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13	IN THE SUPERIOR COURT OF SAN BENITO COUNTY STATE OF CALIFORNIA		
14	ORGANIC PASTURES DAIRY  Case No.: CU-07-00204		
15	COMPANY, LLC, and ) CLARAVALE FARM, INC.,		
16	Plaintiffs,  Plaintiffs,  Plaintiffs,  Plaintiffs,  PLAINTIFFS' REPLY TO  DEFENDANTS' OPPOSITION TO  ORDER FOR PRELIMINARY		
17	v. ) INJUNCTION		
18 19	STATE OF CALIFORNIA and A.G. KAWAMURA, Secretary of California Department of Food and Agriculture,		
20			
21	Defendants.		
22	Coliforms are used as an indicator of food "quality and not food "safety." Food quality is		
23	regulated by the customer and their pocketbooks, i.e., the market. Food safety is regulated by the		
24			
25	State of California. Because coliforms are an inappropriate measurement of food safety AB		
	1735 is unconstitutional.		
26	The testing data submitted by Plaintiffs in this case demonstrates that they cannot comply		
27	with the 10 coliform standard of AB 1735. The declarations of Mark McAfee and Ron		
28	1		
	Plaintiffs' Reply to Defendants' Opposition to Order for Preliminary Injunction, Organic Pastures Dairy and Claravale Farm, Inc v. State of California, et al., Case No.: CU-07-00204		

Garthwaite, Plaintiffs' representatives, also demonstrates that Plaintiffs' two business will be shut down because they cannot consistently comply with AB 1735's coliform standard. These declarations remain unrebutted.

Finally, the declarations submitted by Defendants in their Opposition papers are so replete with misstatements, falsities and inaccuracies that this Reply is not the appropriate forum to rebut them. This Reply will only briefly address those Declarations and Plaintiffs will present two witnesses who will provide sworn testimony in rebuttal to the Declarations.

### I. Plaintiffs will prevail on the merits of their claims.

### A. Coliforms and "sanitation" are indicators of food quality, not food safety.

As explained below, the unrebutted testimony provided by Plaintiffs as well as the scientific literature of leading research institutions demonstrates conclusively that coliforms (or "sanitation" as the State prefers to call it) are an indicator of food quality, not food safety. In other words, coliforms indicate how soon a food product may spoil or how long it may remain on a grocery store shelf. Pathogens, instead, are an indicator that a food product is unsafe for consumption. Because the State does not have the authority to regulate the "quality" of foods consumed by humans, AB 1735's coliform is inappropriate and it cannot be used to protect the public's health.

### 1. Dr. Beals' testimony remains unrebutted.

With respect to the testimony in this case, Plaintiffs have submitted the Affidavit of Michigan physician Dr. Theodore Beals. In his affidavit, Dr. Beals makes two significant statements. First, Dr. Beals states at ¶17 "Although traditionally, coliforms may be an indicator of environmental contamination, the presence of coliforms is not an indicator of the presence of pathogens." Dr. Beals also states at ¶20 that "The purpose of the coliform test is not to detect the presence of pathogens that cause illness to humans." Thus, when it comes to ensuring the safety of food products, coliforms do not serve that need. Dr. Beals then concludes at ¶¶ 32-34 that AB 1735's coliform is not related to any legitimate governmental interest, does not protect the public's safety, and is arbitrary.

None of the declarations submitted by the State dispute this assertion. In fact, nowhere in any of their papers, declarations or exhibits in support of their declarations does the State dispute these two assertions: that there is no correlation between the presence of coliforms and the presence of pathogens, and that pathogens, not coliforms, cause human illness. Thus, this Court has unrebutted testimony that coliforms cannot be used to indicate the presence of pathogens which cause illness in humans. Therefore, AB 1735's use of a coliform standard does not ensure the public's health or safety.

## 2. Educational research institutions agree that coliforms indicate food "quality" and should not be used as an indicator of food "safety."

Not only is there unrebutted testimony that AB 1735's standard does not ensure the public's safety, university research institutions have also come to the conclusion that coliforms are an indicator of product quality, not product safety. Specifically, Cornell University has stated (Exhibit I to the Affidavit of David G. Cox in Reply to Defendants' Opposition to Order for Preliminary Injunction) "the detection of coliforms in milk will indicate the potential for a shortened shelf-life due to concurrent contamination with psychotrophic bacteria." Cornell also states (Exhibit J to the Cox affidavit) that "One of the most common applications of coliform bacteria as indicator organisms is in their association with hygienic conditions and overall quality, especially concerning heat processed foods."

Perhaps most compelling is the statement from the University of California-Davis, that coliforms should not even be used as an indicator of food safety. (Exhibit P to Cox Affidavit.). "Whether talking about Good Agricultural Practices or TMDL's (Total Maximum Daily Loads) in ag-runoff water, developing fruit and vegetable microbial standards, food safety management and certification plans, or setting regional water policy, basing decisions on total numbers of 'Coliform' bacteria or 'Fecal Coliforms' is not supported by current science." This is perhaps the clearest statement that using a coliform standard does not protect the public's health.

### 3. Even Governments recognize that coliforms do not ensure food safety.

In addition to the unrebutted testimony of Plaintiffs' expert and the research performed by leading educational nstitutions, government itself is beginning to discard the use of coliforms as a measure of food safety. For example, in November 2007 the Food and Drug Administration has adopted a "Food Protection Plan" that relies on the techniques of a Hazard Analysis Critical Control Point (HAACP) to ensure the safety of the meats produced by the meat processing industry. (Exhibit H to Cox Affidavit). Nowhere in FDA's Food Protection Plan does there appear a coliform standard to ensure the safety of food. Rather, the provisions of a HAACP for each meat processor will be relied on to ensure safety.

The United States government is not the only government that is moving toward a HAACP approach rather than a coliform approach to ensure food safety. For example, the European Parliament (Exhibit G to Cox Affidavit) does not even use coliforms to ensure food safety. Canada also does not use a coliform standard to ensure food safety for whole milk and cheeses. (Exhibit B to Cox Affidavit). Instead, Canada uses a pathogenic criteria for cheese (Exhibit B, Section B.08.048) and either aerobic bacteria or sediment (Section B.08.024) for milk that will be manufactured into dairy products. Clearly, science has progressed to the point that food safety is ensured by controlling the critical points in the food production process where human pathogens can be introduced.

Food safety is no longer ensured by using a coliform standard, which is more of an indicator of food quality not safety. If this means that "every single public health standard that we have developed as a nation over the last century has been on the wrong track" as Dr. Stephen Beam testified at his deposition, then that is true. See Deposition transcript of Dr. Stephen Beam, Vol. II, April 21, 2008, pg. 25, lines 13-15. Coliforms are inappropriate to measure food safety. Rather, either HAACP's or pathogenic testing should be used to ensure food safety.

Consequently, Plaintiffs' will likely prevail on the merits of their claims because there is no relationship between AB 1735's use of a coliform standard and food safety.

# B. The California Constitution recognizes that running a business is an inalienable right.

Defendants allege at page 7 of their Opposition that "plaintiffs have failed to present any cases holding that the right to run a dairy or processing plant is a fundamental right." That is not true. Plaintiffs will present their argument *verbatim* from their Points and Authorities.

Cal Const., Art. I § 1 refers to inalienable rights, and provides as follows: "All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy." As stated by the Supreme Court of California, a "legion of cases establishes and enforces the entrepreneur's property right of access to, and expectancy of customers." *Crittenden v. Superior Court of Mendocino County* (Cal. 1964), 61 Cal. 2d 565, 568. See also *McKay Jewelers, Inc.* v. *Bowron* (Cal. 1942) 19 Cal.2d 595; *State Board of Dry Cleaners v. Thrift-D-Lux Cleaners, Inc.* (Cal. 1953), 40 Cal. 2d 436, 441; *Guillory* v. *Godfrey* (Cal. 1955) 134 Cal.App.2d 628; *Uptown Enterprises* v. *Strand* (Cal. 1961) 195 Cal.App.2d 45, 50-51 ("Everyone has the right to establish and conduct a lawful business and is entitled to the protection of organized society, through its courts, whenever that right is unlawfully invaded.").

This *verbatim* argument demonstrates that although the United States Constitution may not recognize the running of a business as a "fundamental" right, the California Constitution does. Thus, *Crittenden* recognizes that an entrepreneur has a "property right of access to, and expectancy of customers." Because that right is in the form of property, it is a fundamental property right recognized by the California Constitution. Therefore, the right to property is an inalienable right in the State of California, and the cases cited by Plaintiffs interpret this to include having access to and expecting customers for their business.

Defendant attempts to downplay the significance of these cases by stating on page 7 they "are inapposite." Defendant then goes on to state that these cases deal with "interpretation of a

statute" or "free speech" protections or "interference" with a business or "trespass" onto a business. Those are Defendants' characterizations, not the cases cited.

Indeed, *McKay Jewelers, Inc. v. Bowron* (Cal. 1942), 19 Cal. 2d 595, 600 stated "A business may be inherently lawful and still subject to police regulation, but when such lawful business is regulated, it is a judicial question whether the law or ordinance is a lawful exercise of the police power." *State Board of Dry Cleaners v. Thrift-D-Lux Cleaners, Inc.* (Cal. 1953), 40 Cal. 2d 436, 441 stated that the legislature cannot "under the guise of providing for this component of the police power, impose unnecessary and unreasonable restrictions upon the pursuit of these useful activities. If a statute has no real or substantial relation to any legitimate police power objective, it is the duty of the court to so declare." In neither case did the courts rely on the "rational basis" test to strike down the statute or ordinance in question. Instead, they ruled that a person has the right to engage in a business and that government cannot interfere with that business as long as the business is legal.

In the alternative, and as explained above, even if AB 1735 is analyzed under a rational basis test, it must fail because coliforms are an indicator of food quality, and the state does not regulate quality. The market place and customers with their pocketbooks regulate food quality.

In any event, AB 1735 is unconstitutional.

## II. Balancing the equities in this case favors the Plaintiffs.

Beginning on page 9 of their Opposition, Defendants argue that Plaintiffs "have substantially met the new coliform standards since the beginning of the year." While that may be true, inevitably they will continually fail and go out of business. Moreover, each time they receive a degrade from CDFA they will lose money.

As the test data of Claravale Farm Inc. make clear, Claravale would have failed AB 1735's standard nearly 100% of the time. See Attachment A to Declaration of Ron Garthwaite Regarding Test Data in Support of Temporary Restraining Order. For Claravale, then, it is only a matter of time before they go out of business because they cannot meet the standard. For Organic Pastures, they have already been degraded once this year for their cream. Both Mark

McAfee and Ron Garthwaite have testified that their production is geared for raw milk, not pasteurized milk, and that they will go out of business because they cannot consistently comply with AB 1735's coliform limit. Their testimony is unrebutted by any of the declarations submitted by the Defendants.

Defendants argue on page 10 that raw milk "industries in other states operate \* \* \* under a 10 coliform limit." That is completely irrelevant to the issue of whether AB 1735 is constitutional and whether these individual Plaintiffs will be or are harmed by AB 1735. Moreover, Defendants have presented no evidence from any state other than Washington on what the compliance record of those other raw milk dairies in those other states are. Consequently, this argument lacks merit.

However, the dairy industry and various extension offices suggest that if a coliform limit should be used at all, it should be measured in the bulk tank and that coliforms of up to 50 or even 100 are acceptable. For instance, Virginia recommends less than 100 (Cox Affidavit, Exhibit K, pg. 2); UC – Davis recommends anywhere from 10 to 50 coliform (Cox Affidavit, Exhibit L, pg. 918); and Cornell states that coliform counts have to go above 50 before it indicates poor hygiene (Cox Affidavit, Exhibit O, pg. 2). Consequently, AB 1735's standard is out of line with what other states have required.

Consequently, Plaintiffs' own testing data and their own sworn testimony is the best evidence that they will be going out of business soon if AB 1735's standard is allowed to stand.

### III. The basis upon which AB 1735 was passed is flawed.

As Plaintiffs stated in their Points and Authorities, a party who challenges the constitutionality of a statute "must convince the court that the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the governmental decisionmaker." *Vance v. Bradley*, 440 U.S. 93, 111 (U.S. 1979) (Attachment B to Points and Authorities). See also: *N.Y. State Club Ass'n v. City of New York*, 487 U.S. 1, 17 (U.S. 1988) ("In a case such as this, the plaintiff can carry this burden by submitting evidence to show that the asserted grounds for the legislative classification lack any reasonable support in

fact, but this burden is nonetheless a considerable one.") (Attachment C to Points and Authorities). These cases were not addressed by Defendant. Thus, the argument made by Plaintiffs in their Points and Authorities is well taken.

In brief, Plaintiffs' argument is as follows: (1) the Pasteurized Milk Ordinance, the National Conference on Interstate Milk Shipments, and other federal guidelines do not apply to raw milk for human consumption; and (2) no outbreaks of *E. coli* O157:H7 have ever been caused by OPDC. Thus, the foundation upon which AB 1735 was passed was not true.

When the sponsor of AB 1735, Assemblymember Nicole Parra, realized the untruths of CDFA she initiated efforts at repealing AB 1735. Her efforts resulted in a January 16, 2008 legislative hearing before the Assembly Agriculture Committee that led to the introduction of AB 1604. See Declarations of Timothy Ibbeson and Lynne Covington and copy of transcript attached thereto. During testimony at the hearing, Assemblymember Parra made statements that AB 1604 was necessary "to right a wrong," that CDFA knew AB 1735 would be "very controversial" yet provided no opposition analysis, that her trust in CDFA "is tainted," that CDFA "purposefully omitted that there would be opposition," and that the legislature "never got that opportunity to debate the policy" behind AB 1735.

The co-sponsor of AB 1604, Assemblymember Michael Villines, also testified on January 16th before the Agriculture Committee. Assemblymember Villines stated that AB 1604 was "about giving people their voice back," and that just to "take something away that some people believe passionately and without giving them a voice is not what government is about." Assemblymember Villines also stated that "we should have a hearing and see about more of the science" behind a coliform limit and that with respect to the science behind food safety the legislature "should have heard that first time in committee. There's data on both sides."

In the end, AB 1604 was introduced on an urgency basis.

It defies credulity for the State to argue on page 12 of its Opposition that the "facts behind the passing of AB 1735 are completely irrelevant." For the State to argue this if for the State to argue that its elected leaders have the power to ignore their constituents. That is not the

basis of government this County, and this State, have adopted. As the United States Supreme Court has stated, a party challenging the constitutionality of a statute has the right to show that "the legislative facts on which the classification is apparently based could not reasonably be conceived to be true by the governmental decisionmaker." *Vance v. Bradley*, 440 U.S. 93, 111 (U.S. 1979).

Plaintiffs were denied this right during the legislative hearings that led to the enactment of AB 1735. They should not be denied this right by this Court.

## IV. The Declarations submitted by Defendants are full of falsities, inaccuracies and misstatements.

None of the Declarations submitted by the State rebut the testimony of Dr. Ted Beals that there is no relation between the presence of coliforms and the presence of pathogens, that coliforms do not cause illness, or that coliforms cannot be used to detect the presence of pathogens. Instead, the Declarations submitted by the State attempt to create the impression that milk that is not pasteurized is unsafe for consumption, that milk must be free of bacteria in order to be safe for consumption, and that pathogen testing is either not effective or not available. All of these themes are incorrect and not supported by science and will be dealt with in detail at the hearing scheduled in this matter for April 25, 2008.

In the meantime, this Reply will briefly deal with each of the declarations in turn:

### **Stephen Beam**

Dr. Beam was deposed on April 8<sup>th</sup> (transcript Vol. 1) and April 21<sup>st</sup> (transcript Vol. 2). During those depositions, Dr. Beam admitted the following:

- he is not an expert at microbiology, epidemiology, or pathology (Vol. 1, pgs. 7-8);
- he has never testified as an expert witness (Vol. 1, pg. 8);
- most coliforms in the environment are not harmful and he does not know anything about the immunological effects of consuming raw milk (Vol. 1, pg. 12);

- even after it is pasteurized, CDFA does not test pasteurized milk for pathogens (Vol. 2, pg. 87);
- he is unable to say at what level milk must be "dirty" before it is unsafe for consumption (Vol. 2, pg. 88);
- he agrees that the standards under the PMO, the standards under Title 21 of the Code of Federal Regulations and the regulations adopted by USDA do not directly apply to the consumption of raw milk (Vol. 2, pgs. 89-91);
- the State did not conduct any statistical analysis of raw milk intended for pasteurization prior to the enactment of AB 1735 (Vol. 2, pg. 96).

These admissions demonstrate that there is no correlation between "sanitary" conditions and "safety." They also demonstrate that there is no way a coliform limit can quantify safety.

### **Richard Breitmeyer**

Questions raised by Dr. Breitmeyer's Declaration, assuming he does not attend the April 25<sup>th</sup> hearing, include the following:

- ¶¶2,3 if coliforms are not normally in the milk of a cow, then how can there be harmful pathogens in the cow since pathogens are coliforms?
  - ¶4 does Dr. Breitmeyer know how Plaintiffs' milk their cows?
  - ¶5 does Dr. Breitmeyer know that raw milk kills listeria monocytogenes in 56 hours?
- ¶9 does Dr. Breitmeyer know that the report he relies on (Exhibit D) states on page 5 that "The outbreak strain of *E.coli* 0157:H7 [found in the children] was not found in any environmental or product samples [of Organic Pastures]" and on page 6 that the fecal "patterns of these isolates [obtained from Organic Pastures] differed from the outbreak patterns [of the children]" and also on page 6 that "the PFGE patterns of these isolates did not match that of the children."?

### **Michael Allen Payne**

This Declaration makes the most false statements and misstatements of all the Declarations provided by Defendants. It is apparent from the emails to and from CDFA and the

FDA that Mr. Payne was being fed information by the FDA and that he does not have personal knowledge of the statements made in his declaration. See Exhibit Q to Cox Affidavit. Also, testimony at the April 25<sup>th</sup> hearing will show that Mr. Payne is biased and prejudiced. Suffice it to say at this time, the Affidavit of Sally Fallon contains a rebuttal to the allegations of Mr. Payne.

### **Linda Harris**

Dr. Harris does not have any experience in the dairy industry. Instead, Dr. Harris is a fruit and vegetable person. The statements in paragraphs 5 and 6 of Dr. Harris' Declaration are completely wrong, not supported by science, and are contradicted by the UC-Davis article attached as Exhibit P to the Cox Affidavit. In addition, testimony at the April 25<sup>th</sup> hearing will demonstrate that Dr. Harris believes a pathogen test in conjunction with a HACCP is a better indicator of food safety than is a coliform standard.

#### Hailu Kinde

The statements made by Dr. Kinde in his Declaration will be rebutted at the April 25<sup>th</sup> hearing.

### **Duc Vugia**

This Declaration does not mention either of the Plaintiffs by name. Therefore, it is completely irrelevant to this case.

Moreover, the allegations contained in this Declaration do not have anything to do with whether AB 1735 is constitutional. The import of this Declaration is apparently to suggest that food borne outbreaks associated with the consumption of raw dairy products needs to be regulated in the State of California. That goes without saying.

Plaintiffs are not arguing that the raw dairy industry in California should not be regulated. Instead, Plaintiffs are challenging the manner in which their industry is being regulated. These are two entirely different situations. Consequently, the Declaration of Dr. Vugia is nothing more than prejudicial to Plaintiffs and its probative value is outweighed by its prejudicial effect.

Therefore, Plaintiffs will orally move the Court on April 25th to strike this Declaration.

### V. Conclusion

Plaintiffs have demonstrated that there is no relation between the use of a coliform standard and the public's health or safety. Therefore, whether a strict scrutiny test or a rational basis test is used. AB 1735 is unconstitutional.

Plaintiffs have unrebutted testimony that they cannot consistently meet the coliform standard of AB 1735. In addition, the State's own testing data from 2006 and 2007 demonstrates that they cannot consistently meet the coliform standard of AB 1735.

What is most problematical in this case is that the people were not heard on this issue when AB 1735 was enacted. The people's voice was taken away from them and this violates our democratic form of government. Responsible legislators are attempting to correct this wrong, and it is clear that had the real facts been know to the legislature at the time, AB 1735 would have never become law.

For these reasons, the Court should issue a preliminary injunction until a trial is held in this matter.

Date: April 23, 2008 Respectfully submitted,

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Claravale Farm, Inc.

1	PROOF OF SERVICE			
2 3		I am employed in the County of Franklin, State of Ohio. I am over the age of eighteen years and not a party to the within action. My business address is Two Miranova Place, Suite 500, Columbus, Ohio 43215-7052. On the date set forth below, I caused the following document(s) entitled:  PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO ORDER FOR PRELIMINARY INJUNCTION		
4 5				
5	to be se means:	erved on the party(ies) or its (their) attorney(s) of record in this action listed below by the following		
7   8   9		<b>BY MAIL</b> . By placing each envelope (with postage affixed thereto) in the U.S. Mail at the law offices of Lane, Alton & Horst, LLC, Two Miranova Place, Suite, Columbus, OH 43215-7052, addressed as shown below. I am readily familiar with this firm's practice for collection and processing of correspondence for mailing with the U.S. Postal Service, and in the ordinary course of business, correspondence would be deposited with the U.S. Postal Service the same day it was placed for collection and processing.		
		<b>BY HAND-DELIVERY</b> . By causing a true copy thereof, enclosed in a sealed envelope, to be delivered by hand to the address(es) shown below.		
2	XX	<b>BY OVERNIGHT DELIVERY</b> . By placing with an overnight mail company for delivery a true copy thereof, enclosed in a sealed envelope, with delivery charges to be billed to Lane, Alton & Horst, addressed as shown below.		
		<b>BY FACSIMILE TRANSMISSION</b> . By transmitting a true copy thereof by facsimile transmission from facsimile number (614) 228-0146 to the interested party(ies) or their attorney(s) of record to said action at the facsimile number(s) shown below.		
7	XX	<b>BY ELECTRONIC MAIL.</b> By transmitting a true copy thereof by electronic mail from e-mail address dcox@lanealton.com to the interested party(ies) or their attorney(s) of record to said action at the electronic mail address(es) shown below		
33    33    34    35    36    37	Deputy Office 455 Go Califor San Fra	Anita Ruud Deputy Attorney General Office of the Regional Attorney General 455 Golden Gate Ave., Rm. 6200 California Department of Justice San Francisco, CA 94102 Counsel for Defendants		
3	I declare under penalty of perjury under the laws of the State of Ohio that the foregoing is true and correct.			
1 5	Executed on April 23, 2008 at Columbus, Ohio.			
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7		David G. Cox		
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