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FDA's Domestic and Imported Cheese Compliance Program Results: January 1, 2004—December 31, 2006

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ABSTRACT

Between January 1, 2004, and December 31, 2006, the U.S. Food and Drug Administration tested a total of 17,324 cheese samples as part of the Domestic and Imported Cheese and Cheese Products Compliance Program. Of 2,181 cheese samples examined for the presence of *Listeria monocytogenes,* 2.4% were positive. Approximately half of the positive samples (52%) were traced to imported Mexican-style soft cheese or soft-ripened cheeses, primarily from France and Italy. A total of 3,520 cheese samples were analyzed for the presence of *Salmonella,* with 1.3% testing positive; in general, the majority of samples came from soft or soft-ripened cheeses produced in Mexico or Central America. The FDA also examined 3,360 cheese samples for the presence of enterohemorrhagic *Escherichia coli,* of which only 3 (0.09%) tested positive, including samples of imported Mexican-style soft cheese and imported soft-ripened cheeses. *Staphylococcus aureus* was the most commonly detected pathogen of concern, being present in 6.9% of the 3,449 cheeses samples tested. In summary, these data suggest that increased U.S. regulatory focus should be given to Mexican-style soft cheeses, particularly those produced in Mexico/Central America. These data also help inform risk assessments that evaluate the microbiological safety of cheese.

INTRODUCTION

Current regulations governing the use of raw, heat-treated and pasteurized milk for cheesemaking were promulgated in 1949. One of two options could be selected by cheesemakers to assure the safety of cheese: pasteurize milk intended for cheesemaking, or hold the cheese at a temperature not less than 35°F (1.67 °C) for a minimum of 60 days *(9, 10)*. Research has shown that numerous pathogenic organisms including *Salmonella* spp., *Escherichia coli* O157:H7 and *Listeria monocytogenes* can survive well beyond the mandatory 60-day holding period in various cheese varieties *(5, 14, 34, 36, 37, 38, 40)*. Of particular concern to the U.S. Food and Drug Administration (FDA) was a report by Reitsma and Henning *(34)* detailing the survival of *E. coli* O157:H7 in aged Cheddar cheese. In a referral to the National Advisory Committee on Microbiological Criteria for Foods in April of 1997, the FDA asked if a revision of current policy was necessary, noting that the current aging requirement may be insufficient to provide an adequate level of public health protection. In response to the detection of pathogenic microorganisms in cheese and cheese products as well as

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foodborne outbreaks and illnesses caused by *L. monocytogenes (1*, *22*, *23, 25, 27)*, *Salmonella (2, 6, 16, 18, 24, 32, 33), E. coli (13, 19)* and *Staphylococcus aureus (3*, *28, 36, 39, 42, 43)*, the FDA issued the Domestic and Imported Cheese and Cheese Products Food Compliance Program in November of 1998 *(8)*. The objectives of this program were to authorize the FDA to conduct inspections of domestic cheese firms; to examine samples of imported and domestic cheese for microbiological contamination, presence of phosphatase, and filth; and to take appropriate regulatory action when violations are encountered *(8)*. Under this initiative, direct reference seizure or detention of cheese based on the presence of *L. monocytogenes* was also authorized.

On June 14, 2004, the Cheese of Choice Coalition (CCC) requested, under the Freedom of Information Act, all test results obtained under FDA's "Domestic and Imported Cheese and Cheese Products Compliance Program" for the period 1998 to June 2004. On August 7, 2007, the CCC agreed, at FDA's urging, to amend the time period to include only January 1, 2004–December 31, 2006. The FDA provided data in response to the CCC request on February 6, 2008. This manuscript provides an analysis of those data and the implications for the safety of domestic and imported cheeses analyzed within the FDA program.

MATERIALS AND METHODS

Data acquisition

Under the Freedom of Information Act, the CCC specifically requested the following information: (1) The total number of cheese samples analyzed under this directive, with data broken down with respect to the number of domestic firms inspected and the number of domestic and imported cheese samples analyzed. (2) Data on the specific analyses that FDA had conducted on the cheeses, and results of all analyses. (3) In particular, microbiological data, with a breakdown of data by cheese category, including all microbiological results (negative and positive). (4) Data on appropriate regulatory action (seizure, detention, recall) taken as a result of microbiological/chemical findings. (5) Data from inspections of cheese firms, including the inspection forms utilized, a summary of violations encountered, and regulatory action taken as a result of violations.

Sample collection

Samples were collected in accordance with the procedures detailed in the compliance program *(8)*. During scheduled inspections, samples are collected when the firm had a history of microbiological contamination (such as follow up to illness or injury complaint, recalled/seized product, previous inspectional history). Sampling is also conducted "for cause" (for example; inspectional observations that warrant sample collection for microbiological analyses). Collection priority specifies the sampling of soft cheese, followed by hard cheese and cheese products. For this Compliance Program, "soft cheese" refers to fresh soft (for example, Asiago, Feta, Ricotta, Queso Fresco), semi-soft (for example, Gorgonzola, Limburger, Stilton, Gouda), and soft-ripened (for example, Brie, Camembert and Vacherin) cheese varieties. Hard cheese includes varieties such as Cheddar, Romano, and Swiss, among others. Each sample was analyzed for the presence of *L. monocytogenes*, *Salmonella*, *E. coli,* Enterohemorrhagic *E. coli* (defined as serotype O157:H7) (EHEC), and *S. aureus.* Samples were analyzed for the presence of Enterotoxigenic *E. coli* (ETEC) when *E. coli* was present at $\geq 10^4$ (10,000) CFU/g. Staphylococcal enterotoxin testing was conducted when product abuse was suspected or if viable staphylococcal colonies, MPN results or direct plate counts indicated a level of 10^4 (10,000) CFU/g or above. Cheese varieties sampled in the reports provided by the FDA included Standardized, Not Elsewhere Mentioned (NEC); Cheese and cheese products NEC; Standardized cheese food, Cold pack (Hickory smoked, for example); Non-standardized products NEC; Standardized cheese products NEC; Asiago, fresh, medium, soft and old; Blue; Brick; Cheddar; Colby; Cook, Koch; Cream cheese; Cream cheese with other foods; Edam; Goat; Gorganzola; Gouda; Gruyere; Hard cheese; Hard grating cheese; Havarti, High moisture Jack; Mexican-style soft; Monterey; Muenster; Non-standardized natural, smoked cheese; Parmesan; Standardized pasteurized, blended cheese; Standardized pasteurized process Cheese; Pizza cheese; Provolone; Reggiano; Ricotta; Romano; Roquefort; Semisoft; Semisoft, part skim; Sheep; Standardized, spiced, part skim; Stilton; Standardized stirred curd; Swiss, Emmentaler; Syrian; Standardized washed curd; Cottage (Not < 4% Milkfat); Dry curd Cottage cheese (< 0.5% Milkfat); Pasteurized cheese spread; Pasteurized process cheese spread; Pasteurized process cheese foods; Pasteurized process cheese spread with fruits, vegetables or meats; Queso Crema; Soft-ripened from Cow's milk; Soft-ripened from a mixture of animal milk; Soft-ripened from Goat's milk, Soft-ripened from Sheep's milk; Soft, Semi-soft from Cow's milk.

Sample preparation, isolation and identification

Samples were processed in accordance with the procedures detailed in the compliance program *(8)*. Briefly, since the products were analyzed for multiple pathogens under this program, both compositing and individual subsample analysis on the same sample were necessary. Two (2) composites per sample were analyzed separately for *L. monocytogenes* and *Salmonella*. After the portions were removed for *L. monocytogenes* and *Salmonella* composites, each individual subsample was analyzed for *E. coli*, ETEC (if necessary), EHEC and *S. aureus.* Isolation and identification followed the procedures outlined in the FDA Bacteriological Analytical Manual *(11)*.

RESULTS AND DISCUSSION

During the period January 1, 2004, to December 31, 2006, the FDA tested a total of 17,324 domestic and imported cheese samples. Our analysis of results obtained by FDA focused on the incidence of the primary pathogens of concern, which included *E. coli* O157:H7, *Salmonella*, *L. monocytogenes* and *S. aureus*.

During the aforementioned period, the FDA examined 3,360 cheese samples for the presence of *E. coli* O157:H7. As

TABLE 1. Incidence of enterohemorrhagic *Escherichia coli* (*E. coli* O157:H7) in cheese analyzed under the Domestic and Imported Cheese Compliance Program between January 1, 2004 and December 31, 2006

Year	Category	No. positive/ No. tested (%)	Cheese type	Country of origin
2004	Domestic	0/478 (0)		
2004	Imported	2/1070 (0.2)	Mexican-style soft	Mexico
			Soft-ripened	Honduras
2005	Domestic	0/317 (0)		
2005	Imported	1/699 (0.1)	Mexican-style soft	Mexico
2006	Domestic	0/210 (0)		
2006	Imported	0/586 (0)		
Total		3/3360 (0.09)		

shown in Table 1, only 3 (0.09%) of these tested positive: 2 samples of Mexican-style soft cheese imported from Mexico (one in 2004 and one in 2005), and one sample of soft-ripened cheese imported from Honduras in 2004. No cheese samples tested in 2006 were positive for *E. coli* O157:H7 and no domestically produced cheeses tested positive in any year. Given that *E. coli* O157:H7 was the pathogen of concern that prompted the FDA to consider mandatory pasteurization of all milk intended for cheesemaking, as well as a ban on importation of cheeses made from raw milk, the results are remarkable. Although a major pathogen of concern, *E. coli* O157:H7 was detected in only 0.09% of cheese samples analyzed by the FDA between 2004 and 2006, and not a single sample of domestically produced cheese tested positive for this organism. These data are in agreement with those presented by Bowen and Henning *(4)*, who failed to recover *E. coli* O157:H7 in 50 retail samples of natural cheese. Similarly, no *E. coli* O157 was detected in 153 soft and semi-soft cheeses made with raw cow, ewe or goat milk in a survey conducted in Belgium *(41)*. In addition to the low incidence in cheese, only seven of the 183 (4%) foodborne *E. coli* O157:H7 outbreaks reported in the U.S. from 1982 to 2002 were attributed to dairy products, and of these seven, four were linked to the consumption of unpasteurized fluid milk *(31)*. The only well publicized domestic outbreak linked to the consumption of cheese occurred in Wisconsin in 1998, when vats used to make raw milk Cheddar cheese were inadvertently used to make fresh cheese curds *(13)*.

Throughout the same period, the FDA examined 2,181 cheese samples for the presence of *L. monocytogenes*. A total of 52 samples (2.4%) were positive for this pathogen (Table 2). As can be seen from Table 2, more than half (52%) of the samples positive for *L. monocytogenes* were from Mexican-style soft cheese (17 positive samples) or soft-ripened cheese (10 positive samples). When data from all years are combined, the overall incidence of *L. monocytogenes* in domestic cheese samples (1.2%) is seen to be notably lower than that in imported products (3.2%). The incidence of *L. monocytogenes* in imported samples decreased from 4.25% in 2004 to less than 1% by 2006, suggesting increased control and/or regulatory compliance by cheese producers abroad. These results are in agreement with a review of FDA records by the World Health Organization Working Group on Foodborne Listeriosis which, according to Norton and Braden *(27)*, revealed the presence of *L. monocytogenes* in 12 of 658 (1.82%) domestic cheese samples analyzed in 1986. The following year, in a sampling of domestic aged natural cheese manufactured from raw milk, only one of 181 (0.55%) samples was positive for *L. monocytogenes (27)*. These data could represent a low incidence of *L. monocytogenes* in cheese or could simply be an artifact of the extensive recalls of contaminated cheese in the U.S. prompted by intensive FDA surveillance. Based on the results of multiple surveys, Norton and Braden *(27)* reported incidence rates below 5% for cheeses manufactured in France (4.5%), Germany (4.4%), Italy (3%) and Switzerland (4.9%), with contamination most commonly observed in soft, followed by semi-soft and hard, varieties. A slightly higher incidence, 6%, was reported by Loncarevic and others *(21)* for soft and semi-soft cheeses at retail in Sweden. More recently, a *Listeria* spp. prevalence of 3.49% was reported for fresh soft cheeses purchased at retail in Italy *(29)*. The results of the present review indicate that soft and semi-soft cheese varieties continue to pose the greatest risk in terms of *L. monocytogenes* contamination. No information was provided as to whether or not cheeses tested were manufactured from pasteurized, heat treated or raw milk. This is an important factor to consider, as soft and semi-soft cheeses made from raw milk may have a higher risk of *L. monocytogenes* contamination than those made from milk that has undergone heat treatment *(21)*. However, *Listeria* is an environmental pathogen, and the majority of cheeses contaminated by *Listeria* result from post-process environmental recontamination. In a study of smear rind style cheeses, for example, Rudolf and Sherer *(35)* found a higher incidence of *L. monocytogenes* in cheeses made from pasteurized (8%) versus raw (4.8%) milk. The data reviewed in the pres-

TABLE 2. Incidence of *Listeria monocytogenes* in cheese analyzed under the Domestic and Imported Cheese Compliance Program between January 1, 2004 and December 31, 2006

Year	Category	No. positive/ No. tested (%)	Cheese type (No. samples)	Country of origin
2004	Domestic	6/412 (1.5)	Hard (2)	U.S.
			Mexican-style soft (1)	U.S.
			Soft-ripened (1)	U.S.
			Semisoft, cow (2)	U.S.
2004	Imported	26/612 (4.3)	Mexican-style soft (11)	Mexico
			Blue (2)	Italy
			Parmesan (1)	Argentina
			Semi soft (3)	Italy
			Sheep (2)	Italy
			Soft-ripened, cow (2)	Italy, France
			Soft-ripened, goat (3)	Italy
			Cheese and cheese products, NEC[a] (2)	Mexico
2005	Domestic	2/286 (0.7)	Blue	U.S.
2005	Imported	13/405 (3.2)	Non-standardized products (2)	Portugal
			Blue (1)	Italy
			Cheddar (1)	U.K.
			Mexican-style soft (5)	Mexico
			Sheep cheese (2)	Greece
			Soft-ripened, cow (2)	Columbia, France
2006	Domestic	2/163 2 (1.2)	Cheese products non-standardized (1)	U.S.
			Monterey	U.S.
2006	Imported	3/303 (1)	Soft-ripened, cow (2)	Honduras, Italy
			Semi-soft (1)	Italy
Total		52/2181 (2.4)		

[a]NEC: Not elsewhere mentioned

ent study did not identify the source of *L. monocytogenes* contamination and thus did not consider the possibility of environmental contamination.

Additionally, no data was provided regarding the concentration of *L. monocytogenes* in positive cheese samples detected through the compliance program. This is an important factor to consider, as current U.S. and European Union (EU) cheese regulatory policies differ with respect to allowable limits of *L. monocytogenes.* While the U.S. maintains a "zero tolerance" policy, the EU differentiates those products that support the growth of *L. monocytogenes* from those that do not. According to Regulation No 2073/2005 *(15)*, ready-to-eat foods that can support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes, must be free of *L. monocytogenes* before the food has left the immediate control of the food business operator who produced it. In addition, the *L. monocytogenes* level must not exceed 100 CFU/g during the shelf-life when the products are placed on the market. Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes, must not contain more than 100 CFU/g during their shelf life when placed on the market.

Only 45 (1.3%) of 3,520 samples tested positive for *Salmonella* (Table 3) during this sampling period. Remarkably, 82% (37/45) of the positive samples came from cheeses produced in Mexico,

TABLE 3. Incidence of *Salmonella* in cheese analyzed under the Domestic and Imported Cheese Compliance Program between January 1, 2004 and December 31, 2006

Year	Category	No. positive No. tested (% positive)	Cheese type (No. samples)	Country of origin (No. samples)
2004	Domestic	3/503 (0.6)	Cheese and cheese products, NEC[a] (2)	U.S.
			Hard (1)	U.S.
2004	Imported	27/1122 (2.4)	Mexican-style soft (16)	Mexico (14), Nicaragua (2)
			Pasteurized process (2)	Honduras
			Hard (2)	Honduras
			Standardized (5)	Honduras (2), Mexico (3)
			Cheese and cheese products, NEC	Dominican Republic
2005	Domestic	2/329 (0.6)	Gouda (1)	U.S.
			Provolone (1)	U.S.
2005	Imported	10/744 (1.3)	Mexican-style soft (6)	Mexico
			Cheese and cheese products, NEC (2)	El Salvador
			Soft-ripened, sheep (2)	Bulgaria
2006	Domestic	0/211 (0)		
2006	Imported	3/611 (0.5)	Soft-ripened, cow (3)	Honduras (2), France (1)
Total		45/3520 (1.3)		

[a]NEC: Not elsewhere mentioned

Central America and the Dominican Republic, with soft or soft-ripened cheeses yielding the majority (60%) of positive samples (27/45). With the data from all years combined, the overall incidence of *Salmonella* in imported cheese (1.6%) was more than 3 times that of domestically produced cheese (0.5%). Once again, the overall incidence decreased from 2004 to 2006, with only 3 of 822 tested samples (0.4%) in 2006 yielding positive results for *Salmonella,* suggesting increased regulatory compliance by cheese producers both domestically and abroad. Similar to U.S. regulation for *L. monocytogenes*, both U.S and EU regulations each require the absence of *Salmonella* spp. in 25 g of cheese. Despite notable cheeseborne outbreaks and the ability of *Salmonella* spp. to survive ripening and storage, salmonellae are rarely isolated from commercially produced cheeses *(36)*. The incidence of salmonallae in domestic cheeses reported herein is also low (0.5%), as the majority of *Salmonella* spp. positive cheeses were imported almost entirely from Mexico and Central America. In a recent survey of American farmstead cheeses available for purchase online, only one of 61 cheeses was positive for *Salmonella* spp. *(30)*. Interestingly, this cheese was manufactured from pasteurized milk, prompting the authors to state that cheeses made from pasteurized milk are not necessarily safer than those made from raw milk *(30)*.

Of 3,449 cheese samples tested for *S. aureus*, 239 (6.9%) were positive. Results for individual years are displayed in Tables 4, 5 and 6. Overall, contamination rates were similar for both domestic and imported cheeses, ranging from as low as 5.2 (imported cheese 2004; Table 4) to as high as 9.8% (imported cheese 2005; Table 5). A substantial proportion of cheeses testing positive for *S. aureus* were Mexican-style soft cheeses (38.1%), the vast majority of which came from Mexico or Central America (86.8%). More specific data regarding levels of *S. aureus* from 4,059 samples and their subunits was also provided by the FDA through summary text that accompanied each sample result. It was unclear

TABLE 4. Incidence of *Staphylococcus* aureus in cheese analyzed under the Domestic and Imported Cheese Compliance Program during fiscal year 2004

Category	No. positive/ No. tested (%)	Cheese type (No. samples)	Country of origin
Domestic	25/476 (5.3)	Cheddar (6)	U.S.
		Mexican-style soft (4)	U.S.
		Colby (3)	U.S.
		Gouda (3)	U.S.
		Standardized, NEC[a] (2)	U.S.
		Cheese and cheese products, NEC (1)	U.S.
		Cheese and cheese products, non-standardized (1)	U.S.
		Cheese products, standardized, NEC (1)	U.S.
		Semisoft (1)	U.S.
		Soaked curd (1)	U.S.
		Pasteurized process cheese food (1)	U.S.
Imported	110/1124 (9.8)	Mexican-style soft (56)	Mexico (52), Nicaragua (4)
		Standardized, NEC (8)	Mexico (5), Bolivia (1), Honduras (1), Nicaragua (1)
		Cheese and cheese products, NEC (14)	Nicaragua (9), Mexico (3), Honduras (1), Venezuela (1)
		Cheese products, non-standardized (3)	Nicaragua (2), Armenia (1)
		Asiago (2)	Mexico (1), Nicaragua (1)
		Brick (1)	Mexico
		Cheddar (4)	Dominican Republic
		Gouda (1)	Dominican Republic
		Hard (4)	Nicaragua (3), Honduras (1)
		Hard grating (1)	Mexico
		Pasteurized process (6)	Nicaragua (5), Honduras (1)
		Semisoft (2)	France, Honduras
		Sheep (3)	Greece (2), Italy (1)
		Swiss, Emmentaler (1)	Germany (1)
		Soft-ripened, cow (4)	Honduras (3), Nicaragua (1)
Total	135/1600 (8.4)		

[a]NEC: Not elsewhere mentioned

TABLE 5. Incidence of *Staphylococcus aureus* in cheese analyzed under the Domestic and Imported Cheese Compliance Program during fiscal year 2005

Category	No. positive/ No. tested (%)	Cheese type (No. samples)	Country of origin (No. samples)
Domestic	18/329 (5.5)	Mexican-style soft (7)	U.S.
		Cheese and cheese products, NEC[a] (4)	U.S.
		Cheddar (3)	U.S.
		Gouda (1)	U.S.
		Standardized, NEC[1] (1)	U.S.
		Soft, semisoft, cow (1)	U.S.
		Cheese products, standardized, NEC (1)	U.S.
Imported	37/710 (5.2)	Mexican-style soft (12)	Mexico
		Cheese and cheese products, NEC (8)	Mexico (3), El Salvador (1), Nicaragua (2), Portugal (2)
		Cook, koch (1)	El Salvador
		Gouda (2)	Dominican Republic
		Hard (1)	Nicaragua
		Natural, smoked, non-standardized (1)	Nicaragua
		Pasteurized process (4)	Nicaragua
		Semisoft (4)	France (3), Egypt (1)
		Soft-ripened, cow (2)	Colombia (1), France (1)
		Soft-ripened, sheep (1)	Italy
		Pizza (1)	Italy
Total	55/1039 (5.3)		

[a]NEC: Not elsewhere mentioned

why there is a discrepancy in the number of samples tested (3,449 in contrast to 4,059) between the data sets provided. We assume that the data set containing specific counts in the summary text may have included results from both samples and subunits of composites. Of these 4,059 samples, a total of 313 contained levels of *S. aureus* greater than 1×10^4 MPN/g. Although samples are to be further tested for the presence of staphylococcal enterotoxins when levels exceed this value, additional toxin testing results were not provided for 128 of these samples. It is unclear whether the tests were not performed or the summary text provided by the FDA simply did not include the result. The remaining 185 samples were all negative for the production of target enterotoxins. Overall, none of the 4,059 samples were reported as testing positive for enterotoxin production. The numbers of cheese samples with *S. aureus* counts $>1 \times 10^4$ MPN/g and reported enterotoxin testing results are listed by cheese type in Table 7. The variability in prevalence between cheese types is notable, as is the observation of high rates of excessive contamination in types often considered lower risk, such as Pasteurized processed cheese, and lower rates in some of those considered higher risk, such as Soft-ripened, cow. Although the reporting of MPN results varied greatly, we divided the reported counts into three subgroups (data not shown). Overall, 160 samples had at least one subunit with counts reported simply as > 11,000 MPN/g; 109 of these were reported as negative for toxin. Sixty-three samples had at least one subunit with reported counts between 12,000 and

TABLE 6. Incidence of *Staphylococcus aureus* in cheese analyzed under the Domestic and Imported Cheese Compliance Program during fiscal year 2006

Category	No. positive/ No. tested (%)	Cheese type (No. samples)	Country of origin (No. samples)
Domestic	15/204 (7.4)	Standardized, NEC[a] (2)	U.S.
		Cheese and cheese products, NEC (4)	U.S.
		Cheese products, non-standardized (1)	U.S.
		Blue (1)	U.S.
		Cheddar (1)	U.S.
		Hard (2)	U.S.
		Mexican-style soft (1)	U.S.
		Semisoft (2)	U.S.
		Asiago (1)	U.S.
Imported	34/606 (5.6)	Mexican-style soft (11)	Mexico
		Standardized, NEC (5)	Mexico (4), Italy (1)
		Cheese and cheese products, NEC (2)	Honduras (1), Nicaragua (1)
		Cheese products, non-standardized (1)	Unknown
		Cheddar (4)	Dominican Republic
		Edam (1)	Dominican Republic
		Goat (1)	Portugal
		Hard (2)	Nicaragua (1), Ukraine (1)
		Pasteurized process (1)	Nicaragua
		Ricotta (1)	Canada
		Romano (1)	Italy
		Semisoft (1)	Brazil
		Sheep (1)	Spain
		Soft, semisoft, cow (1)	Unknown
		Brick (1)	Mexico
Total	49/810 (6.0)		

[a]NEC: Not elsewhere mentioned

100,000 MPN/g, with 36 samples testing negative for toxin and 27 with no results reported. Lastly, 90 samples had at least one subunit with counts reported as > 100,000 MPN/g, which 52 were negative for toxin and 38 had no results reported. It is noteworthy that two samples of goat cheese with levels of 18,000,000 MPN/g were also negative for enterotoxin.

The results of the FDA analysis show that *S. aureus* is the most prevalent target pathogen in cheese. According to De Buyser and colleagues *(7)*, *S. aureus* is a leading cause of foodborne disease related to milk and milk products in France. Notable outbreaks related to cheese, however, are relatively rare, as *S. aureus* is generally considered a poor competitor in the presence of active starter culture. Staphylococcal food poisoning occurs not as the result of the ingestion of the organism itself, but through ingestion of one or more of the staphylococcal enterotoxins produced by some strains of *S. aureus (20)*. The behavior and enterotoxin production of *S. aureus* in cheese varies depending on cheese type: activity and type of starter culture utilized *(26)*, the presence of acidic byproducts, pH, and competition for nutrients *(17)*. The lack of detectable enterotoxin in the cheeses tested as part of the FDA compliance program could be explained by any one of the aforementioned factors. It is also possible that the strains detected in these cheeses were not toxigenic or produced toxins not detected by the methods employed. As a result of the variation in survival and enterotoxin production by *S. aureus* in cheese, analyses for coagulase-positive staphylo-

TABLE 7. Incidence of cheese samples analyzed under the Domestic and Imported Cheese Compliance Program between January 1, 2004 and December 31, 2006 with *Staphylococcus aureus* counts >1×10⁴ MPN/g and reported enterotoxin testing results

	Incidence of samples with >1 × 10⁴ MPN/g (%)						
	No toxin results			No toxin detected			Total
Cheese type[a]	2004	2005	2006	2004	2005	2006	All years
Standardized, NEC[b]	0	0	0	4.2	0	1.7	4.1
Cheese and cheese products, NEC	9.8	18	8.3	17.2	3.3	6.2	22.1
Cheese products, standardized, NEC	20	0	0	0	0	0	5.6
Asiago	0	0	0	41.7	0	0	22.7
Cheddar	2.1	0	5.9	12.4	0	5.9	10.6
Goat	0	0	0	0	0	3.7	1.1
Gouda	0	27.8	0	10.9	0	0	13.6
Hard	2.8	0	0	1.4	0	0	1.6
Mexican-style soft	14.1	7	0.9	11.6	8.6	9.4	19.1
Natural, smoked, non-standardized	0	58.3	0	0	0	0	43.8
Pasteurized process	1.2	11.1	0	47.6	0	0	36.8
Ricotta	0	0	0	0	0	23.8	11.9
Semisoft	4.7	0	0	2.9	0	0	3.3
Sheep	1.9	0	0	0	0	0	0.8
Pasteurized process cheese food	0	0	0	13.3	0	0	12.5
Soft-ripened, cow	1.8	0	0	3.9	0	0	3
Soft, semisoft, cow	27.3	0	0	0	0	0	10
Total	5.3	4.5	1.3	9.4	2	3.1	9.8

[a]Does not include cheese types from which *S. aureus* counts did not exceed >1 x 10⁴ MPN/*g*.

[b]NEC: Not elsewhere mentioned

cocci varies in the EU depending on the extent of heat treatment applied to the milk used for manufacture where stricter limits are placed on cheeses manufactured from heat-treated and pasteurized milks. In the case of raw and heat-treated milk, samples must be taken at the time during the manufacturing process when the number of staphylococci is expected to be the highest, as opposed to when the cheese is already on the market, at which point pathogen levels may have decreased substantially. Based on a three-class sampling plan (n = 5, c = 2, m = 10^4, M = 10^5), a cheese batch would be tested for the presence of enterotoxin *(15)*.

In December 2009, a draft guidance document for FDA staff representing the FDA's current thinking on microbial contaminants in dairy products was distributed for comment. This document contains updated microbiological criteria for pathogens, including the addition of testing for *Campylobacter jejuni, Yersinia enterocolitica*, vegetative cells of *Clostridium botulinum*, *C. botulinum toxin* and *Bacillus cereus* enterotoxin *(12)*.

CONCLUSIONS AND RECOMMENDATIONS

These data are extremely useful in helping to inform risk assessments that evaluate the microbiological safety of cheese and incidence of target foodborne pathogens. Decreases in overall incidence of *E. coli* O157:H7, *Salmonella* and *L. monocytogenes* over the sampling period suggest increased control and regulatory compliance by cheese producers both domestically and abroad, while *S. aureus* continues to serve as the dominant target pathogen in cheese. These data also suggest that increased regulatory focus should be given to Mexican-style soft cheeses, particularly those produced in Mexico and Central America.

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