully submitted,

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