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# FDA's Ace in the Hole

by Pete Kennedy, Esq. - October 13, 2010

Despite there being not even a single report of illness, there have been numerous instances over the past four years where licensed raw milk dairies in New York and Pennsylvania have had their sales suspended due to positive tests for *Listeria monocytogenes (*L-mono*)*, a sometimes virulent foodborne pathogen. The farmers typically lost a week to two weeks in sales plus the price of any milk the farms received back after issuing a recall due to the discovery of L-mono in a milk sample. Some farmers were also fined for adulteration because the raw milk was deemed to contain a "harmful substance which may render the milk injurious to health."

**FDA has pressured farmstead cheesemakers in Washington state and Missouri into recalling thousands of pounds of cheese due to samples testing positive for L-mono even though in neither case was there a single report of foodborne illness blamed on the farmstead operations.**

For the last thirty-eight years, and possibly further back, there have been no reports of illness caused by the consumption of raw milk that was attributed to L-mono. According to the CDC, for every case of L-mono reported there are two other unreported cases. By way of comparison, for every reported case of salmonella poisoning, there are thirty-eight cases—in other words, if there is a case of illness from L-mono the likelihood is much greater that it will be reported. [1,2]

Recently, the United States Food and Drug Administration (FDA) has pressured farmstead cheesemakers in Washington state and Missouri into recalling thousands of pounds of cheese due to samples testing positive for L-mono even though in neither case was there a single report of foodborne illness blamed on the farmstead operations. Compared to the raw milk incidents mentioned above, the stakes are much higher here. Unlike the raw milk producers who can only sell in their own states due to the federal interstate ban, raw milk cheese aged at least sixty days can be sold anywhere in the U.S. and has a longer shelf life, meaning a great deal more money can be lost due to a recall.

## Morningland Dairy Case

**The Missouri State Milk Board, pressured by FDA, has ordered that the cheese "be condemned as an adulterated, unlawful product" and has sought a court ruling that the product be destroyed.**

The Missouri farmstead operation, Morningland Dairy, not only recalled over sixty thousand pounds of cheese but there is an additional fifty thousand pounds at the facility that is currently under embargo. The value of the embargoed cheese is around $250,000. In the thirty years it has been in business, there has never been a single case of foodborne attributed to the consumption of any of the dairy's products.

The Missouri State Milk Board, pressured by FDA, has ordered that the cheese "be condemned as an adulterated, unlawful product" and has sought a court ruling that the product be destroyed. An inspector from the Milk Board has told the dairy that it must destroy all of the remaining cheese in order to get back into business; cheese production at Morningland has been shutdown since August 26, shortly after the Milk Board was notified by the California Department of Food and Agriculture (CDFA) that samples of Morningland's cheese products had tested positive for L-mono and *Staphylococcus aureus* [Staph aureus, is present normally on everybody's skin and is considered protective. Most subtypes of this organism do not produce the toxin which can occasionally cause vomiting. Gastrointestinal illness from Staph aureus is self limiting—meaning medical treatment is not necessary]. The cheese had been seized at the Rawesome Food Club during

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the June 30 raid of Rawesome's store in Venice. Subsequently, embargoed cheese at the Morningland facility tested positive for L-mono and Staph aureus. Proper protocols for the collection of samples had not been followed in either California or Missouri.

### Current FDA Recall Power

Under federal law, FDA may request a firm to initiate a recall when "determinations have been made "(1) [t]hat a product that has been distributed presents a risk of illness or injury…; (2) [t]hat the firm has not initiated a recall of the product; and (3) [t]hat an agency action is necessary to protect the public health and welfare" [21 CFR 7.45(a)]. The problem with the Washington and Missouri cheese cases is that, in fact, there has not been an adequate level of proof shown to establish that the cheese in question actually presents a risk of illness or injury. A positive L-mono test can shut down or severely damage a business even when there is no legitimate threat to the public health.

**A positive L-mono test can shut down or severely damage a business even when there is no legitimate threat to the public health.**

There are many subtypes of *Listeria monocytogenes*; many of these subtypes have not been implicated in human illness. There are laboratories in the U.S. that have the capability to identify the subtype of L-mono in a food after the initial test for that bacteria is positive. What is happening is that FDA and state agencies are just relying on the initial positive test for L-mono without doing further testing to determine if the subtype is one that has actually caused illness in humans. If the L-mono subtype found in a food has not caused illness in humans, then the food is not adulterated and there should be no product recall since the detected L-mono poses no risk of illness or injury. In the Morningland case there is no danger to the public health by waiting for follow-up test results while the product remains under embargo.

**FDA didn't find any L-mono in the environment at the Morningland plant but it was not for lack of trying; the agency took one hundred environmental swabs in the plant, all of which came up negative.**

Even if the subtype of L-mono is virulent, it still needs to be determined whether the amount of bacteria in the food is enough to cause illness in humans. FDA has a "zero" tolerance policy for L-mono, a standard widely rejected by the scientific community throughout the world. The European Union (EU) allows up to 100 organisms per gram in food at the end of its shelf life.

L-mono is widespread in the environment. If environmental testing at a food plant is positive for L-mono, foods produced in the plant at that time could be found to be adulterated due their having "been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." FDA didn't find any L-mono in the environment at the Morningland plant but it was not for lack of trying; the agency took one hundred environmental swabs in the plant, all of which came up negative. The agency inspector collecting the swabs promised the dairy's owners, Joe and Denise Dixon, that they would be getting a copy of the report but to this date no report has been received.

The views of FDA and many state health and agriculture departments on L-mono can be summarized in a statement made by a Missouri Milk Board inspector to Joe Dixon, "You are lucky if you find listeria," implying the belief that it is either present in all food or present in the environment of all food processing plants. FDA's position is that if a food sample tests positive for L-mono or any other pathogen, any other food produced on the same equipment is adulterated. This position was also

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taken by the Missouri Milk Board in its handling of the Morningland case. A Milk Board inspector told Joe that the embargoed cheese would still be suspect even if samples of it did test negative. When Joe asked the inspector, "Why do we even test?" There was no response.

**S510 – Dangers of Mandatory Recall Power**

The cheese cases are an indicator of what could happen if S510, the FDA Food Safety Modernization Act, passes into law giving FDA mandatory recall power. The cases show how the recall power along with the food safety plan requirement [see HARPC] in the bill would be an effective way for the agency to cripple raw dairy producers who have harmed no one with their products. If S510 passes, state agencies and laboratories will be getting more funding from FDA and the influence of the agency on states in pushing its anti-raw milk agenda will increase. In working toward this end, "*Listeria monocytogenes*," in Joe Dixon's words, "can be FDA's ace in the hole."

**In pushing its anti-raw milk agenda…. *"Listeria monocytogenes,"* in Joe Dixon's words, "can be FDA's ace in the hole."**

ENDNOTES

1. Centers for Disease Control (CDC), Letter from Enteric Diseases Epidemiology Branch, 8 May 2007. Certified copy of response to FOIA 06-0819 including "Foodborne outbreaks associated with unpasteurized milk reported to CDC's National Foodborne Outbreak Surveillance System, 1973-2005 (N=87)"; posted at http://www.farmtoconsumer.org/cdc-foodborne-illness-report-1973-2005.pdf

2. Mead, Paul S., et al**.** "Food-Related Illness and Death in the United States". *Emerging Infectious Diseases*, vol. 5, 1999, pp. 607-25. Synopses, published monthly by the Centers for Disease Control and Prevention (CDC). Obtained online 2 Feb. 2008 at http://www.cdc.gov/ncidod/EID/vol5no5/pdf/mead.pdf

Published online at http://www.cdc.gov/ncidod/EID/vol5no5/mead.htm

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**HYPERLINKS for PDF**

**June 30 raid of Rawesome's store** - News for July 4, 2010 including "What's the FBI Doing in My Milk?" and "Authorities, Including FBI, Raid Aajonus Vonderplanitz' CA Buying Club and Raw Dairy Herdshare" = http://www.farmtoconsumer.org/news/news-4July2010.htm

**FDA Food Safety Modernization Act =**
http://www.ftcldf.org/federal/111_Cong-S510.htm

**HARPC** – "S510 Revised: FDA Coming to a Farm Near You", 23 September 2010 = http://www.farmtoconsumer.org/s510-revised-fda-coming-kennedy.htm

**response to FOIA 06-0819** =
http://www.farmtoconsumer.org/cdc-foodborne-illness-report-1973-2005.pdf

**Food-Related Illness and Death in the United States** =
http://www.farmtoconsumer.org/refdocs/cdc-eid-mead-article-sep-oct-vol-5-no5.pdf