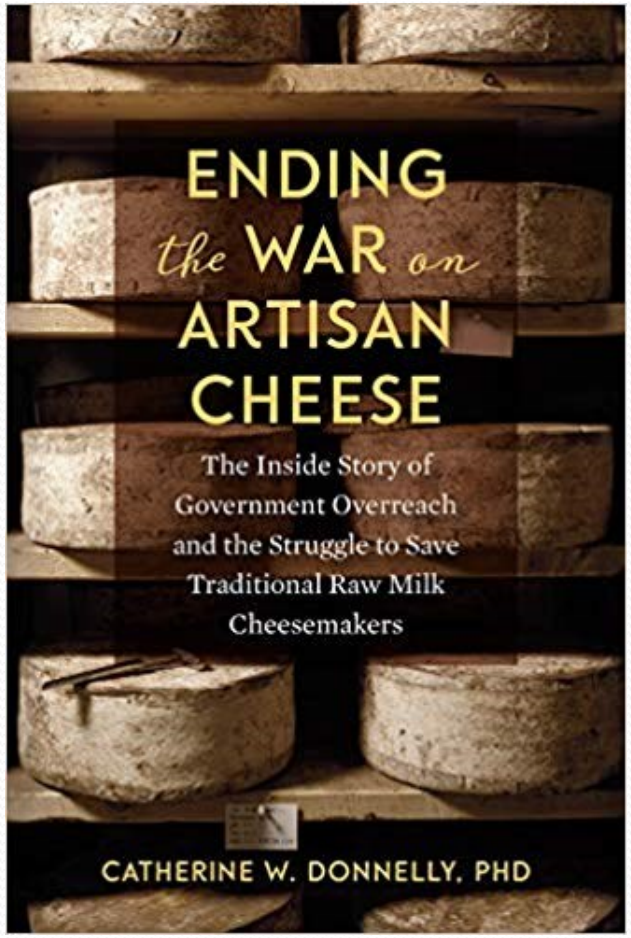
ENDING THE WAR ON ARTISAN CHEESE

- The inside story of government overreach and the struggle to save traditional raw milk cheesemakers



Why I wrote this book:

- To what extent do regulations impact or restrict our food choices?

Previous work

- Interest in food safety and public policy
- Close work with Vermont's artisan cheese industry on food safety
- Guidance from the U.S. Food and Drug Administration (FDA) was in conflict with our research and science-based information being disseminated to cheesemakers
- I used regulations aimed at artisan cheese to answer the question "to what extent do regulations impact or restrict our food choices."

Conclusion

- Perhaps trade and special interests, and not science and public health, were at the heart of FDA's regulations aimed at artisan cheesemakers.

My introduction to the raw milk cheese debate

- Unsolicited letter September 20, 2000 from a consultant to the Cheese of Choice Coalition
- Coalition was developing a body of scientific information to help inform the FDA in its decision making regarding the use of raw milk in cheesemaking
- Identify expert who could perform a literature search on raw milk cheese safety, epidemiology of outbreaks

Current regulations:promulgated in 1949 U.S. FDA, 1950 21 CFR Part 133

- 2 options to assure cheese safety:

  - pasteurize milk

or

  - hold cheese at a temperature of not less than 2C (35F) for a minimum of 60 days

NACMCF 1997

- FDA asked if a revision of policy was necessary
- 60 days might be insufficient to provide public health protection
- Mandatory requirement for use of pasteurized milk in cheesemaking?

"…we reviewed all cheese-associated outbreaks of human illness reported to the CDC with onsets during 1973-1992. The infrequency of large, cheese-associated outbreaks was notable…"

Altekruse et al. 1998. J. Food Prot. 61:1405-1406

American Artisan Cheese Comes of Age


TRAPPE ECHOURGNAC
CROTTIN DE CHAVIGNOL

STATE DINNER

In Honor of

HIS EXCELLENCY FRANÇOIS HOLLANDE
PRESIDENT OF THE FRENCH REPUBLIC

Dinner Menu

First Course
American Osetra Caviar
Fingerling Potato Velouté, Quail Eggs, Crisped Chive Potatoes

Second Course
"The Winter Garden Salad"
Petite Mixed Radish, Baby Carrots, Merlot Lettuce
Red Wine Vinaigrette

Main Course
Dry-aged Rib Eye Beef
Jasper Hill Farm Blue Cheese, Charred Shallots, Oyster Mushrooms, Braised Chard

Dessert
Hawaiian Chocolate-Malted Ganache
Vanilla Ice Cream and Tangerines

Baley Hazen Blue, Jasper Hill Farm, Greensboro, Vermont

The paste of a Bayley Hazen is drier than most blues and the Penicillium roqueforti takes a back seat to an array of flavors that hint at nuts, grasses licorice. Its texture reminds one of chocolate and butter

World Cheese Awards, London Nov. 16, 2014

Bayley Hazen named World's Best Unpasteurized Cheese

Out of nearly 2,600 cheeses from 33 countries, American cheesemakers garnered 10 of 62 Super Golds:

Trends in the U.S. Artisan Industry

- Enhancing the profitability of small and medium sized dairy farms through farmstead and artisan cheese and other value added products. USDA/AFRI. 11/1/2010-12/31/2012

U.S. Artisan Cheese Industry 2012

(Roberts, J. personal communication)

- Top ten states with greatest number of artisan producers:

New York	72
Maine	61
Pennsylvania	58
California	54
Wisconsin	50
Washington	54
Vermont	48
Texas	43
North Carolina	31
Virginia	25

States with greatest percent increases in artisan producers 2006-2011

Michigan	633%
North Carolina	343%
Texas	258%
Maine	165%
Washington	123%
Connecticut	110%
New York	71%
Virginia	67%
Oregon	57%
Wisconsin	47%

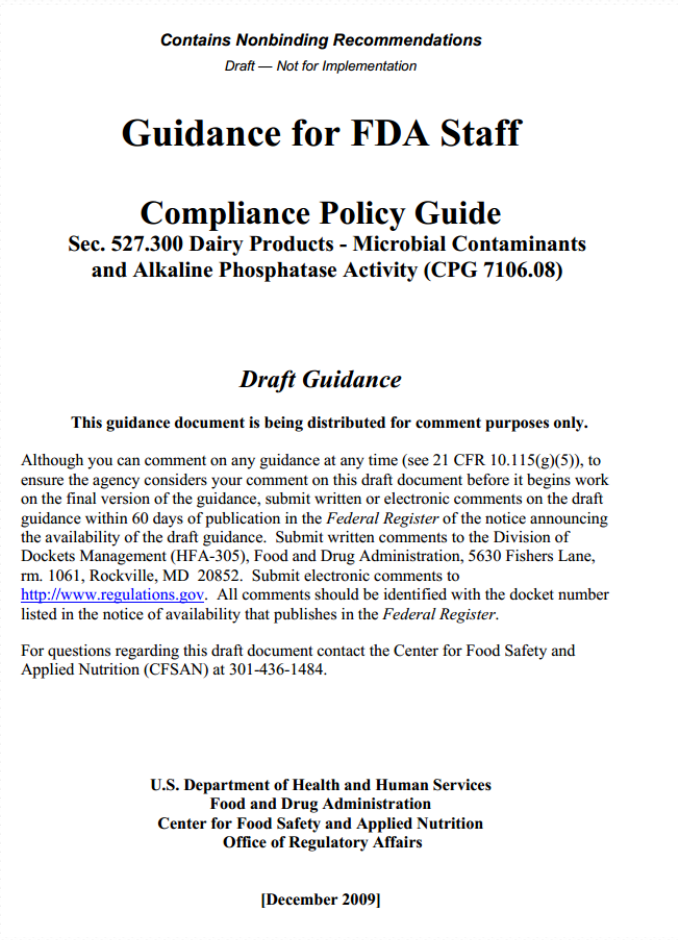
FDA’s assault on artisan cheese: Phase 1

New REGULATION (EU) Nº 2073/2005, microbiological criteria

Food	Bacteria	Sampling Plan n	Sampling Plan c	Limits* (cfu/g) m	Limits* (cfu/g) M	Method
With thermal treatment	*E. Coli* (hygienic index)	5	2	10^2	10^3	ISO 16649-1 ó 2
	Staphylococcus positive coagulase	5	2	both		EN-ISO 6888-2
Raw milk cheese	*Staphylococcus* positive coagulase	5	2	10^4	10^5	EN-ISO 6888-2

n=sample units tested
C=max no. Samples between m and M
M=quality/safety limit; m=GMP limit

Non toxigenic E. coli



Contains Nonbinding Recommendations

Draft — Not for Implementation

Guidance for FDA Staff

Compliance Policy Guide

Sec. 527.300 Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity (CPG 7106.08)

Draft Guidance

This guidance document is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure the agency considers your comment on this draft document before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1484.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs

[December 2009]

The presence of *Escherichia coli* in a cheese and cheese product made from raw milk at a level greater than 100 MPN/g (Most

Probable Number per gram) indicates insanitary conditions relating to contact with fecal matter, including poor employee hygiene practices, improperly sanitized utensils and

equipment, or contaminated raw materials.

ADPI Comments

- …in our view, the permissible level of *Escherichia coli* should be set according to standards of food safety without regard to the treatment of the milk itself. Stated another way, the guidance should be set at a uniform level to ensure food safety across all covered dairy products."

ADPI American Dairy Products Institute

HOME ABOUT US DAIRY PRODUCTS MEMBERSHI

Unleashing the Power of Dairy Ingredients

Our Vision

To be the world's premier authority on dairy ingredients

At ADPI we seek to be the most effective and relevant association representing the dairy ingredient industry today.

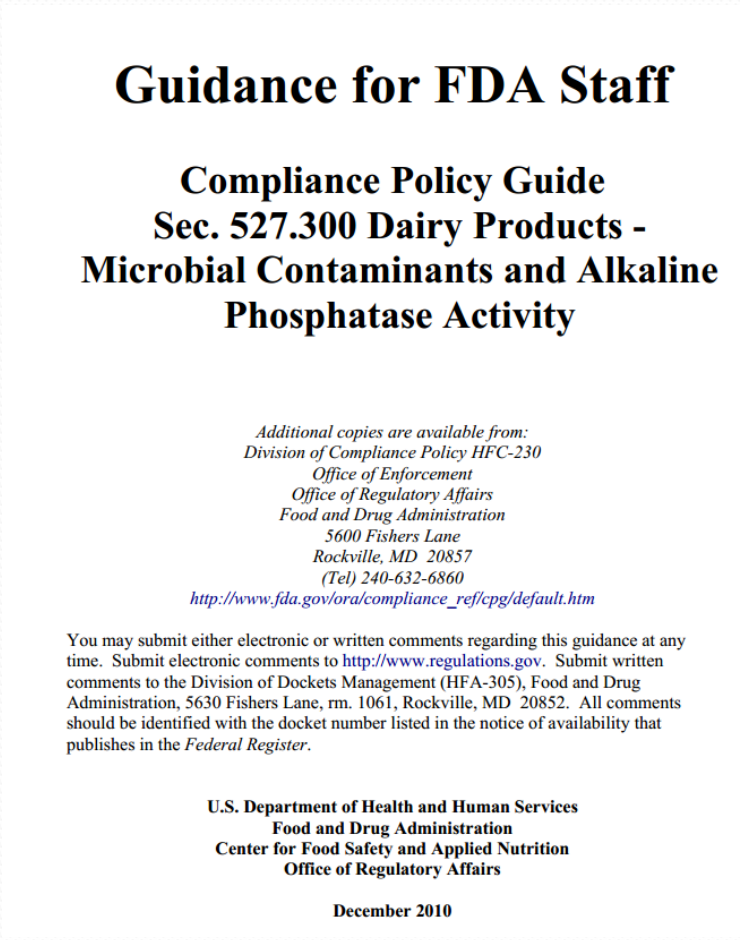
Our members manufacture and market the majority of the milk-based and whey-based ingredients produced in the U.S., including:

» ***Dry Milk Powders:*** *Nonfat Dry Milk, Whole Milk Powder, Milk Protein Concentrates and Isolates, etc.*

» ***Whey Products:*** *Condensed and Dry Whey, Lactose, Whey Protein Concentrates and Isolates, Permeate, Specialty Whey Fractions, etc.*

» ***Evaporated Milk Products:*** *Evaporated Milk, Filled Milk and Sweetened Condensed Milk*

2010 CPG Guidance



Guidance for FDA Staff

Compliance Policy Guide
Sec. 527.300 Dairy Products -
Microbial Contaminants and Alkaline Phosphatase Activity

Additional copies are available from:
Division of Compliance Policy HFC-230
Office of Enforcement
Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(Tel) 240-632-6860
http://www.fda.gov/ora/compliance_ref/cpg/default.htm

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs

December 2010

B. Nontoxigenic *Escherichia coli*

Dairy products may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth when *E. coli* is found at levels greater than 10 MPN per gram in two or more subsamples or greater than 100 MPN per gram in one or more subsamples.

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Workshops, Meetings & Conferences
Food Safety Grants
News from Other Federal Resources

FDA Update on the Status of Artisanal Cheese

September 8, 2014

Recent media reports have incorrectly indicated that the FDA is banning Roquefort and other cheeses.

Earlier in 2014, nine producers of Roquefort, Tomme de Sovie, Morbier, and other cheeses tested above thresho levels set in 2010 for a particular type of bacteria called non-toxigenic E. coli. While these bacteria don't cause illness, their presence suggests that the cheese was produced in unsanitary conditions.

The FDA has been working with the American Cheese Society (ACS) to learn more about artisanal cheeses and measures that cheesemakers take to ensure their products are safe. After hearing ACS' concerns about the test results, the FDA adjusted its criteria for taking regulatory action based on them. As a result, 95 percent of the cheese sampled tested below the level at which FDA would take regulatory action, and six of the nine cheese producers placed on Import Alert 12-10 for exceeding bacterial counts have been removed from that list and can resume sales and distribution in the U.S.

The FDA remains dedicated to ensuring a safe and wholesome food supply using the latest science to protect human health, and promoting dialogue with industry, consumers and other interested parties. The FDA is committed to working and sharing an open dialogue with the artisanal cheesemaking community. Of course, we welcome input from the public at any time and we continue to meet and share information with the artisanal cheesemaking community on this and other topics.

For more information:

International Commission for the Microbiological Specification for Foods (ICMSF), 1986

- "While the coliform problem in cheese is well known, presence of these organisms in many cheese varieties is extremely difficult to prevent completely. With some varieties, if coliforms are present initially, it is virtually impossible to prevent their growth during manufacture or during the ripening period. In several types of cheese *E. coli* can even be considered characteristic. With the exception of some strains of *E coli* high populations of coliforms are unlikely to present a health hazard. There is ample evidence that if pathogenic strains of *E coli* (PEC) are present early in the cheesemaking process their numbers may increase to hazardous levels. However, in view of the scarcity of evidence of recurring outbreaks due to PEC in cheese and the high cost of routine testing, **it is doubtful that establishment of end-product criteria for either coliforms or *E coli* would be justified. Accordingly, no sampling plan is proposed**."

ICMSF, 2011

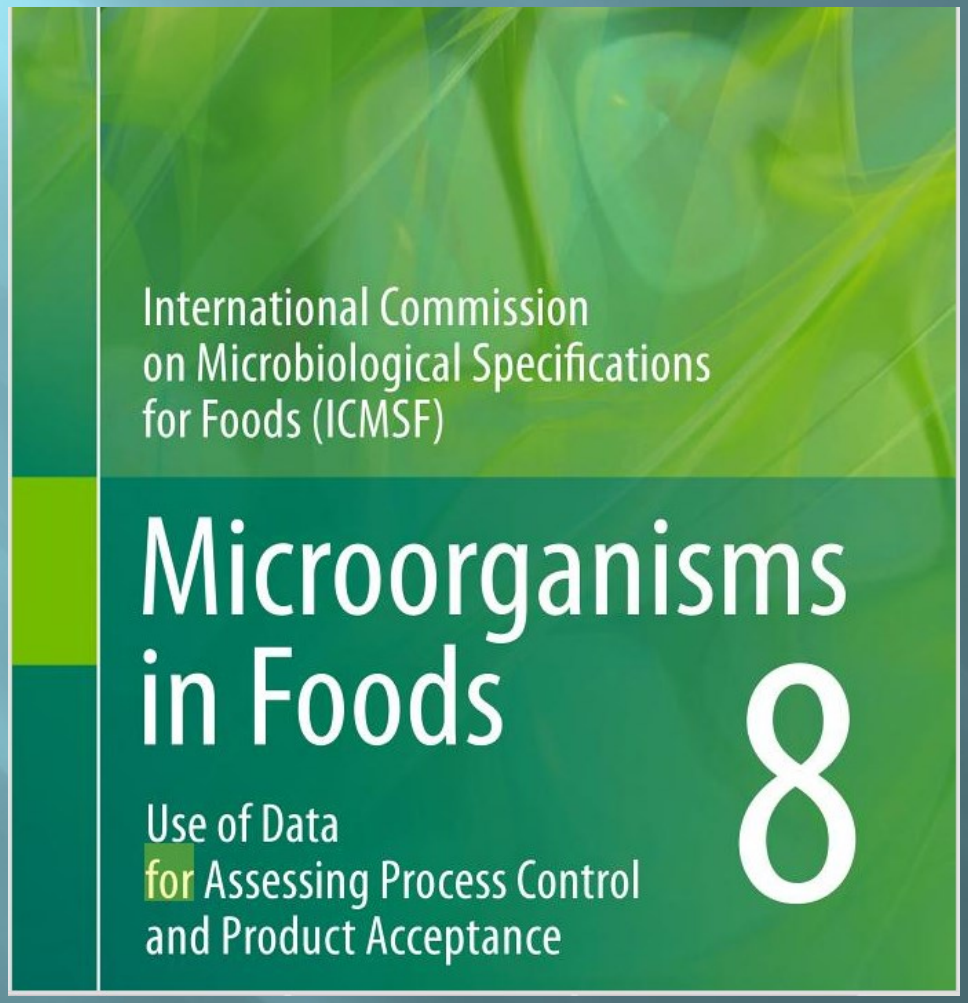

International Commission
on Microbiological Specifications
for Foods (ICMSF)
Microorganisms
in Foods
8
Use of Data
for Assessing Process Control
and Product Acceptance

Table 23.7 Testing of cheeses for microbiological safety and quality

Relative importance		Useful testing
Critical ingredients	High	*Raw milk cheese only*: A good supplier relationship is important, targeting the absence of *Salmonella*, EHEC and *L. monocytogenes* or other pathogens that may survive cheese making
In-process	High	Monitor pH during acidification of the curd to detect slow fermentation. In-process testing for *S. aureus* may be relevant if acidification does not proceed as anticipated using criteria listed in the end product section (see text)
	High to low	For cheeses that support the growth of *L. monocytogenes* and for raw milk cheeses, testing residues and product contact surfaces may be important to verify the effectiveness of the preventive measures implemented. Pathogens of concern vary by cheese type. Typical guidance levels: • *L. monocytogenes* and *Salmonella* – absent
Processing environment	High to low	Significant hazards and routes of contamination vary by type of cheese, and testing the processing environment may be useful to assess the effectiveness of control measures taken. If appropriate, typical guidance levels are: • *L. monocytogenes* and *Salmonella* – absent
Shelf life	Low	Testing may be conducted to determine the fate of pathogens during ripening and storage of cheese. Routine testing, however, is not recommended
End product		Testing for *E. coli* or *S. aureus* is useful to verify process control and hygiene conditions for certain cheese types. Upper limits (M) may vary depending on the extent of heat-treatment but high levels may trigger investigative sampling for pathogens, including EHEC, or staphylococcal enterotoxins (see text)

	Product	Microorganism	Analytical method[a]	Case	Sampling plan and limits/g[b]			
					n	*c*	*m*	*M*
High	Fresh cheese	*S. aureus*[c]	ISO 6888-1	8	5	1	10	10^2
High	Raw milk cheese	*S. aureus*[c]	ISO 6888-1	7	5	2	10^3	10^4
Low	Cheese from mildly heated milk or ripened	*S. aureus*[c]	ISO 6888-1	7	5	2	10^2	10^4
Medium	Cheese made from pasteurized milk	*E. coli*	ISO 16649-2	4	5	3	10	10^2
Low	Cheese: no growth	*L. monocytogenes*	ISO 11290-2	NA[d]	5	0	10^2	–
					Sampling plan and limits/25 g[b]			
					n	*c*	*m*	*M*
High	Cheese: Growth supported	*L. monocytogenes*	ISO 11290-1	NA[d]	5[e]	0	0	–
Medium or low	Cheese from raw or mildly heat-treated milk	*Salmonella*	ISO 6785	10	5[e]	0	0	–

FDA Organization

Office of Foods and Veterinary Medicine

About the Center for Food Safety and Applied Nutrition

CFSAN FOIA Electronic Reading Room

Resources for You

- FDA Update on the Status of Artisanal Cheese

Letter to American Cheese Society (ACS) with an Update on What Has Been Done with Respect to Non-toxigenic Escherichia coli (E. coli) in Raw Milk Cheese

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

August 29, 2014

Peggy Smith
President, American Cheese Society
and
Nora Weiser
Executive Director, American Cheese Society

Dear Ms. Smith and Ms. Weiser:

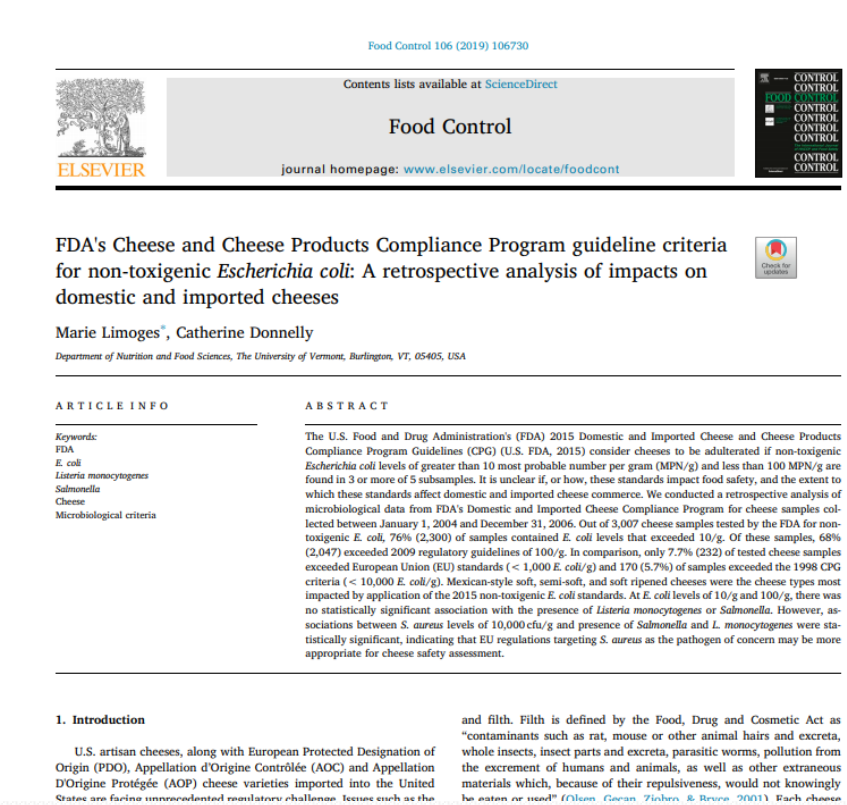
This letter is intended to provide the American Cheese Society (ACS) with an update on what has been done with respect to non-toxigenic Escherichia coli (*E. coli*) in raw milk cheese. FDA officials met with the American Cheese Society's board during ACS's 2014 Annual Conference in Sacramento, California on July 29-30, 2014. ACS invited FDA to the conference in order to share significant concerns of its membership with FDA, to exchange information, and to engage in important dialogue of mutual importance.

Among several topics discussed during the meeting, ACS expressed its concern about FDA's standard for non-toxigenic (*E. coli*) in raw milk cheese. ACS asked FDA to re-examine its policy for non-toxigenic *E. coli* in raw milk cheese outlined in the final Compliance Policy Guide, Section 527.300 Diary Products – Microbial Contaminants and Alkaline Phosphatase Activity published in December 2010 (hereafter, the 2010 CPG). ACS also shared concern about the commercial flow of Roquefort cheese from facilities in France that FDA recently subjected to a process known as detention without physical examination (DWPE) under Import Alert 12-10

FDA, 10/30/2014

- In deciding upon a final level for M, FDA considered ICMSF advice that, as a general hygiene indicator, M should represent clearly unacceptable conditions of hygiene. The scientific literature, international standards in use, and FDA's own analytical results for non-toxigenic *E. coli* in cheese, led the agency **to conclude that M at 100 cfu/g is consistently attainable** and that exceeding this level in cheese is indicative of conditions meeting the adulteration standard of section 402(a)(4) of the FD&C act."

Limoges and Donnelly, 2019



Food Control 106 (2019) 106730

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journal homepage: www.elsevier.com/locate/foodcont

FDA's Cheese and Cheese Products Compliance Program guideline criteria for non-toxigenic *Escherichia coli*: A retrospective analysis of impacts on domestic and imported cheeses

Marie Limoges*, Catherine Donnelly

Department of Nutrition and Food Sciences, The University of Vermont, Burlington, VT, 05405, USA

ARTICLE INFO

Keywords:
FDA
E. coli
Listeria monocytogenes
Salmonella
Cheese
Microbiological criteria

ABSTRACT

The U.S. Food and Drug Administration's (FDA) 2015 Domestic and Imported Cheese and Cheese Products Compliance Program Guidelines (CPG) (U.S. FDA, 2015) consider cheeses to be adulterated if non-toxigenic *Escherichia coli* levels of greater than 10 most probable number per gram (MPN/g) and less than 100 MPN/g are found in 3 or more of 5 subsamples. It is unclear if, or how, these standards impact food safety, and the extent to which these standards affect domestic and imported cheese commerce. We conducted a retrospective analysis of microbiological data from FDA's Domestic and Imported Cheese Compliance Program for cheese samples collected between January 1, 2004 and December 31, 2006. Out of 3,007 cheese samples tested by the FDA for non-toxigenic *E. coli*, 76% (2,300) of samples contained *E. coli* levels that exceeded 10/g. Of these samples, 68% (2,047) exceeded 2009 regulatory guidelines of 100/g. In comparison, only 7.7% (232) of tested cheese samples exceeded European Union (EU) standards (< 1,000 *E. coli*/g) and 170 (5.7%) of samples exceeded the 1998 CPG criteria (< 10,000 *E. coli*/g). Mexican-style soft, semi-soft, and soft ripened cheeses were the cheese types most impacted by application of the 2015 non-toxigenic *E. coli* standards. At *E. coli* levels of 10/g and 100/g, there was no statistically significant association with the presence of *Listeria monocytogenes* or *Salmonella*. However, associations between *S. aureus* levels of 10,000 cfu/g and presence of *Salmonella* and *L. monocytogenes* were statistically significant, indicating that EU regulations targeting *S. aureus* as the pathogen of concern may be more appropriate for cheese safety assessment.

1. Introduction

U.S. artisan cheeses, along with European Protected Designation of Origin (PDO), Appellation d'Origine Contrôlée (AOC) and Appellation D'Origine Protégée (AOP) cheese varieties imported into the United States are facing unprecedented regulatory challenge. Issues such as the and filth. Filth is defined by the Food, Drug and Cosmetic Act as "contaminants such as rat, mouse or other animal hairs and excreta, whole insects, insect parts and excreta, parasitic worms, pollution from the excrement of humans and animals, as well as other extraneous materials which, because of their repulsiveness, would not knowingly be eaten or used" (Olsen, Gecan, Ziobro, & Bryce, 2001). Each cheese

- 3007 cheese samples tested by FDA 2004-2006
- 68% of samples exceeded 2009 regulatory guidelines
- 76% of samples >10/g *E. coli*
- 5.7% exceeded 1998 criteria (<10,000/g)

Given the potential impact of this new standard, we are seeking to better understand its scientific basis. Why did the FDA feel a more stringent *E. coli* standard for raw-milk cheese was warranted? What evidence exists to demonstrate that raw-milk cheeses produced under current practices place public health at risk? Has the science upon which this standard is based been subject to peer review? Is it appropriate to apply the same standards to raw milk and to pasteurized milk cheeses considering that the fate of pathogenic bacteria and the public health risks associated with the two classes of cheese are known to be very different? And to what extent did the FDA consult with international organizations and producers who import cheese into the U.S. in proposing this standard?

We support FDA's efforts to ensure the safety of our nation's food supply; however, we share the concern of our constituents that standards must be scientifically based and be imposed on the industry only when necessary to address a known threat to public health. We urge the FDA to carefully balance these concerns and we look forward to your response.

Sincerely,

PATRICK LEAHY
United States Senator

BERNARD SANDERS
United States Senator

PETER WELCH
United States Representative

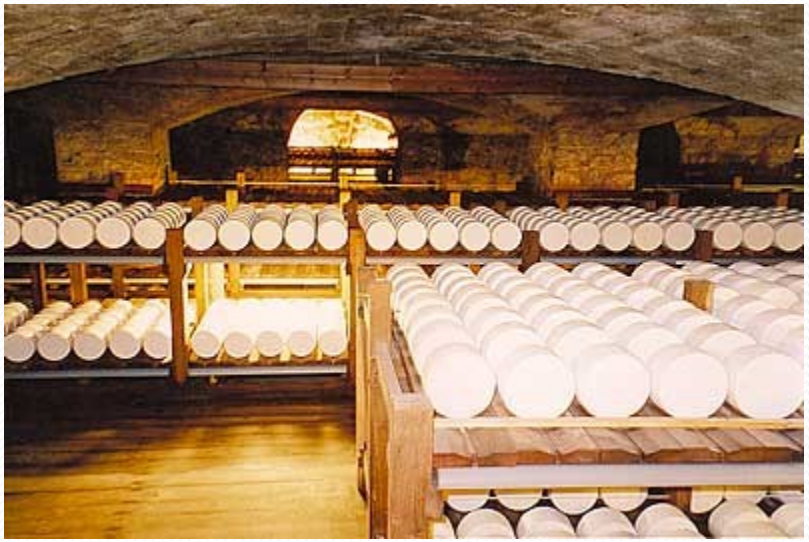
Ending the War on Artisan Cheese, pg. 162

- “Instead of using sound science and education to help artisan cheesemakers, as was done with the Swiss approach, the FDA has instead used fear and intimidation and establishment of microbiological standards in the absence of scientific evaluation and risk assessment to provide requisite scientific evidence that these standards afforded public health protection.”

FDA's assault on artisan cheese: Phase 2

- 2014 FDA Guidance:

"The use of wooden shelves, rough or otherwise, for cheese ripening does not conform to cGMP requirements, which require that "all plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained." 21 CFR 110.40(a).



Regulatory Issues:
Use of Wooden shelves for cheese aging

- Lortal et al. (2014) estimate that 500,000 tons of cheese is ripened on wood shelves per year
- Includes many of the most famous AOC and PDO French cheese varieties (Comté, Reblochon, Beaufort, Munster, Cantal and Roquefort).

Issues of Concern

- Elimination of wooden shelves in cheese aging-adverse economic consequences for U.S. artisan cheesemakers; broader implications for international trade of AOC and PDO cheeses.
- The wooden shelving issue is appearing as the U.S. prepares for negotiations over the Transatlantic Trade and Investment Partnership (T-TIP).
- A sticking point in the negotiations of this agreement has arisen over geographic indications which protect the names of European cheese varieties. U.S. cheesemakers have objected to these protections (Schultz, Feb. 9, 2014).
- By banning wood in cheesemaking, the FDA can effectively ban the importation of European cheeses such as Parmigiano-Reggiano, Comté, Reblochon, Beaufort, Munster, Cantal and Roquefort.

Impact on U.S. artisan cheesemakers

March 27, 2014-FDA's Office of Legislation

- "I inquired with FDA's food center (CFSAN) regarding your question about the use of wooden shelves for the storing or aging of cheeses, and I was told that they are not permitted and never have been…."

JUN 9, 2014 @ 9:21 PM 212,746 VIEWS

FDA May Destroy American Artisan Cheese Industry

Gregory S. McNeal CONTRIBUTOR

I cover law and policy with a focus on security, technology and crime. FULL BIO

Opinions expressed by Forbes Contributors are their own.

FOLLOW

TWEET THIS

The FDA's decision will not only harm American cheese makers, but may also bring a halt to the importation of artisan cheeses from abroad

The Food and Drug Administration (FDA) has issued an executive decree banning the centuries old practice of aging cheese on wooden boards. One

News & Events

Constituent Updates

Resources for You

- September 8, 2014: FDA Update on the Status of Artisanal Cheese

Clarification on Using Wood Shelving in Artisanal Cheesemaking

CFSAN Constituent Update

June 11, 2014

Recently, you may have heard some concerns suggesting the FDA has taken steps to end the long-standing practice in the cheesemaking industry of using wooden boards to age cheese. To be clear, we have not and are not prohibiting or banning the long-standing practice of using wood shelving in artisanal cheese. Nor does the FDA Food Safety Modernization Act (FSMA) require any such action. Reports to the contrary are not accurate.

The agency's regulations do not specifically address the use of shelving made of wood in cheesemaking, nor is there any FSMA requirement in effect that addresses this issue. Moreover, the FDA has not taken any enforcement action based solely on the use of wooden shelves.

At issue is a January 2014 communication from the agency's Center for Food Safety and Applied Nutrition to the New York State Department of Agriculture and Markets' Division of Milk Control and Dairy Services, which was sent in response to questions from New York State.

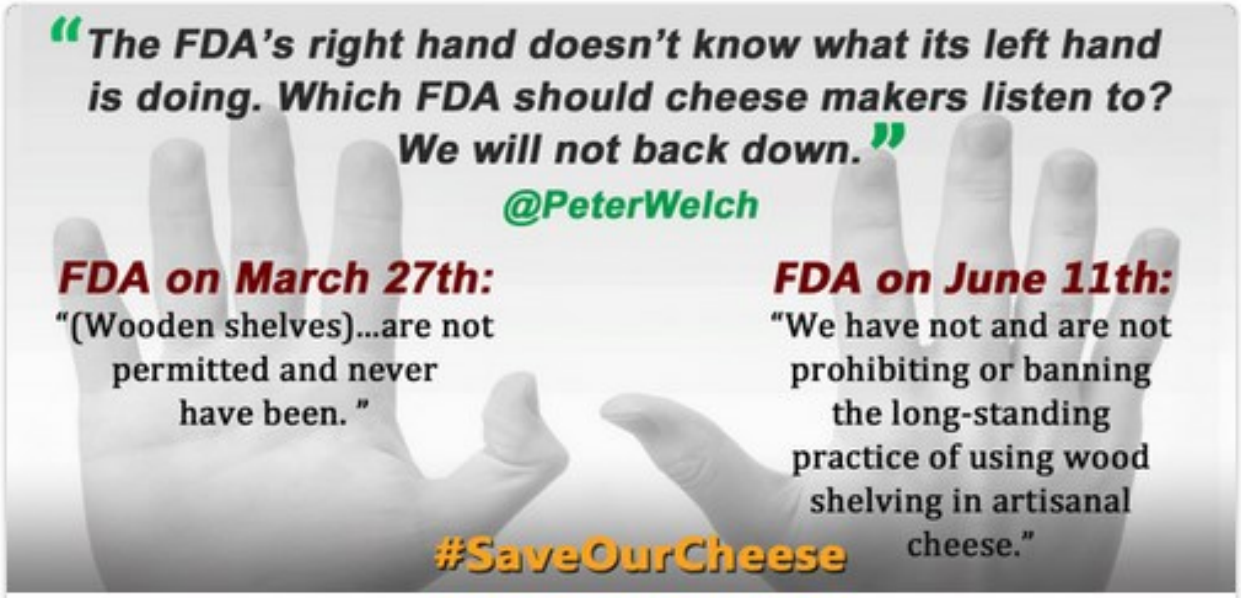
The FDA recognizes that this communication has prompted concerns in the artisanal cheesemaking community. The communication was not intended as an official policy statement, but was provided as background information on the use of wooden shelving for aging cheeses and as an analysis of related scientific publications. Further, we recognize that the language used in this communication may have appeared more definitive than it should have, in light of the agency's actual practices on this issue.

The FDA has taken enforcement action in some situations where we have found the presence of *Listeria monocytogenes* at facilities that used such shelving. Since 2010, FDA inspections have found *Listeria monocytogenes* in more than 20 percent of inspections of artisanal cheesemakers. However, the FDA does not have data that directly associates these instances of contamination with the use of wood shelving.

In the interest of public health, the FDA's current regulations state that utensils and other surfaces that contact food must be "adequately cleanable" and "properly maintained." Historically, the FDA has expressed concern about whether wood meets this requirement and these concerns have been noted in its inspectional findings. However, the FDA will engage with the artisanal cheesemaking community, state officials and others to learn more about current practices and discuss the safety of aging certain types of cheeses on wooden shelving, as well as to invite stakeholders to share any data or evidence they have gathered related to safety and the use of

REP. WELCH REACTS TO FDA "CLARIFICATION" ON USE OF WOOD SHELVES TO AGE CHEESE

06/12/2014



From: The Honorable Peter Welch
Date: 6/11/2014

Stop the FDA from Banning Centuries-old Cheese Making Practice
Support the Welch/Ribble/Kind/Ryan/Duffy/Defazio/
Pocan/Gibson/Pingree/Huffman/Hanna/Courtney/Owens/Kuster/Petri/Walberg/Weber
Amendment

Dear Colleague,

Since the time of Adam and Eve, cheese makers have aged cheese on wood boards and wood shelves. Wood allows the cheese to breathe and develop its tangy and rich flavor during the aging process. In Europe, cheese makers are required to use wood shelves to age the product to develop the proper texture and flavor.

Astonishingly, the Food and Drug Administration has begun a "crackdown" on America's small artisan cheese makers for using wood shelves in the aging process. Without evidence to support its enforcement, the agency has cited the risk of contamination as the cause for its overreach.

According to the FDA, "*The use of wooden shelves for cheese ripening does not conform to current Good Manufacturing Practice (GMP) regulations, which require that 'all plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.'*"

This bureaucratic overreach by the FDA is a solution in search of a problem. Artisan cheese makers already have rigorous protocols in place to assure the safety of their product. Instead of banning a centuries-old aging process and triggering a possible trade war with Europe, the FDA should take a deep breath and work collaboratively with food scientists and cheese makers to ensure their products meet the high standards expected by cheese loving consumers around the world.

The burgeoning artisan cheese industry is made up of small business entrepreneurs dedicated to producing world-class American cheeses and creating the good jobs that go with it. Please support our amendment to stop the FDA in its tracks from doing serious harm to these small businesses.

Sincerely,

PETER WELCH
RON KIND
PETER DEFAZIO
MARK POCAN
CHELLIE PINGREE
JOE COURTNEY
BILL OWENS
ANNE MCLANE KUSTER
JARED HUFFMAN

REID RIBBLE
SEAN DUFFY
PAUL RYAN
CHRIS GIBSON
RICHARD HANNA
THOMAS PETRI
TIM WALBERG
RANDY WEBER

TEXT OF THE PENDING WELCH AMENDMENT TO H.R. 4800, THE FISCAL YEAR 2015 AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT

"At the end of the bill (before the short title) insert the following:

SEC. ll. None of the funds made available by this Act may be used to establish, implement, or enforce any prohibition against aging or ripening cheese on wood under section 110.40 of title 21, Code of Federal Regulations."

Raw Milk Cheese-Safety threat or trade barrier?

- 1992-EU Council Regulation on the Protection of Geographical Indications and Designations of Origin
- Established two types of GI designations:
- PDO-Protected Designation of Origin-"quality essentially due to that region"
- PGI-Protection of Geographical Indication-quality attributable to that region

Parmigiano Reggiano PDO

- Cooked, un-pressed hard cheese
- Produced with raw cow's milk from animals reared in the production areas

Parmesan: EU vs US

EUROPE

EU Court Says Parmesan Cheese Must Come From Italy

The European Union's highest court has upheld the bloc's principle of protected food names, ruling that only "Parmigiano Reggiano" -- or those cheeses made in Italy -- can be sold as "Parmesan."

Raw milk cheese debate

- Countries outside EU complained PDO status prevents lawful competition in marketplace
- Many raw milk cheese imported into U.S. enjoy PDO status
- Requirement for mandatory pasteurization-eliminate importation of PDO cheeses

U.S. dairy trade imbalance

- "US-EU dairy trade is currently pretty much a one-way street, with EU dairy exports to the US running close to $1.5 billion over the last couple of years, while US dairy exports to the EU reached a high of $143 million back in 2013."

  Dick Groves, 2016, *Cheese Reporter*

Consortium for Common Food Names

- Formed in 2012 to protect the right of food producers to use common food names.
- Founding members-U.S. Dairy Export Council, several dairy companies

United States Senate

WASHINGTON, DC 20510

March 11, 2014

The Honorable Tom Vilsack
Secretary
United States Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

The Honorable Michael Froman
United States Trade Representative
Office of the United States Trade Representative
600 17th Street, N. W.
Washington, DC 20508

Dear Secretary Vilsack and U.S. Trade Representative Froman:

We commend your past work to fight the growing geographical indication (GI) restrictions promoted by the European Union (EU). This trade barrier is of great concern to dairy and other food manufacturers in our states. On their behalf, we urge you to continue to push back against the EU's efforts to restrict our cheese exports, particularly to nations with which we already have free trade agreements. In addition, we urge you to make clear to your EU counterparts that the U.S. will reject any proposal in the Trans-Atlantic Trade and Investment Partnership (TTIP) negotiations now underway that would restrict in any way the ability of US producers to use common cheese names.

In country after country, the EU has been using its free trade agreements (FTAs) to persuade its trading partners to impose barriers to U.S. exports under the guise of protection for its geographical indications. This trade-damaging practice is concerning anywhere, but it is most deeply troubling where the U.S. has an established FTA or has been actively in the process of negotiating a new agreement. For example, Canada agreed as part of its recently concluded FTA with the EU to impose new restrictions on the use of "feta" and other common cheese names. Common names for products such as "feta" are clearly generic in Canada, as they are in many other countries. These restrictions not only threaten harm to the companies currently involved in

US Senators shocked by EU's cheese-name claims

EURACTIV.com with Reuters

Mar 12, 2014

italian_food_istockphoto.jpg

Languages: Français

Comments Print

In a rare act of bipartisan unity, dozens of US senators have wheeled into action against what ey call an "absurd" European initiative that would force name changes to common cheese

EURACTIV.com

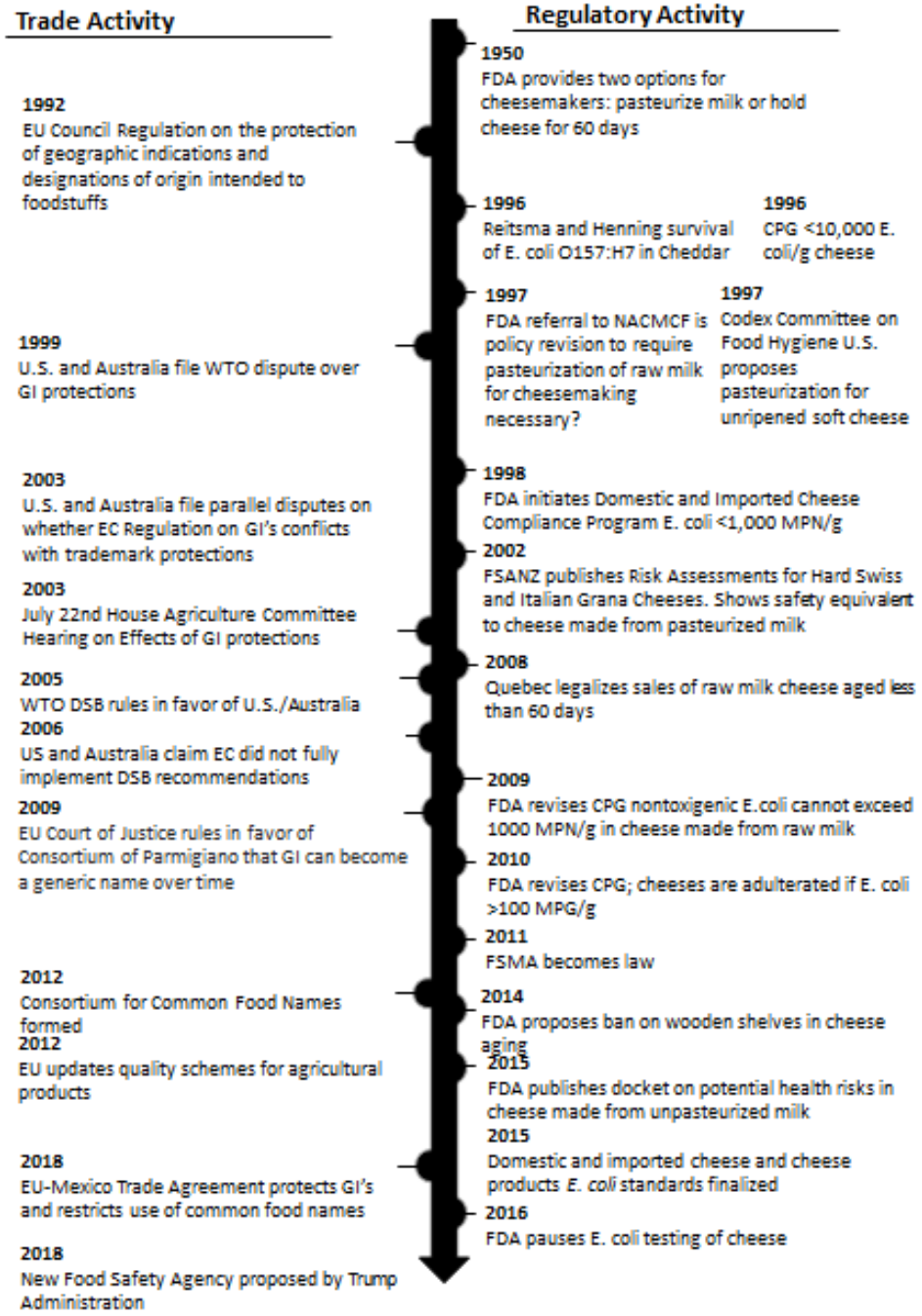
- “The senators said their action was supported by Kraft Foods Group, Denver-based Leprino Foods*, the world’s largest mozzarella maker, and groups such as the National Milk Producers Association, US Dairy Export Council, and the American Farm Bureau Federation.”

Consortium for Common Food Names urges president to address cheese trade deficit

The deficit is being driven by abuse of geographical indications, CCFN said.

The Trump Administration should correct the inequity in cheese sales opportunities between

Timeline of Key Events in FDA's Assault on Raw Milk Cheese Production



Ending the war on artisan cheese

- "The raw milk cheese debate is really a debate over where and how our food is produced and by whom, the values that we individually place on methods of food production, and the conflicting roles of tradition, heritage and quality versus advertising, marketing, politics and profits, which ultimately influence our food choices."

Why should we care?

- FDA, as a public health agency, makes important decisions each day about the safety of drugs, medical devices and our food.
- For credibility, rigorous scientific studies and evidence-based research must support decision-making
- Under the Food Safety Modernization Act (FSMA), FDA has new tools to hold imported foods to same standards as U.S. domestic foods
- The numerous examples offered in this book should give us pause.

Health & Consumer Protection
Directorate-General

Establishment of Community criteria

Criteria should

- enhance food safety
- be feasible in practice
- Be based on the scientific risk assessment

2016 FDA Deputy Commissioner Michael R. Taylor on FSMA

- "This new mandate for FDA must be seen in the context of similar efforts to strengthen food safety systems all over the world. In fact, one of the reasons this is such a historic time for food safety is the great deal of alignment that exists across the global food system on the need to build modern, preventive measures into food production operations and, equally important, to verify that those measures are in place and working. The world's international food safety standard setting body-the *Codex Alimentarius* Commission of the United Nations-calls for this approach. Implementing this philosophy is what FSMA is all about."

Ending the War on Artisan Cheese, page 137

- "But as we have seen we are not philosophically aligned on equivalent approaches to achieve food safety, and FDA cheese regulations are not harmonized with *Codex Alimentarius* or ICMSF. If "modern preventive measures" in FSMA will be used to eliminate traditional cheesemaking practices that use raw milk in cheese production and ban the use of wooden tools and shelves, we will end up with a food system that disregards the contribution of local, healthy and safe traditional products."

Final Thoughts

- The need for advocacy
- Single Food Safety Agency: USDA vs. FDA
- Disappearance of the small family farm

USDA

- "Indicator organisms are bacteria used to determine objectionable microbial conditions of food…Although such tests could provide a measure of general sanitation, they do not indicate the potential presence or absence of the pathogen of concern."

Single food safety agency

The American people deserve a single food safety agency

By Guest Contributor on September 11, 2023

— OPINION —

By Frank Yiannas and Mindy Brashears

Both of us have dedicated our careers to advancing food safety and protecting the public. We've both done so at the height of federal service, in academic settings, as well as within the private sector. That's why we believe we're well qualified to

United States Representative
ROSA DeLAURO
Representing the Third District of Connecticut

ROSA | CONSTITUENT SERVICES | ISSUES | MEDIA CENTER | CONTACT

July 13, 2022 **Press Release**

Legislation would establish a single food safety agency

Chair of the House Appropriations Committee Rosa DeLauro (D-CT-03) and Senator Dick Durbin (D-IL) today introduced *the Food Safety Administration Act,* legislation that would establish the Food Safety Administration, a single food safety agency responsible for keeping the food we consume safe for market.

"Food safety is currently a second-class citizen at the Food and Drug Administration", **said Chair DeLauro.** "Right now, there are no food policy experts in charge of food safety at the FDA. That is unacceptable and contributes to a string of product contaminations and subsequent recalls that disrupt the supply chain, contribute to rising prices, and in many cases, result in consumer illness and death. Look no further than the recent infant formula crisis to understand the need to create a single food safety agency, led by a food policy expert, to ensure the safety of products that go to market. I'm proud to join my friend Senator Durbin in introducing legislation that would strengthen food safety and protect consumers."

"In recent years, FDA has been plagued by one failure after another—from a failure to properly recognize the dangers of prescription opioids, to a failure to protect children from e-cigarette products, to a failure to properly ensure the safety of our nation's food supply," **said Senator Durbin.** "The sad reality is that FDA seems unwilling or unable to use their authority to protect Americans from preventable illness and death. For that reason, Congresswoman DeLauro and I are introducing legislation to transfer all of FDA's food responsibilities to a new agency that, we hope, will have more success in protecting the foods in our kids' lunch boxes and on our dining room tables."

"EWG applauds Senator Durbin and Congresswoman DeLauro for making the safety of our food a priority," **said Scott Faber, Senior Vice President for Government Affairs for the Environmental Working Group.** "Every year, thousands

The War Continues?

The Washington Post
Democracy Dies in Darkness

Democracy Dies in Darkness

Opinion | A court's decision about Gruyère stinks

By Tyler Nottberg
March 15, 2023 at 1:11 p.m. EDT

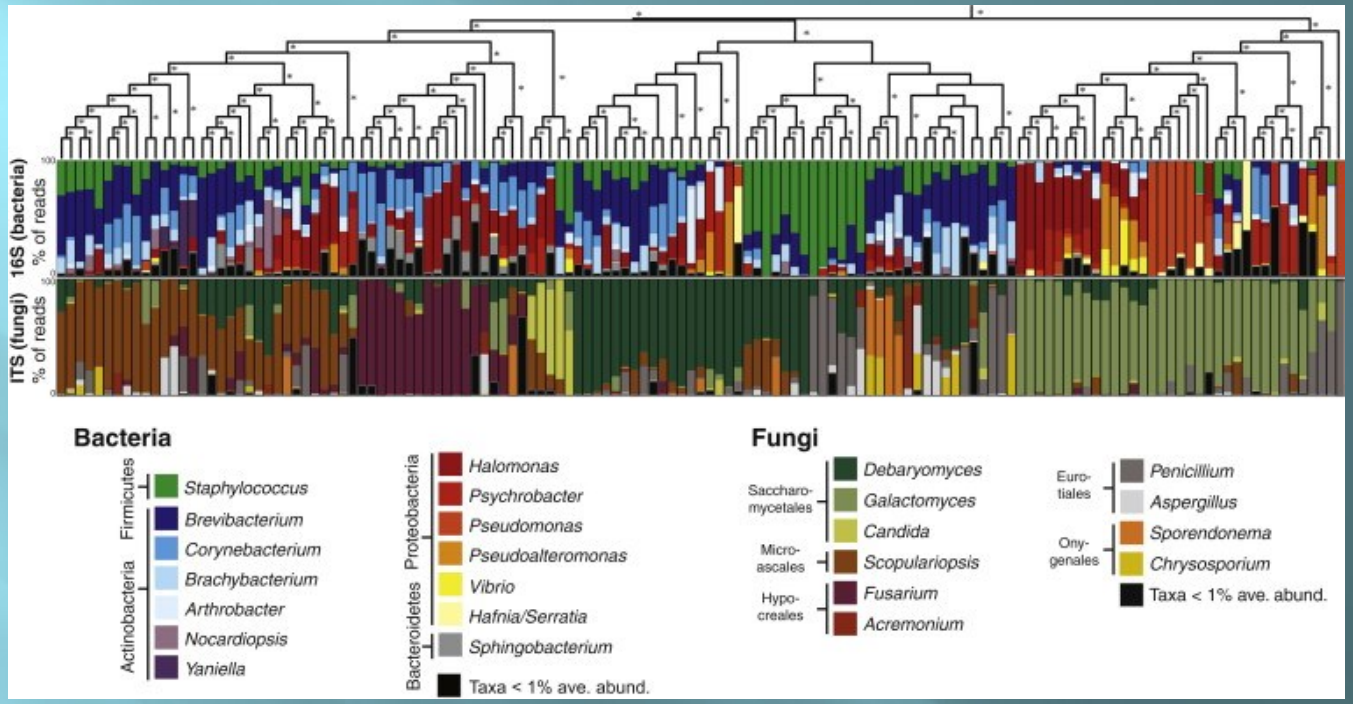


Figure 2 Distribution of Abundant Genera across Cheese Rind Communities Columns show relative abundance of genera within each cheese. Each column represents averaged data for multiple wheels of an individual cheese. Top row shows bacterial (16S rDNA) data...

Benjamin E. Wolfe , Julie E. Button , Marcela Santarelli , Rachel J. Dutton

Cheese Rind Communities Provide Tractable Systems for In Situ and In Vitro Studies of Microbial Diversity

Cell, Volume 158, Issue 2, 2014, 422 - 433

http://dx.doi.org/10.1016/j.cell.2014.05.041

Impact of Regulations on cheese of the Future

- "We are losing cheeses, animal breeds, pastures, herders, skills and ancient knowledge. It is not simply a question of the best milk and cheeses. Our food culture and the freedom to choose what we eat are at stake." Slow Food