Consensus categorization of cheese based on water activity and pH—A rational approach to systemizing cheese diversity

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ABSTRACT

Development of science-based interventions in raw milk cheese production is challenging due to the large diversity of production procedures and final products. Without an agreed upon categorization scheme, science-based food safety evaluations and validation of preventive controls would have to be completed separately on each individual cheese product, which is not feasible considering the large diversity of products and the typically small scale of production. Thus, a need exists to systematically group raw milk cheeses into logically agreed upon categories to be used for food safety evaluations. This paper proposes and outlines one such categorization scheme that provides for 30 general categories of cheese. As a base for this systematization and categorization of raw milk cheese, we used Table B of the US Food and Drug Administration’s 2013 Food Code, which represents the interaction of pH and water activity for control of vegetative cells and spores in non-heat-treated food. Building on this table, we defined a set of more granular pH and water activity categories to better represent the pH and water activity range of different raw milk cheeses. The resulting categorization scheme was effectively validated using pH and water activity values determined for 273 different cheese samples collected in the marketplace throughout New York State, indicating the distribution of commercially available cheeses among the categories proposed here. This consensus categorization of cheese provides a foundation for a feasible approach to developing science-based solutions to assure compliance of the cheese processors with food safety regulations, such as those

required by the US Food Safety Modernization Act. The key purpose of the cheese categorization proposed here is to facilitate product assessment for food safety risks and provide scientifically validated guidance on effective interventions for general cheese categories. Once preventive controls for a given category have been defined, these categories would represent safe havens for cheesemakers, which would allow cheesemakers to safely and legally produce raw milk cheeses that meet appropriate science-based safety requirements (e.g., risk to human health equivalent to pasteurized milk cheeses).

Key words: food safety, risk, pathogen, regulation, Food Safety Modernization Act

INTRODUCTION

In 2011, the US Congress enacted into law the Food Safety Modernization Act (FSMA), a new food safety reform that introduces major changes to food safety procedures established by Federal Food, Drug, and Cosmetic Act in 1938. This reform shifts the US Food and Drug Administration’s (FDA) approach to food safety from a traditional responsive approach to food contamination to a preventive approach, which requires the development and implementation of science-based preventive controls, including process controls that are scientifically validated. Besides implementing new rules for sanitary food transportation, supplier verification, and establishment of food defense plans, the FSMA preventive controls rule for human food requires the food processor to have a written food safety plan. The FSMA also identifies qualified facilities that can be exempt from having a written food safety plan, but requires they submit proof every 2 yr that proper preventive controls were implemented based on potential hazards identified in the production, as well as a proof

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of monitoring and effectiveness of implemented preventive controls. Qualified facilities are defined as businesses that have a limited number of employees, gross food sales, and geographic range of product distribution (FDA, 2015b,d). According to a 2012 cheesemaker industry survey, more than 82% of all cheesemakers in the United States would be considered qualified facilities (ACS, 2012). These facilities typically have limited access to the relevant scientific information that would define their product and offer a base for food safety decisions to comply with the FSMA rules.

According to US Code of Federal Regulation (CFR) 21 part 1240 (FDA, 2015a), all milk and milk products that enter interstate commerce must either be pasteurized or made from dairy ingredients that have been pasteurized. The exception to this rule is when alternative procedures to pasteurization are provided by regulation; an example of this is 21 CFR part 133, which covers the standard of identity for different natural cheeses and cheese products. In order for a cheese to be labeled with a standard name it has to be made according to the published standard. The CFR standards specify the general make procedures, ingredients that can be used, as well as final characteristics of the product, such as moisture and milkfat content. It also specifies which cheese varieties can be made from raw milk; for example, Cheddar, Colby, as well as certain semisoft and soft ripened cheeses can be made from raw milk, whereas cheeses such as Monterey, mozzarella, cottage, and cream cheese have to be made strictly from pasteurized milk. For all cheese that can be made from raw milk, the current standard stipulates an aging period of at least 60 d at a temperature not less than 35°F (1.7°C); other cheese varieties, such as Parmesan, Asiago medium, and Asiago old cheese, must be aged for longer periods of time regardless of whether or not they are made from raw milk.

Whereas aging of certain raw milk cheeses (e.g., for 60 d) currently provides one codified approach for producing a product that complies with regulatory requirements, new food safety standards will require scientific validation of process controls (similar to critical control points), which often will require comprehensive data sets on prevalence, survival, and growth of target pathogens in a given product. Although challenge studies have often been used to validate process controls, a recent risk assessment conducted by the FDA and Health Canada (2015) used *Listeria monocytogenes* in soft ripened cheese as a model to illustrate how a risk assessment approach can be used to identify different practices that are equivalent with regard to risk reduction provided. For example, this risk assessment specifically suggested that alternative interventions, such as testing the raw milk and final cheese for presence of *L.*

monocytogenes, may provide a similar level of protection as pasteurization. Other similar risk-assessment studies also emphasize the importance of the safety of initial raw milk used in production of soft ripened cheese, as well as other cheese varieties such as Cheddar, feta, and blue (FSANZ, 2009). As these studies use specific cheese types as models (e.g., Camembert-like soft ripened cheese), the question remains if and how conclusions of individual risk assessments can be extrapolated to other cheese types and varieties. A wide range of types and varieties of cheese with diverse characteristics have considerable effects on pathogen growth and survival. For example, raw milk cheese currently produced or sold in the United States may include (1) a 60-d aged Brie cheese with pH well above 7 and moisture 55%, as well as (2) 2-yr aged Parmigiano Reggiano with pH 5.4 and 30% moisture. Whereas one may argue that science-based interventions have to be developed and validated individually for each cheese produced by a given facility, considering seasonal variations in milk quality, composition, and possibly aging; this approach would probably be too expensive to be implemented widely, particularly by businesses that FSMA defines as small or very small.

To facilitate widespread use of information obtained from risk-assessment studies, as well as identify the gaps and plan additional studies that would facilitate development and validation of science-based preventive controls, we hereby propose and outline a categorization scheme that provides for 30 general categories of cheese. We are further proposing that this categorization scheme could be used to (1) assess the risk of survival and growth of *L. monocytogenes* and other pathogens (e.g., shiga toxin-producing *Escherichia coli*) and (2) evaluate effectiveness of different interventions (e.g., 60-d aging) for a cheese or set of cheeses chosen to represent the highest-risk make procedures and product characteristics within each of these categories. The ideas detailed here have previously been submitted to the FDA docket (*Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk*; FDA-2015-N-2596, Aug. 3, 2015).

CONSENSUS CATEGORIZATION OF CHEESE FOR ASSESSMENT OF RISK AND EFFECTIVENESS OF INTERVENTIONS

Rationale for Using pH and Water Activity to Categorize Raw Milk Cheese

We believe that separating cheese into categories based on pH and water activity (a_w) at the point of distribution represents the most feasible and pragmatic

approach for categorizing raw milk cheeses for food safety assessment purposes. Both pH and a_w are well-defined physicochemical properties frequently used in food science and technology. Both properties can be simply and quickly measured using relatively inexpensive hand-held or benchtop devices that do not demand costly consumables. Besides being simple to measure, pH and a_w are also relevant in any food product from a practical, microbial safety aspect. In addition to pH and a_w , several other intrinsic and extrinsic factors influence the microbial growth and survival in food products, such as redox potential, nutrient availability, presence of inhibitory substances, presence of competing microbes, temperature, as well as interactions of these factors. Whereas foods with a given pH and a_w profile may still differ in their susceptibility to microbial food safety risks, categorization of food products based on these 2 characteristics has a long history of being used in food safety assessments. For example, Tables A and B in the Food Code (FDA, 2013) use pH and a_w to define food product categories that require specific strategies for control of vegetative cells and spores. Table B (FDA, 2013; see page 23) is relevant to cheeses produced from raw milk, as well as for nonpackaged cheese made from pasteurized milk. According to Table B, a food product is considered safe if the pH is below 4.2 and a_w is below 0.920. Although this combination of low pH and a_w is feasible in other food products, it is not feasible in cheese. Most cheeses have a pH above 5.0 and a_w above 0.940 and thus fall, according to Table B, into a single product category that needs a food safety assessment. Thus, we propose development of a more granular set of product categories based on pH and a_w for categorization of raw milk cheeses into categories that will facilitate assessment of food safety risks and interventions.

We appreciate, though, that for some specific raw milk cheeses other physical factors may provide a clear risk-reduction step that is equally effective as pas-

teurization of raw milk. An example of this would be curd heating in production of some of the stretched or extra-hard cheese varieties where time and temperature combinations can provide for effective risk reduction (e.g., a 5-log pathogen reduction). If a given cheese has such an alternative treatment, that is validated and verified, then this cheese would not require the risk reduction strategies necessary for other cheeses in a given category.

Description of the Proposed Cheese Categories

As a base for our systematization and categorization of raw milk cheese we used Table B of the Food Code (FDA, 2013, see page 23). Building on this table, we defined a set of more granular pH and a_w categories to better represent the pH and a_w range of different raw milk cheeses; our categorization includes 5 a_w categories above 0.920 and 6 pH categories between 4.6 and >6.2 (see Table 1 for the complete proposed categorization scheme). The pH and a_w data from 273 different cheese samples collected in the market place throughout New York State (Trmčić et al., 2016) were used to provide an initial assessment of the distribution of cheeses commercially available in the United States (Table 1). These 273 cheese samples were selected to capture the diversity of cheese present on the market. No attempt was made to create a representative market basket reflecting the quantity of the different cheese types consumed. The category that contained the highest proportion of these cheeses had pH above 6.2 and a_w values of 0.961 to 0.980; 12.4% of cheeses were classified into this category (designated as F4).

Guidance for Taking pH and a_w Measurements for Categorization

Several issues exist concerning how and when the measurements of pH and a_w would be performed. One

Table 1. Categorization of natural cheeses based on water activity (a_w) and pH values

Cheeses that fall into a_w values in cheese ¹	Cheeses that fall into pH value ranges ¹					
	(A) ≤4.60%	(B) 4.61–5.00%	(C) 5.01–5.40%	(D) 5.41–5.80%	(E) 5.81–6.20%	(F) >6.20%
(1) ≤0.920%	N/R ²	0.4	0.7	0.7	0.4	1.1
(2) 0.921–0.940%	N/R ²	0.4	1.8	1.8	2.9	1.1
(3) 0.941–0.960%	1.1	1.1	5.1	9.5	3.3	5.1
(4) 0.961–0.980%	5.9	2.2	10.3	10.3	5.1	12.4
(5) >0.980%	4.4	2.2	1.8	1.5	0.4	7.0

¹Water activity and pH data obtained from 273 different cheese samples available on New York State market are included in this table; numbers in the table indicate the percentage of the total number of tested cheese samples that fall into a given category. For example, category E1 includes 1 cheese (0.4% of all cheese samples tested), this cheese was an aged goat Gouda.

²N/R = none of 273 different cheese samples available on New York State market were categorized in this category based on pH and water activity measurements.

Table 2. Proposed representative cheese types and varieties for each cheese category defined in Table 1 and associated proposed cheese varieties for assessment of food safety risks and interventions

Cheese categories	Representative cheese types ¹	Representative cheese varieties ¹	Proposed cheese variety for challenge studies
A1	NR ²	NR	NA ³
A2	NR	NR	NA
A3	Brined cheese	Feta	Feta cheese [pH = 4.6, water activity (a_w) = 0.96]
A4	Soft cheese	Gammelost cheese ⁴	Feta cheese (pH = 4.6, a_w = 0.98)
A5	Brined cheese	Feta ⁵	Queso blanco (pH = 4.6, a_w = 0.99)
B1	Soft cheese	Queso bica ⁵	Queso bica (pH = 5.0, a_w = 0.92)
B2	Hard cheese ⁴	Sap sago cheese ⁴	Sap sago cheese (pH = 5.0, a_w = 0.94)
B3	Hard cheese ⁴ (direct acid coagulated and dried)	Cotija	Feta cheese (pH = 5.0, a_w = 0.96)
B4	Hard cheese ⁴ (cooked curd cheese)	Feta ⁵	Feta cheese (pH = 5.0, a_w = 0.98)
B5	Brined cheese	Feta ⁵	Feta cheese (pH = 5.0, a_w = 0.99)
C1	Brined cheese	Provola cheese ⁴	Provola cheese (pH = 5.4, a_w = 0.92)
C2	Semisoft cheese ⁴ (stretched cheese)	Cacciocavallo Siciliano cheese ⁴	Asiago medium cheese (pH = 5.4, a_w = 0.94)
	Hard cheese ⁴ (stretched cheese)	Asiago medium cheese ⁴	
	Hard grating cheese ⁴ (cooked curd cheese)	Parmesan and Reggiano cheese, Romano cheese ⁴	
C3	Hard cheese ⁴ (cooked curd cheese)	Cotija	Low-sodium Cheddar cheese (pH = 5.4, a_w = 0.96)
	Hard cheese ⁴ (texturized cheese)	Low-sodium Cheddar cheese, Cheddar cheese ⁴	
	Hard cheese ⁴ (texturized washed curd cheese)	Colby cheese ⁴	
	Semisoft cheese ⁴	Asiago fresh and Asiago soft cheese ⁴	
	Fresh cheese	Cook cheese ⁴	
C4	Granular and stirred curd cheese ⁴	Brick cheese ⁴	Brick cheese (pH = 5.4, a_w = 0.98)
	Semisoft cheese ⁴ (washed rind cheese)	Low-sodium Colby cheese, Queso quesadilla	
	Hard cheese ⁴ (texturized washed curd cheese)		
	Semisoft part-skim cheese ⁴		
	Washed curd and soaked curd cheese ⁴		
C5	Soft cheese	Queso blanco ⁵	Queso blanco (pH = 5.4, a_w = 0.99)
D1	Hard cheese ⁴	Pecorino cheese ⁵	Pecorino cheese (pH = 5.4, a_w = 0.92)
D2	Hard cheese ⁴	Asiago old cheese ⁴	Asiago old cheese (pH = 5.8, a_w = 0.94)
	Hard cheese ⁴ (cooked curd cheese)	Cotija	
	Hard grating cheese ⁴		
D3	Semisoft cheese ⁴ (washed curd cheese)	Edam cheese, Gouda cheese ⁴	Gouda cheese (pH = 5.8, a_w = 0.96)
D4	Soft cheese	Queso blanco	Swiss and Emmentaler cheese (pH = 5.8, a_w = 0.98)
	Hard cheese ⁴ (propionic eyes cheese)	Swiss and Emmentaler cheese ⁴	
D5	Semisoft cheese ⁴ (propionic eyes cheese)	Sansoe cheese ⁴	Panela (pH = 5.8, a_w = 0.99)
E1	Soft cheese	Panela	Blue cheese (pH = 6.2, a_w = 0.92)
E2	Blue cheese	Blue cheese ⁵	Gorgonzola cheese (pH = 6.2, a_w = 0.94)
	Blue cheese ⁴	Gorgonzola cheese, Roquefort cheese and Sheep's milk blue-mold, Niuworld cheese ⁴	
E3	Soft-ripened cheese ⁴ (washed rind cheese)	Blue cheese ⁴	Blue cheese (pH = 6.2, a_w = 0.96)
E4	Soft-ripened cheese ⁴ (bloomy rind cheese)	Reblochon	Reblochon (pH = 6.2, a_w = 0.98)
E5	Soft cheese	Camembert	Camembert (pH = 6.2, a_w = 0.99)
	Blue cheese	Panela	Blue cheese (pH = 7.0, a_w = 0.92)
F1	Blue cheese	Blue cheese ⁵	Blue cheese (pH = 7.0, a_w = 0.94)
F2	Blue cheese ⁴	Blue cheese ⁵	Gruyere cheese (pH = 6.5, a_w = 0.96)
F3	Hard cheese ⁴ (propionic eyes, washed rind cheese)	Gruyere cheese ⁴	Queso fresco (pH = 6.5, a_w = 0.98)
F4	Soft cheese	Queso blanco, Queso fresco	
	Semisoft cheese ⁴ (washed rind cheese)	Limburger cheese ⁴	
	Soft-ripened cheese ⁴ (washed rind cheese)	Reblochon	
	Soft-ripened cheese ⁴ (bloomy rind blue cheese)	Cambozola	

Continued

Table 2 (Continued). Proposed representative cheese types and varieties for each cheese category defined in Table 1 and associated proposed cheese varieties for assessment of food safety risks and interventions

Cheese categories	Representative cheese types ¹	Representative cheese varieties ¹	Proposed cheese variety for challenge studies
F5	Soft-ripened cheese ⁴ (bloomy rind cheese) Soft cheese	Camembert Panela	Camembert (pH = 7.0, a_w = 0.99)

¹The representative cheese type that corresponds to the representative cheese variety is located in the same line within the cell; for example, E5 is represented by cheese type Soft-ripened cheese (bloomy rind cheese)/Camembert, and also by cheese type Soft cheese/Panela. Proposed cheese varieties were selected based on the worst case scenario type of cheese making procedure.

²NR = no representative cheese type or variety. None of 273 different cheese samples available on New York State market were categorized in this category based on pH and water activity measurements.

³NA = not applicable.

⁴As defined by the US Food and Drug Administration (FDA) standard of identity list (FDA, 2015a).

⁵Cheese variety categorized based on pH and water activity measurements obtained from 273 different cheese samples available on New York State market.

concern is how to measure pH in soft ripened cheese. The pH gradient in soft ripened cheese can span more than 3 units between the center of the cheese and its surface. In this case, the pH measurements should focus on the surface part of cheese, typically representing the highest pH value. Also, 3 independent measurements should be made and the highest measurement should be used for categorization, as this would be the pH that is offering the most favorable conditions for the survival and growth of pathogenic bacteria. Another issue is at what point of cheese production and distribution the measurements would be performed. Rapid acid development or active fermentation during production of certain cheeses (e.g., to <5.3 within 6 h for Cheddar) is important in inhibiting growth of pathogenic bacteria (Beresford et al., 2001). Thus, pH measurement is an important tool to verify appropriate fermentation; however, the pH increases during ripening. We thus propose that pH measurements for the cheese classification proposed here be performed at the point of distribution, which we define as the point at which cheese is legally ready for sale and consumption. As a general guide, measurements should be performed at the time point and in a cheese sample, or in a cheese sample portion, that, under legal ripening and storage conditions (≥ 60 d and $\geq 1.7^\circ\text{C}$; FDA, 2015a), represents the worst-case scenario (meaning the time point and cheese sample with the highest pH and a_w). Cheesemakers would periodically determine and record pH and a_w values of all cheese varieties they produce. The frequency of pH and a_w testing and the number of samples tested would depend on risk associated with the specific product(s) or facility as well as, possibly, production practices. For example, we would expect that the producers of soft ripened cheese would determine the pH and a_w for each batch produced. These data would then be used to (1) identify the a_w or pH category a product falls in and to (2) create process control verification records that can be used to show that any given product falls into the category was used to classify a given cheese for the initial food safety assessment.

Proposed Procedures for Selecting Cheese Types for Assessment

The key purpose of the cheese categorization proposed here is to facilitate product assessment for food safety risks and evaluation of interventions for general cheese categories that can be used to create safe haven categories that allow cheesemakers to safely and legally produce raw milk cheeses that meet safety requirements equivalent to pasteurized milk cheeses. For example, if scientific data indicate that cheeses in a given category (e.g., D4, pH 5.41 to 5.8, a_w 0.961 to 0.980; Table 1)

show equivalent safety to pasteurized milk cheeses if treated by a combination of 60-d aging and using, for each batch produced, only raw milk that tested negative (e.g., in 25 mL) for *L. monocytogenes*, then any processor producing a cheese in category D4 can use these or equivalent interventions to legally produce a raw milk cheese. If a given producer believes that the assessment of the food safety risk for a category overestimates the risk for their specific products, a separate assessment of the specific product can be conducted to define equivalent but different interventions (e.g., use of a protective culture).

As even cheeses within a given category in Table 1 may differ considerably in their ability to support pathogen survival and growth, a worst-case scenario approach will need to be taken as a guide to identify 1 or possibly more cheese varieties within a category to assess food safety risks and interventions (Table 2). In each cheese category 1 or more representative cheese varieties would be selected and agreed upon by scientific experts to represent the worst-case scenario. For example, the category C3 (pH 5.01 to 5.40; a_w 0.941 to 0.960) captures cheeses such as Cheddar, low-sodium Cheddar, Colby, Asiago fresh, Asiago soft, and cook cheese. In this case, one could propose the following cheese type and technology to represent the worst-case scenario: low-sodium Cheddar, produced by classical method, without the use of protective products, aged for 60 d, with 39% moisture, 50% fat in DM, pH 5.40, and a_w 0.960. If an individual category represents a large diversity of cheeses, or if it is determined that several different cheeses represent a different possible worst-case scenario in the category, more than 1 representative could be selected. For example, one would argue that 3 different styles of cheese have to be selected as worst-case scenario within the category F4 (pH >6.20; a_w 0.961–0.980) to represent washed rind cheese (Limburger cheese), mold ripened cheese (Cambozola), as well as low-acid Hispanic style cheese (Queso blanco), each with different but equally important characteristics relevant to food safety. We have proposed worst-case scenario cheese types for each category in Table 2; further refinement of these proposed worst-case scenario cheese types may be needed and could be conducted as a formal expert opinion elicitation.

DISCUSSION

As stated in the docket *Understanding Potential Intervention Measures to Reduce the Risk of Foodborne Illness from Consumption of Aged Cheese Manufactured from Unpasteurized Milk* (FDA, 2015c), the FDA recognizes a broad diversity in cheese manufacturing operations and approaches and the many factors that go into

ensuring the safety of the food. Data on behavior of pathogens in different raw milk cheeses is limited and cannot always be completely obtained by predictive models, but will have to be obtained experimentally. To practically implement a system that (experimentally) defines food safety risks and corresponding interventions for different raw milk cheeses, categorization of cheeses is essential. The categorization proposed here will allow for a collaborative effort to define food safety risks and corresponding interventions for different raw milk cheeses (by dividing studies on different cheese categories among research groups), but would still allow individual cheese producers to conduct a separate assessment of the specific product they produce. The categorization system proposed here does not capture all possible variations that can occur within a given category, between different producers of the same cheese type, or even variations within batches produced by the same producer. However, categorizing cheese by easily measurable characteristics will also allow cheesemakers to categorize their cheeses and access initial scientifically validated guidance on effective interventions for cheeses in a given category. This particularly refers to the requirements set forth by the final rule of FSMA (FDA, 2015d), which calls for establishment and implementation of preventive controls that are based on risk and hazard analysis. In addition to process controls such as active fermentation and acid development, preventive controls targeting measures to prevent environmental contamination during the process (e.g., sanitation standard operating procedures, sanitary equipment design) are also essential for production of safe products. This categorization also allows the preventive control measures of a higher-risk cheese category to serve as a guide for the lower-risk cheese category on what process controls should be. Finally, because the categorization proposed here is based on measurable properties, it can be used as a base for monitoring requirements set by the FSMA rule (FDA, 2015b,d).

CONCLUSIONS

Although it may be desirable to come up with a perfect system to categorize cheese manufacturing diversity, we propose that the more pragmatic approach proposed here will provide for a more rapid and efficient pathway to preserve the availability of diverse raw milk cheeses and to ensure a science-based approach to production of raw milk cheeses with enhanced safety. Importantly, we suggest that in the short term all challenge studies or other studies that evaluate pathogen growth and survival or interventions in cheese collect and report pH and a_w data to facilitate future use of data collected in the framework reported here.

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