#### 2017 HOUSE AGRICULTURE

HB 1433

# 2017 HOUSE STANDING COMMITTEE MINUTES

# **Agriculture Committee**

Peace Garden Room, State Capitol

HB 1433 2/9/2017 28171

□ Subcommittee □ Conference Committee

Committee Clerk Signature

# Explanation or reason for introduction of bill/resolution:

9000r

Relating to the sale and production of animal-based products

Minutes:

Attachments 1 - 8

Chairman Johnson: Opens the hearing on HB 1433.

**Rep Simons~District 36, Sponsor:** Attachment 1. Below are main points of his testimony which Rep Simons handed in after he was done testifying.

North Dakota Food Freedom Act.

Raw milk is illegal.

This is about liberty and freedom to choose farm fresh food products.

This would not affect federal meat inspection. The push back is the milk from a goat or cow. Previous generations didn't get sick.

Raw food is the solution not the problem. Let supply and demand work its magic.

Raw milk is sold in herd shares.

Wyoming passed the same bill.

# 10:36

**Rep Boschee:** Page 3 & 4, subsections 8-10, those give me the greatest concern because we are absolving all the responsibility of insuring that it is healthy, wholesome food from the producer passing that completely to the consumer. We don't have that, whether we buy at the grocery store or gas station. Why would we provide those protections directly with Food Freedom?

Rep Simons: Could you repeat that?

**Rep Boschee:** This seems to put all responsibility and inherent risk on the consumer versus having a shared responsibility with the producer. We don't have that for any other form of purchasing food in the state.

**Rep Simons:** That is something we could look at; we would be happy to work with you on something that could be reasonable. Could you work with that?

**Rep Boschee:** It doesn't answer my question but it tells me that you are willing to look at that and there are others that have that concern.

**Rep McWilliams:** How has Wyoming handled that issue and have they had any challenges with unsafe products in passing the law.

**Rep Simons:** To my knowledge, they have not had a problem. I'll let someone else answer that question for you.

**Rep Satrom:** I think there are some states that have labeling of raw products, do you have any comments?

**Rep Simons:** Yes, I think there is somebody that will come and speak on that. On page 2, from the producer to the consumer, it's that simple, if you don't know what you are buying you shouldn't be spending money.

**Rep Satrom:** I'm curious about the potential liability. Can we put something in this that says that you can't sue? Is there insurance that can be purchased for these producers? I have traveled around the world and I've seen chicken that sat outside in the open all day, unrefrigerated. I think their immune systems are used to it.

**Rep Simons:** In a free market if someone is unable to consume, how long will I be in business. Could you repeat your first question?

**Rep Satrom:** I have some concerns about the health aspect of this, there have been people that have gotten very, very sick. The first question was about liability.

**Rep Simons:** If someone has a problem, you go to the court system. The free market really answers that question.

**Rep Schreiber-Beck:** Page 3, lines 10 & 11, this section does not preclude an agency from providing assistant consultation or inspection upon request to the producer. Could you expand upon that?

**Rep Simons:** I'm going to refer to someone smarter than me.

**Rep Schreiber-Beck:** Lines 23 & 24, this does not change any requirements for brand or animal health inspections. Can you elaborate on the inspections that will be related to the sale of raw milk?

**Rep Simons:** I'll let a specialist answer that.

**Rep McWilliams:** In other states that have this law, are they currently requiring a liability waiver in the purchase of raw foods?

Rep Simons: I don't know that answer. The good news is, my cows think I am a genius.

**Chairman D Johnson:** You brought up in your testimony, we don't want government involvement in regulation and inspections, so what kind of protection do we have, that the food isn't coming out in the market?

**Rep Simons:** The nature of these businesses, some people I don't buy from, just from appearance, free market.

**Chairman D Johnson:** I don't believe that sort of profiling because if you go to a farmers' market, the produce really doesn't say how it was produced. The safeguard, but if you are dead the next morning. Where is the information at? No one is talking about the health benefits.

**Rep Simons:** When you say "dead the next morning", how many times did that happen when our country was drinking raw milk?

**Chairman D Johnson:** I wasn't talking about raw milk; I didn't say I didn't support raw milk. There's legislation to provide that opportunity of cow shares to circumvent those regulations. When you start talking about canning you don't know what type of kitchen it is coming out of, about 90% will be great but it's the 10% out there that somebody is going to get sick. Sure, it hasn't happened because it's not allowed. That's my concerns.

**Dr. Greg Chuppe~Chiropractor in Bismarck:** I was raised on a ranch where we raised most of our food. This was a simple, less complicated time. As our state became more industrialized, I saw much of our food industry shift from quality to quantity.

A shift from animal production, from free range to animal confinement took place. With this, the rise of antibiotics has occurred. Last year, 25 million pounds of antibiotics were used in the U.S. Only 6 million of that was for human consumption. American Medical Association and health care professions have let us know that it's a problem. We have become antibiotic resistance and we've had issues with it.

To feed the masses, pasteurization and homogenization of our milk became popular. The people I see in my practice, as a health care professional, are health orientated patients and want to access what they know to be healthier foods. They use their food as medication and seldom are on drugs, which cost the health care system a lot less money.

The people that are looking to do raw foods, milk and eggs, usually know the farmers they are getting them from.

As a doctor, my recommendations to my patients to become healthier is to eat more whole foods, the way God made them. Talks about a couple of case studies.

**Vice Chair Trottier:** I was supportive of this bill when we came in here, now I'm starting to change my mind. I Have five questions for you that take a yes or no answer? Are you against treating sick animals with antibiotics?

Dr Chuppe: No, but am against food from animal that is given antibiotics on a regular basis.

Vice Chair Trottier: What about antibiotics for the rest of its life?

**Dr Chuppe:** Yes, on the basis that the antibiotics were given to keep it alive. If they are in a pasture, they don't need antibiotics.

**Vice Chair Trottier:** The grass-fed beef, most of the time is not fed a supplement. As far as nutritional supplements such as salt, iron, Vitamin A, B, E, is that animal just as healthy as an animal that has not been supplemented and fed in a feed lot with a complete nutritional diet?

Dr Chuppe: Grass fed is healthier.

**Vice Chair Trottier:** What about the grass fed animal on pasture that has been sprayed for weeds?

Dr Chuppe: Anytime you adulterate any food, it become unhealthier.

Vice Chair Trottier: But we don't know that, do we if it's been sprayed?

**Dr Chuppe:** I do, but not everyone may know that.

**Rep Headland:** You said you eat grass-fed beef, raw milk, farm fresh eggs. Why do we need this bill?

**Dr Chuppe:** To allow food freedom and to get access to the food. I prefer to get easier access.

**Rep Schreiber-Beck:** Are you able to answer the questions I asked to Rep Simon?

**Dr Chuppe:** The legal aspects of the questions, I refer to the next person coming up.

# 42:10

**LeAnn Harner~Citizen-Mandan, ND:** Attachment 2a-c. I will be off script because you have questions and I will try to answer those. Rep Schreiber-Beck, you asked the point doesn't preclude agencies from helping if the farmer requests the help. Yes, if I understood that correctly.

**Rep Schreiber-Beck:** The cost of doing that, is that an agency cost or something the producer is going to pay the agency for, how would that work?

**Harner:** The expectation that that would be part of agency operations like any time the public asks for assistance when they ask questions about food health we do that as producers now.

Rep Schreiber-Beck: Are you referring to an extension service?

**Harner:** It could be an extension service, a Department of Health or the Department of Agriculture for their standards.

**Representative Schreiber-Beck:** Lines 23 & 24, page 3, could you expound on the animal health inspections? The inspections do not change any requirement on brand or animal health inspections. I'm not sure how that quite fits in, could you explain?

**Harner:** The reason it was, one, it was part of the Wyoming law. Two, we wanted to make sure that nothing changes how we deal with animals. Our animals are still governed under the other cultural systems.

Rep Schreiber-Beck: Is this identical to the Wyoming bill, is there liability issues?

**Harner:** It is very close but not word for word and that's because our century code is different. Continues on her testimony, attachment 2a.

#### 54:15

**Rep Skroch:** Much has been said about healthy, clean, great product. Can you explain why sections 8-10 are needed?

**Harner:** Section 10 basically means if a producer is negligent the producer is liable. The first two sections were to get the informed consumer to give them a little warning that you ask and question.

Talking to Wyoming to find out how they handled liability. The consumer should also accept some liability.

Representative Boschee: If this bill were to pass as written, how do you see self-policing?

**Harner:** This month we started Dakota Goat Association. The industry will come together and we can become the leaders of policing ourselves. Also, the free market will handle it.

**Rep Skroch:** You talk about being a self-policing industry. Have there been any cases of illness from your products to consumers?

**Harner:** No outbreaks. There may be cases where there was raw milk and also illness, but nothing proven back to the raw milk.

Representative Headland: How does this bill align with federal regulations?

Harner: I have researched about as deep as we can go, what we find is not in code.

Wyoming made it work. There is nothing in here that should impair the meat inspection program and we are not talking about red meat at all.

**Rep Satrom:** The consumer should also accept liability; they are accepting risk. Have you talked to your insurance agent?

Harner: I didn't have a chance.

Rep Satrom: What do you think about labeling?

**Harner:** I have no heart burn about labeling, I can develop my own labels and I will have proof I did that. When I sell herd shares, I have a 7-page contract. For pet consumption, I make them sign a disclosure. We want the consumers to do the talking and make the same decisions that you and I can make.

Rep Satrom: What do you think about a pasteurization requirement?

Harner: I wouldn't, we cannot meet the standards without a commercial kitchen.

**Rep McWilliams:** Have other states had problems with a program that would be similar to ours as far as liability concerns?

**Harner:** There are 18 states that allow some form of raw milk. Wyoming is the only one that is comparable to ours.

**Rep McWilliams:** Would you have any challenges requiring a label on a jar or a bundle of carrots. It says "unprocessed raw goods"?

**Harner:** With raw goods, it's a problem because it's not jarred. We have such a broad group of items. Would that be a challenge? The consumers have to use common sense.

**Rep Oliver:** Your position on pasteurization needs a commercial kitchen, you are wrong. There is a 5-step process to pasteurization. The 5-step process is get it in a pot, heat it up to about 145 degrees, keep it there for 30 minutes, put it in a bath, cool it down to 40 degrees and then put it in the refrigerator.

**Harner:** You are right; I pasteurize for certain cheeses. What I should have said was, I can't meet the pasteurization standards required by the government. At least that is what I've been told.

**Rep Oliver:** You are asking this body of legislature to pass a bill. The question to you, could you not pasteurize it & and you answered, we could not make the standards. The standards are here with a simple search on Google. If you are going to give information, you need to give truthful information. That's all I ask.

Harner: I apologize; I was told that I could not meet the pasteurization standard by the department.

**Rep Schreiber-Beck:** I'm reading right now; carriers are dropping liability coverage for raw milk producers. Do you carry insurance now?

**Harner:** I carry insurance with my herd share program and it's not an issue. I did not have a chance to check with my carrier about this.

**Rep Oliver:** Could you please give me a better address than just P Kennedy, so I can look up some items while we study this.

Harner: The web site is www.farmtoconsumer.org.

**Jared Hendrix~Lives & works in Bismarck:** I brought this concept to Luke a couple months ago to introduce it. This is a consumer choice and a bipartisan bill based on the great American principle of free markets.

We already produce and consume all different foods. All this bill says is we can now take these foods down the street to our neighbor and sell. Current law treats you almost the same as a drug dealer of a dangerous product. Soon you can sell medical marijuana but it would be criminal to sell raw milk directly to consumers.

By my assessment, there is no evidence of any outbreak that presents any wide spread systemic public health threat that is the result of the consumption of raw milk. Yes, there are links to raw milk consumption, but it true of all kinds of foods. These are allegations of links to raw milk rather than confirmed cases. The same is true for all the CDC data. Goes on talking about cases & the CDC.

State Health Department has stated that the only way to drink milk safely is to drink pasteurized milk and raw milk is never a guarantee to be a safe product. This is misleading. The only way to have all safety concerns is to simply not drink milk. Anytime you put food in your mouth, you are taking a risk. We are not claiming that drinking raw milk is zero risk, however the real claim that responsible care reduces these risks to a low level.

We are not saying to put raw milk at Wal-Mart, I believe that 99.9% of most sales will be between people that know one another already or are friends of friends. This legislation will encourage small farmers. I believe we should look at this in a balanced and rational way, we should not exaggerate the risk. Everyone should be able to make choices for themselves. I urge a do pass.

**Chairman D Johnson:** Everyone here is a good player. That is why we have cow shares. When you sell raw milk on the open market, you don't necessarily know the producer.

**Hendrix:** We would be interested in a dialogue to what we can do with legislation. Anyone that I would purchase from, I'm going to know them and go to their facility. To the question of "why herd shares" as a consumer I don't regularly go to farmer's market. I don't want to invest in a cow or milk but would like to buy a gallon here and there. For someone like me, it's a perfect opportunity.

Rep McWilliams: How much is a cow share?

Hendrix: I don't participate in one, so I'm not sure.

**Rep McWilliams:** Where are all the cow shares in the state? My wife would like to make cheese and butter.

**Hendrix:** There are a couple in the back here that might want your money. I don't know a whole lot. Because you can't find cow shares is an example why there is a black market.

**Rep Skroch:** You commented that milk would be regulated even more than marijuana. Are there people doing black market sales of milk?

**Hendrix:** I plead the 5<sup>th</sup> on that one.

**Rep Kiefert:** I would like to see some testing of the milk. We fought hard to get herd shares. We need to have protection for the consumer.

**Hendrix:** I would say somebody here is a lot more experienced in the practice to answer that.

Chairman D Johnson: Anyone here to testify in opposition to HB 1433?

# Julie Wagendorf: North Dakota Department of Health: Attachment 3.

#### 1:40:55

**Rep McWilliams:** The CDC website, 1.2 million illness and 450 deaths occur due to nontypical Salmonella in the U.S. The statistics that you brought forward for raw milk, it seems high, except when you put them into context. I'm wondering is that not an outbreak and what is defined as an outbreak?

**Wagendorf:** I have worked for in the role of Environmental Health Practitioner with the division of ND Department of Health Division of Food & Lodging, also the division for the disease control epidemiologist. The division of disease control based on epidemiology outbreaks of diseases and the data is here if you want to hear agency testimony.

The CDC will identify the definition of an outbreak as two or more ill people associated with a common risk of eating the same food.

**Rep McWilliams:** If you came to my house and had bad chicken you bought from the store. We both became sick, that would be considered an outbreak?

**Wagendorf:** Typically what the CDC would consider in that type of instance, would be they are looking at household members and not looking at that as an outbreak that has been spread outside the home. Not contacts in one house.

**Rep Skroch:** Page 3, chapter 2, we have had listeria outbreaks from muskmelon and continues to be on the store shelf. The FDA has not pulled muskmelon out of the market. Can you comment on that?

**Wagendorf:** Listeria in cantaloupe goes to show that bacteria can be in many different food items and environments. In that particular incidence, the FDA found in their investigation that the cantaloupe processing plant they were using equipment meant for potatoes. They didn't clean some of the components, so in that particular outbreak is was a breakdown in the manufacturing of cutting the cantaloupe, not the whole cantaloupe.

**Rep Skroch:** People remember a huge outbreak from spinach. This was a processor that was well known with an inspected product but we can still buy that spinach with that same brand. My question, that is all under inspection and we still can't prevent the outbreaks.

**Wagendorf:** When outbreaks do occur, we learn and we try to implement proper corrective action. The cause was feral pigs in the fields. The had to do more animal control on those farms.

**Rep Skroch:** I don't think we can assume that government regulation has delivered a safe product. We take risk off the shelf an inherent risk.

**Wagendorf:** In 1993 outbreak, the holding tanks for the ice cream base were in trucks where they were also transporting raw eggs. As far as the restaurant inspections, we strive hard to force the regulations. We can inspect once every six months. Statute only requires once every two years. We only have staff to get the minimum done.

**Rep Skroch:** I think you just made my point, you can't possibly inspect everything. So there is some inherent risk. It is wrong to assume that the product is that much less safe.

**Wagendorf:** I appreciate your comment. We work hard to educate on food safety. It's hard to count the numbers that we prevent on a daily basis.

**Rep Schreiber-Beck:** In all the instances the people were insured and it almost broke the companies when they had to make good to the consumer.

**Rep Boschee:** What other remedies are available to the public consumer if you get something bad?

**Wagendorf:** We try to substantiate that complaint. We try to educate the consumer when they call the health department and ask questions.

**Rep Boschee:** It is more corrective than punitive from the Health Department standpoint.

**Wagendorf:** Under the FDA there is civil action and enforcement for the Health Department regulatory authority. We also help with working within the code.

**Rep Hogan:** How much influence do you have in helping standards and codes for the restaurants and grocery stores.

**Wagendorf:** It is difficult to tangibly show what we prevent. We study risk factors and focus on reducing the risk.

**Rep Kiefert:** With the herd share practice going on, do you have any reports of outbreaks?

**Wagendorf:** I'm not aware of any outbreaks. Maybe a different agency would have that data for you.

**Rep McWilliams:** Knowing that we have instances of massive outbreaks in the U.S. from large operations, do we have any quantifiable data that we can look at for raw milk producers to see if they have a higher outbreak or having more of an outbreak than any other product? Do we have numbers?

**Wagendorf:** The reference sheet gives a number of publications. There appear to be more food borne outbreaks in states that have raw milk that's legal and cause hospitalization.

**Rep McWilliams:** You said that it "appeared to be" but yet we don't have hard data.

**Wagendorf:** I am trying to summarize the study and I don't want to misquote it but we do have that study.

Jerry Messer~Dairy Farmer SW North Dakota: I want to share the understanding of what means to us as dairy farmers of what food safety is. We are the one country that has the safest food supply of anywhere.

I have some concerns about the bill written here:

- 1. With our dairy there is not a truckload that is not inspected. If it is traced back, the farmer pays for the whole truck load but also pays for anyone else's milk that was transported on that truck. You are bypassing those steps in this bill. If there is one instance, every producer pays the price, it takes years to get the consumer back.
- 2. The legal part of it. If someone dies, that family can come back, sue you and you will pay for it.
- 3. The informed consumer, whose responsibility is it going to be? I support the education of what, where and how we do it because now the consumer wants to know.

The cow share, they come back to the same farm every time. We drank raw milk and we were used to it. Gave example of guest who got sick from raw milk because they weren't used to it. It puts a huge risk on dairy farmers even though they think they are doing the right thing for raw milk, it's a great way to get legal money.

**Vice Chair Trottier:** When I was a livestock nutritionist, I called on a big dairy farmer. I was invited in for lunch and had commercial pasteurized milk. I asked, don't you drink your own milk out of the bulk tank? They said, we did until a short time ago, our inspector was out and

came in for lunch. He said he had been in the hospital with a staph infection and they traced it back to his milk. We don't drink our milk any more.

**Messer:** When kids grow up on the farm, they are used to it. When we are talking about taking whole raw milk to a farmer's market and you have no control over who consumes that, that's a huge risk.

**Rep Skroch:** No matter how hard we try, there is some risk. Farm kids have good immune systems. I have a great appreciation for what you do. One thing I would like to say, I think there is a slight difference in attitude about dairy between you and large dairies?

**Jerry Messer:** We have all size dairy farms and it is different. I can tell you this, as we grow as an industry, economics dictates the size of dairy farms. The larger the farm gets, the more adaptable to what the consumers need. It is not about the size of the farm, every dairy farmer, their number one goal is "take care of their animals" because that's their livelihood.

Rep McWilliams: How many times have you had to dump a batch of milk?

**Messer:** We have family labor. We have dumped three times because the truck couldn't get to us. I don't mind dumping milk; it protects the consumer. The inspectors will work with you. They help to understand why the rules are in place.

Rep McWilliams: How much have you had to dump due to pathogens in milk?

Messer: Three times in my life time. We test before it leaves the farm.

Rep McWilliams: There is a test kit, can you explain?

**Messer:** The kit tests for 4 or 5 different types of antibiotics. Put a drop into an incubator & if the milk won't culture. All milk, on all shelves, is antibiotic free.

# Shaun Quissell, Livestock Development Director, North Dakota Department of Ag: Attachment 4a & b.

2:28:30

**Rep Boschee:** Outside of the raw milk portion, for the meat inspection, would we have to put the amendment that Wyoming has in order to be in compliance with federal inspection.

Quissell: Yes.

Deanna Wiese~North Dakota Veterinary Medical Association: Attachment 5.

John Dyste~President of North Dakota Grocers Association: Attachment 6. Amendment to exempt us also and liability.

**Becky Reich~Cow Share:** The cow share was a good thing; I have customers who trust me. The bill, there needs to be some regulations but don't close your eyes. The cow share is

cumbersome. Someone asked me how much it costs to buy a cow share, I divided up the value of my cow into 42 parts because that's the milk she would produce in a week, so my cow share is \$42. They paid me to buy into a cow & then they pay \$18 a month for the care of my cow because they have to pay for the care of the cow. So it's basically for one gallon is \$4.

Rep Kiefert: Are there any limitations for as far as you want to expand?

**Reich:** My limitation is labor force. Cass Clay will not come in the yard for 6 cows. With equity & labor force I can do what I want, but it's cumbersome.

**Rep McWilliams:** How many cows would you need for Cass Clay to come and pick up your milk?

Reich: I would have to milk 20 cows.

Chairman D Johnson: Closes the hearing on HB 1433.

Testimony also provided in support but did not speak:

**Peter Bartlett**, Dairy Manager, Bartlett Farms: Attachment 7 **Frank Christensen**, Courtenay: Attachment 8

# 2017 HOUSE STANDING COMMITTEE MINUTES

Agriculture Committee Peace Garden Room, State Capitol

> HB 1433—Committee work 2/16/2017 Job #28454

□ Subcommittee □ Conference Committee



Explanation or reason for introduction of bill/resolution:

Relating to the sale and production of animal-based products

# Minutes:

Attachment 1-6

**Representative Boschee:** (Attachment 1) Explained the amendments. The first part of the amendments removes the liability concerns. These were on page 3, lines 25-29 and on top of page 4, lines 1-6. It protects the producer and there is no expectation of proper handling or preparation of food. There is an expectation of the consumer to know what they are consuming.

The second part is adding language on page 3 to alleviate concerns Wyoming had in order to be in compliance with their federal meat inspection program. I ran these by the Department of Agriculture and they said it looked good specifically to make sure people are able to sell poultry as long as they under the 1,000 number mark each year.

**Representative McWilliams:** Moved to adopt the amendment.

Representative Skroch: Seconded the motion

Representative Schreiber-Beck: Are we still dealing with direct sale of raw milk?

Representative Boschee: I did not do anything with raw milk.

**Representative Schreiber-Beck:** I oppose based on the fact that I do not want to go into raw milk sales and any other sales of home products without proper labeling. It has to be the same requirements just like other products sold in North Dakota. Based on the number of illness created from consuming raw milk, I wouldn't put it for sale on the marketplace.

**Representative McWilliams:** I also have an amendment that includes a warning label.

**Representative Skroch:** I visited with the President of the North Dakota Grocers Association about the amendments. He is more comfortable with it.

Representative Schreiber-Beck: Did this person review the amendment?

Representative Skroch: I told him and he was aware of those sections.

# A Roll Call vote was taken (Representative Boschee amendments #17.0559.02000): Yes <u>11</u>, No <u>3</u>, Absent <u>0</u>.

Amendment adopted.

## (8:44)

**Representative McWilliams:** Explained second amendment (Attachment 2) We had testimony and concerns with labeling of the product. We drafted a warning label to be put into the bill. It then wouldn't fall back on the department and create a fiscal note. This would have to be put on all raw milk sold.

Representative McWilliams: Moved to adopt the amendment.

Representative Skroch: Seconded the motion.

**Representative Headland:** This amendment would leave the sale of raw milk beyond what we allowed in cow shares. We dug deep into this four years ago. I can't vote for something that will legalize the sale of raw milk beyond what we allowed with cow shares. I oppose the amendment.

**Representative Howe:** We have the label language, who will enforce that the labels are properly put on?

**Representative McWilliams:** We don't. How do we know many things that the law requires? We can require the law to check up on everything. That is how government grows bigger.

I did a quick search on dangerous food. We have dangerous things all around us.

**Chairman Dennis Johnson:** With this amendment you are creating a warning label that will add another cost.

**Representative Satrom:** I would feel more comfortable with something about size. It needs to be legible and large enough to read. I still have serious issues. There are inherent dangers. As taxpayers we would end up with those costs if someone gets ill. There are cases where well intentioned families fed their children raw milk and the children are disabled. We also have nothing about age here. There is a concern when you are feeding something to children that you know has dangers.

**Representative Skroch:** The intent of this bill speaks of people's freedom. The consumers do educate themselves. Consider the responsibility of the consumer and how they care for it after it is purchased. I ask you to support this label.

Representative Howe: Tyson Foods has the label they are mandated to have.

**Representative Satrom:** How can we let this go unregulated and yet regulate Grade A dairy?

**Representative Headland**: I keep going back four years ago. Who is responsible if someone gets sick? We did all we could to try to allow for those who wanted it, through the herd share program, would be able to get it. With this any dairy can bottle a few bottles for any neighbor that calls. We can talk about labels but we have to get rid of the language for the sale of raw milk. If we focus on the herd shares we don't need a label.

## (23:40)

**Representative McWilliams:** I believe there is federal language that details the size of the warning label.

**Representative Skroch:** (Response to Representative Satrom) We regulate Grade A dairy because that allows them to be a privileged product. They are subject and entitled to that recognition.

**Representative Schreiber-Beck:** How many people are interested in this? We don't know how many do the herd share. I have read that raw milk nutritional value is the same as pasteurized milk. My assumption is this is already happening. From a state perspective and the liability that the state may share in this, I don't see why we would do this.

Baked products in the kitchens—Pride of Dakota has to follow all the regulations.

**Representative Oliver:** The federal government has set guidelines for the labels. That is found in 21CFR 101.2 subparagraph c and f. Letters need to be 1/16th of an inch for regular label and smaller for these labels because it is smaller packaging.

**Representative Schreiber-Beck:** It would almost have to say in this amendment that it has to follow the federal guideline.

**Chairman Dennis Johnson:** The label is only as good as the paper. If there is no one inspecting, what good is the label?

A Roll Call vote was taken (Representative McWilliams amendment #17.0559.02002): Yes <u>6</u>, No <u>8</u>, Absent <u>0</u>.

Amendment failed

(30:40)

**Representative McWilliams:** Handed out third amendment (Attachment 3). This amendment would take out raw milk from the bill.

Representative Skroch: Moved to adopt the amendment.

Representative McWilliams: Seconded the motion.

**Representative McWilliams:** This still leaves in the raw fruit and vegetables. It opens it up for cottage industry. Many of us have food in a church potluck.

**Representative Skroch**: We have removed the highest objection which is the raw milk. We are opening up the opportunity for cottage industry to produce products according to the law for sale. I think we can overestimate the safety of those products from corporate producers that are under inspection. We have to allow free enterprise to flourish.

**Representative Howe:** This amendment doesn't remove Representative Boschee's amendment?

Representative Oliver: It removes Sections 1, 2, 3.

Representative Skroch: We cannot adopt both?

Chairman Dennis Johnson: We are further amending.

A Roll Call vote was taken (Representative McWilliams amendment #17.0559.02003): Yes <u>11</u>, No <u>3</u>, Absent <u>0</u>.

Amendment adopted.

Representative McWilliams: Moved Do Pass as amended.

Representative Magrum: Seconded the motion.

**Representative Headland:** During the hearing we received a sheet that listed what type of baked goods are already legal for sale. I think that those are rules. If we are going to pass this bill, we should codify those rules into law. Maybe we need to further amend.

**Representative Boschee:** This is an ongoing conversation with the cottage food industry. The Department of Health has the rules but individual public health units have been able to interpret those rules differently. We should have one set of rules throughout the whole state for one marketplace. Some examples: there is a farmer in Ward County that can't sell his vegetables directly to a restaurant in town but he can sell in Bismarck. The restaurant can go to the farmers' market and buy his vegetables. He can't deliver it to the restaurant. There is a farmer in Stutsman County who can't sell eggs in Stutsman County but can in Bismarck-Mandan.

What we have amended is creating one marketplace throughout the state so producers are treated the same in every county. The public health units will have to adapt to what we are passing.

**Representative Oliver:** Page 4 of Julie Wagendorf's testimony from the Health Department lists what is allowed. It is already in law.

A Roll Call vote was taken: Yes <u>11</u>, No <u>3</u>, Absent <u>0</u>.

Do Pass as amended carries.

Representative McWilliams will carry the bill.

Additional testimony provided to the committee at the beginning of committee work. (Did not speak)

#### **Proponent:**

Bonnie Munsch, Capital Farmers Market, Bismarck (Attachment 4)

#### **Opposition:**

Karen Ehrens, Licensed Registered Dietitian (Attachment 5) Julie Wagendorf, North Dakota Department of Health (Attachment 6) Bill LC# 17.0559.02000

Prepared by Legislative Intern 8 February 9, 2017

## PROPOSED AMENDMENT TO HOUSE BILL NO. 1433

Page 3, remove lines 25 through 29

Page 4, remove lines 1 through 6

Page 3, remove lines 16 and 17 and replace with the following:

#### 4. Transactions under this section may not:

- a. Involve interstate commerce; or
- b. Include the sale of uninspected products made from meat, other than poultry if:
  - (1) The producer slaughters no more than one thousand poultry, raised by the producer, during the calendar year;
  - (2) <u>The producer does not buy or sell poultry products, except products produced from</u> <u>poultry raised by the producer; and</u>
  - (3) The poultry product is not adulterated or misbranded.

Renumber accordingly

17.0559.02002 Title.

#### PROPOSED AMENDMENTS TO HOUSE BILL NO. 1433

Page 3, line 22, remove "labeled,"

Page 3, line 23, after "<u>7.</u>" insert <u>"Raw milk sold under this section must be labeled with the following statement:</u>

"WARNING: Raw milk may contain harmful pathogens such as listeria monocytogenes, salmonella spp, E. Coli, and campylobactor. Consumption of raw milk is not recommended by the Centers for Disease Control and Prevention, the Food and Drug Administration, the State Department of Health, or the North Dakota Department of Agriculture. Raw milk is not regulated by the state and is not subject to inspection by the Department of Agriculture. Product is not for resale and must be refrigerated."

8."

Page 3, line 25, replace "<u>8.</u>" with "<u>9.</u>" Page 4, line 1, replace "<u>9.</u>" with "<u>10.</u>" Page 4, line 4, replace "<u>10.</u>" with "<u>11.</u>" Renumber accordingly



17.0559.02003 Title.

# PROPOSED AMENDMENTS TO HOUSE BILL NO. 1433

Page 1, line 3, remove "4-30-33, 4-30-36, 4-30-55.2,"

Page 1, line 3, remove the fourth comma

Page 1, remove lines 6 through 23

Page 2, remove lines 1 through 10

Renumber accordingly

2/16/17 DB

Adopted by the Agriculture Committee

17.0559.02004 Title.03000

February 16, 2017

#### PROPOSED AMENDMENTS TO HOUSE BILL NO. 1433

Page 1, line 3, remove "4-30-33, 4-30-36, 4-30-55.2,"

Page 1, line 3, remove the fourth comma

Page 1, remove lines 6 through 23

Page 2, remove lines 1 through 10

Page 3, line 16, remove "involve interstate commerce or the sale of"

Page 3, replace line 17 with ":

- a. Involve interstate commerce;
- b. Include the sale of uninspected products made from meat, except as provided under subdivision c; or
- c. Include the sale of uninspected products made from poultry, unless:
  - (1) The producer slaughters no more than one thousand poultry raised by the producer during the calendar year;
  - (2) The producer does not buy or sell poultry products, except products produced from poultry raised by the producer; and
  - (3) The poultry product is not adulterated or misbranded."

Page 3, remove lines 25 through 29

Page 4, remove lines 1 through 6

Renumber accordingly

Roll	Call	Vote	#:	1		
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# 2017 HOUSE STANDING COMMITTEE **ROLL CALL VOTES** BILL/RESOLUTION NO. HB 1433

House

Agriculture

Committee

□ Subcommittee

Amendment LC# or Description: 17.0559.02000

Recommendation

Recommendation			
	🛛 Adopt Ame	endment	
	🗆 Do Pass	Do Not Pass	Without Committee Recommendation
	□ As Amend	ed	Rerefer to Appropriations
	Place on C	onsent Calendar	
Other Actions:	Reconside	r	

Motion Made By	Rep. McWilliams	Seconded By	Rep. Skroch	
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X X	X X	Rep. Joshua Boschee Rep. Kathy Hogan	X X	
	Х	Rep. Kathy Hogan	Х	
X				
Х				
Х				
Х	_			
X				
Х			_	
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	X X X X X X	X X X X X X X X	X X X X X X X X X X X X X X X X X X X	X X X X X X X X X X X X X X X X X X X

Yes \_11 \_\_\_\_\_ No \_3 \_\_\_\_\_ Total

Absent 0

Floor Assignment

Committee

Roll Call Vote #: 2

# 2017 HOUSE STANDING COMMITTEE ROLL CALL VOTES BILL/RESOLUTION NO. <u>HB 1433</u>

House A

Agriculture

□ Subcommittee

Amendment LC# or Description: 17.0559.02002

Recommendation			
:	🛛 Adopt Ame	endment	
	Do Pass	Do Not Pass	Without Committee Recommendation
	🗆 As Amend	ed	Rerefer to Appropriations
	□ Place on C	Consent Calendar	
Other Actions:	Reconside	er	

Motion Made By Rep. McWilliams	Seconded By	Rep. Skroch	
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Representatives	Yes	No	Representatives	Yes	No
Chairman Dennis Johnson		Х	Rep. Joshua Boschee	X	
Vice Chairman Wayne Trottier		Х	Rep. Kathy Hogan		Х
Rep. Jake Blum	Х				
Rep. Craig Headland		Х			
Rep. Michael Howe		Х	10.1		
Rep. Dwight Kiefert	X		tion		
Rep. Jeffery Magrum	Х		Alo. ()		
Rep. Aaron McWilliams	X		C-leck		
Rep. Bill Oliver		Х	fait		
Rep. Bernie Satrom		Х			
Rep. Cynthia Schreiber Beck		Х		_	
Rep. Kathy Skroch	X				
Total Yes <u>6</u> Absent 0		No	<u>8</u>		

Floor Assignment

Committee

Roll Call Vote #: 3

# 2017 HOUSE STANDING COMMITTEE ROLL CALL VOTES BILL/RESOLUTION NO. <u>HB 1433</u>

House Aa

Agriculture

□ Subcommittee

Amendment LC# or Description: 17.0559.02003

# Recommendation

Recommendation			
:	🖂 Adopt Ame	endment	
	🗆 Do Pass	🗆 Do Not Pass	Without Committee Recommendation
	🗆 As Amend	ed	Rerefer to Appropriations
	Place on C	consent Calendar	
Other Actions:	Reconside	r	□

Motion Made By	Rep. Skroch	Seconded By	Rep. McWilliams	
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Representatives Yes No Representatives Yes No Chairman Dennis Johnson Х Rep. Joshua Boschee Х Vice Chairman Wayne Trottier Х Rep. Kathy Hogan Х Rep. Jake Blum Х Rep. Craig Headland Х Rep. Michael Howe Х Х Rep. Dwight Kiefert Rep. Jeffery Magrum Х Rep. Aaron McWilliams Х Rep. Bill Oliver Х Х Rep. Bernie Satrom Rep. Cynthia Schreiber Beck Х Rep. Kathy Skroch X Yes 11 No 3 Total

Absent 0

Floor Assignment

			Roll Call Vote #:	4
	BIL	2017 HOUSE STANDING ROLL CALL VO L/RESOLUTION NO	DTES	
House _	Agricu	ulture		Committee
		□ Subcommitte	ee	
Amendmer	nt LC# or [	Description: 17.0559.02004		
Recomme	ndation	<ul> <li>□ Adopt Amendment</li> <li>⊠ Do Pass</li> <li>□ Do Not Pass</li> <li>⊠ As Amended</li> <li>□ Place on Consent Calendar</li> </ul>	<ul> <li>Without Committee Record</li> <li>Rerefer to Appropriations</li> </ul>	
Other Acti	ons:	Reconsider		

Motion Made By Rep. McWilliams Seconded By Rep. Magrum

Representatives	Yes	No	Representatives	Yes	No
Chairman Dennis Johnson		Х	Rep. Joshua Boschee	X	
Vice Chairman Wayne Trottier		Х	Rep. Kathy Hogan	X	
Rep. Jake Blum	Х				
Rep. Craig Headland	X				
Rep. Michael Howe	X				
Rep. Dwight Kiefert	X				
Rep. Jeffery Magrum	X			_	
Rep. Aaron McWilliams	X				
Rep. Bill Oliver	X				
Rep. Bernie Satrom	X				
Rep. Cynthia Schreiber Beck		Х			
Rep. Kathy Skroch	Х				

 Total
 Yes
 11
 No
 3

Absent 0

Floor Assignment Rep. McWilliams

#### REPORT OF STANDING COMMITTEE

HB 1433: Agriculture Committee (Rep. D. Johnson, Chairman) recommends AMENDMENTS AS FOLLOWS and when so amended, recommends DO PASS (11 YEAS, 3 NAYS, 0 ABSENT AND NOT VOTING). HB 1433 was placed on the Sixth order on the calendar.

Page 1, line 3, remove "4-30-33, 4-30-36, 4-30-55.2,"

Page 1, line 3, remove the fourth comma

Page 1, remove lines 6 through 23

Page 2, remove lines 1 through 10

Page 3, line 16, remove "involve interstate commerce or the sale of"

Page 3, replace line 17 with ":

- a. Involve interstate commerce;
- b. Include the sale of uninspected products made from meat, except as provided under subdivision c; or
- c. Include the sale of uninspected products made from poultry, unless:
  - (1) The producer slaughters no more than one thousand poultry raised by the producer during the calendar year;
  - (2) The producer does not buy or sell poultry products, except products produced from poultry raised by the producer; and
  - (3) The poultry product is not adulterated or misbranded."

Page 3, remove lines 25 through 29

Page 4, remove lines 1 through 6

Renumber accordingly

# **2017 SENATE AGRICULTURE**

HB 1433

# 2017 SENATE STANDING COMMITTEE MINUTES

Agriculture Committee

Roosevelt Park Room, State Capitol

HB 1433 3/17/2017 Job # 29413

□ Subcommittee □ Conference Committee

mmen fictures

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution://

Relating to the direct sale of food by the producer to a consumer; relating to the sale and production of animal-based products.

# Minutes:

Attachments: #1 - 7

Chairman Luick: Opened the hearing HB 1433.

(0:30 – 2:40) Representative Simons: Introduced HB 1433 (See Attachment #1).

Senator Larsen: Do you partake in this kind of cottage industry as a producer or consumer?

Representative Simons: I am just a consumer.

(3:30 - 6:45) Jared Hendrix: Testified in Support of HB 1433 (See Attachment #2).

(6:50) Senator Myrdal: On line 4, how is "informed end consumer" enforced?

**Jared Hendrix:** "Informed end consumer" means that the individual has been informed that the product is not licensed, inspected, or regulated.

**Senator Myrdal:** I understand the definition but how do we know that is happening? How do we enforce that that communication happens?

**Jared Hendrix:** It is self-regulating. It is buyer-beware in situations when you go to a bake sale or a church and there are no regulators enforcing there either. (8:30 -15:45) Mr. Hendrix continued to go through HB 1433 line by line (See Attachment #2).

**Senator Klein:** I like "informed end consumer." I spent my life in the grocery business in a small community where I felt we developed those relationships. If this really worked, instead of having inspectors inspect small businesses, couldn't we just put up a placard stating buybeware and get out of the regulatory burden?

Jared Hendrix: Are you speaking for the grocery store?

**Senator Klein:** I am advocating for the little grocery store to not have the inspection because I've always believed the consumer knows what you are doing which is why we trust each other and trust buying local. Why can't we as merchants forgo the inspection also because the consumer would be informed and could shop at their own risk. Wouldn't that be something we could add on and make it broader?

**Jared Hendrix:** I think that is an interesting philosophical discussion but I think it would be best suited in a different bill. This legislation deals only with direct consumer for a home consumption only and it is separate from retail for a number of reasons. There are products sold in grocery stores that are from out of state and I think that brings in interstate concern. I think that is opening up a different territory. Maybe that should be addressed separately but this is intended to be only cottage food for home use only.

**Senator Larsen:** If an industry in a home moves forward what is the insurance department take on the coverage of this? Do we have to have different coverages?

**Jared Hendrix:** We haven't had a lot of talk on the insurance side. We will have someone from the farmers market come and perhaps they can address this. I know for a lot of farmers there are different aspects to their policy if they have a farm stand or what is considered incidental. There are intricacies to insurance depending upon where you are selling.

**Senator Myrdal:** I am going back to the enforcement part. I fully support philosophical liberty argument but it is difficult for me to attempt to codify good faith so the enforcement of it becomes questionable because as we pass law, enforcement is the end. The second question is the liability issue—where is the liability?

**Jared Hendrix:** I think to some extent that risk is not different than what you might purchase elsewhere. If someone mishandles inspected foods, they can get sick as well. If you go through the process and determine what the cause was, I think you would have a good argument for liability.

**Senator Myrdal:** However, in that situation with inspected foods, there is a system of liability but I know there is a consequence and someone is liable for the chicken I bought at the grocery store. In this instance, I want to know where the liability is.

**Jared Hendrix:** I think it is a valid question. I think some of the other people who are testifying who deal with this would be able to answer that.

**Senator Piepkorn:** If this law was passed, what is the major difference I would notice in my local farmers market?

**Jared Hendrix:** The biggest different will be the variety of products. Anything that could be refrigerated except for raw milk would be allowed so the restrictions amongst the 28 health districts would become uniform.

**Chairman Luick:** We are talking about a more involved business structure than what you are doing currently and I have no problem with that. Has there been any testimony on the House side the number of dollars involved with this process or if there are tax consequences for this?

**Jared Hendrix:** When you say dollars, are you referring to the government side or economic development?

**Chairman Luick:** I think that is hard for you to determine but has the tax department weighed in on this at all?

**Jared Hendrix:** We haven't had any discussions with the tax department but I know that prepared foods at farmers markets already qualify for taxes and other food items do not. That would still be true. There will be increased economic activity and increased sales tax revenues in general.

Chairman Luick: So there is no information from the tax department?

Jared Hendrix: Not that I am aware of.

(28:00 – 33:55) Bonnie Munsch, Member, Capital Farmers Market and Growers Association: Testified in Support of HB 1433 (See Attachment #3).

**Senator Larsen:** Do you think the fundraising and the baked goods isn't so much because of allowance of baked goods but because of the last administration's push to not allow those types of foods in the school districts?

**Bonnie Munsch:** I think that may be part of it but there have been instances where someone has baked something with meringue and then been told that that item could not be sold at the bake sale. There are several factors to why bake sales for clubs have fallen out of favor.

**Senator Larsen:** What is the cost of booth space in farmers markets do they have to contract for the year or can they just do it on the weekend?

**Bonnie Munsch:** If you join the Capitol Farmers Market before June first, it cost \$125 and \$175 after June 1<sup>st</sup>. You get a twenty-foot-wide space and that is for some vegetables and canned goods. If crafters want to show up for one day, it costs \$15. The \$125 you get your space July 1<sup>st</sup> – October 31<sup>st</sup>.

**Senator Klein:** I have heard about the mismatched rules and regulations and it seems that whatever happens with this bill we should take a look at making those regulations uniform. Have you had an opportunity why there is disparity in those regulations?

**Bonnie Munsch:** Previously, the gentleman in Burleigh county didn't want to deal with eggs because they have to be kept in a cooler.

Senator Klein: So you are telling me there is too much discretionary authority?

**Bonnie Munsch:** Correct. Now that that man has retired, Bismarck can sell eggs, canned goods, and baked goods.

Lydia Gessele, Harvey, ND: Testified in Support of HB 1433. I currently sell at farmers markets and I also do a farm coop where people are able to place orders with us and then we drop it off directly with to the people. Our biggest problem is regulation. When I started farmers markets in 2000, I could take refrigerated products as long as I had them in a cooler but as of a few years ago, I could no longer do that because they decided it was dangerous to have any kind of cream or custard things at farmers markets. I had customers who still wanted them but I had to quit selling it so it hurt me great deal.

Chairman Luick: In your particular case, did you ever have anyone get sick?

Lydia Gessele: No I didn't. My policy when I sell stuff like that is that I will bake it, I will freeze it, and it comes in coolers. Customers are told to take it home and eat it or refrigerate it right away. In our coop, we had to put a label on to say that we baked in a commercial kitchen rather than a home kitchen and there may be allergens. The change in rule wasn't because someone got sick or was allergic to something, people just decided it was too dangerous to have that kind of thing at markets. I can sell my sour dough breads at some markets but others will not allow them.

**Chairman Luick:** One of the concerns is the consideration of pets and other allergens. Processed foods goes through an event where those factories are inspected.

Senator Klein: Did you have people call you directly for kugen?

Lydia Gessele: I had people who would call me once a month for kugen.

(45:00 – 57:25) Julie Wagendorf, Director, Division of Food and Lodging, ND Department of Health: Testified in Support of HB 1433 if amended (See Attachment #4).

**Senator Klein:** You spoke to a cottage food rules/law, do we have uniformity across the country? Are we more or less prohibitive in ND? Are you using something here that is being done in other states?

**Julie Wagendorf:** There are several states who have cottage food laws, but they do vary amongst states. Some states don't allow any acidified foods. Some states such as California allow cottage foods under cottage food law but they do require certification and a license from the Health Department so they do vary.

**Senator Klein:** You mentioned the federal food and drug act. Often times in the state, we have to comply to maintain federal regulation to maintain sort of status. Are we treading on any issues that would result in a problem with the federal government?

**Julie Wagendorf:** What sets us differently than what is covered under federal authority is that we are including interest state sales only which is we limit it to just in the state of ND. We have to limit the internet and mail order sales because once you expand into that it is hard to say where you are selling product and if it is going to go over state lines. With that

those restricts, and as long as we can make sure these products stay within the state and do not fall under interstate commerce, the FDA would not have regulatory jurisdiction over these products.

**Senator Klein:** You said that each jar needs to identified but in some cases we can get by with a placard. I would support the idea of a placard but are there some products that absolutely nee a label and others that can get by with a placard?

**Julie Wagendorf:** The way we have proposed and drafted the amendments at this point, either/or would be acceptable because we are looking at it as a direct consumer to producer sale. As long as the placard was legible and visible and in sight it would be acceptable.

Senator Klein: Why are there different rules in each county?

Julie Wagendorf: I can't speak to that. The Health Department is provided authority over food under state statute 23-09. Local health departments also administer their local laws under century code and although they have to be at least as stringent as the state, they do have liberty to implement more stringent law requirements. When it comes to monitoring the sales of these types of food items, it becomes apparent that the different local public health units are looking at these from different approaches. The Health Department at this point is not opposed to uniformity, but as I understand it, it would need to be state in statute if you wanted it uniform.

**Senator Klein:** I think we would not have nearly as many discussions if uniformity was a sense across the state.

Senator Larsen: What is the annual cost of having your water well inspected?

Julie Wagendorf: I don't exactly, but it is around \$25.

**Senator Klein:** If you live in a community that has water and sewer, you just need the city manager to give you a certificate, correct?

**Julie Wagendorf:** Correct. If you are on a municipal or rural supply, the state water program is already monitoring and testing that at the required frequency and those certifications are available.

**Senator Klein:** Years back, we bought farm flock eggs until the inspector asked if they had been licensed and it created a hassle so we decided not to do it anymore. This rule has been in place for a long time and are you suggesting with the asterisks that these producers would have to have additional licensing?

**Julie Wagendorf:** We wanted to make sure the farm flock eggs were addressed specifically. Currently for a retail food store that is licensed, in order to sell farm flock eggs, they need to show it is an approved source. The Department of Agriculture offers a yearly license; it's a \$10 inspection fee so they can go to the farm, offer that inspection, and they train the egg dealer on how to properly wash and handle eggs. It's fairly noninvasive but it provides some oversight. If they are able to meet the Department of Agriculture's standards and become a

licensed egg dealer for \$10 a year, we currently would consider them an approved source and allow them at any retail food. We are suggesting to have that oversight to include the farm flock eggs at the farmers market.

Chairman Luick: Were your amendments offered on the House side?

Julie Wagendorf: These specific amendments were not covered on the House side.

**Representative Oliver:** Testified in Support of HB 1433. He said he was not a sponsor on the bill but he supported it on the House Agriculture committee. He provided a definition of a cottage industry from the Webster Dictionary. In response to questions of the committee stated earlier in the hearing, Representative Oliver provided the following answers: 1. Tax issues would be handled similarly to garage sales. 2. The fact sheets the Health Department provided are outdated. 3. In 27 years, there has only been one case of poisoning from improperly canned food. 4. The amendments were not provided to the sponsors of the bill when they visited with the Health Department.

Representative Oliver said the House Agriculture committee had been 14-0 against the bill in the original form but were 11-3 Do Pass on the amended version.

(1:13:00 – 1:19:00) **Jennifer Dockter, Bakery Owner:** Testified in Opposition to HB 1433 (See Attachment #5a). Miss Dockter provided the committee with pictures of cakes from an unlicensed home baker containing health risks (See Attachment #5b). Miss Dockter provided testimony from Kate Halvorson, small bakery and deli owner (See Attachment #5c).

Senator Myrdal: You mentioned liability. As a licensed kitchen, can you explain liability?

**Jennifer Dockter:** Because I am a licensed kitchen, I am required by the state under current food law to carry a liability insurance through an insurance company. I pay a premium every year and if someone becomes ill from a product in my kitchen and I get sued, the insurance would kick in and would help pay past any deductibles. That protects me just like it would protect anyone. If this would pass, there would be no reason for bakers like myself who have licensed kitchens to be a licensed kitchen or carry liability insurance because they would be just like the home baker.

**Senator Klein:** If I am an individual and I get sick on your produce and I propose to litigate, I could sue you. So you would want to continue to carry your liability, would you not? Whether we have this law or not, you are risk, correct?

**Jennifer Dockter:** That is correct. Because I am a state registered business and because I am in the food industry, I am required to have that insurance before I can obtain my license.

(1:22:18 – 1:27:25) **Javin Bedard, Environmental Health Manager, Grand Forks Public Health Department:** Testified in Opposition to HB 1433 (See Attachment #6).

**Senator Klein:** When you go out to that farmers market do you find a lot of instances of improprieties or are people pretty much following the rules? Are you there educating also?

**Javin Bedard:** A lot of it is education. It's providing information on what is allowed and what isn't under code. We run across the home based bakeries and we deal with it in temporary food issues as well.

**Senator Klein:** Currently you cannot bring any baked goods to farmers markets unless we changed the current law?

**Javin Bedard:** We do allow home backed goods. We are following the state guidance sheet the health department handed out in the amendments. Home baked goods are allowed in farmers market but it does not allow products that require refrigeration. With the licensed facilities that are producing kugen, they bring it frozen and they sell it frozen with instructions to bring it home and refrigerate it.

Senator Larsen: Are food trucks allowed to sell in the state?

**Javin Bedard:** When they come to Grand Forks, those sales obtain a grocery license and we inspect their truck and we verify their sanitation.

**Senator Larsen:** So when I go and buy there I should be able to see a sticker saying they are licensed?

Javin Bedard: You should be able to request to see their license.

**Chairman Luick:** When you go to these markets, do you usually see a placard or an individual stamp on a product?

**Javin Bedard:** We see placards as well as labels. I think it is important to have the product labeled so that people can identify who they brought the product from and what it contains. Allergens are concerns that should be on the product label but we do see the placards just notifying people that it is from an uninspected source. We bring them also so if they don't have them on their table, we can hand them out.

**Chairman Luick:** In the information you provided, it is estimated that roughly forty-eightmillion people get sick from food borne illness each here. How about in ND?

**Javin Bedard:** I don't have the statistics for ND. The safety of the food isn't dictated as to whether it's sold at a farmers market or a civic event or as a direct sale. My concern primarily and my request is that we limit it to the low risk food categories and provide that consumer information they need to verify that the food is safe as the State Health Department has put forth in their amendments.

(1:34:10 – 1:36:30) Donna Magrun, Insurance Agent: Testified Neutral on HB 1433. There are insurance companies that provide product liability for all types of things as long as you follow their guidelines. Homeowners insurance and sometimes farm insurance will cover incidentals. If you are running a business, as an agent you are going to ask them what they do and how they do it and instruct them to get product liability to protect them. Insurance companies can provide liability for all kinds.

**Chairman Luick:** As far as what you are hearing, do you think there is a higher liability in these cases?

**Donna Magrun:** No, because it depends on the company you find. There is a business in Sterling that has product liability and they sell of their farm. If you can find a company that will cover you, there shouldn't be an issue. If something were to happen, you would have to show proof of who was negligent. If the product was brought to the consumer and handled in the right way, they are going to be adjusters that take testimony on both sides to determine whether it was producer or consumer error. It only has to be 51 to 49 that you are fault and then the insurance companies usually cover.

**Chairman Luick:** In your opinion, would the location of the notice make any difference whether it is a seal on the container or a placard?

**Donna Magrun:** It would fall under regulations and the insurance's guidelines. If they are going to insure you, you are going to have to follow certain steps to do certain items.

Senator Larsen: What is a policy cost of something like that?

**Donna Magrun:** It all depends on the company and how much you want to insure for. If it is very small, it is around \$250 a year. You could also have a farm insurance and add another product liability to your farm.

(1:40:00 – 1:49:40) **Julia Petrovic, Manager, Slavic Heritage farm:** Testified in Support of HB 1433. Miss Pedorvich shared with the committee her experience coming to ND from Russia. She said that the guidelines provided by the farmers markets were confusing and regulations provided a false sense of security and it ultimately comes down to a matter of ethics. People who work in certified environments are allowed to be trusted to be ethical but local producers of food not allowed to be ethical people.

If we want rural ND to thrive, we should have freedom to be entrepreneurial. After the first year when we had \$1,000 of income, I decided we should have agritourism at our farm and we have been conducting tours and many times people have asked to try our products. My hands are tied. As an entrepreneur, I do not have the freedom to be a business owner. In five years, I noticed five families moved away from ND and there was one family that moved to Ecuador for freedom because they could make value added products on their farm.

This bill ultimately comes down to freedom and human trust and I would ask you to pass HB 1433.

(1:50:30 – 1:56:55) **Daryl Lies, NDFB:** Testified in Support of HB1433. Mr. Lies said he was confused that the Health Department testified in support of the bill but only with amendments. Mr. Lies said NDFB stood in support of HB 1433 in the form received from the House because the Farm Bureau supported freedom, opportunity, self-reliance. He said freedom and opportunity requires self-reliance and self-reliance enables freedom and opportunity and this is a bill about self-reliance because of the relationship between the producer and consumer. He said that competition made America great.

We don't have the opportunity to have a relationship with a consumer and producer directly as freely as if we pass this bill. Other states are ahead of us and Wyoming says this has been a boom to their agriculture community. NDFB doesn't stand for one segment of agriculture Senate Agriculture Committee HB 1433 3/17/2017 Page 9

over another, we believe there is value in all sizes of agriculture and HB 1433 allows that celebration to happen consumer direct to producer. There will still be a need for the bakery and grocery store and custom cake maker. There is enough business for everyone but there are some who want the ability to look their producer in the eye and say that they have faith and confidence in what you are producing just as the family who can go and buy produce from licensed stores.

(1:57:00 – 2:05:00) **Annie Carlson, Morning Joy Farm and Kitchen, Mercer, ND:** Testified in Support of HB 1433. How we are operating now as a small unlicensed producer is utilizing the fact sheet from the Health Department which does require a label or a placard so that is how the information is getting to consumers. As a vendor at farmers markets, I see my fellow vendors with little stickers on each item also with a placard. A requirement of having a license is that my certified commercial kitchen license be posted in a conspicuous place as well as my retail license which is how I inform my customers.

In regard to Senator Klein's comment about grocery stores—I thoroughly support my local grocery store and I am thankful that they are there but they did not make their produce which is where the distinction comes for me. When you are a home producer, you are crafting that food and putting your stamp on it.

With regard to insurance, our farm carries a multitude of policies including home, vehicle, farm and ranch, commercial, retail, and product liability. Our current bill for all of those policies is \$2,253. That number is based on sales volume and venue. We also have a food truck and if you want to talk about inconsistencies, you can see that in the food truck. When it comes to insurance, they want to know the sales volume. We had to increase sales volume on the food truck, decrease it on the retail needs, increase it on the catering, tec. Your insurance agent would work through with you what sales volumes are which indicates risk to the company.

When you are talking about a home-based business you are not producing as much. In my home kitchen prior to the construction of our big kitchen, I could bake five kugen at a time. In my commercial kitchen, I make 50 kugen at a time. So I can ten time increase my production in my commercial space. When you are starting as a home baker, how do you know if you have good kugen? You have to sell it and put it in fro of the public and if it is popular you can consider making the substantial investment into the commercial kitchen.

The current tax structure is based on whether the food is ready to eat or not whether you pay sales tax on it.

Miss Carlson said that the investment in a commercial kitchen is substantial and it doesn't appropriate to ask these farm families to make a \$100,000 investment on retail space before they are permitted to test market their product. She said passing this bill does absolutely nothing for their farm since they are beyond it but she wants to give other producers the ability to test their products.

**Brandon Dockter:** Testified in Opposition to HB 1433. We agree competition is important. However, according to the taxes we just filed, we just invested \$124,000 between supplies and the bakery itself following the law as it is. There is a lot of mention of low risk items but these are the items we deal with and the reason why we had to get a licensed kitchen and bakery. We are for the freedom of selling goods but there is no one stopping you from doing that. In this case, it's almost not competition but almost discrimination against the current individuals like us who had to go out and do all these things and abide by the law.

Senate Agriculture Committee HB 1433 3/17/2017 Page 10

**Javin Bedard:** Testified in Opposition to HB 1433. As follow-up, the competition aspect is not my issue or concern. I think the science is out there on food borne illness and the risk of food safety. We have a wonderful opportunity in this bill to provide for uniformity and open things up. My comments on the competition is just in acknowledgement that that there are some people who have done things correctly who could stand to suffer from this in the investments they have already made. Again, I would request we take into consideration the science of food safety and limit these items to the low risk food products.

Opposition Testimony: **Grant Larson, President, ND Environmental Health Association** (See Attachment #7).

Chairman Luick: Closed the hearing on B 1433.

### 2017 SENATE STANDING COMMITTEE MINUTES

#### **Agriculture Committee**

Roosevelt Park Room, State Capitol

HB 1433 3/23/2017 Job # 29581

SubcommitteeConference Committee

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Committee Clerk Signature

Explanation or reason for introduction of bill/resolution:

Relating to the direct sale of food by the producer to a consumer; relating to the sale and production of animal-based products.

Minutes:

Attachments: #1 - 2

Chairman Luick: Opened the discussion on HB 1433.

**Senator Klein:** Passed out and explained his amendments on HB 1433 (See Attachments #1 and #2). He said his main concern is that there is uniformity across the state.

Chairman Luick: Closed the discussion on HB1433.

### 2017 SENATE STANDING COMMITTEE MINUTES

#### Agriculture Committee

Roosevelt Park Room, State Capitol

HB 1433 3/24/2017 Job # 29670

□ Subcommittee □ Conference Committee

muneres

Committee Clerk Signature

### Explanation or reason for introduction of bill/resolution:

Relating to the direct sale of food by the producer to a consumer; relating to the sale and production of animal-based products

Minutes:

Attachment: #1

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Chairman Luick: Opened the discussion on HB 1433.

**Senator Klein:** Passed out amendment 17.0559.03002 (See Attachment #1). Senator Klein explained amendments.

(4:50) **Senator Larsen:** I know we don't want interstate commerce but if I live in state and I want to make a transaction over the phone or mail, I would like people to be able to do that.

Senator Myrdal: The way I read it, I don't think it's a concern.

**Senator Klein:** The intent is not to conflict with people in state making purchases but we want to control interstate commerce which may run into conflict and we may be putting our producer in jeopardy.

**Senator Larsen:** I don't have a problem if we want to ship things across state but we can leave this in here and discuss it in conference committee.

Chairman Luick: I think you can do that.

**Senator Klein:** Our biggest concern is that no one wants a federal inspector to come. Senator Klein continued to got through the amendments.

Senator Larsen: I wonder if we should change frozen to proper temperature.

**Senator Klein:** The assumption we have in the store is that we have been inspected and we are following the state and federal rules.

Senate Agriculture Committee HB 1433 3/24/2017 Page 2

**Senator Larsen:** In that situation, do you have the proper temperature or whether it needs to be frozen or not?

**Senator Klein:** There is no label but the inspector looks to see what the temperature is to make sure you are maintain the proper temperature.

Senator Klein: Continued to go through his amendments.

(15:30) **Senator Myrdal:** Does this clearly show the liability issues so that those who do produce this are aware that they are liable if there is such a complaint and inspection?

Senator Klein: I think they understand the risks involved.

**Senator Larsen:** Said he had some concerns about a few of the amendments but supported them as whole.

Committee Discussion: The committee discussed the bill and amendments and language.

Senator Klein: Moved to Adopt Amendment 17.0559.03002.

Senator Myrdal: Seconded the motion.

A Roll Call Vote Was Taken: 6 yeas, 0 nays, 0 absent.

Motion carried.

Senator Klein: Moved Do Pass on Engrossed HB 1433 As Amended.

Senator Myrdal: Seconded the motion.

**Committee Discussion:** The committee discussed selling eggs.

A Roll Call Vote Was Taken: 6 yeas, 0 nays, 0 absent.

Motion Carried.

Senator Klein will carry the committee's recommendation to the floor.

17.0559.03002 Title.04000 Prepared by the Legislative Council staff for Senator Klein March 23, 2017

2124-

#### PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1433

Page 1, line 1, replace "section to chapter 19-02.1" with "chapter to title 23"

- Page 1, remove lines 14 through 21
- Page 2, remove lines 1 through 31

#### Page 3, replace lines 1 through 4 with:

"SECTION 2. A new chapter to title 23 of the North Dakota Century Code is created and enacted as follows:

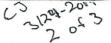
#### **Definitions.**

#### As used in this chapter:

- 1. <u>"Cottage food operator" means an individual who produces or packages</u> cottage food products in a kitchen designed and intended for use by the residents of a private home.
- 2. <u>"Cottage food product" means baked goods, jams, jellies, and other food</u> and drink products produced by a cottage food operator.
- 3. "Delivery" means the transfer of a cottage food product resulting from a transaction between a cottage food operator and an informed end consumer.
- 4. <u>"Farmers market" means a market or group of booths where farmers and other cottage food operators sell cottage food products directly to consumers.</u>
- 5. <u>"Home consumption" means food consumed within a private home or food</u> from a private home consumed only by family members, employees, or nonpaying guests.
- 6. <u>"Informed end consumer" means an individual who is the last individual to</u> purchase a cottage food product and has been informed the cottage food product is not licensed, regulated, or inspected.
- 7. "Transaction" means the exchange of buying and selling.

#### Direct producer to consumer sales of cottage food products.

1. Notwithstanding any other provision of law, a state agency or political subdivision may not require licensure, permitting, certification, inspection, packaging, or labeling that pertains to the preparation or sale of cottage food products under this section. This section does not preclude an agency from providing assistance, consultation, or inspection, upon request, of a producer.



- 2. <u>Transactions under this section must be directly between the cottage food</u> <u>operator and the informed end consumer and be only for home</u> <u>consumption. Transactions may occur at a farm, ranch, farmers market,</u> <u>farm stand, home-based kitchen, or any other venue not otherwise</u> <u>prohibited by law or through delivery.</u>
- 3. Transactions under this section may not:
  - a. Involve interstate commerce;
  - b. <u>Be conducted over the internet or phone, through the mail, or by</u> <u>consignment;</u>
  - <u>c.</u> Include the sale of uninspected products made from meat, except as provided under subdivision d; or
  - d. Include the sale of uninspected products made from poultry, unless:
    - (1) The cottage food operator slaughters no more than one thousand poultry raised by the cottage food operator during the calendar year;
    - (2) The cottage food operator does not buy or sell poultry products, except products produced from poultry raised by the cottage food operator; and
    - (3) The poultry product is not adulterated or misbranded.
- <u>4.</u> Except for whole, unprocessed fruits and vegetables, food prepared by a cottage food operator may not be sold or used in any food establishment, food processing plant, or food store.
- 5. The cottage food operator shall inform the end consumer that any cottage food product or food sold under this section is not certified, labeled, licensed, packaged, regulated, or inspected.
- 6. This section does not change any requirement for brand inspection or animal health inspections.
- 7. A cottage food operator shall label all cottage food products that require refrigeration, such as baked goods containing cream, custard, meringue, cheesecake, pumpkin pie, and cream cheese, with safe handling instructions and a product disclosure statement indicating the product was transported and maintained frozen.
- 8. A cottage food operator shall display a consumer advisory sign at the point of sale or place a label on the cottage food product with the following statement:

"This product is made in a home kitchen that is not inspected by the state or local health department."

<u>9.</u> The state department of health or a local regulating authority may conduct an investigation upon complaint of an illness or environmental health complaint."

Page 3, line 8, replace "chapter 19-02.1" with "section 1 of this Act"

Renumber accordingly

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Date:	
Roll Call Vote #:	1

		ROLL C	ALL V	G COMMITTEE DTES . <u>1433</u>	
Senate Agricult	ure				Committee
		🗆 Sub	commi	ttee	
Amendment LC# or	Description: <u>/7.</u>	0559.	0300	12 Title: 04000	
Recommendation:	<ul> <li>☑ Adopt Amendr</li> <li>□ Do Pass</li> <li>□ As Amended</li> <li>□ Do Pase</li> </ul>	Do Not		<ul> <li>☐ Without Committee Re</li> <li>☐ Rerefer to Appropriation</li> </ul>	
Other Actions:	<ul> <li>□ Place on Cons</li> <li>□ Reconsider</li> </ul>	sent Cale	endar	□	
Motion Made By _	Sen. Kleir	٦	Se	conded By <u>Sen</u>	Myrdal
Sen	ators	Yes	No	Senators	Yes No
Senator Luick		V		Senator Piepkorn	V
Senator Myrdal		V			
Senator Myrdal Senator Klein		V			
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Senator Myrdal Senator Klein Senator Larsen	6		Nc	Senator Piepkorn	
Senator Myrdal Senator Klein Senator Larsen Senator Osland	6		Nc	Senator Piepkorn	

If the vote is on an amendment, briefly indicate intent:

Date:	3/24
Roll Call Vote #:	2

2017 SENATE STANDING	COMMITTEE
ROLL CALL VO	TES
BILL/RESOLUTION NO.	1433

Senate	Agricultu	re					Comn	nittee
			□ Sub	commit	tee			
Amendme	ent LC# or	Description:						
Recomme Other Acti		<ul> <li>□ Adopt Amendm</li> <li>□ Do Pass</li> <li>□ Do Pass</li> <li>□ As Amended</li> <li>□ Place on Cons</li> <li>□ Reconsider</li> </ul>	Do Not			ommittee Reco Appropriations		ation
Other Acti	ons.							
Motion M	lade By _	Sen. Klei	'n	Sec	onded By	Sen M	lyrd	al
	Sena	ators	Yes	No	Sena	ators	Yes	No

Senators	Yes	NO	Senators	Yes	NO
Senator Luick	V		Senator Piepkorn	V	
Senator Myrdal	VI				
Senator Klein	VI				
Senator Larsen	V/				
Senator Osland					

Total	Yes _	6		No	0	 
Absent	_0					 
Floor Ass	ignment	Sen.	Klein			

If the vote is on an amendment, briefly indicate intent:

#### **REPORT OF STANDING COMMITTEE**

HB 1433, as engrossed: Agriculture Committee (Sen. Luick, Chairman) recommends AMENDMENTS AS FOLLOWS and when so amended, recommends DO PASS (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1433 was placed on the Sixth order on the calendar.

Page 1, line 1, replace "section to chapter 19-02.1" with "chapter to title 23"

- Page 1, remove lines 14 through 21
- Page 2, remove lines 1 through 31
- Page 3, replace lines 1 through 4 with:

"SECTION 2. A new chapter to title 23 of the North Dakota Century Code is created and enacted as follows:

#### Definitions.

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- 3. <u>"Delivery" means the transfer of a cottage food product resulting from a transaction between a cottage food operator and an informed end consumer.</u>
- <u>4.</u> <u>"Farmers market" means a market or group of booths where farmers and other cottage food operators sell cottage food products directly to consumers.</u>
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- 7. "Transaction" means the exchange of buying and selling.

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- 2. Transactions under this section must be directly between the cottage food operator and the informed end consumer and be only for home consumption. Transactions may occur at a farm, ranch, farmers market, farm stand, home-based kitchen, or any other venue not otherwise prohibited by law or through delivery.

- 3. Transactions under this section may not:
  - a. Involve interstate commerce;
  - b. <u>Be conducted over the internet or phone, through the mail, or by</u> <u>consignment;</u>
  - <u>c.</u> <u>Include the sale of uninspected products made from meat, except as</u> provided under subdivision d; or
  - d. Include the sale of uninspected products made from poultry, unless:
    - (1) The cottage food operator slaughters no more than one thousand poultry raised by the cottage food operator during the calendar year;
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- <u>4.</u> Except for whole, unprocessed fruits and vegetables, food prepared by a cottage food operator may not be sold or used in any food establishment, food processing plant, or food store.
- 5. <u>The cottage food operator shall inform the end consumer that any</u> <u>cottage food product or food sold under this section is not certified,</u> <u>labeled, licensed, packaged, regulated, or inspected.</u>
- <u>6.</u> <u>This section does not change any requirement for brand inspection or animal health inspections.</u>
- 7. A cottage food operator shall label all cottage food products that require refrigeration, such as baked goods containing cream, custard, meringue, cheesecake, pumpkin pie, and cream cheese, with safe handling instructions and a product disclosure statement indicating the product was transported and maintained frozen.
- 8. A cottage food operator shall display a consumer advisory sign at the point of sale or place a label on the cottage food product with the following statement:

"This product is made in a home kitchen that is not inspected by the state or local health department."

9. <u>The state department of health or a local regulating authority may</u> <u>conduct an investigation upon complaint of an illness or environmental</u> <u>health complaint.</u>"

Page 3, line 8, replace "chapter 19-02.1" with "section 1 of this Act"

Renumber accordingly

2017 TESTIMONY

HB 1433

I am representative Luke Simons from District 36. I'm here today to present to you HB 1433, which thousands of North Dakotans lovingly refer to as the North Dakota Food Freeder I think it is very important to note market.

market issue!

We are talking about food freedom here -- but healthy wholesome food. This bill is more than just food it's about liberty and the freedom to choose.

I think it is important to note we are not wanting to put food or drinks on the market as in grocery stores or restaurants, but rather straight from a producer to consumer. That means straight off the farm or ranch, farmers market or even a food stand.

This bill would not affect federal meat inspection under current law at all.

HB 1433 would open a free market in a free country. I recently was in Honduras; food markets were everywhere, all types of farm fresh food products were bountiful. It was so refreshing to see wholesome food available in a supposedly non-free country!

The big push back here from the agencies is really about milk straight from a cow or a goat. I would remind you growing up a lot of you drank milk straight from a cow (fresh milk is what is referred to as raw milk) If you did not drink fresh milk, your parents most likely did and your grandparents did not know anything but fresh milk. Did they get sick?

Over 97% of the world drinks fresh milk, so where is the problem? Where is all the proof? The problem is not with wholesome foods. In fact, when it comes to health and wellness, they are the answer to the problem.

At a time when North Dakota is looking for fewer laws and fewer ways to accuse law-abiding citizens. Let's push back. Give the consumer freedom to choose. Give the producer freedom of to sell. Let supply and demand work its magic.

Raw milk is currently being sold here in North Dakota as we speak through the herd-shares program. And there is no proof of any public outbreak of illness.

Do we not find it sad that in a free country you cannot sell a bowl of chicken noodle soup? Currently, you can legally grow carrots, make noodles and butcher up to 1000 chickens on your own farm and sell those products to the consumer. However, you cannot mix the ingredients?!?

How about kuchen, a true North Dakota tradition? But from your own home, you're an outlaw? I ask you how many of you have gotten sick from your own kitchen?

We must push back on these overreaching government agencies who tell us what we can and cannot do in our own home! After all, this is a free country and consumer choice s a beautiful thing.

North Dakotan's want food freedom. Our ND Food freedom Facebook page & website, are getting tens of thousands of views and support from all over North Dakota.

We all know the phrase: "I'm from the government, and I'm here to help!"

We don't need the government's help. Informed people can make their own choices. And we can help ourselves.

Thank you Mr. Chairman, and members of the committee. I so very much appreciate your time. Ladies and gentlemen, I will be happy to take questions but I know for a fact that at least dozen or so folks have come from all over the state to testify. I would like to step aside and allow them to share their thoughts.

2a 2/9/17

## HB 1433 Supporting Testimony

Presented by LeAnn Harner, Mandan, ND Phone: 701-667-4185 Email: <u>goat@harnerfarm.net</u>

#### It's about consumer choice:

- I'm a consumer and a producer.
- This is about informed consumers talking to the source of their food.
- This is giving consumers another option for food, and, in some areas, an option that is far closer to home than a grocery store.
- This is keeping rural dollars in rural communities.

#### We are concerned about food safety, but accept life has risks.

- No one in this room wants anyone to get sick from their products.
- As producers, we're the first line of defense.
- As consumers, we have to use good common sense.
- Nothing in this legislation prevents a consumer from pasteurizing their own milk.
- Together, we need to do a lot of education...but it's hard to do education when a product is illegal.

#### Already, we are doing some education with producers.

- Since 2012, the dairy goat community has hosted an event for goat evaluation that always includes a milking demonstration and informal discussion.
- Last fall we hosted a tour of two dairy goat operations which included milking parlors and equipment with plenty of information on sanitation, herd shares and other issues relating to milk.
- This month, we launched the Dakota Goat Association to facilitate better communication between all types of goat owners and help broaden our educational efforts.
- We're working with county extension agents on all these efforts.
- Personally, I host the BSC animal nutrition class each year for an experiment with milk production. The students all milk a goat and we discuss proper procedures and sanitation.

#### We've had discussions on doing more.

- Group just for people selling herd shares/raw milk to develop our own standards and information for the public in cooperation with agencies.
- This possibly could be expanded to include all producers in the Food Freedom Act.

#### But there's more.....

- DNA testing for proteins. Some people are allergic to individual milk proteins. Through testing, we can identify individual animals who produce milk with certain proteins that the person may not react to.
- Just starting preliminary work with USDA-ARS Human Nutrition Center to test goat milk for certain fatty acids and see if we can relate certain acids with a particular type of animal nutrition.

#### We always say ND farmers are the best! Please put your confidence in our producers and support HB 1433.

## Feb. 9, 2017.

## HB 1433



United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW, Washington, D.C. 20250

Mr. Dean Finkenbinder, Manager Consumer Health Services Wyoming Department of Agriculture 2219 Carey Avenue Cheyenne, WY 82002

MAR 2 1 2016

Dear Mr. Finkenbinder:

This letter is in response to your e-mail of February 18, 2016, in which you told us that the proposed bill in Wyoming titled "Wyoming Food Freedom Act" (WFFA) (Wyoming Statues (W.S.) § 11-49-101 et seq.) had been updated by new proposed legislation, House Bill 0104 (HB0104). This new legislation would create an exemption for the sale of prepared food products containing meat in Wyoming if the meat was sold or provided by a commercial food establishment, as defined by the WFFA.

FSIS remains concerned that the WFFA, as amended by HB0104, would contravene Federal food safety laws and regulations. If such legislation is enacted and implemented, the Wyoming meat inspection program operated by the Wyoming Department of Agriculture would likely no longer be maintaining requirements that are "at least equal to" those set out in the Federal Meat Inspection Act (FMIA) in Title 21 of the United States Code (U.S.C.) (601-683).

As we discussed in our previous letter to you, dated February 18, 2016, the FMIA (21 U.S.C. 661(a)(1)) authorizes the Secretary to cooperate with States in developing and administering a State meat inspection program in any State that has enacted a State meat inspection law that imposes mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements that are at least equal to those under found in the Act<sup>1</sup> (9 CFR 321.1(a)). Under section 623(d) of the FMIA, the adulteration and misbranding provisions of the Act apply to articles exempted or not required to be inspected under the FMIA (9 CFR 303.1(f)).

If a State is going to exempt any meat products from regular inspection under its own inspection program, the provisions allowing that exemption must be "at least equal to" corresponding provisions found in the FMIA or FSIS's meat inspection regulations.<sup>2</sup>

2 An "at least equal to" exemption is one that addresses the same issue addressed by the Federal exemption.



<sup>1</sup> With respect to all or certain classes of persons engaged in the State in slaughtering cattle, sheep, swine, goats, or equines, or preparing the carcasses, parts thereof, meat or meat food products, of any such animals for use as human food solely for distribution within such State.

#### Mr. Finkenbinder

If any producer or producer's agent were to sell to any consumer or other entity meat or meat products that were not exempted by specific provisions in the FMIA and that were not inspected and passed by an employee or official of FSIS or Wyoming under its cooperative inspection agreement with FSIS, then the sale would violate Federal law. The exemption proposed by Wyoming would create a requirement that is different from that included in the FMIA, and would therefore violate the Act.

HB0104 contains an exemption similar to that in the FMIA and its implementing regulations for retail stores or restaurants. The requirements of the Act and the meat inspection regulations for the inspection of the preparation of products do not apply to operations traditionally and usually conducted at retail stores and restaurants, when conducted for sale in normal retail quantities or services of such articles to consumers at such establishments. Under HB0104, the sale of prepared food products containing meat is exempt from the WFFA if the meat was sold or provided by a commercial food establishment as defined by W.S. 35-7-110(a)(xxxi). A commercial food establishment defined by W.S. 35-7-11(a)(xxxi) "means and includes any place or area of any establishment that is a wholesale or retail business where food, drugs, devices and cosmetics are displayed for sale, *manufactured, processed*, packed, held and stored."

The inclusion of a wholesale business and the manufacturing and processing of foods in the definition of a commercial food establishment in HB0104 makes the WFFA not "at least equal" to FSIS's meat inspection program. The FMIA's retail exemption applies only to operations conducted at retail stores and restaurants. It does not apply to entities that "... otherwise manufacture or process" meat or meat food products (21 U.S.C. 601(1)), such as wholesalers. The meat inspection regulations define a retail store, among other things, as a business where sales of products are made to consumers only and no sale of product is made in excess of a normal retail quantity (9 CFR 303.1(d)(2)(iii)(a) and (d)). A wholesaler, by contrast, not only sells goods to retailers for resale to consumers and in relatively large quantities, i.e., in excess of normal retail quantity, but it manufactures or processes meat or meat products. Wholesalers also use meat ... products that are federally or State-inspected and passed (Original Honey Baked Ham Co. of Georgia, Inc., v. Glickman, 172 F.3d 885 (1999)). By permitting wholesalers that manufacture or process meat or meat products to sell or provide prepared food products containing meat that is not federally or State-inspected and passed to informed end users, HB0104's exemption creates a requirement that is different from that included in the meat inspection regulations, and would therefore violate the those regulations.

FSIS is also concerned that other provisions of the WFFA would contravene Federal food safety laws and regulations. Section 1, paragraph D, of the WFFA (§ 11-49-103(v)(D)) covers transactions involving the sale of prepared food products containing meat if the meat was sold or provided by a commercial food establishment – which may be a wholesale or retail establishment.

An Equal Opportunity Provider and Employer





As discussed previously, FSIS requires meat and meat products sold in commerce, other than those under specific exemptions, to have been inspected. Meat products sold at retail must be made from inspected meat or meat products. To be at least equal to FSIS requirements, the Wyoming legislation must similarly require meat and meat products that are sold at retail to have been prepared from inspected meat.

Section 11-49-103(c), on transactions under the WFFA, contains imprecisions, classifying with sales of "meat products," for the purpose of including them in WFFA coverage, sales of live animals and sales of portions of animals for future delivery – said portions having derived from custom slaughter or processing, or personal slaughter or processing at a State-licensed facility. The provision, in spite of its awkward wording, appears to be setting out requirements "at least equal to" the Federal, in so far as it concerns custom slaughter and processing, because Federal regulations do not require licensing of custom slaughtering and processing facilities.

On the other hand, the provision contains an ambiguity, permitting "the sale of portions of animals for future delivery." The sale could be of portions processed by the purchaser – in effect, the product of personal slaughter or further processing. The sale could also be by a State-licensed facility, which could be a custom slaughter or processing facility, but to whom? If to any "informed end-user," the sale might be of the product of custom slaughter or processing to a person other than the one who initially arranged the slaughter or processing. This would be, in effect, a retail sale, but of an uninspected product. To the extent that the Wyoming legislation permits this type of transaction, it would not be "at least equal to" Federal requirements.

FSIS is also concerned that the WFFA would violate the requirements of the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451-472) and its implementing regulations (9 CFR Part 381). If such legislation is enacted and implemented, the Wyoming poultry inspection program that the Wyoming Department of Agriculture has the authority to operate would likely no longer maintain requirements "at least equal to" those set out in the PPIA.

As with meat, Congress has articulated a policy to protect the consuming public from poultry and poultry products that are adulterated or misbranded and to assist efforts by States and other jurisdictions to accomplish this objective. The PPIA (21 U.S.C. 454(a)(1)) authorizes the Secretary to cooperate with States in developing and administering a State poultry product inspection program in any State which has enacted a mandatory State poultry product inspection law that imposes ante mortem and post-mortem inspection, reinspection and sanitation requirements that are at least equal to those under the PPIA<sup>3</sup> (9 CFR 381.185(a)).

3 With respect to all or certain classes of persons engaged in the State in slaughtering poultry or processing poultry products for use as human food solely for distribution within such State. An Equal Opportunity Provider and Employer

#### Mr. Finkenbinder

The PPIA stipulates that States may not impose requirements for premises, facilities and operations of any official establishment which are in addition to, or different than those found in the Act (U.S.C. 467(e)). In addition, the adulteration and misbranding provisions of the PPIA apply to articles exempted or not required to be inspected under the PPIA (21 U.S.C. 464(e) and 9 CFR 381.10(d)(4)). The exemption proposed by Wyoming would create a requirement that is different from those included in the PPIA, and would therefore violate the Act.

Each proposed exemption must be "at least equal to" an exemption found in the PPIA or FSIS regulations. If any producer or producer's agent were to sell to any consumer or other entity poultry products that were not exempted by specific provisions in the PPIA (for example, but not limited to, 21 U.S.C. 464), and that were not inspected and passed by an employee or official of FSIS or Wyoming under its cooperative inspection agreement with FSIS, then the sale would violate Federal law.

The WFFA would permit the sale of poultry and poultry products consistent with the Act without inspection, packaging, or labeling being required by the State or any political subdivision of the State (W.S. § 11-49-103(c)(v)(A)). This provision is not similar to any of the PPIA's seven exemptions from inspection. All of the PPIA's exemptions permitting the sale of poultry or poultry products require the poultry or poultry products from which the retail products are derived to have been inspected, except for those retail products processed by a poultry grower who slaughters, in a calendar year for use as human food, no more than 1,000 poultry of his or her own raising. However, the WFFA does not restrict the sale of poultry or poultry products to poultry growers who slaughter no more than 1,000 poultry of their own raising in a calendar year. Further, that Act does not restrict the buying or selling of poultry products to those produced from poultry raised on the poultry grower's own farm nor does it require the grower to keep records necessary for the effective enforcement of that Act. Before the exemption for poultry growers who slaughter no more than 1,000 poultry in a calendar year for use as human food may be used to produce such products without inspection, in accordance with the PPIA, these other requirements must also be met. For these reasons, the WFFA is not "at least equal" to the PPIA.

Further, the PPIA requires exempted articles or articles not required to be inspected under the Act to be in compliance with its adulteration or misbranding provisions, other than the requirement for the products to bear the inspection legend (21 U.S.C. 464(e) and 9 CFR 381.10(d)(4)). Wyoming's legislation, however, specifically exempts the sale of poultry and poultry products from inspection, packaging, or labeling standards required by the State or any political subdivision of the State. As a result, those products, which could be capable of human food, might be adulterated or misbranded at the time of such sale or offer for sale, in violation of the PPIA.

An Equal Opportunity Provider and Employer







#### Mr. Finkenbinder

As a result, those products, which could be capable of human food, might be adulterated or misbranded at the time of such sale or offer for sale, in violation of the PPIA.

Thank you again for your e-mail on this issue. If you have additional questions, please contact Elizabeth Starrett at (402) 344-5113, or me or my staff at (202) 205-0495.

Sincerely,

phin

Daniel L. Engeljohn, Ph.D. Assistant Administrator Office of Policy and Program Development

17LSO-0441

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STATE OF WYOMING HB1433

HOUSE BILL NO. HB0129

Food freedom act-amendments.

2017

Feb. 9,2017

Sponsored by: Representative(s) Lindholm, Blackburn, Blake, Halverson, Hunt, Laursen, Pelkey, Salazar, Steinmetz and Winters and Senator(s) Barnard, Boner, Christensen and Driskill

#### A BILL

#### for

1	AN ACT relating to agriculture; extending the Wyoming Food
2	Freedom Act to apply to home processed food; authorizing
3	sales of certain meat products and animals under the act;
4	allowing transactions at producers' homes; amending
5	definitions; authorizing agencies to provide requested
6	assistance to producers; and providing for an effective
7	date.
8	
9	Be It Enacted by the Legislature of the State of Wyoming:
10	
11	Section 1. W.S. 11-49-101, 11-49-102(a)(intro), (iv),
12	(vi) and by creating new paragraphs (viii) and (ix),
13	11-49-103(a)(intro), (b), (c)(intro), (v), by creating a

HB0129

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2017
                    STATE OF WYOMING
new paragraph (vi), (d), (e), (g), (h) and by creating a
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17LSO-0441
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1
    new subsection (j) are amended to read:
 2
 3
 4
         11-49-101. Short title.
 5
 6
    This article act is known and may be cited as the "Wyoming
 7
    Food Freedom Act."
 8
         11-49-102. Definitions.
 9
10
11
       (a) As used in this article act:
12
              (iv) "Homemade" means food that is prepared or
13
14
    processed in a private home kitchen, that is not licensed,
15
    inspected or regulated;
16
17
              (vi) "Producer" means any person who grows,
18
    harvests, or produces prepares or processes any product
19
    which may be consumed as food or drink food or drink
20
    products on the person's owned or leased property;
21
```

(viii) "Process" means operations a producer 1 performs in the making or treatment of the producer's food 2 3 or drink products; 4 5 (ix) "This act" means W.S. 11-49-101 through 11-49-103. 6 7 8 11-49-103. Wyoming Food Freedom Act; purpose; 9 exemptions; assumption of risk. 10 (a) The purpose of the Wyoming Food Freedom Act is to 11 12 allow for the a producer's production and sale and consumption of homemade foods food or drink products for an 13 14 informed end consumer's home consumption and to encourage 15 the expansion of agricultural sales by at farmers markets, ranches, farms and home based producers and accessibility 16 17 of the same to informed end consumers producers' homes by: 18 19 (b) Notwithstanding any other provisions of law, 20 there shall be no Homemade food products produced, sold and 21 consumed in compliance with the Wyoming Food Freedom Act shall be exempt from state licensure, permitting, 22 23 certification, inspection, packaging or and labeling

2017

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STATE OF WYOMING 17LSO-0441

1	required by any state governmental agency or any agency of
2	any political subdivision of the state which pertains to
3	the preparation, serving, use, consumption or storage of
4	foods or food products under the Wyoming Food Freedom Act.
5	Nothing in this article shall preclude an agency from
6	providing assistance, consultation or inspection, when
7	requested by the producer requirements.
8	
9	(c) Transactions under this section act shall:
10	
11	(v) Not involve the sale of meat products,
12	except with the following exceptions:
13	
14	(A) The sale of poultry and poultry
15	products <del>consistent with this article so long as the</del>
16	poultry product is not adulterated or misbranded under
17	Wyoming law;
18	
19	(B) The sale of live animals <u>; intended for</u>
20	slaughter;
21	
22	(C) The sale of portions of <u>live</u> animals
23	before slaughter for future delivery; provided that the

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HB0129

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17LSO-0441

1	processing of the animals is done by the purchaser or by a
2	Wyoming or federally licensed processing facility.
3	
4	(D) The sale of domestic rabbit meat.
5	
6	(vi) Only occur at farmers markets, farms,
7	ranches, producer's homes or offices or any location the
8	producer and the informed end consumer agree to.
9	
10	(d) Except for raw, unprocessed <del>fruit <u>fruits</u> and</del>
11	vegetables, food shall not be sold or used in any
12	commercial food establishment unless the food has been
13	labeled, licensed, packaged, regulated or inspected as
14	required by law.
15	
16	(e) The producer shall inform the end consumer that
17	any food product or food sold at a farmers market or
18	through ranch, farm or home based sales pursuant to this
19	section act is not certified, labeled, licensed, packaged,
20	regulated or inspected.
21	

STATE OF WYOMING

1 (g) Nothing in this article act shall be construed to impede the Wyoming department of health in 2 any 3 investigation of food borne illness. 4 5 (h) Nothing in this article act shall be construed to 6 change the requirements for brand inspection or animal 7 health inspections. 8 9 (j) Nothing in this act shall preclude an agency from providing assistance, consultation or inspection, at the 10 11 request of the producer. 12 13 Section 2. W.S. 11-49-103(f) is repealed. 14 15 Section 3. This act is effective July 1, 2017. 16 17 (END)

HB0129HS001

....

1	Page 4-lines 14 through 17 Delete entirely and insert:
2	
3	"(A) The sale of poultry and poultry products
4	consistent with this article; provided:
5	
6	(I) The producer slaughters not more than
7	one thousand (1,000) poultry of his own raising during any one
8	(1) calendar year;
9	
10	(II) The producer does not engage in buying
11	or selling poultry products other than those produced from
12	poultry of his own raising; and
13	
14	(III) The poultry product is not adulterated
15	or misbranded.". HUNT, VICE-CHAIRMAN
16	

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### Testimony House Bill 1433 House Agriculture Committee February 9, 2017; 2:30 p.m. North Dakota Department of Health

Good morning Chairman Johnson and members of the House Agriculture Committee. My name is Julie Wagendorf. I am an environmental health practitioner for the North Dakota Department of Health Division of Food and Lodging. The Division of Disease Control also provided information included in this written testimony. I am here today to testify on the behalf of the Department in opposition to House Bill 1433.

The Department of Health opposes House Bill 1433 largely due to the inclusion of unpasteurized 'raw milk and raw milk products' in the ND Food Drug and Cosmetic Act NDCC Chapter 19-02.1 which the Department of Health is responsible for enforcing. The Department of Health, as well as the Centers for Disease Control and Prevention (CDC) and the U. S. Food and Drug Administration (FDA), recommends against consuming raw milk and raw milk products because these products can carry harmful bacteria, viruses, or parasites that can make people sick (examples include *Salmonella*, *E. coli*, *Campylobacter*, *Listeria*, *Mycobacteria bovis*, *Brucella*, *Giardia*, and others).

Getting sick from raw milk or raw dairy products can involve several days of diarrhea, sometimes bloody diarrhea, stomach cramping, and vomiting. Although not as common, severe infections can lead to kidney failure, paralysis, chronic health conditions, and even death. Young children are more likely to suffer the consequences of severe illness than adults. Pregnant women, senior citizens, and people with weakened immune systems also are more likely to get seriously ill from the germs in raw milk.

Nationwide, of dairy product-associated outbreaks reported to the CDC through 2007 and 2012, 81 percent were found to be associated with consumption of raw milk or cheeses made from raw milk. During this 6-year time frame, the CDC analyzed 81 outbreaks due to the consumption of raw milk reported from 26 states. The most frequent organisms responsible for these outbreaks were *Campylobacter*, *E. coli* O157, or *Salmonella*, accounting for 979 sick people and 73 hospitalizations. A substantial proportion of the raw milk-associated disease burden was found in children – nearly 60 percent involved at least one child under

the age of five. In addition, CDC reported that unpasteurized milk is 150 times more likely to cause foodborne illness and results in 13 times more hospitalizations than illnesses involving pasteurized milk products.

In North Dakota, from 2012-2016 there were 23 *Salmonella, E. coli,* and *Campylobacter* cases who reported consuming raw milk or raw milk products during their incubation period. Approximately one-third of confirmed cases consuming raw milk in North Dakota were children under the age of 18. By enacting this legislation, the likelihood of exposure to illness-causing germs will increase, resulting in higher case counts, increased hospitalizations, and an increased number of foodborne outbreaks in the state. Analysis by the CDC has revealed that the states where the sale of raw milk was legal had more than twice the rate of raw milk-related outbreaks as states where it was illegal.

The occurrence and determinants of disease outbreaks associated with consuming raw milk in the U.S. is well documented and widely received by local, state, and federal public health officials, health care providers, and academia. For instance, the American Academy of Pediatrics released a position statement that advises against the consumption of nonpasteurized (raw) dairy products by infants, children, and pregnant women, and recommends that pediatricians counsel caregivers against consumption of these products. Please refer to the provided reference handout for additional examples. A producer may contest this information by underscoring the need for the end consumer to become educated and be more informed by asking the right questions, getting to know your farmer, and only buying raw milk from 'clean' farms with 'healthy animals.' Salmonella, E. coli, Campylobacter, and Listeria are types of bacteria that are commonly found in an animal farm environment and can be carried in milking animals including cows, sheep, and goats. Animals that carry these and other germs usually appear healthy; therefore, a health assessment of the animal is not an effective means for controlling harmful bacteria on the farm or in milk.

Furthermore, presence of bacteria in the environment or in a milk product is not obvious by sight, smell, or taste. Milk can get contaminated on a farm by different ways such as from the environment (e.g., cow feces, dirt, processing equipment), infection of the cow's udder, cow disease (bovine tuberculosis or brucellosis), insects, rodents, or by humans cross-contaminating with soiled hands. The concern the Department of Health has about introducing raw milk and raw milk products into markets does not necessarily reflect on the producer, how the producer cares for and keeps their animals, or how clean and sanitary the environment on the farm is. Pasteurization provides a 'kill step' and is the only way to eliminate bacteria in milk that can make people sick.

No matter what precautions are taken by the producer, there is no guarantee that the unpasteurized milk is free of harmful germs. Furthermore, raw milk products – yogurt, cottage cheese, cheeses, whipping cream, cheese curds, sour cream, buttermilk, ice cream – lead to an even higher risk for contamination since these products undergo more complex processing then the raw milk they are made from.

In addition to pasteurization, controlling for the growth of harmful bacteria such as *Listeria* in dairy products also requires monitoring of cold holding temperatures at or below 41° F and controlling the shelf-life of product using date marking. House Bill 1433 could potentially allow raw milk and raw milk products that already have a higher probability of *Listeria* contamination to be transported from the farm to farmers markets, farm stands, meeting places for end consumers, etc., without oversight of proper packaging and temperature controls during storage, transportation, or while on display. *Listeria* grows readily in the environment at temperatures as low as 45° F and can survive for long periods of time. In order to control for this dangerous bacteria, proper cleaning methods are needed, temperature monitoring for cold holding is required, and disposal of expired products is important. *Listeria* infection is extremely dangerous for a pregnant woman and her fetus. This bacteria can cross the placenta and infect an unborn fetus resulting in stillbirth, pre-term labor, or spontaneous abortion.

Section 4-30-55.2 on page two of HB 1433 does not include any requirements of a label or availability of a written statement that informs the end consumer about safe handling instructions and, most importantly, a consumer advisory that clearly warns people of the health risks they are assuming. Additionally, this law will allow for the consumption of raw milk and raw milk products by individuals unable to make informed decisions such as young children and even some aging seniors. As you recall from earlier in my testimony, these groups are at increased risk for infection and severe complications from illness.

Some people may think that drinking raw milk is a healthy choice. Instead they put themselves at increased risk for illnesses that cause diarrhea, stomach cramping, vomiting, and, although not as common, serious complications including kidney failure, paralysis, stroke, or death. According to the FDA, research shows no meaningful difference in the nutritional values of pasteurized and unpasteurized milk. Regardless of the health benefits that might be claimed by others, these

unsubstantiated claims do not outweigh the risk of negative health outcomes that I have described to you today.

Currently in North Dakota, under the Food Handler's Education Act NDCC 23-09.2, low-risk food items that are home-processed, home-canned, and home-baked are allowed for direct sale from the producer to the consumer at farmers markets and food stands. A list of low-risk food items and labeling requirements are referenced on the enclosed fact sheet. The Department of Health could support a law allowing direct producer to consumer sale of foods, administered uniformly throughout the state, provided necessary guidelines are provided to mitigate the risk of disease-causing germs and other forms of adulteration resulting in injury or harmful health effects to the end consumer.

Chairman Johnson and members of the committee, thank you for listening to my testimony. I am happy to answer any questions you may have.

HB 1433-Wagendorf-Food Freedom Act-2017-02-09



# FOODFACTS

From the U.S. Food and Drug Administration

## The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk



Milk and milk products provide a wealth of nutrition benefits. But raw milk can harbor dangerous microorganisms that can pose serious health risks to you and your family. According to an analysis by the Centers for Disease Control and Prevention (CDC), between 1993 and 2006 more than 1500 people in the United States became sick from drinking raw milk or eating cheese made from raw milk. In addition, CDC reported that unpasteurized milk is 150 times more likely to cause foodborne illness and results in 13 times more hospitalizations than illnesses involving pasteurized dairy products.

Raw milk is milk from cows, sheep, or goats that has not been pasteurized to kill harmful bacteria. This raw, unpasteurized milk can carry dangerous bacteria such as *Salmonella*, *E. coli*, and *Listeria*, which are responsible for causing numerous foodborne illnesses.

These harmful bacteria can seriously affect the health of anyone who drinks raw milk or eats foods made from raw milk. However, the bacteria in raw milk can be especially dangerous to **people with weakened immune systems, older adults, pregnant women, and children**. In fact, the CDC analysis found that foodborne illness from raw milk especially affected children and teenagers.

## "Pasteurized Milk" Explained

Pasteurization is a process that kills harmful bacteria by heating milk to a specific temperature for a set period of time. First developed by Louis Pasteur in 1864, pasteurization kills harmful organisms responsible for such diseases as listeriosis, typhoid ver, tuberculosis, diphtheria, and brucellosis.

Research shows no meaningful difference in the nutritional values of pasteurized and unpasteurized milk. Pasteurized milk contains low levels of the type of nonpathogenic bacteria that can cause food spoilage, so storing your pasteurized milk in the refrigerator is still important.

Raw Milk & Pasteurization: Debunking Milk Myths

While pasteurization has helped provide safe, nutrient-rich milk and cheese for over 120 years, some people continue to believe that pasteurization harms milk and that raw milk is a safe, healthier alternative.

Here are some common myths and proven facts about milk and pasteurization:

- Pasteurizing milk DOES NOT cause lactose intolerance and allergic reactions. Both raw milk and pasteurized milk can cause allergic reactions in people sensitive to milk proteins.
- Raw milk DOES NOT kill dangerous pathogens by itself.
- Pasteurization **DOES NOT** reduce milk's nutritional value.
- Pasteurization DOES NOT mean that it is safe to leave milk out of the refrigerator for extended time, particularly after it has been opened.
   Pasteurization DOES kill harmful bacteria.

Pasteurization **DOES** kill harmful bacter Pasteurization **DOES** save lives.

Safety 🖬 Health 🖬 Science 🔳 Nutrition

## Raw Milk and Serious Illness

#### Symptoms and Advice

Symptoms of foodborne illness include:

- · Vomiting, diarrhea, and abdominal pain
- Flulike symptoms such as fever, headache, and body ache

While most healthy people will recover from an illness caused by harmful bacteria in raw milk — or in foods made with raw milk — within a short period of time, some can develop symptoms that are chronic, severe, or even life-threatening.

If you or someone you know becomes ill after consuming raw milk or products made from raw milk — or, if you are pregnant and think you could have consumed contaminated raw milk or cheese — see a doctor or healthcare provider immediately.

#### The Dangers of Listeria and Pregnancy

Pregnant women run a serious risk of becoming ill from the bacteria *Listeria*, which can cause miscarriage, fetal death, or illness or death of a newborn. If you are pregnant, consuming raw milk — or foods made from raw milk, such as Mexican-style cheese like Queso Blanco or Queso Fresco — can harm your baby even if *you* don't feel sick.



August 2012

## **FOOD**FACTS

## Protect Your Family with Wise Food Choices

Most milk and milk products sold commercially in the United States contain pasteurized milk or cream, or the products have been produced in a manner that kills any dangerous bacteria that may be present. But unpasteurized milk and products made from unpasteurized milk are sold and may be harmful to your health. To avoid getting sick from the dangerous bacteria found in raw milk, you should choose your milk and milk products carefully. Consider these guidelines:

## Okay to Eat

- Pasteurized milk or cream
- · Hard cheeses such as cheddar, and extra hard grating cheeses such as Parmesan
- · Soft cheeses, such as Brie, Camembert, blue-veined cheeses, and Mexican-style soft cheeses such as Oueso Fresco. Panela, Asadero, and Queso Blanco 10 0 made from
- pasteurized milk Processed cheeses
- · Cream, cottage, and Ricotta cheese made from pasteurized milk
- · Yogurt made from pasteurized milk
- Pudding made from pasteurized milk
- · Ice cream or frozen yogurt made from pasteurized milk

## Unsafe to Eat

- · Unpasteurized milk or cream
- · Soft cheeses, such as Brie and Camembert, and Mexican-style soft cheeses such as Queso Fresco, Panela, Asadero, and Queso Blanco made from unpasteurized milk
- Yogurt made from unpasteurized milk
- Pudding made from unpasteurized milk
- Ice cream or frozen yogurt made from unpasteurized milk

### When in Doubt — Ask!

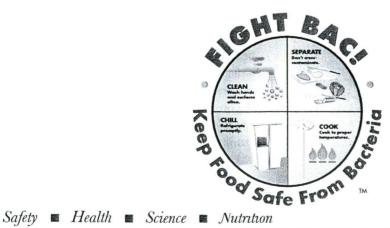
Taking a few moments to make sure milk is pasteurized — or that a product isn't made from raw milk — can protect you or your loved ones from serious illness.

- · Read the label. Safe milk will have the word "pasteurized" on the label. If the word "pasteurized" does not appear on a product's label, it may contain raw milk.
- · Don't hesitate to ask your grocer or store clerk whether milk or cream has been pasteurized, especially milk or milk products sold in refrigerated cases at grocery or health food stores.
- · Don't buy milk or milk products at farm stands or farmers' markets unless you can confirm that it has been pasteurized.

## Is Your Homemade Ice Cream Safe?

Each year, homemade ice cream causes serious outbreaks of infection from Salmonella. The ingredient responsible? Raw or undercooked eggs. If you choose to make ice cream at home, use a pasteurized egg product, egg substitute, or pasteurized shell eggs in place of the raw eggs in your favorite recipe. There are also numerous egg-free ice cream recipes available.

Everyone can practice safe food handling by following these four simple steps:



August 2012

For more information, contact: The U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Food Information Line at 1-888-SAFEFOOD (toll free), 10 AM to 4 PM ET, Monday through Friday. Or visit the FDA Web site at www.fda.gov



Made from PASTEURIZED MILK

## Legal Status of the Sale of Raw Milk, and Outbreaks\* Linked to Raw Milk, by State, 2007-2012

6

2

2

Updated: March 2015

3

\* Source of outbreak data: CDC, published data

5

1

3

\*\* Source of legal status of the sale of raw milk data: National Association of State Departments of Agriculture (NASDA) and online search of state regulations



DEDICATED TO THE HEALTH OF ALL CHILDREN"



Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

#### POLICY STATEMENT

American Academy

of Pediatrics

## Consumption of Raw or Unpasteurized Milk and Milk Products by Pregnant Women and Children

COMMITTEE ON INFECTIOUS DISEASES and COMMITTEE ON NUTRITION

#### **KEY WORDS**

raw milk/milk products, unpasteurized milk/milk products, pregnant women, children

#### ABBREVIATIONS

AAP—American Academy of Pediatrics FDA—Food and Drug Administration

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275). Copyright © 2014 by the American Academy of Pediatrics

## abstract

Sales of raw or unpasteurized milk and milk products are still legal in at least 30 states in the United States. Raw milk and milk products from cows, goats, and sheep continue to be a source of bacterial infections attributable to a number of virulent pathogens, including Listeria monocytogenes, Campylobacter jejuni, Salmonella species, Brucella species, and Escherichia coli 0157. These infections can occur in both healthy and immunocompromised individuals, including older adults. infants, young children, and pregnant women and their unborn fetuses, in whom life-threatening infections and fetal miscarriage can occur. Efforts to limit the sale of raw milk products have met with opposition from those who are proponents of the purported health benefits of consuming raw milk products, which contain natural or unprocessed factors not inactivated by pasteurization. However, the benefits of these natural factors have not been clearly demonstrated in evidence-based studies and, therefore, do not outweigh the risks of raw milk consumption. Substantial data suggest that pasteurized milk confers equivalent health benefits compared with raw milk, without the additional risk of bacterial infections. The purpose of this policy statement was to review the risks of raw milk consumption in the United States and to provide evidence of the risks of infectious complications associated with consumption of unpasteurized milk and milk products, especially among pregnant women, infants, and children.

Pediatrics 2014;133:175-179

#### INTRODUCTION

Foodborne illness accounts for substantial morbidity and mortality in the United States. Estimates suggest that each year, as many as 48 million Americans experience foodborne illness, accounting for 128 000 hospitalizations and 3000 deaths.<sup>1</sup> In addition, surveillance estimates by the Centers for Disease Control and Prevention demonstrated no overall improvement in the incidence of foodborne illness in the United States from 2006 to 2009.<sup>2</sup> Among the most preventable of these foodborne illnesses are infections related to ingestion of raw or unpasteurized milk and milk products because of ubiquitous access to healthy, pasteurized milk and milk products, as well as legislation prohibiting the sale of raw dairy products in much of the United States. Reasons for the continued burden of disease related to raw or unpasteurized milk or milk products are primarily related to misinformation regarding the purported benefits of these raw dairy products. Consumption of raw dairy products is especially risky among populations such as pregnant women, infants, the elderly, and immunocompromised individuals, who are most susceptible to infection with pathogens ingested in raw milk or milk products. Evidence demonstrates the overwhelming benefits to food safety conferred by pasteurization and consumption of pasteurized dairy products.

## EPIDEMIOLOGY OF DISEASES CAUSED BY RAW OR UNPASTEURIZED MILK AND MILK PRODUCTS IN THE UNITED STATES

Before pasteurization of milk began in the United States in the 1920s, consumption of raw dairy products accounted for a significant proportion of foodborne illnesses among Americans and resulted in hundreds of outbreaks of tuberculosis and infections caused by bacteria, such as Brucella abortus, streptococcal species, and enteric pathogens.<sup>3</sup> Although most milk and milk products consumed today in the United States are pasteurized, an estimated 1% to 3% of all dairy products consumed are not pasteurized. From 1998 through 2009 alone, consumption of raw milk or milk products in the United States resulted in 93 illness outbreaks, 1837 illnesses, 195 hospitalizations, and 2 deaths.<sup>4</sup> These foodborne illnesses were caused primarily by ingestion of raw milk or milk products contaminated with Escherichia coli 0157. Campylobacter species, or Salmonella species. Seventy-nine percent of the outbreaks involved at least 1 person younger than 20 years.<sup>4</sup> In a second study, 121 dairy-associated foodborne illness outbreaks were identified in the United States from 1993 to 2006 Of these, 73 (60%) were associated with unpasteurized dairy products, resulting in 1571 cases, 202 hospitalizations, and 2 deaths; 60% of the patients were younger than 20 years. Thirteen percent of patients involved in raw milk or milk product foodborne illness outbreaks were hospitalized, compared with 1% of patients involved in outbreaks associated with pasteurized products. In addition, 55 (75%) of all 121 outbreaks occurred in 21 states that permitted the sale of unpasteurized dairy products.<sup>5</sup> Immigrant groups are another population at risk for illness from consumption of traditional foods made with raw milk.<sup>6,7</sup>

A number of pathogenic and opportunistic bacteria, parasites, and viruses (see Organisms Detected in Raw or Unpasteurized Milk or Milk Products) have been detected in raw milk or milk products.4-22 In addition, patterns of dairy consumption appear to have affected the prevalence of illnesses associated with different dairy products. Among milk- or milk product-associated foodborne illness outbreaks reported to the Centers for Disease Control and Prevention between 1973 and 2009, 82% were attributable to raw milk or cheese. However, increasingly, recent illnesses associated with raw or unpasteurized cheese have been reported. This underscores the importance of all raw milk products as potential sources of illness.

Populations at highest risk of morbidity and mortality from foodborne illnesses include older adults, immunocompromised individuals, young infants, and children. The risks involved with infections attributable to consumption of raw milk and milk products are particularly high among pregnant women and their fetuses, as well as young children. For example, consumption of raw milk or milk products has been associated with a fivefold increase in toxoplasmosis among pregnant women<sup>23</sup>; listeriosis associated with high rates of stillbirths, preterm delivery, and neonatal infections, such as sepsis and meningitis<sup>6</sup>;

and *E coli* 0157–associated diarrheal disease and hemolytic-uremic syndrome, primarily among young children.<sup>24</sup> Between 17% and 33% of all cases of invasive disease attributable to *Listeria monocytogenes* in the United States occur among pregnant women, unborn fetuses, or newborn infants, a 13- to 17-fold increase compared with the general population.<sup>25–27</sup> Complications include a 20% risk of spontaneous abortion or stillbirth, with two-thirds of infants developing neonatal infection, including pneumonia, sepsis, or meningitis.<sup>28</sup>

## GUIDELINES FOR SALES OF RAW OR UNPASTEURIZED MILK AND MILK PRODUCTS BY THE FOOD AND DRUG ADMINISTRATION AND INDIVIDUAL STATES

The modern pasteurization process consists of raising the temperature of milk to at least 161°F for more than 15 seconds, followed by rapid cooling. Since 1924, the Food and Drug Administration (FDA) has regulated the production, handling, transportation, processing, testing, and sale of milk in all 50 states in the United States. In 1987, the FDA prohibited the interstate shipment of raw milk for human consumption, effectively banning interstate commerce of raw milk or milk products. No federal agencies, however, including the FDA, have jurisdiction in the regulation and enforcement of milk sanitation within individual states. In 2011, the National Association of State Departments of Agriculture conducted a review demonstrating that 30 states allow raw milk sales, but only a few of these allow sales in grocery stores. In addition, the 1987 FDA ban on interstate raw dairy transport allows for an exception of cheese made from raw milk, provided the cheese has been aged a minimum of 60 days and is clearly labeled as unpasteurized. However, there is evidence that E coli can survive in cheese products even



after a 60-day aging period,<sup>29</sup> and recent outbreaks of *E coli* 0157 illness associated with such unpasteurized, aged cheese have been documented in Arizona, California, Colorado, and New Mexico.<sup>30</sup>

## RISKS AND BENEFITS OF RAW VERSUS PASTEURIZED MILK AND MILK PRODUCTS

Infections associated with consumption of raw and unpasteurized milk and milk products are related to contamination with pathogenic and opportunistic organisms from a variety of sources. Contamination of raw milk occurs by a number of mechanisms, including direct contact with bovine fecal matter; transmission of organisms from bovine skin or hide; clinical or subclinical mastitis; primary bovine diseases, such as tuberculosis; environmental contamination; and contact with insects, animals, and humans, for example, by contamination from soiled clothing.

Proponents of the health benefits of raw or unpasteurized milk and milk products claim that pasteurization destroys or neutralizes important nutrients in milks, such as proteins, carbohydrates, calcium, vitamins, and enzymes.<sup>31–33</sup> For example, claims that consumption of raw milk is not associated with lactose intolerance and that destruction of lactase by pasteurization of milk leads to lactose intolerance have not been substantiated by independent studies.<sup>34-37</sup> Other claims purporting links between pasteurized milk and autism, allergic reactions, and asthma have largely been based on testimonials or anecdotes and have not been demonstrated based on scientific data. In contrast, numerous scientific analyses have demonstrated that pasteurized milk and milk products contain equivalent levels of such nutrients compared with raw, unpasteurized milk and milk products.31-39

## RECOMMENDATIONS FROM NATIONAL AND INTERNATIONAL ORGANIZATIONS REGARDING CONSUMPTION OF RAW OR UNPASTEURIZED MILK AND MILK PRODUCTS

Virtually all national and international advisory and regulatory committees related to food safety have strongly endorsed the principles of consuming only pasteurized milk and milk products. These include the American Medical Association, the American Veterinary Medical Association, the International Association for Food Protection, the National Environmental Health Association, the FDA, and the World Health Association. In January 2012, the US federal government denied a petition requesting federal-level legalization of all raw milk sales on the basis of its analysis of the scientific basis for the food safety benefits of pasteurization.40

The American Academy of Pediatrics (AAP) has strongly endorsed the use of pasteurized milk in its 2012 *Red Book*.<sup>41</sup>

## CONCLUSIONS

In summary, the AAP strongly supports the position of the FDA and other national and international associations in endorsing the consumption of only pasteurized milk and milk products for pregnant women, infants, and children. The AAP also endorses a ban on the sale of raw or unpasteurized milk and milk products throughout the United States, including the sale of certain raw milk cheeses, such as fresh cheeses, soft cheeses, and soft-ripened cheeses. This recommendation is based on the multiplicity of data regarding the burden of illness associated with consumption of raw and unpasteurized milk and milk products, especially among pregnant women, fetuses and newborn infants, and infants and young children. as well as the strong scientific evidence that pasteurization does not alter the nutritional value of milk. The AAP also

encourages pediatricians to contact their state representatives to support a ban on sale of raw milk and milk products. Additional resources containing information regarding the safety of pasteurization and the risks of consuming raw or unpasteurized milk or milk products are provided in this statement.

## ORGANISMS DETECTED IN RAW OR UNPASTEURIZED MILK OR MILK PRODUCTS Bacteria

#### Brucella species Campylobacter jejuni Coxiella burnetii Cryptosporidium species Enterotoxigenic Staphylococcus aureus Listeria monocytogenes Mycobacterium bovis Salmonella species Escherichia coli Shiga toxin-producing E coli (STEC [eg, E coli 0157]) Enterohemorrhagic E coli (EHEC) Enterotoxigenic E coli (EHEC) Enterotoxigenic E coli (ETEC) Shigella species Yersinia entercolitica Parasites

*Giardia* species **Viruses** Norovirus Rabies Vaccinia

### RESOURCES

- http://www.realrawmilkfacts.com/
- www.cdc.gov/foodsafety/rawmilk/ raw-milk-index.html
- http://www.fda.gov/Food/FoodbornellInessContaminants/BuyStore-ServeSafeFood/ucm277854.htm
- FDA "Grade 'A' Pasteurized Milk Ordinance." 2011 Revision: http://www. fda.gov/downloads/Food/Guidance-Regulation/UCM291757.pdf
- FoodSafety.gov "Myths About Raw Milk": www.foodsafety.gov/keep/types/ milk
- www.nationaldairycouncil.org/sitecollectiondocuments/research/ dairy\_council\_digests/2011/dcd11-1w.pdf

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# Consumption of Raw or Unpasteurized Milk and Milk Products by Pregnant Women and Children

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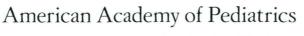
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# FACT SHEET

# for certain homeprocessed. home-canned & home-baked foods

This fact sheet addresses recent issues relating to certain home-processed, home-canned and home-baked foods.

Products covered are pickles, vegetables or fruits having an equilibrium pH value of 4.6 or lower and non-temperature-controlled baked goods that do not require refrigeration.

The food products can only be sold at community and nonprofit events or farmers markets located in North Dakota. This includes such events as: county fairs, nonprofit and charitable events, public spirited and/ or community celebrations and farmers markets and roadside stands.



## It does NOT include:

Craft shows, food festivals, or other for profit events nor sales to other businesses; interstate or Internet sales, or sales from one's home or business.

The individual who is selling home-processed, homecanned and home-baked foods under this exemption should have available, upon request of the regulatory authority, the product's recipe and/or pH results.

The seller must display a sign or placard at the point of sale which states:

# These canned goods/baked goods are homemade and not subject to state inspection

Persons producing and selling these products are urged to have the recipe and manufacturing process reviewed by a person knowledgeable in the food canning/ processing industry and recognized as a process authority.

# Labeling requirements:

Each food container and/or food item sold must include the following statement using a font size that is prominent, conspicuous, and easy to read.

"These food products were produced in an uninspected home kitchen where major food allergens may also have been handled and prepared, such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish."

If you have questions, please contact your local health unit or:

# KENAN BULLINGER, DIRECTOR

Division of Food and Lodging North Dakota Department of Health Call: 701.328.1291 or Toll Free: 1.800.472.2927 http://www.ndhealth.gov/DoH/contact.htm

# Home-Processed & Home-Canned Foods

# You may not sell

Foods that require refrigeration

Fresh-processed (not canned) foods that require refrigeration such as fresh salsa, pesto, etc.

Foods that are home-processed or home-canned such as home-canned fish, pickled eggs and meat.

**NOT ALLOWED:** Certain foods are not allowed to be sold under these rules.

Any non-acidified foods processed by either the use of a boiling water bath or by the use of a home pressure cooker.

Some foods naturally have a pH of 4.6 or greater.

# These foods are not allowed unless the pH of these foods is reduced to pH 4.6 or less.

These foods include:

artichokes	asparagus
beans (lima, string, kie	dney, Boston style, soy,
waxed)	
beets	broccoli
Brussels sprouts	cabbage
carrots	cauliflower
horseradish	sweet corn
egg plant	mushrooms
peas	most peppers
potatoes	squash
spinach	vegetable soups

# **Home-Baked Foods**

ALLOWED: Home-baked foods may include but are not limited to lefse, bread, rolls, fruit pies, candies/ confectioneries, and cookies & bars.

**NOT ALLOWED:** Foods that require refrigeration may not be sold under this ruling.

These foods include home-baked foods such as custards, custard-filled pastries, meringue-topped pies or pastries, kuchen, pumpkin pies, cream pies or other pies, pastries or baked goods that are considered potentially hazardous or require temperature control.

# Products not covered under this rule

Certain foods fall under regulatory jurisdiction and are not exempted by this ruling. *YOU MAY NOT SELL:* 

- fish
- dairy
- poultry
- meat products including: smoked fish
  - butter
  - raw milk
  - jerky

potentially hazardous products such as garlic and oil mixtures or other flavored oils.

# You may sell

**ALLOWED:** Foods that have a natural pH of 4.6 or less and acidified foods which have acid(s) or acid food(s) added. *The final pH of the food must be 4.6 or less.* 

Home-canned high acid foods such as:

- sweet or dill pickles
- tomatoes
- salsa
- apples
- cherries
- grapes
- plums
- peaches,
- flavored vinegars
- naturally fermented foods such as sauerkraut pickles and KimChi

# When in doubt check it out!

Please contact your local health unit or: **KENAN BULLINGER, DIRECTOR** Division of Food and Lodging North Dakota Department of Health

Call: 701.328.1291 or Toll Free: 1.800.472.2927 www.ndhealth.gov/DoH/contact.htm COMMISSIONER DOUG GOEHRING



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ndda@nd.gov www.agdepartment.com

NORTH DAKOTA DEPARTMENT OF AGRICULTURE STATE CAPITOL 600 E BOULEVARD AVE DEPT 602 BISMARCK ND 58505-0020

Testimony of Shaun Quissell Livestock Development Director HB Bill 1433 House Agriculture Committee Peace Garden Room February 9, 2017

Chairman Johnson and members of the House Agriculture Committee, I am Shaun Quissell, division director of livestock development for the North Dakota Department of Agriculture (NDDA), and I am here on behalf of Agriculture Commissioner Doug Goehring. I am here today in opposition of HB 1433, which is being labeled the Food Freedom Act.

NDDA regulates meat and dairy production in the state. At the heart of this bill, those two items are being directly affected. Most of the language in this bill is the same as a law that was passed in Wyoming called the Wyoming Food Freedom Bill. There are two issues concerning meat and poultry that have caused us concern.

The first issue that I will address is the meat and poultry provision in this bill. The state of Wyoming, which passed a similar law in 2013, has received a notification from the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS), that the language in the Wyoming Food Freedom Bill supersedes federal legislation, and that the state will likely no longer be able to operate their meat inspection program. The language that FSIS is concerned

about in Wyoming is the same language that can be found in this bill here in North Dakota. If the committee would like, I can provide you with a copy of the amendments that Wyoming has been working on, along with the letter sent to them from FSIS.

The second concern with this bill is with the raw milk and milk products portion. It was this legislative body that repealed the sale of raw milk in 1985. The legislative assembly determined that the law contradicted the established law of making grade A milk the only fluid milk product allowed for sale, for human consumption, in our state (NDCC 4-30-36). Raw milk sales were disallowed because the evidence against the safety of raw milk and the bacteria, which can proliferate in raw milk, has been well established.

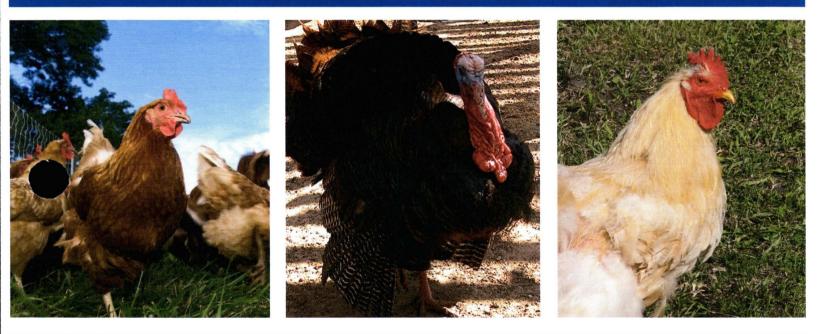
Allowing sales of raw milk would turn back the food safety clock by 100 years. It was in the late 1890's Nathan Strauss, after taking control of Macy's department store and becoming one of the wealthiest families in New York, promoted pasteurization. The Strauss' discovered a cow from their dairy herd died from tuberculosis. Concerned about the health of his six children, Strauss employed Louis Pasteur's method of pasteurization, which is the process of heating milk to stop bacterial contamination and decided, because of the increased safety this provided, that his children would only drink pasteurized milk. At the same time he set out to establish milk stations in poor neighborhoods to provide pasteurized milk. In 1891, 24 percent of babies born in New York City (NYC) did not make it to their first birthday. But of the 20,111 children provided with pasteurized milk from Nathan Strauss, only six died in a four-year period. The NYC orphan asylum lost 44 percent of their children in 1897. The following year Strauss donated pasteurization equipment resulting in the rate dropping to 20 percent. Over a 34-year time span, as pasteurization grew and became more widely adopted, our nation saw its infant mortality rate

drop from over 12 percent to less than 2 percent (1891-1925). It is estimated that Nathan Strauss saved 445,000 children's lives simply with the crusade for mandatory pasteurization.

The NDDA supports all forms of agriculture and have assisted many cottage food industries through various programs. As the health department has previously stated we are also tasked with the job of ensuring public health and food safety through our inspection programs. Chairman Johnson and committee members, I want to thank you for your time and again, would urge a do NOT pass on HB1433. I would be happy to answer any questions you may have.



# North Dakota Poultry Slaughter, Processing, and Sales Guidelines for Small-scale Producers



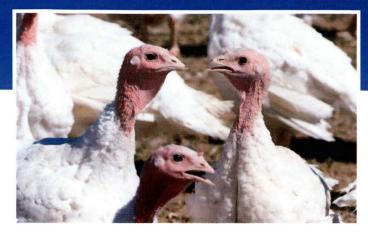


Equal Opportunity in Employment and Services

This publication is to help small-scale poultry producers operating in the state of North Dakota understand regulations related to the slaughter, processing, and marketing of poultry.

The regulations allow for several exemptions which are limited to different types of business transactions. Unlike meat, poultry plants must operate under <u>one</u> exemption only. All businesses must slaughter healthy poultry and operate under sanitary standards, practices and procedures that produce poultry products that are sound, clean and fit for human food (not adulterated.)

This information is subject to legislative and administrative change, and this guide will be updated as necessary.



## Officially Inspected Poultry Establishment: Birds

# North Dakota EST. 000 Inspected & Passed

slaughtered under official inspection are inspected by the North Dakota Meat and Poultry Inspection Program (NDMPIP) or the United States Department of

Agriculture's Food Safety Inspection Service (FSIS). The carcass is marked with a state or federal mark of inspection that looks similar to the images above or below. If the carcass is processed under official inspection (only birds slaughtered under official inspection are eligible for this), all parts will also bear a state or federal mark of inspection. Any poultry carcasses or parts produced under NDMPIP's Cooperative Interstate Shipment Program (CISP) or that bear a FSIS official mark of inspection may be retailed or wholesaled across state lines (interstate commerce). Any poultry carcasses or parts bearing an NDMPIP or FSIS official mark of inspection may be retailed or wholesaled within state (intrastate commerce). Official inspection has several regulatory requirements, including: an approved facility, ante-mortem (before death) and post-mortem



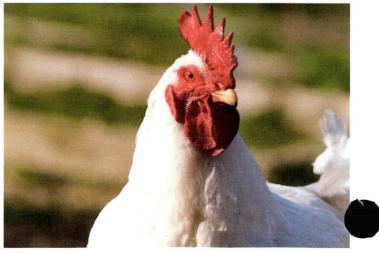
(after death) inspection both performed by an inspector, inspection related activities (verifying carcass hygiene, microbiological testing, etc.), carcass chilling standards, a HACCP plan, a SSOP plan, approved labeling, potable water

certification, a waste water disposal certificate, and several recordkeeping requirements.

**Producer-Grower less than 1,000 Birds (per year)** Exemption: A producer/grower may slaughter and sell up to 1,000 healthy birds per year of any domesticated poultry on their farm. The producer/grower may only slaughter birds they raised themselves. Birds must be slaughtered and sold at the owner's farm under sanitary conditions and may be sold only to household consumers. The producer/ grower may not buy or sell poultry products other than those produced from poultry raised on their own farm. Carcasses or parts from birds under this exemption may not be sold to hotels, restaurants, institutions, retail stores, or at farmers markets. Producers must maintain complete and accurate records, including: number of birds processed in a calendar year, and customers' names and dates for each sale. The facility used to slaughter or process the poultry may not be used to slaughter or process another person's poultry. Producer/growers under this exemption are required to register with the NDMPIP.

There are five additional exemptions under the Poultry Products Inspection Act (PPIA). All of the following exemptions include the subsequent requirements: approved facilities, potable water certification, wastewater disposal certification, sanitation standards, and recordkeeping requirements. NDMPIP inspectors inspect these establishments on a risk-based system to ensure compliance with regulatory requirements. These exemptions differ based on the amount of birds that can be processed, how the birds can be processed, and to whom the products can be sold.

**Custom-Exempt Inspection:** A bird slaughtered and/or processed at a custom-exempt facility is not inspected, does not bear a mark of inspection, and must be returned to the owner of the animal. Custom-exempt product is intended to be used exclusively by the owner of the animal, the owner's immediate family, nonpaying guests and employees of the



# **Additional Exemptions**

owner. Custom slaughtered poultry must be marked with the owner's name and address and the statement "Exempted – P.L. 90-492." Custom poultry slaughterers may not engage in the business of buying or selling poultry products capable of use as human food. <u>Custom-exempt products cannot be</u> <u>sold or donated</u>.

Producer-Grower less than 20,000 Birds (per year) Exemption: A producer/grower may slaughter and sell up to 20,000 healthy birds per year of any domesticated poultry raised on their farm. The producer/grower may only slaughter birds they raised. Birds must be slaughtered and processed at the producer's farm under sanitary conditions and may be sold only to household consumers. The poultry products may be distributed within North Dakota; however, carcasses or parts from birds under this exemption may not be sold to hotels, restaurants, institutions, retail stores, or at farmers markets. Complete and accurate records must be maintained, including: number of birds processed in a calendar year and customers' names and dates for each sale. e producer/grower may not buy or sell poultry products her than those produced from poultry raised on their own farm. Shipping containers must bear the producer's name, the producer's address and the statement "Exempt P.L. 90-492." The facility used to slaughter or process the poultry may not be used to slaughter or process another person's poultry.

**Producer-Grower or Other Person (PGOP) less than 20,000 Birds (per year) Exemption:** This exemption refers to a single entity, which may be:

(1) A poultry grower who slaughters and processes





healthy poultry that he or she raised directly for sale to household consumers.

(2) A person who purchases live poultry from a grower, slaughters these healthy poultry, and processes such poultry for sale directly to household consumers.

Processing is limited to poultry slaughtered by the PGOP. The poultry products may be distributed within North Dakota; however, carcasses or parts from birds under this exemption may not be sold to hotels, restaurants, institutions, retail stores, or at farmers markets. The PGOP may not buy or sell poultry or poultry products prepared under other exemptions. The facility used to slaughter or process the poultry may not be used to slaughter or process another person's poultry. The PGOP must maintain complete and accurate records, including: number of live birds purchased, birds processed in a calendar year and customers' names and dates for each sale. Shipping containers must bear the producer's name, the producer's address and the statement "Exempt P.L. 90-492."

**Small Enterprise (less than 20,000 birds per year) Exemption:** A business that qualifies for the Small Enterprise Exemption may be:

- (1) A producer/grower who raises, slaughters and dresses (cut-up only) healthy poultry for use as human food.
- (2) A business that purchases live, healthy poultry that it slaughters and dresses (cut-up only) for use as human food.
- (3) A business that purchases federally or state inspected and passed, dressed poultry, which it sells as carcasses or processes (cut-up only) and sells.

The poultry products may be distributed within North Dakota; however, carcasses or parts from birds under this exemption may not be sold to hotels, restaurants,



institutions, retail stores, or at farmers markets. The small enterprise may not buy or sell poultry or poultry products prepared under other exemptions. The facility used to slaughter or process the poultry may not be used to slaughter or process another person's poultry. The small enterprise must maintain complete and accurate records, including: number of birds processed in a calendar year and customers' names and dates for each sale. Businesses under this exemption are subject to more stringent labeling regulations. Labels must include: name of the product, ingredients statement, net weight, name and address of establishment, handling instructions, safe handling instructions, date of packaging, and an explanatory statement indicating why inspection is not required such as "Small Enterprise Exemption from Inspection."



Retail Exemption: Under retail exemption, a business may purchase officially inspected poultry carcasses or parts, further process them, and sell them to end consumers and certain products to hotels, restaurants and institutions (HRIs) in limited quantities. The North Dakota Department of Health inspects these businesses. Product labeling requirements are as follows: name of product, ingredients statement, quantity of contents, name and address of establishment, name of food source for each major allergen, and, unless exempt, nutrition facts. Products must be sold in "normal retail quantities," 75 pounds or less, to household consumers and 150 pounds or less to HRIs per sale. Sales to HRIs are also limited to 25% of the dollar value of total poultry sales or the calendar year dollar limit established by FSIS (changes yearly). Records must fully and correctly disclose all transactions involved in the business.

Criteria	USDA Inspected	NDMPIP Inspected	Custom Exemption	Producer/ Grower 1,000 Bird Exemption	Producer/ Grower 20,000 Bird Exemption	Producer/ Grower or Other Person Exemption	Small Enterprise Exemption
Slaughter Limit/ Calendar Year	No Limit	No Limit	No Limit	1,000 Birds	20,000 Birds	20,000 Birds	20,000 Birds
Further Processing	Yes	Yes	Yes	Yes	Yes	Yes	Cut-Up Only
Sell to Home Consumer	Yes	Yes	No	Yes	Yes	Yes	Yes
Sell to Distributor	Yes	Yes	No	No	No	No	No
Sell to Retail Store	Yes	Yes	No	No	No	No	No
Sell Interstate Commerce	Yes	Yes - Under the CIS Program	No	No	No	No	No

If you are interested in operating a business under one of the above exemptions, contact the North Dakota Meat and Poultry Inspection Program. If you have any questions, please contact:

Telephone: (701) 328-2231 or (800) 242-7535

Fax: (701) 328-4567

E-mail: <u>ndda@nd.gov</u>

Website: www.nd.gov/ndda/program/meat-inspection

Equal Opportunity in Employment and Services



# North Dakota Veterinary Medical Association

#5 2/9/17 HB 1433

2304 Jackson Avenue Bismarck, ND 58501 Phone: 701-221-7740 • Fax: 701-751-4451 E-mail: ndvma@btinet.net • Website: www.ndvma.com

Testimony of Deana Wiese North Dakota Veterinary Medical Association In Opposition to HB 1433 February 9, 2017

Chairman Johnson and Members of the House Agriculture Committee:

My name is Deana Wiese, and I am representing the North Dakota Veterinary Medical Association (NDVMA). I am here today in opposition to HB 1433, which would allow for the direct sale by the producer to the consumer.

NDVMA has spent more than a century representing the interests of veterinarians, their clients and patients. Today, the organization has more than 275 members representing small, large animal, exotic, bovine and equine practitioners and those veterinarians working in research, academic and government capacities.

NDVMA is concerned with the unintended public health implications that could result from this bill. The integration between veterinary medicine and public health are ever increasing, and members of NDMVA are dedicated to providing quality care for patients and services for clients. Therefore, we encourage a Do Not Pass recommendation on HB 1433.

#62/9/17

# Testimony on HB 1433

Chairman Johnson and Members of the House Agriculture Committee. My name is John Dyste and I am President of the North Dakota Grocers Association. (NDGA)

The North Dakota Grocers Association opposes House Bill 1433 in its current form. We represent over 200 grocery stores, suppliers and distributors who have worked diligently to ensure that we provide quality products which are fresh and safe.

Through the years, we have acted with local, state and federal agencies to develop programs and procedures which regulate the growing, processing, shipping and retailing of meats, poultry and produce. Our products are monitored from the farm all the way to the consumers.

House Bill 1433, starting on line 7 on page 3 basically states that no state or local agency can inspect or regulate any food products. Furthermore, starting on line 25 on page 3 it grants producers protection from any liability. The producer simply must say they are selling unregulated products.

NDGA feels the potential for serious illness or death dramatically increases under the provisions of this bill. An outbreak of illness could have grave consequences for the "Farm to Market" efforts in the state and could affect the efforts of grocery retailers to sell locally grown products.

Chairman Johnson and Committee members, we urge you to oppose HB 1433. If, however, you pass this bill in its current form we would like you to amend it to include all retailers, suppliers, and distributors of food products. The lack of regulation and protection from liability should be afforded to all.

Thank you. If there are any questions I will attempt to answere them.

John Dyste

President, North Dakota Grocers Association

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# Testimony In Support Of HB 1433 Peter Bartlett, Dairy Manager, Bartlett Farms

My name is Peter Bartlett and my family and I operate Bartlett Farms in Bottineau, North Dakota. We specialize in grass-fed meats and raw milk delivered through our cow share program.

Four years ago, our customers responded to the Department of Agriculture's bill that would put us and one other cow-share dairy out of business.

After sending the bill back to committee more than four times, you succeeded in passing legislation that would limit the state from regulating cow-share dairies. This legislation allowed us and others to continue producing food that consumers believe is beneficial to the health of themselves and their families.

During our committee meetings, you repeatedly told us to bring to you a bill that would represent what we want in the state.

I am happy to say that the North Dakota Food Freedom Act takes a step in that direction.

In my testimony, I will give you two ways that this bill will positively impact consumers and make North Dakota a better place to raise a family.

# First, this bill will impact consumers by increasing the availability of foods they believe they need to raise their family in good health.

There is a growing movement of people nationwide that believe raw milk is not only safe for human consumption, but actually beneficial to many people's health. This belief is supported by a growing body of research.

The reference in your sheet gives you a picture painted by Canadian researcher Nadine Ijaz of the British Columbia Center for Disease Control, where she concludes with the fact that "high quality evidence affirms unpasteurized milk's low risk." She refers to the United Nations' international food safety standards for microbial risk assessment.

Our nation had a history of raw milk problems in the thirties. Lack of refrigeration, sanitation, and proper handling caused many illnesses and spread of many diseases. That is why regulation was put in place regarding raw milk.

In today's world, stainless steel has replaced wooden buckets. Chlorine has replaced lye soap. When you regulate based on yesterday's problems, you miss the opportunity to plan for the future.

On the ND Department of Health website, you'll find a download that lists reported cases of foodborne illness in North Dakota during the past 16 years. From 1988 to 2014, 10 people from two instances reported getting sick with unpasteurized milk. That's less than one per year. Thousands got sick from instances like roast beef at an ag show, ham sandwiches, school cafeterias, home cooked chicken, roasted turkey, and rotisserie pork. Pathogens are in our world and they are they are no more a concern in raw milk than they are at Ruby Tuesday's salad bar here in Bismarck.

Raw milk is not a radical thing. Many of you likely grew up drinking it when you were young.

Right now, options are limited for health-conscious consumers. Jolene from Williston would love to buy extra milk while her sister-in-law and 3-year-old son are visiting from Denver, but they can't. This bill would allow Iven, a 63 year old cancer survivor from Emerado, to feel better because he can buy extra milk when he needs it from his neighbor who has just a cow and plenty of extra time to milk. But that's not allowed.

Alexa Johnson from Williston has a son with autism. His picture is in your handout. After visiting eight doctors, Alexa was forced to decide between steroids and raw milk, and for the past six years Ronnie Johnson has lived on raw milk as a main staple of his diet. Raw milk has been a vital part of Ronnie's health as an autistic child.

Today's informed consumers want to take responsibility for their own food choices. By passing this bill, more people will be able to make their own decisions about where they purchase their food. The highest form of quality control--customer satisfaction--will ensure that producers always sell the highest quality product.

This bill increases the range of options for health-conscious consumers and it should be supported for that reason.

## Second, House Bill 1433 will impact consumers by decreasing the cost of healthy food options.

People who have limited budgets and more knowledge than dollars still want to give their family the foods that made America's farm kids healthy. The current law makes obtaining raw milk through a shared animal ownership agreement an expensive, long term investment.

Carissa is one example. She is struggling financially and lives here in Bismarck, and can't get raw milk because she and her husband are unable to invest in a long-term plan for cow-share milk.

This bill would allow people like Carissa to do what they believe is best for their family's health, without breaking their budget.

In conclusion, I ask you to allow consumers to be fully responsible for their food choices. I ask that you use this bill to encourage healthy, financially stable families in North Dakota. Leave a legacy that positively impacts children and families after you. Limit unjust government intervention and recommend Do Pass on House Bill 1433.

Respectfully submitted,

Peter Bartlett Dairy Manager Bartlett Farms <u>www.bartlettfarms.us</u> office@bartlettfarms.us

2

HB1433 2/9/11

2-9-2017 HB 1433 Dear Committee Members,

Thank you for the opportunity to speak in support of the Food Freedom Act.

As a lifelong resident of our state, growing up on a small grain farm by Cooperstown, I married a dairy farm girl from Valley City and we have raised four kids on a small farm north of Jamestown.

I would ask the committee members to support this HB 1433 and give us the freedom to allow the marketplace to operate in our great state. We need LESS regulation in ALL aspects of our lives.

Regulations and restriction on food production and commerce is detrimental.

The worn out idea that we tax anything that is alive and subsidize whatever is dead has to stop.

A truly free market has and <u>always will be</u> economically viable for this wonderful state we call home. Our problem is not drinking raw milk, *our problem is* government intervention in our lives that restricts freedom and opportunity.

Please give us a free market for our state's abundant food production to thrive and prosper.

Please give HB 1433 a **DO PASS** recommendation.

Thank you very much.

stensor

Frank Christensen

8454 16<sup>th</sup> St SE

Courtenay,ND 58426



720 South Colorado Blvd. Suite 1000-N Denver, Colorado 80246-1926 Phone (303) 756-9090 Fax (303) 691-9490 www.neha.org

February 9, 2017

# SUBJECT: North Dakota House Bill HB 1433 (Sale of Raw Milk/shared animal ownership) POSITION: Opposed

To the Honorable Members of the North Dakota Legislature

The National Environmental Health Association – which represents the interests and expertise of the environmental health profession across our nation – through the efforts of our North Dakota affiliate, the North Dakota Environmental Health Association, became aware of the above-captioned North Dakota House Bill which would allow the sale or distribution of raw, unpasteurized milk to North Dakota consumers. In January of 2008, the NEHA Board of Directors adopted a position paper in opposition to any legislation that would allow any such practice. That position paper is attached. In addition, NEHA strongly supports consumer education about the dangers of consuming raw, unpasteurized milk. Unfortunately, the average consumer has received conflicting information on the benefits of consuming raw milk. This could lead well-meaning parents to serve raw milk to their children.

Public Health in the United States has made great strides in the elimination and reduction of disease during the 20<sup>th</sup> Century and pasteurization is one of the main reasons. Let's not take a step back. Contaminated raw milk can be a source of harmful disease-causing bacteria such as those that can cause undulant fever, dysentery, salmonellosis, listeriosis, campylobacteriosis, and tuberculosis. The association between raw milk with disease carrying organisms is well documented. The Centers for Disease Control and Prevention has recommended strengthening laws regarding the consumption of raw milk to minimize the exposure of the public to the hazards of raw milk consumption. There have been outbreaks of illness associated with raw milk all across the United States. Milkborne disease has been reduced greatly by the use of pasteurization. Prior to 1938, milkborne illness represented 25 percent of all foodborne illness outbreaks. As a result of efforts by the U.S. Public Health Service and individual states requiring the mandatory use of pasteurization, milkborne illness represents less than 1 percent of foodborne illness outbreaks today. Cases of illness caused by the consumption of raw, unpasteurized milk have continued to occur and are noted in the aforementioned position paper.

Michael T. Osterholm, Ph.D., M.P.H., Director of the Center for Infectious Disease Research and Policy at the University of Minnesota, and former Minnesota Department of Health chief epidemiologist, described the investigation of a disease outbreak in that state.

After months of investigation, in which 94 families had been contacted, the investigators knew the method of transmission was undisputed. Unpasteurized milk produced by one dairy had been consumed by all 122 victims during the three weeks before onset. For those under age 18, the median length of illness was 76 days' duration.

Other national public health professional organizations including the American Public Health Association, The National Association of County and City Health Officials, and the Association of Food and Drug Officials have all taken positions against legalization of the sale of raw milk.

The National Environmental Health Association, in support of our North Dakota state affiliate, strongly urges the North Dakota Legislature to defeat HB1433 that would allow for the sale of unpasteurized raw milk in any form.

Very truly yours,

1

David Riggs NEHA, President



# National Environmental Health Association Position Regarding

# Sale or Distribution of Raw Milk

# Adopted: January 28, 2008 Revised February 6, 2017

Editor's Note: The NEHA Board of Directors recently adopted this position in opposition to any legislation that would allow the sale or distribution of raw, unpasteurized milk to the consumer. NEHA strongly supports pasteurization before sale to the consumer. In addition, NEHA strongly supports consumer education about the dangers of consuming raw, unpasteurized milk. Below is the full text of the NEHA position.

The Cornell University Department of Food Safety has stated that —milk is a natural food. It is nutrientrich: it contributes high-quality protein, essential vitamins and minerals including calcium to the diet (Scott, 2002). Milk in its raw state contains a number of bacteria, some of which may be pathogenic such as enterotoxigenic *Staphylcoccus aureus, Campylobacter, Escherichia coli, Listeria, Salmonella, Yersinia, Brucella,* and *Mycobacterium tuberculosis* (Headrick et al., 1998). This is the case for all dairy animals, including cows, goats, and sheep. The process of pasteurization has been used for a hundred years to destroy pathogenic bacteria that are present in raw milk (International Association for Food Protection [IAFP], 2008). The Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA) (U.S. Food and Drug Administration, 2006), and the World Health Organization (WHO) (WHO, 2006) endorse the process of pasteurizing milk as a public health control measure.

Milkborne disease has been reduced greatly by the use of pasteurization. Prior to 1938, milkborne illness represented 25 percent of all foodborne illness outbreaks. As a result of efforts by the U.S. Public Health Service and individual states requiring the mandatory use of pasteurization, milkborne illness represents less than 1 percent of foodborne illness outbreaks today. Cases of illness caused by the consumption of raw, unpasteurized milk have continued to occur (Headrick et al., 1998). From 2006-2015 (most recent year available), CDC has recorded outbreaks associated with raw milk (no outbreaks were reported in 2009 and 2013) (CDC, 2017). A sample of the outbreaks investigated by FDA and CDC are noted below:

- April 2012 Herd share in Oregon leads to 21 people becoming ill (19 *E. coli*, 1 *Camplylobacter*, and 1 *Cryptosporidium* cases), 4 children were hospitalized and 1 received a kidney transplant (OHA, 2012)
- January 2012 Dairy farm (direct sales) in Pennsylvania lead to 148 illnesses in Pennsylvania, Maryland, New Jersey and West Virginia (Longenberger et al, 2012)
- December 2007: Three counties in North Carolina reported cases of *Listeria monocytogenes* from the consumption of illegally produced soft Mexican type cheeses made from raw milk (State of North Carolina, 2007).
- 2007: CDC reported 29 cases of Salmonella typhimurium infection that were associated with the consumption of raw milk and cheese made from raw milk in York County, Pennsylvania (CDC, 2007b).
- 2007: CDC's *Morbidity and Mortality Weekly Report* for the week of March 2, 2007, noted that from 1998 to May of 2005 CDC identified 45 outbreaks of foodborne illness that implicated unpasteurized milk, or cheese made from unpasteurized milk. They noted:

-These outbreaks accounted for 1,007 illnesses, 104 hospitalizations, and two deathsll (CDC,

2007b).

- 2005–2006: The U.S. Food and Drug Administration recorded more than 10 outbreaks caused by the consumption of raw milk or raw milk cheese (FDA, 2007).
- 2004: The National Association of State Departments of Agriculture (NASDA) survey indicated that 29 states have recorded milkborne outbreaks traceable to raw milk consumption (FDA, 2007).
- 2002–2003: Two children were hospitalized in Ohio for infection with Salmonella enterica serotype *typhimurium*. These children and 60 other people in Illinois, Indiana, Ohio, and Tennessee developed bloody diarrhea, cramps, fever, chills and vomiting from *S. typhimurium* tracked to consuming raw milk (CDC, 2003).
- 2001: An outbreak of *Campylobacter jejuni* infections from drinking raw or unpasteurized milk occurred in Wisconsin associated with milk procured through a cow-leasing program (CDC, 2002).
- 2000–2001: In North Carolina, 12 adults were infected with *Listeria monocytogenes* linked to homemade, Mexican-style fresh soft cheese produced from contaminated raw milk sold by a local dairy farm. Ten of the 12 victims were pregnant women, and infection with the bacterium resulted in five stillbirths, three premature deliveries, and two infected newborns (CDC, 2001).
- 1998: In Massachusetts, 66 people received injections to protect against potential exposure to rabies after drinking unpasteurized milk from a local dairy. A cow that died at the dairy was found to be infected with rabies. Transmission of the rabies virus through unpasteurized milk, although not the common route of infection, is theoretically possible according the Centers for Disease Control and Prevention (CDC, 1999).

Moreover, the occurrence of outbreaks due to raw milk has been found to correlate with the legal status of raw milk sale within a state. In a review of raw milk–associated outbreaks reported to CDC during 1972–1992, Marcia L. Headrick, D.V.M., M.P.H., and colleagues found that the rate of raw milk–associated outbreaks was higher in states in which the sale of raw milk was legal. The authors concluded that banning the intrastate sale of raw milk could reduce the number of milk-associated outbreaks (Headrick et al., 1998). This association was revalidated in an examination of outbreaks between 2007-2012 (Mungai, 2015).

Recently, advocates of the consumption of natural food have approached legislators in a number of states to allow the sale of raw milk to the consumer. They have contended that the pasteurization process destroys the nutritional benefits of milk. In some instances, they have pushed for the adoption of legislation that would allow individuals to purchase a portion of the production of a milk cow through an arrangement know as —Cow Share.

John Sheehan, Director of the U.S. Food and Drug Administration's Division of Dairy and Egg Safety, stated that research showed that there is no significant difference in the nutritional value of pasteurized and unpasteurized milk. He indicated that the caseins, the major family of milk proteins, is largely unaffected and any modification in whey protein that might occur is barely perceptible (Bren, 2004). Sheehan further stated: —Raw milk is inherently dangerous and should not be consumed. Raw milk continues to be a source of foodborne illness and even a cause of death within the United States.... Pasteurization destroys pathogens and most other vegetative microbes which might be expected and have shown to be present in milk (Testimony of John F. Sheenan, 2007).

A number of regulatory, educational, and public health organizations have issued position papers regarding the dangers associated with the consumption of raw milk. These include:

- Association of Food & Drug Officials (AFDO),
- American Public Health Association (APHA),
- American Medical Association (AMA),
- American Academy of Pediatrics,
- U.S. Animal Health Association,
- National Association of State Public Health Veterinarians,
- Council of State and Territorial Epidemiologists,
- · House of Delegates of the American Veterinary Medical Association,
- U.S. Food & Drug Administration, and
- International Association for Food Protection (IAFP).

The National Environmental Health Association recognizes the nutritional value of milk, and it further recognizes the overwhelming scientific evidence that raw milk can transmit pathogenic bacteria to the consumer. The National Environmental Health Association further recognizes the overwhelming

scientific and public health evidence that pasteurization of milk has been proven to be a sound method of preventing milkborne disease. NEHA therefore

- Opposes any legislation that would allow the sale or distribution of raw, unpasteurized milk to the consumer. NEHA further opposes arrangements such as —Cow Shares, —Herd Sharing, bartering, exchange, or any other action that would allow the consumer to obtain a portion of the production of raw, unpasteurized milk from a bovine, ovine, or caprine animal.
- Supports legislation that requires pasteurization of milk prior to sale or distribution to the consumer.
- Supports efforts to educate the consumer about the dangers inherent in consuming unpasteurized milk or
  - products made from raw milk.

The National Environmental Health Association has long supported preventive measures to protect the safety of food for the public. NEHA acknowledges the importance of milk as source of nutrition and is concerned about the safety of milk and products made from milk. NEHA's position regarding raw milk is consistent with sound, science-based, preventive public health measures.

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February 13, 2017

The Honorable Dennis Johnson Chair, Agriculture Committee North Dakota House of Representatives 7871 45th Street NE Devils Lake, ND 58301-9089

The Honorable Larry Luick Chair, Agriculture Committee North Dakota Senate 17945 101st Street SE Fairmount, ND 58030-9522

# Re: Oppose HB 1433 allowing state-wide direct sale of raw milk and milk products

Dear Chair Johnson and Chair Luick:

Due to the significant public health risks associated with the consumption of raw milk, the National Milk Producers Federation (NMPF) and the International Dairy Foods Association (IDFA) respectfully urge that you **oppose HB 1433**, legislation designed to allow the sale of unpasteurized milk in North Dakota. HB 1433 would remove existing regulations prohibiting the direct sale of raw milk, consumption of which has been opposed by every major health organization in the United States, including the American Medical Association and the American Academy of Pediatrics.

Consumption of raw milk is a demonstrated public health risk. The link between raw milk and foodborne illness has been well-documented in the scientific literature, with evidence spanning nearly 100 years. Raw milk is a key vehicle in the transmission of human pathogens, including *E. coli* O157:H7, *Campylobacter, Listeria monocytogenes*, and *Salmonella*.

Based on a 2012 report<sup>1</sup> from the Centers for Disease Control and Prevention (CDC), between 1993 and 2006, unpasteurized dairy products resulted in 73 known outbreaks – causing 1,571 cases of foodborne illness, 202 hospitalizations, and 2 deaths. The CDC also concluded that unpasteurized milk was 150 times more likely to cause food-borne illness outbreaks than pasteurized milk, and such outbreaks had a hospitalization rate 13 times higher than those involving pasteurized dairy products.

<sup>&</sup>lt;sup>1</sup> Langer, AJ, et al. Non-pasteurized dairy products, disease outbreaks, and state laws – United States, 1993-2006. Emerging Infectious Diseases. 2012; 18(3):385

The CDC has reported nearly 75% of raw milk-associated outbreaks have occurred in states where sale of raw milk was legal. Eliminating the regulations that currently prohibit the sale of raw milk in North Dakota increases the risk to public health, opening up the state's consumers to the inevitable consequence of falling victim to a foodborne illness. No matter how carefully it is produced, raw milk is inherently dangerous. Americans have become ill after consuming raw milk obtained from farms of varying sizes, from cow-share programs, and from licensed, permitted, or certified raw milk producers.

Nearly two-thirds of all outbreaks associated with raw-milk or raw-milk products involve children. For example, in 2011, five children in California were infected with *E. coli* O157:H7 after drinking raw milk; three required hospitalization with hemolytic uremic syndrome (HUS), a serious condition that may lead to kidney failure. At a school event in Wisconsin, also in 2011, sixteen fourth grade students and adults who drank raw milk donated by a parent later suffered from diarrhea, abdominal cramping, nausea, and vomiting from *Campylobacter* infections. It is the responsibility of North Dakota's leaders to make decisions to protect the health of the public, most especially those who are minors and are unable to make fully informed decisions that could have profound consequences for the rest of their lives.

One critical aspect of this high-profile issue is the tremendous amount of misinformation that has been disseminated regarding the supposed health benefits of raw milk. It is important to emphasize that <u>no claim related to the health benefits of consuming raw milk has been</u> <u>substantiated in any of the medical literature</u>. The scientific consensus is that raw milk can cause serious illnesses and hospitalizations, as well as result in life-long negative health complications and death.

Another misleading claim is that testing or regulating the sale of raw milk will protect consumers from the risks of raw milk consumption. This is also unfounded. Product testing is not an adequate substitute and cannot ensure the same level of safety as pasteurization. Legalizing and regulating the sale of raw milk sends a signal to consumers that drinking unpasteurized milk is safe when, in fact, the opposite is true.

Nationally, our dairy industry benefits from a very high degree of consumer confidence – confidence built in large part due to the excellent food safety record of milk and dairy products. Current statistics estimate only 1-2% of reported foodborne outbreaks are attributed to dairy products. However, of those, over 70% have been attributed to raw milk and inappropriately-aged raw milk cheeses. In a 2007 report<sup>2</sup>, the CDC concluded that "State milk regulations and methods for their enforcement should be reviewed and strengthened to minimize the hazards of raw milk". Allowing the sale of raw milk through HB 1433 would be a step in the wrong direction.

<sup>&</sup>lt;sup>2</sup> Bhat, M, et al. *Escherichia coli* O157:H7 Infection Associated with Drinking Raw Milk – Washington and Oregon, November–December 2005. MMWR. 2007; 56(8):165.

While choice is an important value, it should not pre-empt consumers' well-being. To allow the state-wide sale of raw milk is an unnecessary risk to consumer safety. Therefore, we strongly urge you to oppose HB 1433.

Please feel free to contact us with any questions.

Sincerely,

James Mulhern President and CEO National Milk Producers Federation

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Michael Dykes, DVM President and CEO International Dairy Foods Association

Enclosures cc: Members of the North Dakota House and Senate Agriculture Committees

The National Milk Producers Federation (<u>www.nmpf.org</u>), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

The International Dairy Foods Association (<u>www.idfa.org</u>), Washington, D.C., represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies representing a \$125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members run more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States.

# Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993–2006

Adam J. Langer, Tracy Ayers, Julian Grass, Michael Lynch, Frederick J. Angulo, and Barbara E. Mahon

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#### Release date: February 21, 2012; Expiration date: February 21, 2013

#### **Learning Objectives**

Upon completion of this activity, participants will be able to:

- Evaluate the epidemiology of foodborne illness related to the consumption of dairy products
- Analyze the clinical presentation and outcomes of foodborne disease related to the consumption of dairy products
- Distinguish the organism most commonly associated with foodborne illness after consumption of unpasteurized dairy products
- · Assess sources of contamination of pasteurized dairy products

#### Editor

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Although pasteurization eliminates pathogens and consumption of nonpasteurized dairy products is uncommon, dairy-associated disease outbreaks continue to occur. To determine the association of outbreaks caused by nonpasteurized dairy products with state laws regarding sale of these products, we reviewed dairy-associated outbreaks during 1993–2006. We found 121 outbreaks for which the product's pasteurization status was known;

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among these, 73 (60%) involved nonpasteurized products and resulted in 1,571 cases, 202 hospitalizations, and 2 deaths. A total of 55 (75%) outbreaks occurred in 21 states that permitted sale of nonpasteurized products; incidence of nonpasteurized product–associated outbreaks was higher in these states. Nonpasteurized products caused a disproportionate number (≈150× greater/unit of product consumed) of outbreaks and outbreak-associated illnesses and also disproportionately affected persons <20 years of age. States that restricted sale of nonpasteurized products had fewer outbreaks and illnesses; stronger restrictions and enforcement should be considered.

#### RESEARCH

In the United States, milk and other dairy products are dietary staples; the 2010 Dietary Guidelines for Americans recommend that most Americans include dairy products in their diet (1). However, numerous pathogens can contaminate dairy products and cause illness and death. Milkborne infections were relatively common before the advent of pasteurization in the late 19th century (2), and in the United States today, illness related to consumption of nonpasteurized dairy products remains a public health problem.

In 1948, Michigan enacted the first statewide requirement that dairy products be pasteurized, and many other states soon did the same (2). In 1987, the United States Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers (3). However, sale of nonpasteurized dairy products within the state where they are produced is regulated by each state, and some states permit sale of these products. Despite the federal ban on the sale of nonpasteurized products in interstate commerce, the broad use of pasteurization by the dairy industry, and the infrequency with which nonpasteurized dairy products are consumed, illnesses and outbreaks associated with consumption of these products continue to occur (4-23).

State and local health departments report foodborne disease outbreaks to the Centers for Disease Control and Prevention (CDC) through the Foodborne Disease Outbreak Surveillance System. As a result of efforts to enhance outbreak surveillance starting in 1998, the total number of outbreak reports increased substantially (24). A recent comprehensive analysis of foodborne disease outbreaks associated with dairy products (dairy-associated outbreaks) reported to CDC reviewed outbreaks that occurred during 1973–1992 (4). We reviewed subsequent dairy-associated outbreaks, reported in the United States during 1993–2006. We characterized the outbreaks and examined their association with state laws regarding sale of nonpasteurized dairy products.

#### Methods

To compare the incidence of foodborne outbreaks involving nonpasteurized dairy products among states with differing laws with regard to the sale of these products (i.e., states that permitted their sale vs. states that prohibited their sale), we reviewed reports of foodborne disease outbreaks involving dairy products reported to CDC during 1993–2006. These reports, completed by state and local health departments, typically included the number of cases associated with the outbreak; the age and sex distribution of outbreak-associated case-patients; the number of hospitalizations and deaths; the etiologic agent associated with the outbreak; the type of dairy product implicated (e.g., fluid milk, cheese); and whether the implicated dairy product was marketed, labeled, or otherwise presented to the consumer as pasteurized or nonpasteurized. Hereafter, we refer to these products as pasteurized or nonpasteurized. Thus, any outbreak involving a dairy product that was contaminated after pasteurization or that was intended to be pasteurized but underwent inadequate pasteurization was classified as involving pasteurized product. When possible, we corrected missing or incomplete data by asking the health department that conducted the investigation for more information.

To determine whether the sale of nonpasteurized dairy products was legal at the time of each outbreak, we contacted the 50 state departments of health and agriculture and requested data on whether the state permitted the sale of nonpasteurized dairy products produced in that state for each year from 1993 through 2006. We defined an illegal state-year as a year in which a state prohibited the sale of all nonpasteurized products, and we defined a legal state-year as a year in which a state permitted the sale of nonpasteurized dairy products produced in that state. Data on the estimated population, by state, for each year were obtained from the US Census Bureau. To compare the incidence of outbreak and outbreak-associated cases during illegal state-years to that during legal state-years, we stratified the outbreaks by legal status of the state in which the outbreak occurred at the time of the outbreak and calculated incidence density ratios for reported outbreaks (Poisson model) and for outbreak-associated cases (zeroinflated negative binomial model).

### Results

During 1993–2006, a total of 30 states reported 122 foodborne disease outbreaks caused by contaminated dairy products. Dairy-associated outbreaks occurred in all years except 1996, and outbreaks involving nonpasteurized dairy products occurred in all years except 1994 and 1996. The number of reported dairy-associated outbreaks increased in 1998 after surveillance for foodborne disease outbreaks was enhanced (Figure 1).

Whether the product was pasteurized or nonpasteurized was known for 121 of the 122 outbreaks, and most outbreaks (73 [60%]) involved nonpasteurized dairy products. Of the 121 outbreaks for which product pasteurization status was known, 65 (54%) involved cheese and 56 (46%) involved fluid milk. Of the 65 outbreaks involving cheese, 27 (42%) involved cheese made from nonpasteurized milk. Of the 56 outbreaks involving fluid milk, an even higher percentage (82%) involved nonpasteurized milk.

The 121 outbreaks involving dairy products for which pasteurization status was known resulted in 4,413 reported illnesses. Among these illnesses, 1,571 (36%) resulted from nonpasteurized dairy products. The median number of persons reported ill during outbreaks involving

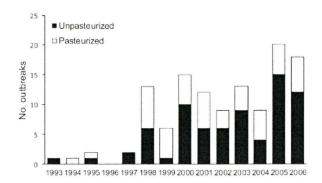


Figure 1. Number of dairy product–associated outbreaks, by year and pasteurization status of product, United States, 1993–2006.

nonpasteurized dairy products was 11 (range 2–202). Outbreaks involving nonpasteurized dairy products resulted in 202 hospitalizations (hospitalization rate 13%). In contrast, outbreaks involving pasteurized dairy products resulted in 37 hospitalizations (hospitalization rate 1%). Two deaths were associated with an outbreak caused by consuming nonpasteurized dairy products, and 1 death was associated with an outbreak caused by a pasteurized product (Table).

Ill persons in outbreaks involving nonpasteurized dairy products were generally younger than those in outbreaks involving pasteurized dairy products. For the 60 outbreaks involving nonpasteurized dairy products for which age of patients was known, 60% of patients were <20 years of age; for the 37 outbreaks involving pasteurized dairy products for which age of patients was known, 23% of patients were <20 years of age (p<0.001).

The causative agent was identified for all 73 outbreaks involving nonpasteurized dairy products; all were caused by bacteria. One outbreak was caused by *Campylobacter* spp. and Shiga toxin–producing *Escherichia coli*. Among the remaining 72 outbreaks, 39 (54%) were caused by *Campylobacter* spp., 16 (22%) by *Salmonella* spp., 9 (13%) by Shiga toxin–producing *E. coli*, 3 (4%) by *Brucella* spp., 3 (4%) by *Listeria* spp., and 2 (3%) by *Shigella* spp. Among the 30 outbreaks involving pasteurized dairy products for which the causative agent was reported, 13 (44%) were caused by norovirus, 6 (20%) by *Salmonella* spp., 4 (13%) by *Campylobacter* spp., 3 (10%) by *Staphylococcus aureus*, and 1 (3%) each by *Clostridium perfringens*, *Bacillus cereus*, *Listeria* spp., and *Shigella* spp.

A total of 48 reported outbreaks involved pasteurized dairy products. The source of contamination was reported for 7 (14%) of these outbreaks, of which at least 4 (57%) probably resulted from post-pasteurization contamination by an infected food handler. Failure of the consumer to store the dairy product at an appropriate temperature probably contributed to 3 other outbreaks. Such temperature abuse can enable pathogens (present because they either survived pasteurization in low numbers or were introduced after pasteurization) to multiply to concentrations capable of causing illness.

During the study period, 43 (86%) states did not change their legal status regarding the sale of nonpasteurized dairy products produced in that state. Among these 43 states, selling nonpasteurized dairy products produced in that state was legal in 21 (49%). Of the 7 states that changed their legal status, 3 changed from legal to illegal (Mississippi in 2005, Ohio in 2003, and Wisconsin in 2005), 3 changed from illegal to legal (Arkansas in 2005, Illinois in 2005, and Nevada in 2005), and 1 (Oregon) changed from legal to illegal in 1999 and then back to legal in 2005 (Figure 2).

Among the 700 state-years (14 years  $\times$  50 states) included in our analysis of the association of legal sales status and nonpasteurized dairy-associated outbreaks, sale of nonpasteurized dairy products produced in the state was legal for 342 state-years and illegal for 358 stateyears. We excluded from analysis 2 outbreaks caused by nonpasteurized dairy products because each occurred in multiple states with differing laws. Of the 71 remaining outbreaks involving nonpasteurized dairy products, 55 (77%) occurred in states where sale of nonpasteurized dairy products produced in that state was legal. Among these 71 outbreaks involving nonpasteurized dairy products, 1,526 persons became ill and 1,112 (73%) of these illnesses occurred in states where it was legal to sell nonpasteurized dairy products. Also among these 71 outbreaks involving nonpasteurized dairy products, 15 occurred in states where sale of nonpasteurized dairy

Product	Outbreak characteristic, no.						
	Total	Associated illnesses	Associated hospitalizations	Associated deaths			
Nonpasteurized							
Fluid milk	46	930	71	0			
Cheese	27	641	131	2			
Total	73	1,571	202	2			
Pasteurized							
Fluid milk	10	2,098	20	0			
Cheese	38	744	17	1			
Total	48	2,842	37	1			
All dairy	121	4,413	239	3			

### RESEARCH

products was illegal. The source of the nonpasteurized dairy products was reported for 9 of these outbreaks: 7 (78%) were associated with nonpasteurized dairy products obtained directly from the producing dairy farm, 1 was associated with nonpasteurized dairy products obtained under a communal program to purchase shares in dairy cows (i.e., cow shares, a scheme used to circumvent state restrictions on commercial sales of nonpasteurized dairy products) (11), and 1 was limited to members of a large extended family who consumed nonpasteurized milk from their own cow.

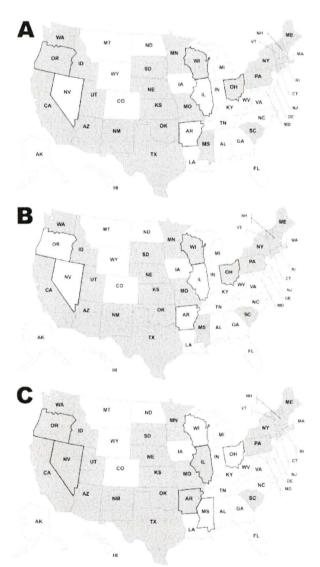


Figure 2. Legal status of nonpasteurized dairy product sale or distribution, by state, United States, for A) 1993, B) 1999, and C) 2006. Gray shading indicates states where nonpasteurized dairy product sale or distribution was permitted. States outlined in black changed legal status during the study period.

Incidence density ratios (IDRs) for nonpasteurized product-associated outbreaks and outbreak-associated cases during legal and illegal state-years varied by the type of dairy product (milk or cheese) and are reported separately. In states where it was legal to sell nonpasteurized dairy products, the rate of outbreaks caused by nonpasteurized fluid milk was  $>2\times$  as high as in states where it was illegal to sell nonpasteurized dairy products (IDR 2.20, 95% CI 1.14-4.25). The rate of outbreak-associated illnesses caused by nonpasteurized fluid milk was 15% higher in states where it was legal to sell nonpasteurized dairy products, but this result was not statistically significant (IDR 1.15, 95% CI 0.24-5.54). States where it was legal to sell nonpasteurized dairy products had nearly 6× the rate of outbreaks caused by cheese made from nonpasteurized milk (IDR 5.70, 95% CI 1.71-19.05) and nearly 6× the rate of outbreak-associated illnesses (IDR 5.77, 95% CI 0.59-56.31), although the IDR for outbreak-associated illnesses was not statistically significant.

## Discussion

Incidence of outbreaks caused by nonpasteurized dairy products was higher in states that permitted the sale of nonpasteurized dairy products than in states that prohibited such sale. This association was evident for nonpasteurized fluid milk and cheese made from nonpasteurized milk. Although this association did not extend to the rates of outbreak-associated cases, factors other than whether it was legal to sell nonpasteurized dairy products probably affect the number of cases that occur in an outbreak. These factors include the volume and area of distribution of the contaminated product, the pathogen involved, the underlying health status of the exposed persons, and the ability of the responding public health agency to swiftly intervene to terminate the outbreak.

Because consumption of nonpasteurized dairy products is uncommon in the United States, the high incidence of outbreaks and outbreak-associated illness involving nonpasteurized dairy products is remarkable and greatly disproportionate to the incidence involving dairy products that were marketed, labeled, or otherwise presented as pasteurized. In a population-based survey conducted in 1996-1997, only 1.5% of respondents reported having consumed nonpasteurized dairy products in the 7 days before being interviewed; and in the 2003-2004 and 2005-2006 National Health and Nutrition Examination Surveys, only <1% of respondents who drank milk reported that they usually drank nonpasteurized milk (21,25,26). Because many of these respondents also reported consuming pasteurized dairy products, the proportion of dairy products consumed nonpasteurized by volume or weight is probably <1%. To illustrate this point, it is useful if we provide a hypothetical weighting of the findings in this study by the amount of nonpasteurized and pasteurized dairy products consumed. Total milk production in the United States in 2010 was estimated at 193 billion pounds, suggesting that  $\approx$ 2.7 trillion pounds of milk were consumed during the 14 years from 1993 through 2006 (27). If 1% of dairy products were consumed nonpasteurized, then during these 14 years, 73 outbreaks were caused by the 27 billion pounds of nonpasteurized dairy products that were consumed and 48 by the 2,673 billion pounds of pasteurized products that were consumed. Therefore, the incidence of reported outbreaks involving nonpasteurized dairy products was  $\approx 150 \times$  greater, per unit of dairy product consumed, than the incidence involving pasteurized products. If, as is probably more likely, <1% of dairy products are consumed nonpasteurized, then the relative risk per unit of nonpasteurized dairy product consumed would be even higher.

After 1998, when surveillance for foodborne outbreaks was enhanced, the number of reported foodborne disease outbreaks caused by dairy products increased, as did the total number of reported foodborne outbreaks. Outbreaks involving nonpasteurized dairy products were all associated with bacterial enteric pathogens, most of which have known animal reservoirs. In contrast, among outbreaks in which a pasteurized dairy product was implicated, the most commonly reported causative agent was norovirus (44% of outbreaks), a pathogen with a human reservoir. These results suggest that outbreaks caused by nonpasteurized dairy products are probably caused by pathogens in the dairy environment, which would be eliminated by proper pasteurization, and that outbreaks caused by pasteurized dairy products are probably caused by contamination of the products at some point after pasteurization.

The objective of pasteurization is to eliminate from fluid milk those pathogens that originate in the dairy environment; however, pasteurization does not protect against contamination that might occur later, such as during food handling. In addition, if pasteurization is not performed properly (for appropriate times and at appropriate temperatures), pathogens might not be eliminated from the milk. Appropriate post-pasteurization food-handling practices can minimize the risk for reintroduction of pathogens into dairy products after pasteurization. In addition, other precautions, such as maintaining the dairy product at an appropriate temperature and disposing of expired products, reduce the risk to the consumer should the product become contaminated after pasteurization. When outbreaks do occur because of contamination of dairy products that are marketed as pasteurized, the source of contamination is typically traced to improper pasteurization, improper storage, or improper handling of the products after marketing (28-30). In our study, all outbreaks associated with pasteurized products for which

information on the source of contamination was available were attributed to post-pasteurization mishandling.

Among outbreak-associated cases involving nonpasteurized dairy products, 60% involved persons <20 years of age. Public health and regulatory authorities are obligated to protect persons who cannot make fully informed decisions (e.g., children) from potential health hazards. Dietary decisions for younger children, in particular, are often made by caregivers. The American Academy of Pediatrics advises against giving nonpasteurized dairy products to children and recommends that pediatricians counsel caregivers against use of these products (*31*).

Proportionately more persons were hospitalized during outbreaks caused by nonpasteurized (13%) than by pasteurized dairy products (1%). This observation suggests that infections associated with nonpasteurized dairy products might be more severe, and it is consistent with the more frequent identification of bacterial, rather than viral or toxic, causative agents and with the larger proportion of illnesses affecting children.

Limitations of this analysis are primarily associated with the nature of the CDC Foodborne Disease Outbreak Surveillance System. Outbreak reporting by state and local health departments is voluntary, and outbreak reports are not always complete. For this analysis, we obtained missing data whenever possible by contacting the reporting state health department. In addition, the CDC outbreak surveillance database is dynamic; reporting agencies can submit new reports and can change or delete previous reports at any time as new information becomes available. Therefore, the results of this analysis represent data available at 1 point in time and might differ from those published earlier or subsequently.

In summary, foodborne outbreaks involving dairy products continue to be a public health problem in the United States, and this problem is disproportionately attributable to nonpasteurized dairy products. Since the US Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers in 1987, all legal sale and distribution has occurred within states that permit the sale of nonpasteurized dairy products that originated in that state. How much illegal distribution in interstate commerce continues is unknown. The increased risk for outbreaks associated with legal intrastate sale of nonpasteurized dairy products demonstrated in this analysis can be weighed against the purported nutritional or other health benefits attributed to these products. Scientifically credible evidence for the health benefits of nonpasteurized dairy products beyond the benefits of those of otherwise equivalent pasteurized products is lacking (32). The risk for outbreaks resulting from cheese made from nonpasteurized milk in states where nonpasteurized

#### RESEARCH

milk sale is legal may be higher for particular groups within those states. For example, in recent years, foodborne outbreaks involving nonpasteurized dairy products have been reported in association with traditional nonpasteurized products marketed to the growing Hispanic community in the United States (5,33).

Our analysis shows that legal intrastate sale of nonpasteurized dairy products is associated with a higher risk for dairy-related outbreaks and implies that restricting sale of nonpasteurized dairy products reduces the risk for dairy-related outbreaks within that state. Pasteurization is the most reliable and feasible way to render dairy products safe for consumption. Although warning labels and signs or government-issued permits are prudent where the sale of nonpasteurized dairy products is legal, they have not been shown to be effective and, given the results of this analysis, do not seem to reduce the incidence of outbreaks involving nonpasteurized dairy products to the degree that pasteurization does (18). Whether certain types of warnings or more explicit health advisories might be more effective than others is unknown. Public health officials at all levels should continue to develop innovative methods to educate consumers and caregivers about the dangers associated with nonpasteurized dairy products. State officials should consider further restricting or prohibiting the sale or distribution of nonpasteurized dairy products within their states. Federal and state regulators should continue to enforce existing regulations to prevent distribution of nonpasteurized dairy products to consumers. Consumption of nonpasteurized dairy products cannot be considered safe under any circumstances.

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Dr Langer was a CDC Preventive Medicine Fellow assigned to the Division of Foodborne, Bacterial, and Mycotic Diseases at the time of this study. He is now an epidemiologist with the CDC Division of Tuberculosis Elimination. His research interests include the investigation of infectious disease outbreaks and animal-to-human transmission of infectious agents.

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a lesser prevalence of stage 1 and stage 2 CKD compared with using one urine test, resulting in more conservative estimates for CKD overall (11.0% versus 14.5%). Thus, CKD in this report might be overestimated (4). Third, the data are crosssectional, not longitudinal, preventing assessment of whether risk factors caused or resulted from CKD. Finally, the number of persons with stages 3, 4, and 5 CKD is small, limiting the power of the analysis and precluding separate estimates for persons with stage 4 and stage 5 and comparison of estimates by demographic characteristic and risk factor.

New programs aimed at decreasing the number of CKD cases were established recently (*1,10*). The National Kidney Disease Education Program provides resources to the public, patients, and health-care professionals with the goal of reducing morbidity and mortality from kidney disease complications. World Kidney Day was instituted in 2006 to increase awareness of kidney disease and promote early detection. Continued surveillance of albuminuria and serum creatinine using NHANES can track the prevalence of CKD, monitor trends, and identify groups at high risk, enabling targeted programs. Finally, CDC is working with Johns Hopkins University and the University of Michigan to develop a comprehensive national surveillance system for CKD that will monitor early stages of the disease and its risk factors and the effects of CKD on the U.S. population.

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## Escherichia coli O157:H7 Infection Associated with Drinking Raw Milk — Washington and Oregon, November–December 2005

During the week of December 5, 2005, public health officials in Clark County, Washington, were notified of four county residents with laboratory-confirmed Escherichia coli O157:H7 infection. All four residents reported having consumed raw (i.e., unpasteurized) milk obtained from a farm in neighboring Cowlitz County, Washington. The farm participated in a cow-share program, in which persons purchase interests in, or shares of, dairy cows in return for a portion of the milk produced.\* The farm had five dairy cows and regularly provided raw milk to shareholders. Although the sale of raw milk and cow-share agreements are illegal in certain states, they are legal in Washington; however, Washington farms that provide raw milk to consumers must be licensed, meet state milk-production and processing standards, and pass health and sanitation inspections by the state department of agriculture (1). The Cowlitz County farm was not licensed. This report summarizes the investigation of E. coli O157:H7 cases associated with the farm and reinforces previous warnings about the health hazards of consuming raw milk.

The farm's shareholder list, obtained through a court order, was used to conduct a retrospective cohort study to identify risks for infection. During December 16–19, 2005, shareholders were interviewed by telephone using a standard question-naire to collect information regarding their milk consumption since November 20, 2005. Forty-three of the 45 families who held shares in the dairy cows from the farm were interviewed; information regarding 157 persons was collected. A case was defined as either 1) laboratory-confirmed *E. coli* O157:H7 infection or 2) diarrhea with abdominal cramping or blood in a person with illness onset during November 20–December 13, 2005, who was a customer of the farm. Additional cases in the community were identified using faxed health alerts

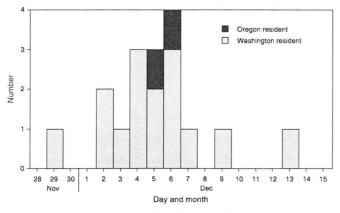
<sup>\*</sup> In a cow-share agreement, a person who does not own, house, or care for the milking cow signs a contract or an agreement with the owner of the cow, pays an initial contract fee, and pays a monthly fee for the boarding and care of the cow. Depending on state law, the person might subsequently have partial ownership in the cow. In exchange for the fees, the person has the right receive on a weekly basis a certain amount of unpasteurized milk, milk products, or both produced from the cow. The person can either pick up the unpasteurized milk at the farm or pay someone else to pick it up and deliver it or can pay a fee to the owner of the cow to have the products delivered.

and media releases to notify health-care providers, infectioncontrol practitioners, neighboring public health agencies, and the public of the cluster of illnesses.

Eighteen cases were identified among the 43 families who were interviewed, and eight (44%) of these were laboratory confirmed. Dates of illness onset ranged from November 29 to December 13, 2005 (Figure). Patients were residents of two southwest Washington counties and one northwest Oregon county. The median age was 9 years (range: 1–47 years); nine (50%) were female. Among the 18 patients, 17 (94%) reported diarrhea, 13 (72%) bloody diarrhea, and 13 (72%) abdominal cramps. Five patients (28%), aged 1–13 years, were hospitalized; four of these had hemolytic uremic syndrome (HUS). Seventeen patients were farm shareholders or children of shareholders; one patient, a child aged 10 years, was a friend of a shareholder.

Of 140 persons who reported consuming raw milk from the farm, 18 (13%) became ill; among the 157 persons for whom information was obtained, no illness was reported among those who did not consume raw milk. Among 102 of 140 exposed persons who provided information about their raw milk consumption during November 20–December 13, the relative risk for illness increased with the average number of cups of milk consumed daily. The dose-response trend for average daily consumption was statistically significant (p=0.008 by expanded Mantel-Haenszel chi-square test), with attack rates of 3.6% for 0–0.9 cups of milk, 6.7% for 1–1.9 cups, 14.3% for 2–2.9 cups, and 37.5% for  $\geq$ 3 cups. Visiting the farm and consumption of raw milk products from other sources were not associated with illness.

#### FIGURE. Number of persons reported with *Escherichia coli* O157:H7 infections who were customers of a Cowlitz County, Washington, farm, by date of illness onset and state of residence — Washington and Oregon, November–December 2005



\* n = 17. Although 18 cases were identified during the investigation, for one patient who was asymptomatic, date of illness onset could not be established.

Pulsed-field gel electrophoresis (PFGE) was used to analyze *E. coli* O157:H7 isolates from stool samples from eight patients; seven (88.0%) isolates had PFGE patterns that were indistinguishable (pattern A), and one isolate from an Oregon patient had a PFGE pattern that differed from pattern A by one band.

*E. coli* O157:H7 also was isolated from raw milk samples obtained from the farm and one shareholder. In addition, *E. coli* O157:H7 was isolated from seven environmental samples collected from the floor of the farm milking parlor. All *E. coli* O157:H7 isolates from milk and environmental samples had PFGE pattern A. No *E. coli* O157:H7 was isolated from stool samples of any of the farm's five cows.

During inspections of the farm, officials from the Washington State Department of Agriculture (WSDA) noted mud and manure accumulation in the entrance to the milking parlor and on the rubber mats covering the dirt floors of the parlor. The bucket used for milk collection had direct contact with these surfaces. Inspectors also noted inadequate handwashing facilities and improper procedures for cleaning milking equipment and handling fresh milk.

On December 9, 2005, the farm contacted shareholders and advised them to discard any remaining raw milk. After a court order was obtained by the Cowlitz County Health Department and an embargo was placed by WSDA, the farm discontinued sales of raw milk on December 13, 2005. No additional reports of illness associated with the farm have been received.

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**Editorial Note:** *E. coli* O157:H7 causes an estimated 73,000 illnesses and 61 deaths annually in the United States (2). Approximately 8% of reported infections lead to HUS, particularly in children aged <5 years and older adults (3); 4% of patients with HUS die (4). Raw milk is an important vehicle of transmission of *E. coli* O157:H7 and other pathogens, including *Mycobacterium bovis, Listeria monocytogenes,* and *Campylobacter, Brucella,* and *Salmonella* species (5,6). During 1988–2005, a total of 33 outbreaks of *Campylobacter* species, *E. coli* O157:H7, and *Salmonella* species infections associated with raw milk consumption were reported to CDC (7).

Several findings from this investigation indicate that consumption of raw milk was the cause of the outbreak: 1) all ill persons drank raw milk; 2) the illness risk increased with the amount of milk consumed; 3) *E. coli* O157:H7 was isolated from raw milk samples and environmental samples collected from the milking-parlor floor; and 4) PFGE patterns of isolates from patient, milk, and environmental samples were indistinguishable. Investigators found several factors that might have contributed to contamination of milk at the farm, although previous outbreaks have demonstrated that even raw milk collected using stringent hygiene methods might be contaminated with pathogens (9).

Although many consumers are aware that raw milk can contain pathogens, some believe that it has potential benefits (e.g., vitamins that are present naturally rather than added, enhanced fertility, and protection against tooth decay). However, the validity of any health or nutritional benefits from consuming raw milk has not been proven scientifically (6).

Raw milk is a well-documented cause of enteric infections and was first recognized as one approximately 100 years ago (6). Pathogens that infect humans, including E. coli O157:H7, are shed in the feces of cows and can contaminate milk during the milking process. Using standard hygiene practices during milking (e.g., washing hands, keeping equipment clean, and keeping the milking area separated from other areas) can reduce but not eliminate the risk for milk contamination. Pasteurization decreases the number of pathogenic organisms, prevents transmission of pathogens, and has been determined to improve the safety of raw milk more than other measures, including certification of raw milk (8). Because raw milk certification has failed to prevent many raw-milk-associated infections in the past, consumers should not assume that certified raw milk is free of pathogens (9). To prevent E. coli O157:H7 and other infections, consumers should not drink raw milk.

In Washington, cow-share programs and the regulated sale of raw milk are legal; however, the Cowlitz County farm was not licensed, and it did not follow applicable sanitation and public health safety regulations. As a result of this outbreak, WSDA revised regulations to help ensure that milk producers who sell pasteurized milk and those who sell raw milk through cow-share programs obtain the appropriate state licenses and comply with milk-processing sanitation and public health guidelines. As of February 2007, raw milk could be sold legally in 27 states, including Washington. During 1973–1992, a total of 40 (87%) of the 46 reported raw-milk–associated illness outbreaks occurred in states in which the intrastate sale of raw milk was legal (5). State milk regulations and methods for their enforcement should be reviewed and strengthened to minimize the hazards of raw milk.

Early in the 20th century, widespread adoption of the pasteurization process led to substantial reductions in milk-associated disease, a milestone in the history of food safety (10). In the 21st century, more effective consumer education regarding the hazards of drinking raw milk is needed to further reduce milk-associated diseases.

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## Rates of Hospitalization Related to Traumatic Brain Injury — Nine States, 2003

Traumatic brain injury (TBI) is a major cause of morbidity and mortality in the United States. Each year, on average, TBIs are associated with an estimated 1.1 million emergency department visits, 235,000 hospitalizations, and 50,000 deaths in the United States (1). For 2002, the overall rate of TBIrelated hospitalization reported by the 12 states in the CDC TBI surveillance system was 79.0 per 100,000 population (2); across these states, however, the rates varied substantially (from 50.6 in Nebraska to 96.9 in Arizona). To update results from the CDC TBI surveillance system, CDC analyzed data from 2003, the most recent year for which data were available. This report summarizes the results of that analysis, which indicated that an estimated 28,819 persons (87.9 per 100,000 population) were hospitalized with a TBI-related diagnosis in the nine states that reported data for 2003. For all age groups combined, rates were higher among males. Age-specific rates

# Food Safety News

Breaking news for everyone's consumption

## A Mom and a Dairyman Plead: Don't Feed Children Raw Milk

Kylee Young was a healthy two-year-old when she contracted an E. coli infection from drinking raw milk, an illness that caused a stroke and culminated in a kidney transplanted from her mom.

By Cookson Beecher | February 18, 2014



Two years ago, when Oregon parents Jill Brown and Jason Young met Brad and Tricia Salyers, the families had no idea that they would eventually be sharing in a tragedy that sickened four of the Salyers' children and left Brown and Young's youngest child, Kylee – 23 months old at the time – with such severe medical complications that she would need a kidney transplant from her mother.

All of that and more happened beginning in April 2012 when the children were among 19 people -15 of them under the age of 19 — who fell ill with E. coli O157:H7, a potentially fatal foodborne pathogen. Soon after, Oregon health officials determined that the outbreak was caused by raw milk from Foundation Farm near Wilsonville in Western Oregon — the Salyers' family farm. Four of the sickened children were hospitalized with kidney failure.

Foundation Farm had been providing 48 families with raw milk. Raw milk is milk that hasn't been pasteurized to

kill harmful and sometimes deadly foodborne pathogens such as E. coli, Listeria, Salmonella and Campylobacter.

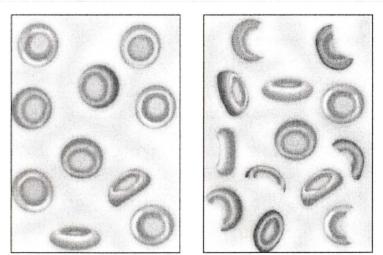
While many raw milk advocates say it has inherent nutritional advantages and even helps cure or ease the symptoms of ailments such as asthma and various allergies, most food-safety experts discount those claims as anecdotal, saying they're not based on science. They also warn of the serious risks to human health associated with drinking milk that hasn't been pasteurized.

The symptoms of E. coli O157:H7 infection typically include bloody diarrhea and other digestive-tract problems. In some people, this type of E. coli may also cause severe anemia or hemolytic uremic syndrome (HUS), a complication in which toxins destroy red blood cells, which are typically smooth and round. The misshapen or deformed blood cells can clog the tiny blood vessels in the kidneys, causing them to fail.

Statistics from the Centers for Disease Control and Prevention (CDC) underscore the potential dangers of raw milk. According to the agency, between 1998 and 2011, 148 outbreaks due to consumption of raw milk or raw milk products were reported. In those outbreaks, there were 2,384 illnesses, 284 hospitalizations and two deaths. Estimates from the agency put raw milk consumption at 3 percent of total milk consumption.

Currently, 29 states allow some form of on- or off-farm raw milk sales, but only a few allow sales in grocery stores. In Oregon, it is against the law to sell raw cow's milk, although there is an exemption for very small herds (no more than three cows on the premises, with no more than two of them being milked). Under that exemption, the milk must be sold on the farm and no advertising of the product is allowed. CDC has documented fewer illnesses and outbreaks from raw milk in states that prohibit sales.

## Goals in common



Healthy red blood cells (left) are smooth and round, while blood cells damaged by E. coli toxins are misshapen and may clog the blood vessels in the kidney, causing HUS.

The irony of this story is that the two families shared a common goal to provide their children with nutritious food. Now they share another goal: to warn people that raw milk can be dangerous to drink, or even deadly. As parents, they want to let other parents know that they shouldn't feed raw milk to their children, no matter what some raw-milk farmers and advocacy organizations might say.

"There might be some benefits of raw milk, but there are huge risks," Jill Brown, Kylee's mother, told **Food Safety News**. "There needs to be more public awareness that this is a high-risk food. If I had known what I know now, I would never have fed it to my daughter."

Despite formerly selling raw milk, the Salyers agree.

"The people who bought our milk thought it was the healthiest choice for their kids," said Brad Salyers, co-owner of Foundation Farm. "But I see things differently now. By far, it's the most dangerous food you can feed them because of the chance it can be contaminated with E. coli or other harmful pathogens." Knowing he fed raw milk to his children, Salyers' thoughts on the topic now veer into the emotional:

"It breaks my heart that anyone would give it to their children," he said. "What's even more troubling is that some of our friends who saw what our kids went through are still feeding raw milk to their children."

Salyers rankles at what he says is the proliferation of too much misinformation about raw milk's purported health benefits.

"It's duping people into thinking you can safely drink raw milk," he said.

The worst part of this, he added, is that children are especially vulnerable to contracting E. coli or other pathogens from raw milk, primarily because their immune systems are still developing.

According to a recently released statement from the American Academy of Pediatrics, the health claims related to drinking raw milk have not been verified by scientific evidence, and, therefore, do not outweigh the potential health risks that raw milk poses to pregnant women and children.

"Children depend on their parents," Salyers said. "They don't make the decision to drink or not to drink raw milk. They're at the mercy of their caretakers."

"We definitely want to get the word out about the dangers of raw milk," Tricia Salyers said.

## Sold their cows

Once the Salyers saw what Brad Salyers refers to as the "devastation that HUS can cause in children," they immediately sold their cows.

"We didn't want to put kids at risk," Salyers said, pointing out that four of his family's five children came down with E. coli, with one of the four developing HUS.

"She fought for her life for 27 days," he said.

He objects to conspiracy theories that paint the government and food-safety scientists as "the enemy" when it comes to restrictive raw milk laws and the information they provide to customers (and farmers) about the potential dangers of raw milk.

"They're so cynical that they can't see straight," said Salyers. "They put their trust in some organizations with myopic agendas — places that glorify raw milk as 'miracle' food. That's nonsense. It's based on a lot of misinformation."

So why do people ignore warnings about the potential dangers of raw milk? According to a 2011 study that looked at what motivated people in Michigan to drink raw milk, cynicism about government surfaced. The study's authors told **Food Safety News** that they were surprised to find that only a small percentage of those surveyed trusted public health officials regarding which foods are safe to eat or drink.

The survey respondents also took issue with some of the survey's other statements, once again revealing sharp differences of opinion with official government views on the potential health hazards of drinking raw milk. For example, when asked if they agreed or disagreed with the statement that, "Drinking raw milk increases your risk of getting a foodborne disease," an average of 44 (or 78.6 percent) disagreed. Only six respondents agreed with

the statement, and another five (or 8.9 percent) respondents said they weren't sure.

As for those who think that "knowing your farmer" is safeguard enough, even raw-milk dairies with high sanitation standards and licensed and inspected by states that allow raw milk sales – California and Washington state are two of these – have been subject to recalls due to the presence of pathogens such as E. coli and Campylobacter in their milk. Those recalls are typically triggered by foodborne-illness outbreaks that have sickened people.

According to CDC, while adherence to good hygienic practices during milking can reduce contamination, it cannot eliminate it.

"The dairy farm environment is a reservoir for illness-causing germs," CDC says. "No matter what precautions farmers take, and even if their raw milk tests come back negative, they cannot guarantee that their milk, or the products made from their milk, are free of harmful germs."

Logistics come into the picture here. There's no way to test every part of every batch of milk 365 days a year. While testing will provide important clues about whether things are being done right, it doesn't ensure that all of the milk a farm produces will be safe.

Or, as Dr. Tim Jones, epidemiologist with the Tennessee Department of Health, puts it: "Those who consume raw milk are playing Russian roulette with their health; the glass they drink today may not have deadly microorganisms, but the one they drink tomorrow may cause serious health problems or even death."

Germs such as E.coli, Campylobacter and Salmonella can contaminate milk during the process of milking dairy animals, including cows, sheep and goats. Animals that carry these germs usually appear healthy.

Brad Salyers said that a health official who visited his farm after the outbreak told him that it's not just about making sure the cow's udder is clean. Contamination could occur from something as simple as one drop of rain containing some E. coli O157:H7 bacteria picked up from the cow's hide trickling down the side of the cow. Not only are these germs extremely tiny, it takes only one or two of them to replicate inside the milk and make someone sick. And, unlike earlier strains of E. coli, this toxin-releasing strain, which wasn't identified as a cause of human illness until the 1980s, is far more virulent.

This chronology can confuse people. They don't understand how their grandparents who drank raw milk all of their lives never got sick from E. coli. But scientists believe E. coli didn't pick up the genes that cause human illness until late last century. Now that this disease-causing strain of the bacterium is commonly found in most cowherds, people can, and do, become ill from drinking contaminated milk.

Even more confusing for some is that cows that have this strain of E. coli in their systems generally don't show any signs of being infected with it. Then, too, it can come and go on a farm. It can be present in some of the cows or in water tanks or the soil for awhile and then disappear from one or all of these possible "harboring" places, only to return again.

## What happened?

Like most mothers, Jill Brown wanted to feed her family the best food possible. For her, that meant growing a garden, buying as much food as she could from local farmers,



http://www.foodsafetynews.com/2014/02/a-mom-and-a-dairymans-plea-...

and eventually buying raw milk for her toddler, who was an avid milk drinker.

Her quest to find raw milk was in large part triggered by her desire to steer clear of "industrial agriculture" and buy from a local farm instead. She saw it as a good fit with the philosophy of the "local food movement," which her family and many of their friends embrace.



"I wanted to know where the milk I was buying was coming from," she said. "My research led me to believe that raw milk from a local farm would be healthier than the milk I bought at the store."

After finding Foundation Farm through an Internet search, Brown became a herd-share member. Under a herd-share arrangement, people can buy a share of the herd, or even an individual cow, with the understanding that they are not customers of the dairy but rather owners of the herd and the milk produced by the herd. Some refer to this arrangement as a "legal loophole." In Oregon, herd shares have not been challenged in court, according to information from the state's agriculture department.

Foundation Farm was providing raw milk to 48 households under a herd-share arrangement. On the legal front, the families couldn't sue the Salyers after the outbreak because the Salyers didn't have insurance, and they were leasing the land where they were farming. In short, they had no assets that could be taken and sold to raise money for the aggrieved families.

While it was a commitment to go to the farm once a week to get the milk, Brown believed it was well worth it, despite the inconvenience and additional cost.

"It felt good to know that we were getting 'real, actual milk," she said. "[The Salyers] seemed to be doing everything right."

In talking with them, she had learned that, before setting up a herd share, they had visited other raw-milk dairies and had improved on what they saw.

Even though, for the most part, no one in her family except Kylee drank milk, the toddler loved it and thrived on the raw milk from Foundation Farm. But it was short-lived. Brown said that Kylee probably only drank it for three months before things went wrong.

"It was pretty sudden," Brown said. "We went to the farm to get some milk on Friday, the last day of spring break."

The following Wednesday, Kylee was sick, an "exploding diaper" the first sign of problems to come. On Friday, her dad stayed home with her and took her to the pediatrician, who said she had a stomach bug.

By Saturday, she couldn't keep food down and was becoming dehydrated. They took her to the emergency room, where she was put on an IV, with oral rehydration administered every 10 minutes.

They chose to take her home that night, and, on Sunday, she was starting to feel better. But, on Monday night, they were called back to the hospital.

When Brown stood Kylee up, she was dismayed to see her walking backward, apparently disoriented. She rushed Kylee to the emergency room and was told that her kidneys had shut down. Kylee was admitted to the pediatric intensive care unit, and, the next day, she received the necessary set-up lines to start dialysis.

"That's when our whole life changed," Brown said. "From there, every step of the way, things got worse and worse. Each day brought more bad news."

Kylee developed edema, was having a hard time breathing, and her eyes were crossing.

"She had had a stroke," said Brown.

Once a happy, energetic toddler, Kylee now couldn't walk or say words, although for the first couple of days she did say "mama," "papa," and "no."

Even though test results from a stool sample submitted on Monday were not back yet, Kylee was diagnosed with HUS.

Brown went to work researching the medical problem.

"When you're Googling 'bloody stool or vomiting,' one of the top things that comes up is raw milk," she said.

Several days after Kylee had been admitted to the hospital, another child with E. coli was admitted. By April 21, a total of 19 people were confirmed ill with E. coli traced to raw milk from Foundation Farm. Of those, 15 were under the age of 19. Four of the Salyers' five children were among those ill, with one of them among four children suffering from HUS.

Kylee was on a ventilator, but she wasn't getting better. Before long, the other children who had been hospitalized were talking about going home. But that wasn't in store for Kylee.

The lab results came back and showed that her bowels were necrotic and that she needed surgery. Her heart stopped while she was in surgery and she had to be brought back to life.

"That was probably the hardest part," said Brown.

But then suddenly, Kylee started doing much better. They took her off of dialysis in early June. She had been on dialysis for eight weeks.

After five weeks of rehab in the hospital, Kylee could go home, and Brown started going to work two days a week. November and December were good months. Kylee was getting stronger and sitting up on her own.

But then in January, lab tests came back that didn't look good. By February, the toddler had to go to the dialysis center in the

## It's Not Your Grandfather's E. coli

Many farmers and old-timers believe that E. coli illness outbreaks are caused by the "over-pampered" immune systems of city and suburban dwellers.

"We drank raw milk all of the time and never got sick," they'll say.

Or: "No one we knew ever got E. coli."

But the potentially fatal form of E. coli that's causing the outbreaks today weren't around 35 years ago.

As explained in simple layman's terms by microbiology food scientist Karen Killinger of Washington State University, what led to "the birth" of E. coli O157:H7 was a disease-causing form of E. coli that absorbed some genes from another pathogen to produce a virulent toxin and adjust to acidic environments. The new form of pathogenic E. coli that emerged was many times more virulent than its hospital three times a week for three hours a day. She was also admitted frequently throughout 2013 for multiple staph infections and other issues related to her kidneys.

#### weaker cousins.

Brown quit her job in May to stay home, finding it too hard to manage a household with two other children and be at the hospital for Kylee. In the meantime, Kylee struggled. Being on dialysis, she had only 15 percent kidney function and didn't have the energy for weekly physical therapy sessions.

The doctors decided that the toddler needed a kidney transplant. Brown and Young started the donor "work up" for a kidney transplant in June and July and were scheduled for the transplant on Sept. 9.

"She'll get 120 percent of her kidney function from this," Brown told **Food Safety News** several days before the surgery. "The hope is that she'll feel better and have the energy for therapy."

Kylee's father Jason Young told videographer Terry Tainter that when they realized that their toddler was going to need a kidney transplant, the word "now" took on new meaning.

"One of the biggest things that went through my mind at that point is that this is now," he said. "This is now a lifelong thing. There is no full recovery from this anymore. And there never will be. It's always going to have to be someone else's organ that keeps her alive."

People who have kidney transplants often have to have another in future years, something that both Brown and Young know.

All in all, the little girl has spent close to 200 days in the hospital since she was admitted in April 2012, with her mother by her side much of the time. The good news is that, as of mid-February 2014, the last time she had to be hospitalized was September 2013.

Before the transplant surgery, Tricia Salyers started a fundraiser. After the operation, she let Facebook readers know that Kylee was making "HUGE" strides forward in her recovery.

"What a miracle this transplant has been," she said, adding that all sorts of bills have been coming in from, among them, the insurance company, the hospital, and pharmacies. Salyers said that the \$7,500 fundraising goal would get Brown and Young through the end of the year and pay off current medical debts.

On Jan. 26, Brown was happy to report that the goal was met, although medical bills will burden the family for years to come.

Through all of this, Brown and Tricia Salyers became friends.

"I'm so glad I chose to move on and forgive," Brown said. "It's so easy to blame the farmer. But they were just as much blindsided as we were. They fed all of their kids the milk. I do believe they thought they were doing things right."

Kylee will continue to need physical therapy and speech therapy for a long time, only part of which insurance will cover. But the family recently received some good news. The Wheel to Walk Foundation has approved Kylee for a grant to help cover the cost of her intensive therapy that insurance doesn't cover. Even so, there are still a lot of uncovered expenses, including medical equipment and medications such as immunosuppressants to prevent her system from rejecting her mother's kidney.

Although Kylee is for the most part stable medically, she still can't speak words, can't walk, uses a special table to stand, and eats through a special tube. Because she understands what's going on around her, she experiences a lot of frustration in not being able to express her thoughts and feelings in words.

With limited insurance and no chance of getting a settlement to help pay the bills, and with their two-story house no longer suitable for a child with Kylee's disabilities, Brown and Young have had to sell their home. The sale is expected to close in mid-March.

In another unforeseen bond tying the two families together, Tricia Salvers, who went into real estate after she and her husband sold the cows, handled the sale of Brown and Young's home.

## The farmer's perspective



"We were foodie-type people," said Brad Salyers. "We felt the food system in this country was messed up. We were trying to get back to basics."

That led them to information that extolled the benefits of raw milk from grass-fed cows.

"We believed all the hype about its benefits," he said.

They started buying raw milk from a farm but eventually decided to buy their own cow, thinking they could improve on what

they saw at the farm. Once they had their own cow, they quickly realized they were going to have a surplus of milk. Thinking that they could find people who would want it, the Salyers visited other farmers known for their dedication to cleanliness and learned from them.

"I felt I had enough information to put the necessary safeguards into place," Brad Salyers said. "I'm not one to take shortcuts or wing it."

Once they started making their raw milk available, demand grew and soon there was a waiting list.

"It snowballed," he said. "We got more cows. Before long, we had five and were milking three."

Now when he hears people talk about the safety of raw milk from grass-fed cows, he warns them not to jump to conclusions.

"Cows aren't like horses," he said. "Cows like to lie down a lot. Their udders and hides can be in manure. It's dangerous because that's where E. coli can be."

But he said he also thinks there can also be problems with an imbalance of nutrients and bacteria in their digestive system. He thinks that's what happened when he switched the cows from dry forage to pasture too quickly.

He called the vet because one of his cows wasn't acting quite right. When the vet came, he found an improper pH balance in the urine. He told Salyers he was pretty sure he'd find some bacteria.

David Smith, a veterinarian and professor at Mississippi State University College of Veterinary Science, told **Food Safety News** that it's possible that the switch in diet resulted in the cows' shedding E. coli O157:H7 in their manure, but he also said the diet change "did not make it appear out of nowhere."

"It was on the farm," he said, pointing out that this strain of E. coli is common to all beef and dairy herds and that it should be assumed that it is present in some cattle on all cattle farms.

It was while the vet was there that Tricia Salyers came out to the barn and told her husband that the doctors at the hospital had confirmed that Kylee was ill with E. coli O157:H7.

When Salyers walked back into the house, the phone was ringing. It was a state official asking him if they had informed their customers about the problem. Tricia, meanwhile, had already e-mailed their customers the information.

"It was the scariest time of our lives," he said.

## Why did they do it?

"I blamed myself for the longest time," Brown said about the devastating effects raw milk had on her daughter. "But I know that I'm an amazing mom who was trying to do the best for my family."

When doing research on raw milk, she discovered that "it's a two-edged topic with no middle ground between. On one side are government and dairy industry representatives pointing to the inherent risks of raw milk. On the other hand are the raw-milk advocates who fervently believe that locally grown and produced foods, including raw milk, are healthier than foods produced on what they refer to as 'industrialized farms.'

"I do follow their philosophies about local foods, and since raw milk was part of what they believed in, I went along with it," Brown said.

The fact that she did still baffles her, especially since she considers herself to be levelheaded. She was on debate teams in high school and college and knows how important it is to gather objective information and not to be swayed by emotion.

"Debate is all about being well-researched," she said. "You learn to look at every side. That's why I get so frustrated about what I did. I know now that different choices could have been made."

It discourages her that despite continuing news about E. coli outbreaks caused by raw milk, so much of the information spread about raw milk praises its health benefits.

The Weston A. Price Foundation is a good example of one such information source. Its website shows a happy, healthy-looking family with this headline above the photo: "They're happy because they eat butter." Under the picture is some more information: "They also eat plenty of raw milk, cheese, eggs, liver, meat, cod liver oil, seafood, and other nutrient-dense foods that have nourished generations of healthy people worldwide."

Brown doesn't think that raw-milk dairy farmers are dishonest or "sleazy," and she thinks that they're trying to offer the community what they believe is a "valuable resource."

"But many of them are not educated enough," she said. "Our farmer didn't know the risk. I do believe that they thought they were doing it right."

Like Brown, Brad Salyers also has misgivings about his experience with raw milk. Describing himself as a Christian, he said he trusted in the Lord to help him deal with what he describes as "the guilt and shame that was mentally devastating."

"I had to believe that in my heart I was making the best decision for my children with the information I had," he said.

Salyers said he would like to see farmers be more educated about raw milk. As a contractor, he had to take classes to get his license, and he believes something similar should be put in place for raw-milk producers.

He also believes that raw-milk producers should be required to carry liability insurance.

"It's just part of running a business," he said. "I don't see why a farmer producing such a potentially dangerous product shouldn't have to have insurance."

In retrospect, he said he wouldn't hesitate to support legislation that would safeguard children from raw milk, even though he knows it goes against the principle of "freedom of choice."

"It's just too dangerous for the children," he said.

## What about locally produced, 'gently pasteurized' milk?

Buying milk from a local farm conjures up scenes of contented cows grazing on lush green pastures, complete with a farm family dedicated to the health of the cows and the quality of the milk.

For the most part, but not always, this is "raw-milk country"— small-scale dairy farmers who can sell their milk at higher prices than milk sold in the stores. Those higher prices are based in part on the higher expenses that come with producing milk on such a small scale but also on the willingness of raw-milk customers to spend more money for what they consider to be a premium product.

Raw-milk farmers and raw-milk customers alike extoll this business model, saying it helps keep family-scale dairy farmers in business instead of being pushed off the map by ever-expanding dairy operations that depend on what's referred to as "efficiency of scale" to stay in business.

"It used to be that the only alternative to conventional mass-produced milk was raw milk," said Steve Judge, founder of Bob-White Systems and developer of the LiLi (Low Input-Low Impact) Pasteurizer. "But our goal is to give people the choice of either raw milk or farm-fresh 'gently' pasteurized milk."

The LiLi pasteurizes the milk without homogenizing, separating or standardizing its nutritional value and farm-fresh flavor, according to the company's website.

Judge said that in designing the LiLi Pasteurizer, he wanted a small machine that would allow small-scale farms to sell farm-fresh pasteurized milk direct to consumers.

With the LiLi Pasteurizer, the milk gets heated to 163 degrees F and held at that temperature for 15 seconds, after which it is immediately cooled to less than 60 degrees F. After the milk is pasteurized, it's sent to a cooling tank

where it can be cooled to 38 degrees F in less than an hour. This allows for a pasteurization speed of two gallons a minute.

"I believe that the minimal damage done to milk by properly done, high-temperature, short-time pasteurization is a worthwhile compromise if it also expands the availability of locally produced farm fresh milk," he said.

Although the LiLi can work for small dairies of four to 10 cows, Judge said it could handle milk from up to 100 cows. Bottom line, he said, "Anywhere you grow grass, you can do this." Better yet, it meets all state and federal regulations.

While raw-milk proponents say that pasteurization kills many of the healthful components such as vitamins and enzymes, Judge said that he sent samples of raw milk and milk pasteurized with the LiLi to a food-safety lab for a comparison of 50 different nutrients. While there was a drop in lactic acid colonies and a slight drop in Vitamin B-12 in the pasteurized sample, other vitamins did just fine, including vitamins C and D.

"There was minimal damage," he said.

That pretty much lines up with a recent rundown of a nutrient comparison between raw and pasteurized milk provided by the Purdue University Extension.

As for flavor, Judge said that one taste of milk pasteurized with the LiLi would convince anyone that it's indistinguishable from raw milk. "It has a bright, clean, fresh flavor," he said.

Other farms offer vat, or batch, pasteurized milk, which they also describe as "gently pasteurized." In this method, the milk is heated to 145 degrees F and held at that temperature for 30 minutes and then cooled as quickly as possible. Proponents of this method also say that it provides a good option to raw milk.

In contrast, said Judge, most conventional milk bottlers use a method that heats milk to 170 degrees F and holds it at that temperature for no less than 15 seconds. Proponents of this method say that it destroys most bacterial pathogens, while largely protecting milk proteins from degradation.

"Ultra-pasteurized" refers to milk heated to at least 280°F for not less than two seconds.

Unfortunately, said Judge, as of yet, there is no association of dairy farms that produce "gently pasteurized milk," although an Internet search will yield some farms in various locations that do.

Of course, for those whose main reason for buying raw milk is that they want to support local farms, there's always the option of pasteurizing the milk at home.

## What about those allergies?

Many parents who buy raw milk for their children do so because their children have allergic reactions to pasteurized milk. Many say that their children do better on raw milk. Some go so far as to say that raw milk can cure allergies, eczema, asthma and other ailments.



Like other raw-milk farmers, Brad Salvers said that many of his customers had children with allergies.

It's not surprising that milk comes into the picture. According to the U.S. Food and Drug Administration (FDA), milk is at the



top of the list of the eight major food allergens that account for 90 percent of food-allergic reactions.

And, even though most food allergies cause relatively mild and minor symptoms, some food allergies can cause severe reactions and may even be life-threatening, says FDA.

Also, according to the agency's site, there is no cure for food allergies. And the agency recommends strict avoidance of food allergens and early recognition and management of allergic reactions to food.

Following this line of thinking, Mike Tringale, an official with the Asthma and Allergic Foundation of America, told **Food Safety News** that raw milk isn't a cure for an allergy to pasteurized milk.

"The milk protein in pasteurized milk is in raw milk, too, so anyone with a milk allergy would still be affected," he said. "Allergies in general are caused by a chronic disease of the immune system, and it's genetic – you inherit a hypersensitive immune system."

Interestingly enough, though, people don't inherit specific allergies. For example, a person's mother can be allergic to cats and the dad to dogs, yet the child can develop an allergy to peanuts, or other triggers.

Tringale describes allergies as "what happens when a person's body misinterprets the foods or pollens in his or her environment."

Speaking specifically about milk, he said that pasteurized or raw milk doesn't eliminate the allergenic protein in milk, which is what makes milk white.

He discounts assumptions such as the idea that getting back to simple agrarian life makes the body more defensive against allergies, calling them "old wives' tales."

He does say, however, that some research is turning up evidence that babies raised on farms or with cats and dogs may have a lower prevalence of allergies later in life.

"But the jury is still out on that," he said.

But when it comes to raw milk, he pointed out that it is not going to change your immune system.

"The thought that this can cure allergies is actually a dangerous thought," he said.

As for doing "their homework" on milk allergies, Tringale said that parents need to work with their doctor to make sure they're on the right path. If they don't do that, they haven't done their homework.

And, when all is said and done, it doesn't come down to deciding in favor of either pasteurized or raw milk.

"The real question is, 'How do I supply nutrition for my children if I can't feed them milk?" he said.

Fortunately, said Tringale, this doesn't have to be hard – at least if a child has only one or two allergies. There are ways to make sure that children have nutritious diets. He recommends an interactive website, kidswithfoodallergies.org, which allows parents of kids with allergies to talk with one another for support, to find recipes and share ideas.

However, parents with children who have more than one or two allergies need to work with a nutritionist to make sure their children are getting all of the necessary nutrients.

"Getting as close to good health as possible is what people should be aiming for," he said. "It's important that in trying to do that, they're not making poor choices."

Updates on Kylee's progress can be found on her Facebook page.

Food Safety News will feature a video interview with Kylee's parents on Wednesday, February 19.

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## Subject: FDA Testimony to North Dakota Senate and House Agriculture Committees - HB 1433

Mr. Chair Johnson, Mr. Chair Luick and Honorable Members of the North Dakota Senate and House Agriculture Committees,

Attached is Testimony from John Sheehan, Director of the Division of Dairy, Egg and Meat Products, U.S. Food and Drug Administration, to the North Dakota Senate and House Agriculture Committees regarding the public health concerns and science of consuming raw milk and the importance of pasteurization. The information below is in the testimony, in regards to House Bill 1433.

There is and has been a lot of misinformation published or otherwise communicated by various parties to the general public at large about raw milk and pasteurized milk. We very much welcome this opportunity to discuss with the North Dakota Senate and House Agriculture Committees the reality of the dangers of raw milk consumption and the safety and healthfulness of pasteurized milk consumption.

House Bill 1433 which is now before this body for consideration would operate to weaken North Dakota laws governing public health protection. House Bill 1433 significantly relaxes the current regulation by allowing the sale of raw milk and raw milk products for human consumption directly by "a producer to a consumer" and by "a shared animal ownership agreement." Such animal or herd share operations, as described above, do not protect public health. Allowing any type of raw milk sales directly to consumers does increase the probability of serious harm occurring to North Dakota consumers, especially children, the aged, infirm and immunocompromised, and this bill would actually increase the probability of a state-wide outbreak occurring within North Dakota.

Permitting raw milk sales or the operation of so-called "cow share" schemes to occur within any given jurisdiction will not result in the maintenance or further strengthening of our food safety systems. To the contrary, permitting such sales and schemes will inevitably result in an increased incidence of foodborne illness. Indeed, a farm operating a cow-sharing scheme in the state of Washington and which was engaged in the unlawful interstate distribution of raw milk, was determined to have produced milk which was adulterated with E.coli O157:H7 and to have caused an outbreak of foodborne illness. There were eighteen victims identified in that outbreak, which represented 13% of those who reported consuming raw milk originating from the culprit farm. Unfortunately, the median age of the victims was just 9 years. Five of these victims, aged between 1-13 years, were hospitalized and four of these unfortunate children developed Hemolytic Uremic Syndrome. Seventeen of the victims were farm "shareholders" or the children of "shareholders" and one other victim, a child of ten years of age, was a friend of a "shareholder". The Centers for Disease Control and Prevention (CDC) issued, on March 2, 2007, a report on this outbreak in its Morbidity and Mortality Weekly Report (MMWR). That MMWR report may be found at <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a3.htm</u>

House Bill 1433 also would significantly distance North Dakota's regulation of raw milk from the advice being given by the CDC, FDA, and many notable others.

In a press release issued jointly by both CDC and FDA on March 1, 2007, the agencies noted that in addition to CDC and the FDA, "the American Medical Association, the American Academy of Pediatrics (AAP), the National Conference on Interstate Milk Shipments, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials and other organizations have endorsed the pasteurization of milk and prohibition of the sale of raw milk and products containing raw milk."

On May 9, 2014, CDC recommended, "To protect the health of the public, state regulators should continue to support pasteurization and consider further restricting or prohibiting the sale and distribution of raw milk and other unpasteurized dairy products in their states."

On April 1, 2016, CDC reported in its MMWR that **ninety-nine (99) cases of campylobacteriosis**, including **one death** and **ten hospitalizations**, occurred in a 2014 outbreak in Utah associated with a single raw milk dairy. CDC stated that despite state required routine testing of raw milk showing results within acceptable limits, the milk still contained dangerous bacteria.

In January, 2015, Mungai et al. from CDC reported that the number of outbreaks associated with nonpasteurized (raw) milk increased 400%, from an average of 3.3 outbreaks per year to an average of 13.5 outbreaks per year during 1993 to 2006.

In 2012, Langer et al. from CDC reported that during 1993 to 2006, of the 121 dairy-associated outbreaks with known pasteurization status, 73 outbreaks were associated with unpasteurized products. These 73 unpasteurized dairy outbreaks resulted in 1,571 cases, 202 hospitalizations, and 2 deaths. Seventy-five percent (55 outbreaks) of the unpasteurized dairy outbreaks occurred in 21 states where raw milk sale is legal.

In the January, 2014 issue of *Pediatrics*, the AAP published its updated policy statement regarding human consumption of raw milk: "In summary, the AAP strongly supports the position of the FDA and other national and international associations in endorsing the consumption of only pasteurized milk and milk products for pregnant women, infants, and children. The AAP also endorses a ban on the sale of raw or unpasteurized milk and milk products throughout the United States, including the sale of certain raw milk cheeses, such as fresh cheeses, soft cheeses, and soft-ripened cheeses. This recommendation is based on the multiplicity of data regarding the burden of illness associated with consumption of raw and unpasteurized milk and milk products, especially among pregnant women, fetuses and newborn infants, and infants and young children, as well as the strong scientific evidence that pasteurization does not alter the nutritional value of milk. The AAP also encourages pediatricians to contact their state representatives to support a ban on sale of raw milk and milk products."

Raw milk continues to be a source of foodborne illness and even a cause of death within the United States. Despite the claims of raw milk advocates, raw milk is not a magical elixir possessing miraculous curative properties. Pasteurization destroys pathogens and most other vegetative microbes which might be expected and have been shown to be present in milk.

Pasteurization does not appreciably alter the nutritive value of milk. Claims to the contrary by raw milk advocates are without scientific support.

FDA encourages everyone charged with protecting the public health to prevent the sale of raw milk to consumers and not permit the operation of so-called "cow-sharing" or other schemes designed as attempts at circumventing laws prohibiting sales of raw milk to consumers. To do otherwise would be to take a giant step backwards with public health protection.

We would like to thank the North Dakota Senate and House Agriculture Committees for affording us the opportunity to provide this information and trust that the above will prove useful to you in your deliberations. If we may be of any further assistance, we will be happy to do so.

Sincerely,

Cynthia Leonard

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## Testimony of John F. Sheehan, B.Sc. (Dy.), J.D., Director, Division of Dairy, Egg, and Meat Products Office of Food Safety Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration Before the Agriculture Committees North Dakota Senate North Dakota House of Representatives February 14, 2017

Mr. Chair Johnson, Mr. Chair Luick and Honorable Members of the North Dakota Senate and House Agriculture Committees, thank you for the opportunity to submit written testimony in which we will discuss the public health and food safety concerns of consuming raw milk and the importance of pasteurization. There is and has been a lot of misinformation published or otherwise communicated by various parties to the general public at large about raw milk and pasteurized milk. We very much welcome this opportunity to discuss with the North Dakota Senate and House Agriculture Committees the reality of the dangers of raw milk consumption and the safety and healthfulness of pasteurized milk consumption.

Much of what I will present here today has been stated previously in our testimony provided to several other states.

## **RAW MILK IS INHERENTLY DANGEROUS**

Raw milk is inherently dangerous and may contain a whole host of pathogens including Enterotoxigenic *Staphylococcus aureus, Campylobacter jejuni (C. jejuni), Salmonella* species, *Escherichia coli (E. coli* O157:H7, Enterohemorrhagic *E .coli* - EHEC, Enterotoxigenic *E. coli* -ETEC), *Listeria monocytogenes, Mycobacterium tuberculosis, Mycobacterium bovis (M. bovis), Brucella species (B. abortus* being mainly associated with cattle and *B. melitensis* being mainly associated with goats ), *Coxiella burnetii* and *Yersinia enterocolitica* to name but a few. Incidence rates for the presence of these pathogens in raw milk reported in the literature are variable. As one might expect, there are variations in incidence rates between countries and even

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within regions of countries. There are also variations in incidence rates reported for the three main commercial milks (bovine [cow], ovine [sheep] and caprine [goat]). Van Kessel et al. (1) reported in 2004 on the prevalence of Salmonellae and Listeria monocytogenes in bulk tanks on U.S. dairies. They reported a 2.6% incidence rate for Salmonellae and a 6.5% incidence rate for *Listeria monocytogenes.* They commented that "although the prevalence of these organisms was low, inappropriate handling of raw milk could result in bacterial growth and substantially increase the potential risk to consumers of raw milk and raw milk products." These incidence rates were reported even with very low standard plate counts (SPC, total bacterial counts) at <5,000 cfu's /ml (less than 5000 colony forming units per milliliter) being reported for the vast majority of samples analyzed for the pathogens. In 2008, Van Kessel et al. reported (38) that raw milk samples taken from farm bulk tanks had SPC's which ranged from 197 - 3,248 colony-forming units(CFU)/ml and coliform counts which ranged from 3-164 CFU/ml, indicating very high quality; yet 11% of all samples were positive for the presence of Salmonella. It is important to note these clear illustrations of the fact that a simple standard plate count (or "bacteria count") is not an indication of the safety of milk. A low standard plate count clearly does **not** mean that milk will be pathogen-free. Furthermore, even though Van Kessel et al. in 2004 characterized the incidence rate as "low," the mere possibility of Salmonella contamination often leads to food recalls even where Salmonella may not be present in all of the food recalled. For example, in 2009, hundreds of firms recalled products made with certain peanuts and peanut products because of the possibility that they may have been contaminated with Salmonella.

The notion that compliance with quality standards means that raw milk is safe is not a new notion. Indeed, that argument was made to FDA during the rulemaking process for 21 CFR 1240.61, which requires that all milk and milk products in final package form intended for direct human consumption that move in interstate commerce be pasteurized. In addressing that argument in the preamble to 21 CFR 1240.61, FDA stated, "supporters of certified raw milk pointed to standards such as total bacterial counts as proof of safety, but the high incidence of disease associated with certified raw milk is strong evidence that these standards are unreliable indexes of safety," and further stated that "In FDA's view, "certification" does not provide a reliable index of whether milk or milk products are contaminated with pathogenic bacteria," and finally "FDA concludes that the certification process alone provides no assurance that raw milk is free of Salmonella and other harmful organisms." See 52 Federal Register (FR) 29512.

As reflected in the preamble of 21 CFR 1240.61, FDA concluded in 1987 that the available record "demonstrate[d] an association between the consumption of raw milk and the outbreak of disease." *See* 52 FR 29511. FDA also found that the record demonstrated "an association between the consumption of certified raw milk and the outbreak of disease, particularly among consumers who are young, elderly, or infirm." *See* 52 FR 29511. As FDA noted at the time, its findings paralleled the conclusions of a study published in the Journal of the American Medical Association that "the role of unpasteurized dairy products, including raw and certified raw milk, in the transmission of disease has been established repeatedly." Particularly persuasive to FDA were statistics collected by the California Department of Health Services ("CDHS") on the incidence of *Salmonella dublin* ("*S. dublin*") infections. *Id.* at 29511-12. FDA summarized these statistics as follows:

"[CDHS] has reported that 50 percent of all the S. dublin infection cases reported in California in 1984 involved the use of certified raw milk. According to CDHS, no other risk factor has been prevalent among cases. For example, even though S. dublin is host adapted to cattle, only a small percent (15 percent or less) of cases report use of either lightly cooked or uncooked beef or beef products. CDHS concluded that the relative risk of contracting S. dublin is 158 times greater for those Californians who consume certified raw milk than for those who do not drink any form of raw milk. CDHS considered this relative risk extremely large and among the largest obtained in any epidemiologic investigation." Clearly, "certification" of raw milk is of no utility with respect to public health protection.

Many of the above-mentioned microorganisms can cause very serious, sometimes life altering and sometimes even fatal disease conditions in humans. With pregnant women, *Listeria monocytogenes*-caused illness can result in miscarriage, fetal death, or illness or death of a newborn infant. Enterohemorrhagic *E.coli* (EHEC) infection has been linked to hemolytic uremic syndrome (HUS), a condition that can cause kidney failure and death. If infected with EHEC, young children are particularly susceptible to contracting HUS as unfortunately has recently happened in this country. Raw milk should not be consumed by anyone, at any time, for any reason. FDA's opinion in this matter is entirely consistent with that of the American Medical Association, which holds as policy the position that "all milk sold for human consumption should be required to be pasteurized" (H-150.980, Milk and Human Health). The aged, infirm, young and immuno-compromised are most at risk for severe infections from pathogens that may be present in raw milk.

Yet, oftentimes, we hear arguments made by raw milk advocates that these are the very people who should consume raw milk because of its alleged curative or medicinal properties. Claims that raw milk has miraculous disease-curing properties are not supported by the scientific literature. The scientific literature is, however, rife with reports of foodborne illness attributed to the consumption of raw milk, including an article by Werner et al. (2) which reported on the incidence of *Salmonella* Dublin infections in California between 1971-1975. During that time, the mean annual incidence of *Salmonella* Dublin infections in California increased five-fold. Investigations of the cases showed an association with raw milk consumption and that all of the implicated raw milk came from just one dairy. Eighty-nine of the 113 victims were hospitalized and 22 of them died. Almost half of the patients had serious underlying, non-infectious diseases such as leukemias and lymphomas. As we know, the immune system of such persons is often compromised as a result of the treatments they are receiving.

In 1997, Keene et al. (3) reported on a prolonged outbreak of *E.coli* O157:H7 which was caused by the consumption of raw milk sold at Oregon grocery stores. Outbreaks began in 1992 and continued until June of 1994. When the dairy that was the source of the raw milk was identified, it was discovered that 4 of the 132 animals in the herd were initially positive for *E.coli* O157:H7. Despite public warnings, new labeling requirements and increased monitoring of the culprit dairy, illnesses continued until June 1994, when retail sales were finally stopped. The authors concluded that without restrictions on distribution, *E.coli* O157:H7 outbreaks caused by raw milk consumption can continue indefinitely, with infections occurring intermittently and unpredictably.

Proctor and Davis (4) reported on *E.coli* O157:H7 infections in Wisconsin between 1992-1999. During that timeframe, there were 1,333 cases, even though the disease only became reportable in Wisconsin in April 2000. The highest age-specific mean annual incidence, at 13.2

cases per 100,000 population, occurred in children aged 3-5 years old. Among case patient identifiable exposures, consumption of raw milk/milk products was among the top three causes most frequently noted. Kernland et al. (5) reported on the causes of HUS in childhood in Switzerland. Among the causes was the consumption of raw milk, which resulted in the authors concluding that pasteurization of raw milk is likely to have a positive influence on the incidence of HUS. Allerberger et al. (6) reported on a specific incident in Austria in which two children contracted *E.coli* O157:H7 infection and subsequently developed HUS after consuming raw milk. The authors concluded that "it is prudent to remind them (parents and teachers) that children should not be given unpasteurized milk."

When one reads all of the literature available on the association between *E.coli* O157:H7, HUS and raw milk, one wonders whether children themselves would choose to drink raw milk if they knew that raw milk might make them very ill, cause them to lose their kidneys, or even kill them. Given a child's enthusiasm for life, I doubt very much that they would. Since children cannot and do not know about such matters, however, it is incumbent upon those of us who do know and are responsible for protecting them to ensure that the likelihood of their contracting foodborne disease from any food, including the milk that they drink, is an ever-diminishing prospect. Our collective actions should tend to make the food supply safer overall and not result in a lessening of the level of protection which we afford ourselves as a society.

Permitting raw milk sales or the operation of so-called "cow share" schemes to occur within any given jurisdiction will not result in the maintenance or further strengthening of our food safety systems. To the contrary, permitting such sales and schemes will inevitably result in an increased incidence of foodborne illness. Indeed, a farm operating a cow-sharing scheme in the state of Washington and which was engaged in the unlawful interstate distribution of raw milk, was determined to have produced milk which was adulterated with *E.coli* O157:H7 and to have caused an outbreak of foodborne illness. There were eighteen victims identified in that outbreak, which represented 13% of those who reported consuming raw milk originating from the culprit farm. Unfortunately, the median age of the victims was just 9 years. Five of these victims, aged between 1-13 years, were hospitalized and four of these unfortunate children developed HUS. Seventeen of the victims were farm "shareholders" or the children of "shareholders" and one other victim, a child of ten years of age, was a friend of a "shareholder".

The Centers for Disease Control and Prevention (CDC) issued, on March 2, 2007, a report on this outbreak in its Morbidity and Mortality Weekly Report (MMWR). That MMWR report may be found at <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a3.htm</u>.

On the day of the publication of this MMWR, March 2, 2007, the state of Pennsylvania issued a press release announcing that a Pennsylvania farm engaged in the practice of selling raw milk had been determined to be responsible for an outbreak of Salmonellosis in that State. The CDC has since issued an MMWR describing the Pennsylvania outbreak in 2007. It may be found at <u>http://www.cdc.gov/mmwR/preview/mmwrhtml/mm5644a3.htm</u>.

An outbreak of foodborne illness involving *E.coli* O157:H7 also occurred in California in 2006. This outbreak was determined by California to likely have been caused by a dairy owned by a raw milk advocate. The evidence linking these illnesses to this dairy was strong enough to prompt California authorities to order the milk to be recalled. According to California authorities, all of the victims in this outbreak were children. FDA had previously issued a warning letter to this same dairy farm on February 24, 2005, for the unlawful distribution of unpasteurized milk, buttermilk, butter, cream and colostrum in interstate commerce, in finished form for human consumption, an action which is in violation of the Public Health Service Act, Title 42, U.S. Code, Sections 264 (a) and 271 (a) and Title 21, Code of Federal Regulations, Section 1240.61 (a). A copy of this warning letter is available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075299.htm .

*E.coli* O157:H7 is not the only pathogen of concern for the very young. Schmid et al. (7) reported on *Campylobacter jejuni* infections in Dubuque, Iowa over a twelve-month period. Forty-six of 53 victims participated in the case control study. Twenty-one of the 46 cases occurred in children less than ten years of age. The age-specific attack-rate was highest for children aged one to four years. Fifteen of the 46 had consumed raw milk in the week before the onset of their illness. Twelve of the 15 who had consumed raw milk were less than 10 years old. The authors concluded "eliminating the consumption of raw milk will depend on educational efforts."

On April 1, 2016, CDC reported in its MMWR that ninety-nine (99) cases of campylobacteriosis, including one death and ten hospitalizations, occurred in a 2014 outbreak in Utah associated with a single raw milk dairy. CDC stated that despite state required routine

testing of raw milk showing results within acceptable limits, the milk still contained dangerous bacteria. That MMWR may be found at

## http://www.cdc.gov/mmwr/volumes/65/wr/mm6512a1.htm?s\_cid=mm6512a1\_w.

In order to protect the public health, raw milk should not be permitted to be sold for human consumption, nor should people be allowed to attempt to skirt laws banning direct raw milk sales by operating so-called "cow share" schemes. The CDC agrees with FDA in this regard. In the March 2, 2007, MMWR discussed above, CDC stated that "State milk regulations and methods for their enforcement should be reviewed <u>and strengthened</u> to minimize the hazards of raw milk" (emphasis added).

House Bill 1433 which is now before this body for consideration would operate to weaken North Dakota laws governing public health protection. House Bill 1433 significantly relaxes the current regulation by allowing the sale of raw milk and raw milk products for human consumption directly by "a producer to a consumer" and by "a shared animal ownership agreement." Such animal or herd share operations, as described above, do not protect public health. Allowing any type of raw milk sales directly to consumers does increase the probability of serious harm occurring to North Dakota consumers, especially children, the aged, infirm and immunocompromised, and this bill would actually increase the probability of a state-wide outbreak occurring within North Dakota. House Bill 1433 also would significantly distance North Dakota's regulation of raw milk from the advice being given by the CDC, FDA, and many notable others. In a press release issued jointly by both CDC and FDA on March 1, 2007, the agencies noted that in addition to CDC and the FDA, "the American Medical Association, the American Academy of Pediatrics (AAP), the National Conference on Interstate Milk Shipments, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials and other organizations have endorsed the pasteurization of milk and prohibition of the sale of raw milk and products containing raw milk." On May 9, 2014, CDC (41) recommended, "To protect the health of the public, state regulators should continue to support pasteurization and consider further restricting or prohibiting the sale and distribution of raw milk and other unpasteurized dairy products in their states."

In the January, 2014 issue of *Pediatrics*, the AAP (39) published its updated policy statement regarding human consumption of raw milk: "In summary, the AAP strongly supports

the position of the FDA and other national and international associations in endorsing the consumption of only pasteurized milk and milk products for pregnant women, infants, and children. The AAP also endorses a ban on the sale of raw or unpasteurized milk and milk products throughout the United States, including the sale of certain raw milk cheeses, such as fresh cheeses, soft cheeses, and soft-ripened cheeses. This recommendation is based on the multiplicity of data regarding the burden of illness associated with consumption of raw and unpasteurized milk and milk products, especially among pregnant women, fetuses and newborn infants, and infants and young children, as well as the strong scientific evidence that pasteurization does not alter the nutritional value of milk. The AAP also encourages pediatricians to contact their state representatives to support a ban on sale of raw milk and milk products."

It is not only the very young, the aged, infirm and immunocompromised that can fall victim to the pathogens which may be present in raw milk. Anyone can be a victim, including healthy young adults, as was reported by Blaser and Williams (8) when they described how 19 of 31 college students developed an acute gastrointestinal illness caused by *C. jejuni* infection after a visit to an Oregon farm. It was determined that 3 others had an asymptomatic infection. Twenty-two of 25 students who had consumed raw milk for the first time became infected.

Raw milk advocates have claimed that "it is not even clear that tuberculosis (TB) can be contracted from milk products." (Weston A. Price Foundation PowerPoint presentation available on-line entitled "Raw Milk and Raw Milk Products") These advocates are wrong. It is clear to the medical community, to scientists, food technologists and those otherwise familiar with milk and milk products and the history of pasteurization that TB can be contracted from raw milk and raw milk products. Prior to the advent of pasteurization, *M. bovis* was reported to cause between 6-30% of all TB cases in the United States. (Karlsen and Carr) (9). De la Rua-Domenech has also recently produced a very useful review on human *M. bovis* infections (10) which might be of further interest to the North Dakota Senate and House Agriculture Committees.

## STATISTICS ON DISEASE OUTBREAKS ASSOCIATED WITH RAW MILK OR RAW MILK PRODUCTS

In 2015, Mungai et al. from CDC (44) reported that the number of outbreaks associated

with nonpasteurized (raw) milk increased 400%, from an average of 3.3 outbreaks per year to an average of 13.5 outbreaks per year during 1993 to 2006.

In 2012, Langer et al. from CDC (37) reported that during 1993 to 2006, of the 121 dairyassociated outbreaks with known pasteurization status, 73 outbreaks were associated with unpasteurized products. These 73 unpasteurized dairy outbreaks resulted in 1,571 cases, 202 hospitalizations, and 2 deaths (37). Seventy-five percent (55 outbreaks) of the unpasteurized dairy outbreaks occurred in 21 states where raw milk sale is legal. Langer et al. (37) made several key conclusions, including: 1) legal intrastate sale of unpasteurized dairy products is associated with a high risk for dairy-related outbreaks; 2) the rate of outbreaks caused by unpasteurized dairy products was about 150 times greater than outbreaks linked to pasteurized dairy; and 3) unpasteurized dairy outbreaks led to much more severe illnesses in, and disproportionately affected, younger people (under age 20).

In CDC's May 9, 2014 Letter to State and Territorial Epidemiologists and State Public Health Veterinarians, titled "The Ongoing Public Health Hazard of Consuming Raw Milk" (41), CDC stated that CDC data shows that the rate of raw milk-associated outbreaks is 2.2 times higher in states in which the sale of raw milk is legal compared with states where sale of raw milk is illegal. "From 2007 to 2012, the CDC National Outbreak Reporting System received reports indicating 81 outbreaks of infections due to consumption of raw milk resulting in 979 illnesses, 73 hospitalizations and no deaths. Most infections were caused by Campylobacter, Shiga toxin-producing Escherichia coli, or Salmonella bacteria, pathogens that are carried by cattle that appear healthy. The number of outbreaks increased during this time, from 30 in the three year span 2007–2009 to 51 in 2010–2012. Eighty-one percent of outbreaks were reported from states where the sale of raw milk was legal in some form; only 19% occurred in states where the sale of raw milk was illegal. The reported outbreaks represent only the tip of the iceberg. For every outbreak and illness that is reported, many others occur that are not reported; the actual number of illnesses associated with raw milk and raw milk products is likely much greater. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; 59 % of outbreaks involved at least one person aged less than 5 years."

Also, CDC's 2011 and 2012 data for foodborne disease outbreaks (42, 43) indicate that of the thirty-seven (37) outbreaks caused by *Campylobacter* linked to food, unpasteurized (raw)

milk was responsible for the largest number of outbreaks. Among the 18 *Campylobacter* outbreaks with a known food vehicle in 2011, 15 (83%) were attributed to unpasteurized (raw) dairy products. Among the 19 *Campylobacter* outbreaks with a known food vehicle in 2012, 10 (53%) were attributed to unpasteurized (raw) dairy products.

In January 2014, Robinson et al. from the Minnesota Department of Health (40) reported that analysis of routine surveillance data reportable in Minnesota between 2001 and 2010 involving illnesses caused by enteric pathogens revealed that 3.7% of patients with sporadic, domestically acquired enteric infections had reported raw milk consumption. Severe illness including HUS among 21% of *Escherichia coli* O157-infected patients reporting raw milk consumption was noted, and 1 death was reported. Children were disproportionately affected and 76% (age 5 years and under) were served raw milk from their own or a relative's farm. The study suggests that farm family members, particularly young children, who consume raw milk are susceptible to illness from it. During the 10 year study period, the number of patients with sporadic laboratory-confirmed infections who reported consuming raw milk was 25 times greater than the number of raw milk-associated outbreak cases among Minnesota residents. Thus, sporadic cases of illness associated with consuming raw milk far outnumber cases associated with recognized outbreaks. An estimated 20,502 Minnesotans, or 17% of raw milk consumers, may have become ill with enteric pathogens during the study period after consuming raw milk. Robinson et al. states that this finding suggests that outbreaks represent a small number of the illnesses associated with raw milk consumption and that the risk for illness associated with consuming raw milk is far greater than determined based on the occurrence of recognized outbreaks. Robinson et al. also states that "Raw milk consumers, potential consumers, and policy makers who might consider relaxing regulations regarding raw milk sales should be educated regarding illnesses associated with raw milk consumption."

CDC's MMWR for the week of March 2, 2007, which I discussed above, reported that from 1998 to May 2005, 45 outbreaks of foodborne illness implicated unpasteurized milk, or cheese made from unpasteurized milk. Those outbreaks accounted for 1,007 illnesses, 104 hospitalizations, and two deaths. The CDC also noted that between 1973-1992, 87% of the raw milk outbreaks occurred in those states which allowed for raw milk sales to consumers while

consumption of raw milk was estimated to have been less than 1% of the total milk sold in those states.

Raw milk advocates have claimed that "between 1984 and 2002, reports of outbreaks associated with raw milk produced in the U.S. are almost non-existent." (Weston A. Price Foundation PowerPoint presentation available on-line entitled "Raw Milk and Raw Milk Products") This is not the case. FDA's review of outbreaks for this period indicates that there were 35 outbreaks attributed to raw milk, an average of two outbreaks per year. FDA's recent review of CDC data indicates that the average annual number of outbreaks associated with the consumption of raw milk has more than tripled (340%) from an average of 5 outbreaks during 1993 to 2006 to an average of 17 outbreaks during 2010 to 2012. The average annual number of illnesses associated with the consumption of raw milk increased 62% from 112 average number of illnesses during 1993-2006 to 182 average number of illnesses during 2010-2012.

When considering these statistics, it is important to consider that not all outbreaks are actually recognized and that, even when they are recognized, not all of them are reported to CDC. Additionally, it is impossible to capture all of the incidences of individual illness. Generally, for each outbreak reported, there is a much greater incidence of unreported sporadic illness from a food, such as raw milk.

## PASTEURIZATION

Pasteurization is required for all milk and milk products in final package form intended for direct human consumption that move in interstate commerce. (21 CFR 1240.61) The only exceptions to this requirement are for certain cheeses and those exceptions are not absolute, but are tied to certain other requirements relative to the manner in which any raw milk cheese must be ripened. In promulgating 21 CFR 1240.61, FDA made a number of findings relative to raw milk, including that "[r]aw milk, no matter how carefully produced, may be unsafe" (52 FR 29514, Aug. 10, 1987).

The case that prompted FDA to promulgate 21 CFR 1240.61 was <u>Public Citizen v</u>. <u>Heckler</u>, 653 F. Supp. 1229 (D.D.C. 1986). In its holding, the federal district court concluded that the record presented "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified." <u>Id</u>. at 1238. The court stated that the evidence FDA has accumulated concerning raw milk had "conclusively shown.... raw milk is unsafe" and that "[t]here is no longer any question of fact as to whether raw milk is unsafe". <u>Id</u>. at 1241.

Pasteurization will destroy all of the pathogens that I have mentioned thus far and others that I have not mentioned. For example, pasteurization is also destructive of *Mycobacterium paratuberculosis*, the causative organism of Johne's disease in cattle. Clearly, pasteurized milk can never rationally be considered more hazardous than raw milk, contrary to the claims of raw milk advocates. In fact, it is universally agreed within the scientific community that pasteurization has made milk a much safer food for human nutrition.

Raw milk advocates have mentioned that *Bacillus cereus* and *Clostridium botulinum* spores may survive pasteurization, labeling these microbes as "heat-resistant pathogens." Microbial endospores are indeed very resistant to heat and chemical treatments, but the vegetative cells of these microbes are not heat resistant and will be destroyed by pasteurization.

B. cereus spores are quite common in milk, raw or otherwise, and are thus a common cause of spoilage concerns within the dairy industry. However, the presence of C. botulinum spores in milk is not a very common occurrence. Before either of these microbes can pose food safety concerns with milk or milk products, very high population levels must be reached, a condition that does not ordinarily occur in the collection and processing of milk and milk products. Interestingly, in alleging that consumers are avoiding commercial milk because it is pasteurized (which is not true insofar as FDA is aware), raw milk advocates also claim that consumers do not like the fact that cows are allegedly kept in confinement and fed rations designed to enhance milk production, a situation which they claim causes poor health and disease. In support of such a notion, raw milk advocates claim that Dutch researchers found much lower rates of Salmonella infections in dairy herds and cows with access to pasture, but they neglect to mention, or are perhaps unaware, of other Dutch research (Slaghuis et al.) (11) that indicates that cows fed on pasture during the summer had **higher** levels of *B. cereus* spores in their milk than cows which were housed during the summer. Thus, it appears that raw milk advocates are somewhat selective about the research which they choose to discuss when it comes to the subject of cattle feeding and its impact upon milk microflora. In any event, microorganisms may be found in milk from both cows fed on pasture and cows fed rations, and

pasteurization is required in both cases.

## CLAIMS ABOUT RAW MILK AND PASTEURIZED MILK

Raw milk advocates are wont to claim that pasteurization, in addition to killing any pathogens which might be present, also destroys the nutritive value of milk. Nothing could be further from the truth.

Because there is so much misinformation currently circulating about raw milk and pasteurized milk, I developed a presentation which was given at the biennial meeting of the National Conference on Interstate Milk Shipments at Columbus, Ohio in May 2005 by Ms. Cynthia Leonard, M.S., who is a member of my Division. In that presentation, we addressed several of the more common and egregious fallacies about pasteurization. Due to the constant and heavy demand for that presentation, we have placed it on the FDA website. It can be found at:

## http://www.fda.gov/food/foodborneillnesscontaminants/buystoreservesafefood/ucm165048.htm .

In addition to the fallacies that we addressed in the presentation, we have been made aware of several other erroneous statements being made by raw milk advocates about raw milk and pasteurized milk, and it may be useful for me to address some of these here:

## RAW MILK IS NOT A "MAGIC FOOD FOR CHILDREN"

Relatively recently, a raw milk advocate claimed that "raw milk is a magic food for children." There is nothing magical about the possibility of contracting foodborne disease from raw milk, having that progress into hemolytic uremic syndrome, ending up having to fight for your young life as best you can and (if you are fortunate enough to survive), and having to suffer lifelong complications from your illness, knowing all the while that your life likely has been shortened as a result of your illness.

Raw milk advocates have mischaracterized scientific literature in the past and indeed, where we have seen them do so, we have exposed their errors. Their mischaracterization of the article on the PARSIFAL study (Waser et al.) (36) is therefore not at all surprising and, indeed, the journal article on the PARSIFAL study has been mischaracterized by raw milk advocates since it first appeared. The study is about farm milk, not raw milk. The authors of the study took

great pains to explain as much in their Clinical and Experimental Allergy article. The authors clearly state also in the article that "[t]he present study does not allow evaluating the effects of pasteurized vs. raw milk consumption because no objective confirmation of the raw milk status of the farm milk samples was available." They go on to say that "[a]bout half of the parents indicated that they usually did not boil the milk before consumption but no differential effects were observed between those boiling and those not boiling the milk. This might be a result of biased parental answers or may indicate that pasteurization is not of key importance because compounds other than microbes play a role." They also go on to say that "raw milk may contain pathogens such as Salmonella or EHEC and its consumption may therefore imply serious health risks." Finally, the authors state that "[a]t this stage, consumption of raw farm milk cannot be recommended as a preventive measure." The study does not indicate, as some raw milk advocates claim, that raw milk prevents allergies and asthma in children.

#### **RAW MILK DOES NOT KILL PATHOGENS**

The claim that raw milk per se kills pathogens and thus is safe is simply incorrect. Milk contains certain indigenous enzymes to which antimicrobial properties have been ascribed, and milk may contain certain strains of bacteria that might be able to produce anti-bacterial compounds known as bacteriocins, but these enzymes and microbes (if present) do not render raw milk safe. With raw milk, the temperature of storage, coupled with the nature and composition of the microflora initially present and simple microbial competition and outgrowth, play an important part in the determination of which microbes will grow and which will not. Some micro-organisms are more fastidious than others. Some do not grow well in cold temperatures, whereas others do. Some pathogens can survive and grow at refrigeration temperatures.

Another version of the claim that raw milk kills pathogens is that "pathogens can multiply in pasteurized milk and other foods but not in raw milk." That too is untrue. In support of this claim, we have seen raw milk advocates cite a 1982 study by Doyle and Roman (12) and selectively present data from that study which, at first glance, appears to support the raw milk advocates' claim. However, the authors of that study found and reported in that same article that "[s]urvival of the eight *Campylobacter* strains in refrigerated unpasteurized milk varied greatly."

Furthermore, the authors stated that "one strain of *C. jejuni*, bovine isolate FRI-CF147B, survived exceptionally well in unpasteurized milk at 4° C. A less than 2-log reduction in cells occurred after 14 days, indicating that under the appropriate conditions, large numbers of campylobacters may survive in raw milk for several days." The authors also determined that "[i]nactivation of *Campylobacter* strains in unpasteurized milk paralleled but was greater than the inactivation of strains in sterile milk." Note that the authors report **an inactivation** in sterile (not merely pasteurized) milk. Finally, the authors concluded: "The presence and possible persistence of *C. jejuni* in raw Grade A milk reaffirms the need for pasteurization." Thus, <u>far from providing a support for raw milk advocates</u>, the Doyle and Roman study clearly advocates pasteurization of raw milk.

### PASTEURIZATION DOES NOT DESTROY THE ENZYMES IN MILK

The claim that pasteurization destroys all the "built-in safety systems" or "enzymes that kill pathogens" also is simply not supported by the scientific literature. For example, it has been claimed that pasteurization inactivates lactoferrin. Lactoferrin is an iron-binding protein believed to have dual roles; the one being a facilitator of iron absorption and the other a bacteriostatic role. Paulsson et al. (13) determined that "unheated and pasteurized bLf (bovine lactoferrin) preparations showed similar antibacterial properties and caused an effective metabolic inhibition with a moderate bacteriostasis." They further stated that "pasteurization seems to be the method of choice (when making a lactoferrin product) because it did not alter either the bacterial interactive capacity or the antibacterial activity of bLf." Tomita et al. (14) discussed how a pasteurization process was developed for lactoferrin in order to apply active lactoferrin usage to various products. Plainly, lactoferrin is not destroyed or inactivated by pasteurization.

Similarly, lactoperoxidase, an enzyme which is integral to the lactoperoxidase system of milk preservation, has been described as being "inactivated" by pasteurization, when actually lactoperoxidase is a very heat stable enzyme which is not destroyed by minimum legal pasteurization conditions, although some literature indicates moderate inactivation. In fact, because it will survive pasteurization intact, measurement of residual lactoperoxidase activity has been proposed as a means of indicating if a heat treatment applied to milk has exceeded high temperature short time (HTST) pasteurization conditions. Contrary to the claim that the

lactoperoxidase system can be an alternative to pasteurization, the lactoperoxidase system is not, and could never be an alternative to pasteurization. (Some researchers do consider that it might possibly be used synergistically with pasteurization to extend the shelf life of dairy products).

The lactoperoxidase system, which requires the addition of hydrogen peroxide and thiocyanate ion to milk to be activated, functions as a bacteriostatic mechanism generally, i.e., it serves to keep microbial populations from growing and spoiling milk. It is used in regions of the world where it is difficult, if not impossible, to cool milk, due either to a lack of electricity or cooling equipment. It is reported by some researchers to be bactericidal to certain enteric pathogens. Seifu et al. (15), in 2005, published an excellent review article on lactoperoxidase, which may be of further interest to the North Dakota Senate and House Agriculture Committees. The claim that lysozyme, which, in conjunction with lactoferrin does have a bactericidal effect, is destroyed by pasteurization is also simply not true. In excess of 70% of bovine milk lysozyme will survive normal HTST conditions, as reported by Griffiths (16).

With respect to indigenous dairy enzymes in general, Stepaniak (17), in 2004, published an excellent review article of the literature available to which I would refer anyone interested in learning what the current science is on the effect of pasteurization on milk enzymes.

Claims have been made by raw milk advocates that Immunoglobulin G (referred to as "IgG antibodies" by raw milk advocates) is destroyed by pasteurization. However, Kulczycki (18) reported in 1987 that his research on bovine IgG suggested "the possibility that pasteurization of milk (and condensed milk) may not destroy the receptor-binding ability of IgG, but instead might enhance its binding by causing aggregation of the bovine IgG."

## PASTEURIZATION DOES NOT CAUSE LACTOSE INTOLERANCE

Raw milk advocates have also claimed that pasteurized milk causes lactose intolerance (which is an inborn error of metabolism), despite the fact that all milks, raw or pasteurized, contain lactose and that pasteurization does not change the concentration of lactose. A person who is lactose intolerant has a reduced ability to synthesize the enzyme Beta-galactosidase, which hydrolyzes the disaccharide lactose into its monosaccharide constituents, glucose and galactose. Any such person might be expected to experience the symptoms of lactose intolerance when consuming either raw or pasteurized milk.

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Recently, a new version of this fallacy has been brought to our attention. A raw milk advocate has begun to claim that raw milk does not cause lactose intolerance because it contains bacteria (which he describes as being "bifido and lacto") which he believes create their own lactase (beta-galactosidase) when consumed, thus allegedly preventing the symptoms of lactose intolerance. Among the numerous difficulties with this proposition is the fact that the Bifidobacteria in the gastrointestinal tracts of humans are different to those found in animals (Gavini et al.) (24) and thus the milk from animals also. Furthermore, if Bifidobacteria consumed as a therapeutic or prophylactic measure are to be of any benefit, they must be consumed in appreciable quantities (as might be found, for example in a fermented milk product containing an adjunct Bifidobacteria culture) and be of human origin in order to withstand transit through the intestinal tract (Arunachalam) (25). Finally, it has actually been proposed that the Bifidobacteria present in bovine milk be used as indicator organisms to gauge the extent of fecal contamination of milk. (Beerens et al.) (26). Thus, <u>far from being of any health benefit, the Bifidobacteria present in raw milk are considered by scientists to be an indication of the extent to which it has been contaminated with manure.</u>

Although many potential health benefits have been ascribed to Bifidobacteria in the literature, curing lactose intolerance is not among them. (Arunachalam) (22). De Vrese et al. (27) published a useful paper entitled "Probiotics- compensation for lactase insufficiency" wherein they synopsize some of the research done on the utility of Bifidobacteria as promoters of lactose hydrolysis and state that Bifidobacteria "affected lactose digestion less than did lactobacilli or had no effect at all."

Although we are uncertain just what the raw milk advocate in question is referring to when he mentions "lacto bacteria," if we assume that he is referring to *Lactobacillus* species, it is true that several *Lactobacillus* species are generally considered to be probiotic and that among the possible benefits suggested as being conferred by consumption of fermented dairy products containing appreciable quantities of Lactobacilli are reduced symptoms of lactose intolerance, as reported by De Vrese et al., Holzapfel and Schillinger, McBean and Miller, Savaiano et al. (27, 28, 29, 30) However, *Lactobacilli* typically are but a small portion of the microflora in milk.

## **RAW MILK IS NOT A PROBIOTIC FOOD**

While making the above claims and perhaps because of them, this same raw milk advocate has described his milk as being "probiotic." Raw milk is certainly not a probiotic food, as that term is defined within the FAO/WHO Guidelines for the Evaluation of Probiotics in Food, which was published in 2002 (31), and it is scientifically improper to describe raw milk as being probiotic. That document defines probiotics as being "[1]ive microorganisms which when administered in adequate amounts confer a health benefit on the host". According to FAO/WHO, in order for that term to be used, stringent requirements must be met, including strain identification, functional characterization, a safety assessment, efficacy studies, and comparison with standard treatments as well as labeling requirements. None of that has been done for raw milk.

## PASTEURIZATION DOES NOT DESTROY MILK PROTEINS

Raw milk advocates claim that pasteurization either destroys the proteins of milk or that it renders milk proteins more allergenic, even though the milk proteins that cause allergic reactions (including lactoferrin) in dairy-sensitive people are present in raw milk as well as pasteurized milk. Interestingly, these same sorts of claims were addressed directly over twenty years ago by Coveny and Darnton-Hill (19) when they wrote in their article entitled "Goat milk and infant feeding" that "there are some who feel that pasteurization is unnecessary and even detrimental. Concern appears to centre (sic) on possible increased allergenicity and nutrient losses. However, studies show that the sensitizing capacity of cow's milk is retained or – more usually – reduced after heat treatment (cites) while pasteurization minimizes the heat destruction of nutrients (cite). There would appear to be little advantage therefore in the use of raw milk."

Caseins, the major family of milk proteins, are largely unaffected by pasteurization (Farrell and Douglas) (20). Any changes which might occur with whey proteins are barely perceptible.

## PASTEURIZATION DOES NOT DESTROY VITAMINS AND MINERALS IN MILK

With respect to vitamins, the claims about the destructive capacity of pasteurization have been many and varied and virtually none of what has been said is accurate. Milk is a good source of the B-complex vitamins thiamine, folate and riboflavin. Pasteurization will result in losses of each of these of anywhere between zero to 10 percent, which most would consider to be merely a marginal reduction (17), (21). Pasteurization does not cause appreciable losses of the fat-soluble vitamins, A, D, E and K (21). Milk does contain a small amount of Vitamin C, but it is not considered to be a good dietary source of that vitamin. Pasteurization will result in a loss of anywhere from 0-10% of the Vitamin C present (21). Most vitamin C losses in milk occur during storage and such will occur whether milk is pasteurized or not.

With respect to the minerals present in milk, raw milk advocates have made several different claims about the allegedly destructive impact of pasteurization. FDA has not been able to substantiate any of these claims. In fact, the scientific literature that we have reviewed thus far contradicts most of the claims being made. Where raw milk advocates indicate that "no significant change" occurs with sodium, potassium and magnesium, FDA would agree, however. Williamson et al. (22) and Zurera-Cosano et al. (23).

## **RAW MILK IS RAW MILK**

Finally, raw milk advocates have recently begun to claim that only raw milk produced at large commercial dairy farms, which is intended to be subsequently pasteurized, is unsafe and that raw milk produced at small farms is safe. The history of raw milk outbreaks, however, does not support such claims. Additionally, literature indicates that somatic cell counts, which are a measure of dairy herd health (with lower counts being better), tend to be lower in larger, high intensity dairy farming operations as reported by Windig et al., Norman et al., Berry et al. and Oleggini et al. (32, 33, 34, 35).

Another variation on this theme that we sometimes encounter is the claim that raw milk is safe if it originates from "certified" dairies. That is simply not correct. As is discussed above and as was stated in <u>Public Citizen v. Heckler</u>, 653 F Supp. 1229 (D.D.C. 1986), there exists "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified." <u>Id</u>. at 1238.

### SUMMARY

Raw milk, even a "certified" raw milk, is inherently dangerous and should not be consumed. Raw milk continues to be a source of foodborne illness and even a cause of death within the United States. Despite the claims of raw milk advocates, raw milk is not a magical elixir possessing miraculous curative properties. Pasteurization destroys pathogens and most other vegetative microbes which might be expected and have been shown to be present in milk. Pasteurization does not appreciably alter the nutritive value of milk. Claims to the contrary by raw milk advocates are without scientific support. FDA encourages everyone charged with protecting the public health to prevent the sale of raw milk to consumers and not permit the operation of so-called "cow-sharing" or other schemes designed as attempts at circumventing laws prohibiting sales of raw milk to consumers. To do otherwise would be to take a giant step backwards with public health protection.

We would like to thank the North Dakota Senate and House Agriculture Committees for affording us the opportunity to provide this information and trust that the above will prove useful to you in your deliberations. If we may be of any further assistance, we will be happy to do so.

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#1 2/16/17

Bill LC# 17.0559.02000

Prepared by Legislative Intern 8 February 9, 2017

PROPOSED AMENDMENT TO HOUSE BILL NO. 1433

Page 3, remove lines 25 through 29

Page 4, remove lines 1 through 6

Page 3, remove lines 16 and 17 and replace with the following:

4. Transactions under this section may not:

- a. Involve interstate commerce; or
- b. Include the sale of uninspected products made from meat, other than poultry if:
  - (1) The producer slaughters no more than one thousand poultry, raised by the producer, during the calendar year;
  - (2) The producer does not buy or sell poultry products, except products produced from poultry raised by the producer; and
  - (3) The poultry product is not adulterated or misbranded.

Renumber accordingly

17.0559.02002 Title. Prepared by the Legislative Council staff for  $\frac{42}{2/16/17}$ Representative McWilliams February 15, 2017

## PROPOSED AMENDMENTS TO HOUSE BILL NO. 1433

Page 3, line 22, remove "labeled,"

Page 3, line 23, after "<u>7.</u>" insert <u>"Raw milk sold under this section must be labeled with the following statement:</u>

"WARNING: Raw milk may contain harmful pathogens such as listeria monocytogenes, salmonella spp, E. Coli, and campylobactor. Consumption of raw milk is not recommended by the Centers for Disease Control and Prevention, the Food and Drug Administration, the State Department of Health, or the North Dakota Department of Agriculture. Raw milk is not regulated by the state and is not subject to inspection by the Department of Agriculture. Product is not for resale and must be refrigerated."

8."

Page 3, line 25, replace "<u>8.</u>" with "<u>9.</u>" Page 4, line 1, replace "<u>9.</u>" with "<u>10.</u>" Page 4, line 4, replace "<u>10.</u>" with "<u>11.</u>" Renumber accordingly



### 17.0559.02002

Sixty-fifth Legislative Assembly of North Dakota

## HOUSE BILL NO. 1433

Introduced by

Representatives Simons, Rick C. Becker, Johnston, Kiefert, B. Koppelman, Magrum, Olson, Schatz, Toman

Senators Kannianen, O. Larsen

1 A BILL for an Act to create and enact a new section to chapter 19-02.1 of the North Dakota

2 Century Code, relating to the direct sale of food by the producer to a consumer; to amend and

3 reenact sections 4-30-33, 4-30-36, 4-30-55.2, 19-07-01, and 36-24-06 of the North Dakota

4 Century Code, relating to the sale and production of animal-based products.

## 5 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

6 SECTION 1. AMENDMENT. Section 4-30-33 of the North Dakota Century Code is amended
 7 and reenacted as follows:

# 4-30-33. Standards for dairy manufacturing or processing - Commissioner to adopt rules.

10 TheUnless otherwise provided in chapter 19-02.1, the commissioner may adopt rules 11 governing the approval of dairy processing and manufacturing plants and standards for grades 12 of dairy products. Rules must, at a minimum, comply with United States department of 13 agriculture general specifications for approved dairy plants and standards for grades of dairy 14 products. No plant may be operated or any dairy products sold in violation of these rules. 15 SECTION 2. AMENDMENT. Section 4-30-36 of the North Dakota Century Code is amended 16 and reenacted as follows: 17 4-30-36. Standards for grade A milk and milk products - Adoption of amendments.

## 18 OnlyUnless otherwise provided in chapter 19-02.1, only grade A milk may be sold as fluid

19 beverage for human consumption. The minimum standards for milk and milk products

20 designated as grade A are the same as the minimum requirements of the Pasteurized Milk

21 Ordinance which includes provisions from the "Grade A Condensed and Dry Milk Products and

- 22 Condensed and Dry Whey Supplement 1 to the Grade A PMO". The commissioner may adopt
- as regulations other standards in the interest of public safety, wholesomeness of product,

1	consum	er inte	erest, sanitation, good supply, salability, and promotion of grade A milk and milk				
2	products	5.					
3	<b>SECTION 3. AMENDMENT.</b> Section 4-30-55.2 of the North Dakota Century Code is amended and reenacted as follows:						
4	amende	d and	reenacted as follows:				
5	4-30	)-55.2	2. Commissioner - Rulemaking authority - Limitation.				
6	Not	withst	anding chapter 28-32, the commissioner may not adopt any rule that restricts,				
7	limits, or	' impo	oses additional requirements on any individual transferring or obtaining raw milk in				
8	accordance with the terms of a shared animal ownership agreement or on any individual						
9	participa	ating i	n the direct sale of raw milk and raw milk products directly from a producer to a				
10	<u>consum</u>	<u>er</u> .					
11	SEC		<b>4. AMENDMENT.</b> Section 19-07-01 of the North Dakota Century Code is				
12							
13	19-07-01. Eggs to be graded - Exemption.						
14	All eggs sold or offered for sale to an ultimate consumer in this state must be candled,						
15	graded, and labeled with the correct grade designation. "Eggs" in this chapter means eggs in						
16	the shell which are the product of the domesticated chickenpoultry. A producer of eggs when						
17	selling only eggs of the producer's own flock production is exempt from the provisions of this						
18	chapter.						
19	SEC	OIT	<b>1 5.</b> A new section to chapter 19-02.1 of the North Dakota Century Code is created				
20	and ena	cted	as follows:				
21	Dire	ect pr	oducer to consumer sales of foods.				
22	<u>1.</u>	<u>As ι</u>	used in this section:				
23		<u>a.</u>	"Delivery" means the transfer of a product resulting from a transaction between a				
24			producer and an informed end consumer.				
25		<u>b.</u>	"Farmers market" means a market or group of booths where farmers and other				
26			producers sell products directly to consumers.				
27		<u>C.</u>	"Home consumption" means food consumed within a private home or food from a				
28			private home consumed only by family members, employees, or nonpaying				
29			guests.				

x

5

Sixty-fifth Legislative Assembly

	1		d. <u>"Informed end consumer" means an individual who is the last individual to</u>
	2		purchase a product and has been informed the product is not licensed, regulated,
	3		or inspected.
	4		e. "Producer" means any individual who harvests or produces any product that may
	5		be consumed as food or drink.
	6		f. "Transaction" means the exchange of buying and selling.
	7	<u>2.</u>	Notwithstanding any other provision of law, a state agency or political subdivision may
	8		not require licensure, permitting, certification, inspection, packaging, or labeling that
	9		pertains to the preparation, serving, use, consumption, or storage of foods or food
	10		products under this section. This section does not preclude an agency from providing
	11		assistance, consultation, or inspection, upon request, of a producer.
	12	<u>3.</u>	Transactions under this section must be directly between the producer and the
	13		informed end consumer and be only for home consumption. Transactions may occur
	14		at a farm, ranch, farmers market, farm stand, home-based kitchen, or any other venue
	15		not otherwise prohibited by law or through delivery.
	16	<u>4.</u>	Transactions under this section may not involve interstate commerce or the sale of
	17		products made from meat, other than poultry, which has not been inspected.
	18	<u>5.</u>	Except for raw, unprocessed fruits and vegetables, food may not be sold or used in
	19		any commercial food establishment unless the food has been labeled, licensed,
	20		packaged, or inspected as required by law.
	21	<u>6.</u>	The producer shall inform the end consumer that any food product or food sold under
	22		this section is not certified, licensed, packaged, regulated, or inspected.
	23	<u>7.</u>	Raw milk sold under this section must be labeled with the following statement:
	24		"WARNING: Raw milk may contain harmful pathogens such as listeria
	25		monocytogenes, salmonella spp, E. Coli, and campylobactor. Consumption of raw milk
	26		is not recommended by the Centers for Disease Control and Prevention, the Food and
	27		Drug Administration, the State Department of Health, or the North Dakota Department
	28		of Agriculture. Raw milk is not regulated by the state and is not subject to inspection
	29		by the Department of Agriculture. Product is not for resale and must be refrigerated."
	30	8.	This section does not change any requirement for brand inspection or animal health
	31		inspections.

1					
<u>8.9.</u>	Any informed end consumer who purchases products under this section assumes the				
	inherent risks in the purchase, use, or ingestion of the food or food product purchased,				
	whether those risks are known or unknown, and is legally responsible for any property				
	damage or other damage, injury, or death resulting from the inherent risks of				
1	purchasing or ingesting a food product under this section.				
<del>9.</del> 10.	A producer is not required to eliminate, alter, or control the inherent risks related to the				
	purchase, ingestion, or use of the food or food product related to a transaction under				
ĩ	this section.				
<u> <del>10.</del>11.</u>	An action based on the negligence of the producer where the damage, injury, or death				
	is not the result of an inherent risk of the purchase, ingestion, or use of the food or				
	food product related to a transaction may be pursued under section 32-03.2-02.				
12 SECTION 6. AMENDMENT. Section 36-24-06 of the North Dakota Century Code is					
13 amended and reenacted as follows:					
14 <b>36-24-06. Prohibitions.</b>					
AUnless otherwise provided in chapter 19-02.1, a person may not:					
1.	1. Slaughter an animal or prepare an article usable as human food at any establishment				
	preparing articles solely for intrastate commerce, unless the person complies with this				
	chapter;				
2.	Sell, transport, offer for sale or transportation, or receive for transportation, in				
	intrastate commerce any article that is usable as human food and which is adulterated				
	or misbranded or any article that has not been inspected and passed under this				
	chapter; or				
3.	Alter an article that is usable as human food while the article is being transported in				
	intrastate commerce or held for sale after transportation, if the alteration is intended to				
	9.10. <u>10.</u> 11. SEC amende 36-2 A <u>Ur</u> 1. 2.				

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17.0559.02003 Title. Prepared by the Legislative Council staff for Representative McWilliams February 15, 2017

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1433

Page 1, line 3, remove "4-30-33, 4-30-36, 4-30-55.2,"

Page 1, line 3, remove the fourth comma

Page 1, remove lines 6 through 23

Page 2, remove lines 1 through 10

Renumber accordingly

## 17.0559.02003

Sixty-fifth Legislative Assembly of North Dakota

## HOUSE BILL NO. 1433

## Introduced by

Representatives Simons, Rick C. Becker, Johnston, Kiefert, B. Koppelman, Magrum, Olson, Schatz, Toman

Senators Kannianen, O. Larsen

- 1 A BILL for an Act to create and enact a new section to chapter 19-02.1 of the North Dakota
- 2 Century Code, relating to the direct sale of food by the producer to a consumer; to amend and
- 3 reenact sections 4-30-33, 4-30-36, 4-30-55.2, 19-07-01, and 36-24-06 of the North Dakota
- 4 Century Code, relating to the sale and production of animal-based products.

## 5 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

- SECTION 1. AMENDMENT. Section 4-30-33 of the North Dakota Century Code is amended
   and reenacted as follows:
- 8 4-30-33. Standards for dairy manufacturing or processing Commissioner to adopt
   9 rules.

10 — The<u>Unless otherwise provided in chapter 19-02.1, the</u> commissioner may adopt rules

11 governing the approval of dairy processing and manufacturing plants and standards for grades

12 of dairy products. Rules must, at a minimum, comply with United States department of

13 agriculture general specifications for approved dairy plants and standards for grades of dairy

14 products. No plant may be operated or any dairy products sold in violation of these rules.

15 SECTION 2. AMENDMENT. Section 4-30-36 of the North Dakota Century Code is amended
 16 and reenacted as follows:

## 17 4-30-36. Standards for grade A milk and milk products - Adoption of amendments.

18 — Only<u>Unless otherwise provided in chapter 19-02.1, only</u> grade A milk may be sold as fluid

- 19 beverage for human consumption. The minimum standards for milk and milk products
- 20 designated as grade A are the same as the minimum requirements of the Pasteurized Milk
- 21 Ordinance which includes provisions from the "Grade A Condensed and Dry Milk Products and
- 22 Condensed and Dry Whey Supplement 1 to the Grade A PMO". The commissioner may adopt
- 23 as regulations other standards in the interest of public safety, wholesomeness of product,

1	consum	<del>er inte</del>	erest, sanitation, good supply, salability, and promotion of grade A milk and milk				
2	products.						
3	SECTION 3. AMENDMENT. Section 4-30-55.2 of the North Dakota Century Code is						
4	amended and reenacted as follows: 						
5							
6	— 4-30-55.2. Commissioner - Rulemaking authority - Limitation. — Notwithstanding chapter 28-32, the commissioner may not adopt any rule that restricts,						
7	<del>limits, or</del>	· impo	oses additional requirements on any individual transferring or obtaining raw milk in				
8	accorda	nce v	vith the terms of a shared animal ownership agreement or on any individual				
9	participa	iting i	n the direct sale of raw milk and raw milk products directly from a producer to a				
10	consum	er.					
11	SEC		<b>1. AMENDMENT.</b> Section 19-07-01 of the North Dakota Century Code is				
12	amende	d and	reenacted as follows:				
13	19-0	7-01	. Eggs to be graded - Exemption.				
14	All e	eggs s	sold or offered for sale to an ultimate consumer in this state must be candled,				
15	graded, and labeled with the correct grade designation. "Eggs" in this chapter means eggs in						
16	the shell which are the product of the domesticated chickenpoultry. A producer of eggs when						
17	selling only eggs of the producer's own flock production is exempt from the provisions of this						
18	chapter.						
19	SEC		<b>12.</b> A new section to chapter 19-02.1 of the North Dakota Century Code is created				
20	and ena	cted	as follows:				
21	Dire	ect pr	oducer to consumer sales of foods.				
22	<u>1.</u>	<u>As ι</u>	used in this section:				
23		<u>a.</u>	"Delivery" means the transfer of a product resulting from a transaction between a				
24			producer and an informed end consumer.				
25		<u>b.</u>	"Farmers market" means a market or group of booths where farmers and other				
26			producers sell products directly to consumers.				
27		<u>C.</u>	"Home consumption" means food consumed within a private home or food from a				
28			private home consumed only by family members, employees, or nonpaying				
29			guests.				

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1		d. "Informed end consumer" means an individual who is the last individual to						
2		purchase a product and has been informed the product is not licensed, regulated						
3		or inspected.						
4		e. "Producer" means any individual who harvests or produces any product that may						
5		be consumed as food or drink.						
6		f. <u>"Transaction" means the exchange of buying and selling.</u>						
7	<u>2.</u>	Notwithstanding any other provision of law, a state agency or political subdivision may						
8		not require licensure, permitting, certification, inspection, packaging, or labeling that						
9		pertains to the preparation, serving, use, consumption, or storage of foods or food						
10		products under this section. This section does not preclude an agency from providing						
11		assistance, consultation, or inspection, upon request, of a producer.						
12	<u>3.</u>	Transactions under this section must be directly between the producer and the						
13		informed end consumer and be only for home consumption. Transactions may occur						
14		at a farm, ranch, farmers market, farm stand, home-based kitchen, or any other venue						
15		not otherwise prohibited by law or through delivery.						
16	<u>4.</u>	Transactions under this section may not involve interstate commerce or the sale of						
17		products made from meat, other than poultry, which has not been inspected.						
18	<u>5.</u>	Except for raw, unprocessed fruits and vegetables, food may not be sold or used in						
19		any commercial food establishment unless the food has been labeled, licensed,						
20		packaged, or inspected as required by law.						
21	<u>6.</u>	The producer shall inform the end consumer that any food product or food sold under						
22		this section is not certified, labeled, licensed, packaged, regulated, or inspected.						
23	<u>7.</u>	This section does not change any requirement for brand inspection or animal health						
24		inspections.						
25	<u>8.</u>	Any informed end consumer who purchases products under this section assumes the						
26		inherent risks in the purchase, use, or ingestion of the food or food product purchased,						
27		whether those risks are known or unknown, and is legally responsible for any property						
28		damage or other damage, injury, or death resulting from the inherent risks of						
29		purchasing or ingesting a food product under this section.						

17.0559.02003

1	<u>9.</u>	A producer is not required to eliminate, alter, or control the inherent risks related to the			
2		purchase, ingestion, or use of the food or food product related to a transaction under			
3		this section.			
4	<u>10.</u>	An action based on the negligence of the producer where the damage, injury, or death			
5		is not the result of an inherent risk of the purchase, ingestion, or use of the food or			
6		food product related to a transaction may be pursued under section 32-03.2-02.			
7	SEC	TION 3. AMENDMENT. Section 36-24-06 of the North Dakota Century Code is			
8	amende	d and reenacted as follows:			
9	36-2	24-06. Prohibitions.			
10	0 A <u>Unless otherwise provided in chapter 19-02.1, a</u> person may not:				
11	1.	Slaughter an animal or prepare an article usable as human food at any establishment			
12		preparing articles solely for intrastate commerce, unless the person complies with this			
13		chapter;			
14	2.	Sell, transport, offer for sale or transportation, or receive for transportation, in			
15		intrastate commerce any article that is usable as human food and which is adulterated			
16		or misbranded or any article that has not been inspected and passed under this			
17		chapter; or			
18	3.	Alter an article that is usable as human food while the article is being transported in			
19		intrastate commerce or held for sale after transportation, if the alteration is intended to			
20		cause or has the effect of causing the article to be adulterated or misbranded.			

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ND Food Freedom Act HB 1433

2/16/11

Bonnie Munsch representing Capital Farmers Market from Bismarck ND

We believe this bill to be beneficial to both food producers and the consumer. It simplifies and unifies what can be sold at markets throughout the state.

It makes state wide regulations. Bismarck for years could not sell canned or baked goods at the farmers market, while just across the river Mandan could.

It makes it much easier for a customer to buy fresh milk or dairy products, currently a consumer must buy a share in the animal the consumer themselves want to be able to buy directly from the producer and find the current process can be confusing and frustrating. The past 5 years we have had an influx of customers from different areas of the country and the world who prefer to purchase dairy products direct.

HB 1143 HB 1143 will allow farmers and producers to be able to fill a growing demand of what the people want. Producers find it cumbersome explaining why customers cannot find what they are looking for when they know we have the product.

It places the responsibility on the consumer who wants and asked for this type of product and gives protection to the farmer/ producer. The marketers is responsible for informing the consumer that the item purchased is made in an unregulated and uninspected facility for their own personal use and not to be used to make something for resale to someone else.

Bonnie Munsch

3229 123<sup>rd</sup> Ave NW

Bismarck ND 58503

701-202-1181

#3 2/16/17



February 2, 2017



Chairman Johnson and Members of the House Agriculture Committee:

Good afternoon. I am Karen Ehrens, a Licensed Registered Dietitian, and I am here today on behalf of the 280 members of the North Dakota Academy (NDAND). At the national level, it is the position of the Academy of Nutrition and Dietetics that all people should have access to a safe food and water supply. North Dakota Registered Dietitians support local foods and the people who grow and raise them, but not HB1433 in its current form.

NDAND is the advocate of the dietetic profession, serving the public through the promotion of optimal nutrition, health and well-being. We support local food efforts because local foods:

- can be more nutritious if they travel for shorter periods of time over less distance;
- can provide increased access to flavorful foods, like tomatoes bred and raised for flavor, rather than for travelling;
- as part of a shorter food chain, can mean fewer changing of hands, fewer steps along the way, and less chance of contamination at each step in the food chain;
- can lead to increased diversity of plant and animal health in the landscape that is the North Dakota we all love.

NDAND members work in hospitals, nursing homes, schools, universities, food-related businesses, community and senior meals programs and in public health. Our Registered Dietitian members educate and inform about food safety as part of our daily work in medical nutrition therapy, developing meal plans and menus for seniors, children and people in hospitals, working in and with local health departments, and training foodservice workers in food safety principles.

Our members recognize and address dangers of exposure to food and water-borne pathogens to individuals who are highly susceptible to food and waterborne illnesses: children, pregnant women, the elderly, people with reduced immune function, including individuals who have damage to their gastrointestinal tracts, people who have liver and kidney damage, people undergoing cancer treatments. It is a big responsibility and one our members don't take lightly. We know that getting nutrition and food safety messages to people in ways that they are understood and acted upon is a big task. Nutrition and food safety communication needs to be carried out in different media – spoken and written, at different levels – for those who can read and may not read as well, for people of different ages and backgrounds.

NDAND members subscribe to the belief that food safety is a shared responsibility. This bill appears to try to remove any responsibility from the producers as long as consumers are "informed." It is not clear how producers get their messages to consumers with no labels or other means of "informing" consumers identified or required.

Consumers of food do have a role to play in keeping food safe at minimum through practices like clean, separate, cook, and chill to reduce exposure to foodborne illnesses. Food safety precautions do not just start here, but need to start with the producer and continue along the food's journey through the food chain.

Good agricultural practices (GAPS), good handling practices and hazard analysis of critical control points (HACCP) are processes designed to reduce risks from the contamination by bacteria and toxins of the food we eat during agriculture production. It is not clear from the language of the bill, "A producer is not required to eliminate, alter, or control the inherent risks related to the purchase, ingestion, or use of the food or food product related to a transaction under this section" is in the best interests of the people who will eat the food or for the producers. Education of people all along the food chain and carrying out proven methods to reduce contamination of foods is important for all our health and for reducing cost burdens to our health and medical systems.

The NDDA supports efforts to help build more locally based, self-reliant food economies to enhance the economic, environmental, and social health of North Dakota and the personal health of North Dakotans. But we have questions including, should any group should be relieved of their responsibility to do all they can to ensure food safety from the field to the fork?

\_\_\_\_\_

Julie Wagendorf

## Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993–2006

Adam J. Langer, Tracy Ayers, Julian Grass, Michael Lynch, Frederick J. Angulo, and Barbara E. Mahon

## Medscape ACTIVITY

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#### Release date: February 21, 2012; Expiration date: February 21, 2013

#### Learning Objectives

Upon completion of this activity, participants will be able to:

- Evaluate the epidemiology of foodborne illness related to the consumption of dairy products
- Analyze the clinical presentation and outcomes of foodborne disease related to the consumption of dairy products
- Distinguish the organism most commonly associated with foodborne illness after consumption of unpasteurized dairy products
- · Assess sources of contamination of pasteurized dairy products

#### Editor

**P. Lynne Stockton, VMD, MS, ELS(D),** Technical Writer/Editor, *Emerging Infectious Diseases. Disclosure: P. Lynne Stockton, VMD, MS, ELS(D), has disclosed no relevant financial relationships.* 

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Disclosures: Adam J. Langer, DVM, MPH; Tracy Ayers, MS; Julian Grass, MPH; Michael Lynch MPH, MD; Frederick J. Angulo, DVM, PhD; and Barbara E. Mahon, MD, MPH, have disclosed no relevant financial relationships.

Although pasteurization eliminates pathogens and consumption of nonpasteurized dairy products is uncommon, dairy-associated disease outbreaks continue to occur. To determine the association of outbreaks caused by nonpasteurized dairy products with state laws regarding sale of these products, we reviewed dairy-associated outbreaks during 1993–2006. We found 121 outbreaks for which the product's pasteurization status was known;

Author affiliation: Centers for Disease Control and Prevention, Atlanta, Georgia, USA

among these, 73 (60%) involved nonpasteurized products and resulted in 1,571 cases, 202 hospitalizations, and 2 deaths. A total of 55 (75%) outbreaks occurred in 21 states that permitted sale of nonpasteurized products; incidence of nonpasteurized product–associated outbreaks was higher in these states. Nonpasteurized products caused a disproportionate number (≈150× greater/unit of product consumed) of outbreaks and outbreak-associated illnesses and also disproportionately affected persons <20 years of age. States that restricted sale of nonpasteurized products had fewer outbreaks and illnesses; stronger restrictions and enforcement should be considered.

DOI: http://dx.doi.org/10.3201/eid1803.111370

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#### RESEARCH

In the United States, milk and other dairy products are dietary staples; the 2010 Dietary Guidelines for Americans recommend that most Americans include dairy products in their diet (1). However, numerous pathogens can contaminate dairy products and cause illness and death. Milkborne infections were relatively common before the advent of pasteurization in the late 19th century (2), and in the United States today, illness related to consumption of nonpasteurized dairy products remains a public health problem.

In 1948, Michigan enacted the first statewide requirement that dairy products be pasteurized, and many other states soon did the same (2). In 1987, the United States Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers (3). However, sale of nonpasteurized dairy products within the state where they are produced is regulated by each state, and some states permit sale of these products. Despite the federal ban on the sale of nonpasteurized products in interstate commerce, the broad use of pasteurization by the dairy industry, and the infrequency with which nonpasteurized dairy products are consumed, illnesses and outbreaks associated with consumption of these products continue to occur (4-23).

State and local health departments report foodborne disease outbreaks to the Centers for Disease Control and Prevention (CDC) through the Foodborne Disease Outbreak Surveillance System. As a result of efforts to enhance outbreak surveillance starting in 1998, the total number of outbreak reports increased substantially (24). A recent comprehensive analysis of foodborne disease outbreaks associated with dairy products (dairy-associated outbreaks) reported to CDC reviewed outbreaks that occurred during 1973–1992 (4). We reviewed subsequent dairy-associated outbreaks, reported in the United States during 1993–2006. We characterized the outbreaks and examined their association with state laws regarding sale of nonpasteurized dairy products.

#### Methods

To compare the incidence of foodborne outbreaks involving nonpasteurized dairy products among states with differing laws with regard to the sale of these products (i.e., states that permitted their sale vs. states that prohibited their sale), we reviewed reports of foodborne disease outbreaks involving dairy products reported to CDC during 1993–2006. These reports, completed by state and local health departments, typically included the number of cases associated with the outbreak; the age and sex distribution of outbreak-associated case-patients; the number of hospitalizations and deaths; the etiologic agent associated with the outbreak; the type of dairy product implicated (e.g., fluid milk, cheese); and whether the implicated dairy product was marketed, labeled, or otherwise presented to the consumer as pasteurized or nonpasteurized. Hereafter, we refer to these products as pasteurized or nonpasteurized. Thus, any outbreak involving a dairy product that was contaminated after pasteurization or that was intended to be pasteurized but underwent inadequate pasteurization was classified as involving pasteurized product. When possible, we corrected missing or incomplete data by asking the health department that conducted the investigation for more information.

To determine whether the sale of nonpasteurized dairy products was legal at the time of each outbreak, we contacted the 50 state departments of health and agriculture and requested data on whether the state permitted the sale of nonpasteurized dairy products produced in that state for each year from 1993 through 2006. We defined an illegal state-year as a year in which a state prohibited the sale of all nonpasteurized products, and we defined a legal state-year as a year in which a state permitted the sale of nonpasteurized dairy products produced in that state. Data on the estimated population, by state, for each year were obtained from the US Census Bureau. To compare the incidence of outbreak and outbreak-associated cases during illegal state-years to that during legal state-years, we stratified the outbreaks by legal status of the state in which the outbreak occurred at the time of the outbreak and calculated incidence density ratios for reported outbreaks (Poisson model) and for outbreak-associated cases (zeroinflated negative binomial model).

#### Results

During 1993–2006, a total of 30 states reported 122 foodborne disease outbreaks caused by contaminated dairy products. Dairy-associated outbreaks occurred in all years except 1996, and outbreaks involving nonpasteurized dairy products occurred in all years except 1994 and 1996. The number of reported dairy-associated outbreaks increased in 1998 after surveillance for foodborne disease outbreaks was enhanced (Figure 1).

Whether the product was pasteurized or nonpasteurized was known for 121 of the 122 outbreaks, and most outbreaks (73 [60%]) involved nonpasteurized dairy products. Of the 121 outbreaks for which product pasteurization status was known, 65 (54%) involved cheese and 56 (46%) involved fluid milk. Of the 65 outbreaks involving cheese, 27 (42%) involved cheese made from nonpasteurized milk. Of the 56 outbreaks involving fluid milk, an even higher percentage (82%) involved nonpasteurized milk.

The 121 outbreaks involving dairy products for which pasteurization status was known resulted in 4,413 reported illnesses. Among these illnesses, 1,571 (36%) resulted from nonpasteurized dairy products. The median number of persons reported ill during outbreaks involving

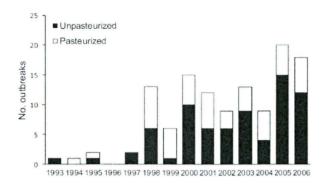


Figure 1. Number of dairy product–associated outbreaks, by year and pasteurization status of product, United States, 1993–2006.

nonpasteurized dairy products was 11 (range 2–202). Outbreaks involving nonpasteurized dairy products resulted in 202 hospitalizations (hospitalization rate 13%). In contrast, outbreaks involving pasteurized dairy products resulted in 37 hospitalizations (hospitalization rate 1%). Two deaths were associated with an outbreak caused by consuming nonpasteurized dairy products, and 1 death was associated with an outbreak caused by a pasteurized product (Table).

Ill persons in outbreaks involving nonpasteurized dairy products were generally younger than those in outbreaks involving pasteurized dairy products. For the 60 outbreaks involving nonpasteurized dairy products for which age of patients was known, 60% of patients were <20 years of age; for the 37 outbreaks involving pasteurized dairy products for which age of patients was known, 23% of patients were <20 years of age (p<0.001).

The causative agent was identified for all 73 outbreaks involving nonpasteurized dairy products; all were caused by bacteria. One outbreak was caused by *Campylobacter* spp. and Shiga toxin–producing *Escherichia coli*. Among the remaining 72 outbreaks, 39 (54%) were caused by *Campylobacter* spp., 16 (22%) by *Salmonella* spp., 9 (13%) by Shiga toxin–producing *E. coli*, 3 (4%) by *Brucella* spp., 3 (4%) by *Listeria* spp., and 2 (3%) by *Shigella* spp. Among the 30 outbreaks involving pasteurized dairy products for which the causative agent was reported, 13 (44%) were caused by norovirus, 6 (20%) by *Salmonella* spp., 4 (13%) by *Campylobacter* spp., 3 (10%) by *Staphylococcus aureus*, and 1 (3%) each by *Clostridium perfringens*, *Bacillus cereus*, *Listeria* spp., and *Shigella* spp.

A total of 48 reported outbreaks involved pasteurized dairy products. The source of contamination was reported for 7 (14%) of these outbreaks, of which at least 4 (57%) probably resulted from post-pasteurization contamination by an infected food handler. Failure of the consumer to store the dairy product at an appropriate temperature probably contributed to 3 other outbreaks. Such temperature abuse can enable pathogens (present because they either survived pasteurization in low numbers or were introduced after pasteurization) to multiply to concentrations capable of causing illness.

During the study period, 43 (86%) states did not change their legal status regarding the sale of nonpasteurized dairy products produced in that state. Among these 43 states, selling nonpasteurized dairy products produced in that state was legal in 21 (49%). Of the 7 states that changed their legal status, 3 changed from legal to illegal (Mississippi in 2005, Ohio in 2003, and Wisconsin in 2005), 3 changed from illegal to legal (Arkansas in 2005, Illinois in 2005, and Nevada in 2005), and 1 (Oregon) changed from legal to illegal in 1999 and then back to legal in 2005 (Figure 2).

Among the 700 state-years (14 years  $\times$  50 states) included in our analysis of the association of legal sales status and nonpasteurized dairy-associated outbreaks, sale of nonpasteurized dairy products produced in the state was legal for 342 state-years and illegal for 358 stateyears. We excluded from analysis 2 outbreaks caused by nonpasteurized dairy products because each occurred in multiple states with differing laws. Of the 71 remaining outbreaks involving nonpasteurized dairy products, 55 (77%) occurred in states where sale of nonpasteurized dairy products produced in that state was legal. Among these 71 outbreaks involving nonpasteurized dairy products, 1,526 persons became ill and 1,112 (73%) of these illnesses occurred in states where it was legal to sell nonpasteurized dairy products. Also among these 71 outbreaks involving nonpasteurized dairy products, 15 occurred in states where sale of nonpasteurized dairy

	Outbreak characteristic, no.						
Product	Total	Associated illnesses	Associated hospitalizations	Associated deaths			
Nonpasteurized							
Fluid milk	46	930	71	0			
Cheese	27	641	131	2			
Total	73	1,571	202	2			
Pasteurized							
Fluid milk	10	2,098	20	0			
Cheese	38	744	17	1			
Total	48	2,842	37	1			
All dairy	121	4,413	239	3			

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### RESEARCH

products was illegal. The source of the nonpasteurized dairy products was reported for 9 of these outbreaks: 7 (78%) were associated with nonpasteurized dairy products obtained directly from the producing dairy farm, 1 was associated with nonpasteurized dairy products obtained under a communal program to purchase shares in dairy cows (i.e., cow shares, a scheme used to circumvent state restrictions on commercial sales of nonpasteurized dairy products) (11), and 1 was limited to members of a large extended family who consumed nonpasteurized milk from their own cow.

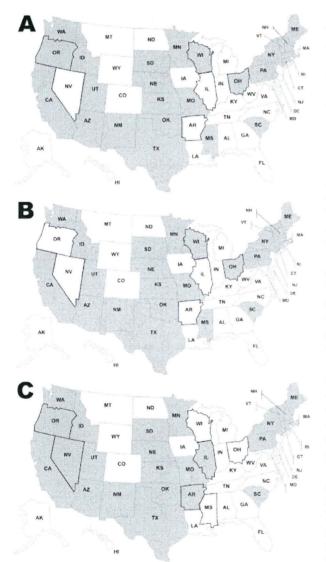


Figure 2. Legal status of nonpasteurized dairy product sale or distribution, by state, United States, for A) 1993, B) 1999, and C) 2006. Gray shading indicates states where nonpasteurized dairy product sale or distribution was permitted. States outlined in black changed legal status during the study period.

Incidence density ratios (IDRs) for nonpasteurized product-associated outbreaks and outbreak-associated cases during legal and illegal state-years varied by the type of dairy product (milk or cheese) and are reported separately. In states where it was legal to sell nonpasteurized dairy products, the rate of outbreaks caused by nonpasteurized fluid milk was  $>2\times$  as high as in states where it was illegal to sell nonpasteurized dairy products (IDR 2.20, 95% Cl 1.14-4.25). The rate of outbreak-associated illnesses caused by nonpasteurized fluid milk was 15% higher in states where it was legal to sell nonpasteurized dairy products, but this result was not statistically significant (IDR 1.15, 95% CI 0.24-5.54). States where it was legal to sell nonpasteurized dairy products had nearly 6× the rate of outbreaks caused by cheese made from nonpasteurized milk (IDR 5.70, 95% CI 1.71-19.05) and nearly 6× the rate of outbreak-associated illnesses (IDR 5.77, 95% CI 0.59-56.31), although the IDR for outbreak-associated illnesses was not statistically significant.

#### Discussion

Incidence of outbreaks caused by nonpasteurized dairy products was higher in states that permitted the sale of nonpasteurized dairy products than in states that prohibited such sale. This association was evident for nonpasteurized fluid milk and cheese made from nonpasteurized milk. Although this association did not extend to the rates of outbreak-associated cases, factors other than whether it was legal to sell nonpasteurized dairy products probably affect the number of cases that occur in an outbreak. These factors include the volume and area of distribution of the contaminated product, the pathogen involved, the underlying health status of the exposed persons, and the ability of the responding public health agency to swiftly intervene to terminate the outbreak.

Because consumption of nonpasteurized dairy products is uncommon in the United States, the high incidence of outbreaks and outbreak-associated illness involving nonpasteurized dairy products is remarkable and greatly disproportionate to the incidence involving dairy products that were marketed, labeled, or otherwise presented as pasteurized. In a population-based survey conducted in 1996-1997, only 1.5% of respondents reported having consumed nonpasteurized dairy products in the 7 days before being interviewed; and in the 2003-2004 and 2005-2006 National Health and Nutrition Examination Surveys. only <1% of respondents who drank milk reported that they usually drank nonpasteurized milk (21,25,26). Because many of these respondents also reported consuming pasteurized dairy products, the proportion of dairy products consumed nonpasteurized by volume or weight is probably <1%. To illustrate this point, it is useful if we provide a hypothetical weighting of the findings in this study by the

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amount of nonpasteurized and pasteurized dairy products consumed. Total milk production in the United States in 2010 was estimated at 193 billion pounds, suggesting that  $\approx$ 2.7 trillion pounds of milk were consumed during the 14 years from 1993 through 2006 (27). If 1% of dairy products were consumed nonpasteurized, then during these 14 years, 73 outbreaks were caused by the 27 billion pounds of nonpasteurized dairy products that were consumed and 48 by the 2,673 billion pounds of pasteurized products that were consumed. Therefore, the incidence of reported outbreaks involving nonpasteurized dairy products was  $\approx 150 \times$  greater, per unit of dairy product consumed, than the incidence involving pasteurized products. If, as is probably more likely, <1% of dairy products are consumed nonpasteurized, then the relative risk per unit of nonpasteurized dairy product consumed would be even higher.

After 1998, when surveillance for foodborne outbreaks was enhanced, the number of reported foodborne disease outbreaks caused by dairy products increased, as did the total number of reported foodborne outbreaks. Outbreaks involving nonpasteurized dairy products were all associated with bacterial enteric pathogens, most of which have known animal reservoirs. In contrast, among outbreaks in which a pasteurized dairy product was implicated, the most commonly reported causative agent was norovirus (44% of outbreaks), a pathogen with a human reservoir. These results suggest that outbreaks caused by nonpasteurized dairy products are probably caused by pathogens in the dairy environment, which would be eliminated by proper pasteurization, and that outbreaks caused by pasteurized dairy products are probably caused by contamination of the products at some point after pasteurization.

The objective of pasteurization is to eliminate from fluid milk those pathogens that originate in the dairy environment; however, pasteurization does not protect against contamination that might occur later, such as during food handling. In addition, if pasteurization is not performed properly (for appropriate times and at appropriate temperatures), pathogens might not be eliminated from the milk. Appropriate post-pasteurization food-handling practices can minimize the risk for reintroduction of pathogens into dairy products after pasteurization. In addition, other precautions, such as maintaining the dairy product at an appropriate temperature and disposing of expired products, reduce the risk to the consumer should the product become contaminated after pasteurization. When outbreaks do occur because of contamination of dairy products that are marketed as pasteurized, the source of contamination is typically traced to improper pasteurization, improper storage, or improper handling of the products after marketing (28-30). In our study, all outbreaks associated with pasteurized products for which information on the source of contamination was available were attributed to post-pasteurization mishandling.

Among outbreak-associated cases involving nonpasteurized dairy products, 60% involved persons <20 years of age. Public health and regulatory authorities are obligated to protect persons who cannot make fully informed decisions (e.g., children) from potential health hazards. Dietary decisions for younger children, in particular, are often made by caregivers. The American Academy of Pediatrics advises against giving nonpasteurized dairy products to children and recommends that pediatricians counsel caregivers against use of these products (*31*).

Proportionately more persons were hospitalized during outbreaks caused by nonpasteurized (13%) than by pasteurized dairy products (1%). This observation suggests that infections associated with nonpasteurized dairy products might be more severe, and it is consistent with the more frequent identification of bacterial, rather than viral or toxic, causative agents and with the larger proportion of illnesses affecting children.

Limitations of this analysis are primarily associated with the nature of the CDC Foodborne Disease Outbreak Surveillance System. Outbreak reporting by state and local health departments is voluntary, and outbreak reports are not always complete. For this analysis, we obtained missing data whenever possible by contacting the reporting state health department. In addition, the CDC outbreak surveillance database is dynamic; reporting agencies can submit new reports and can change or delete previous reports at any time as new information becomes available. Therefore, the results of this analysis represent data available at 1 point in time and might differ from those published earlier or subsequently.

In summary, foodborne outbreaks involving dairy products continue to be a public health problem in the United States, and this problem is disproportionately attributable to nonpasteurized dairy products. Since the US Food and Drug Administration prohibited distribution of nonpasteurized dairy products in interstate commerce for sale to consumers in 1987, all legal sale and distribution has occurred within states that permit the sale of nonpasteurized dairy products that originated in that state. How much illegal distribution in interstate commerce continues is unknown. The increased risk for outbreaks associated with legal intrastate sale of nonpasteurized dairy products demonstrated in this analysis can be weighed against the purported nutritional or other health benefits attributed to these products. Scientifically credible evidence for the health benefits of nonpasteurized dairy products beyond the benefits of those of otherwise equivalent pasteurized products is lacking (32). The risk for outbreaks resulting from cheese made from nonpasteurized milk in states where nonpasteurized

### RESEARCH

milk sale is legal may be higher for particular groups within those states. For example, in recent years, foodborne outbreaks involving nonpasteurized dairy products have been reported in association with traditional nonpasteurized products marketed to the growing Hispanic community in the United States (5,33).

Our analysis shows that legal intrastate sale of nonpasteurized dairy products is associated with a higher risk for dairy-related outbreaks and implies that restricting sale of nonpasteurized dairy products reduces the risk for dairy-related outbreaks within that state. Pasteurization is the most reliable and feasible way to render dairy products safe for consumption. Although warning labels and signs or government-issued permits are prudent where the sale of nonpasteurized dairy products is legal, they have not been shown to be effective and, given the results of this analysis, do not seem to reduce the incidence of outbreaks involving nonpasteurized dairy products to the degree that pasteurization does (18). Whether certain types of warnings or more explicit health advisories might be more effective than others is unknown. Public health officials at all levels should continue to develop innovative methods to educate consumers and caregivers about the dangers associated with nonpasteurized dairy products. State officials should consider further restricting or prohibiting the sale or distribution of nonpasteurized dairy products within their states. Federal and state regulators should continue to enforce existing regulations to prevent distribution of nonpasteurized dairy products to consumers. Consumption of nonpasteurized dairy products cannot be considered safe under any circumstances.

#### Acknowledgments

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Dr Langer was a CDC Preventive Medicine Fellow assigned to the Division of Foodborne, Bacterial, and Mycotic Diseases at the time of this study. He is now an epidemiologist with the CDC Division of Tuberculosis Elimination. His research interests include the investigation of infectious disease outbreaks and animal-to-human transmission of infectious agents.

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## Increased Outbreaks Associated with Nonpasteurized Milk, United States, 2007–2012

### Elisabeth A. Mungai, Casey Barton Behravesh, and L. Hannah Gould

The number of US outbreaks caused by nonpasteurized milk increased from 30 during 2007–2009 to 51 during 2010–2012. Most outbreaks were caused by *Campylobacter* spp. (77%) and by nonpasteurized milk purchased from states in which nonpasteurized milk sale was legal (81%). Regulations to prevent distribution of nonpasteurized milk should be enforced.

Pasteurization is an effective way to improve milk safety; however, in the United States, illness related to consumption of nonpasteurized milk continues to be a public health problem. The first statewide requirements that dairy products be pasteurized were enacted in Michigan in 1948 (1). In 1987, the US Food and Drug Administration banned the interstate sale or distribution of nonpasteurized milk. However, the laws regulating intrastate sales are set by each state (2). Regulations for intrastate sales of nonpasteurized milk vary from complete bans to permitting sales from farms or retail outlets (2). Even in states in which sale of nonpasteurized milk is illegal, milk can often be obtained through other means. For example, some states allow cow-share or herd-share agreements, in which buyers pay farmers a fee for the care of a cow in exchange for a percentage of the milk produced (3,4).

Consumption of nonpasteurized milk has been associated with serious illnesses caused by several pathogens, including *Campylobacter* spp., Shiga toxin-producing *Escherichia coli*, and *Salmonella enterica* serotype Typhimurium (3,4). Despite the health risks associated with consuming nonpasteurized milk, the demand for nonpasteurized milk has increased (3,5,6). Recently, many state legislatures have considered relaxing restrictions on the sale of nonpasteurized milk (2,6). We report that the number of outbreaks associated with nonpasteurized milk increased from 2007 through 2012.

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The Study

A foodborne disease outbreak is defined as the occurrence of >2 cases of a similar illness resulting from ingestion of a common food. State and local health departments voluntarily report outbreaks to the Foodborne Disease Outbreak Surveillance System of the Centers for Disease Control and Prevention through a standard webbased form (http://www.cdc.gov/nors). We reviewed outbreaks reported during 2007-2012 in which the food vehicle was nonpasteurized milk. Outbreaks attributed to consumption of other dairy products made with nonpasteurized milk, such as cheese, were excluded. We analyzed outbreak frequency, number of illnesses, outcomes (hospitalization, death), pathogens, and age groups of patients. Data on the legal status of nonpasteurized milk sales in each state were obtained from the National Association of State Departments of Agriculture (7-9) and an online search of state regulations. The sources from which nonpasteurized milk was obtained or purchased were categorized according to the description from the state outbreak reports, when available.

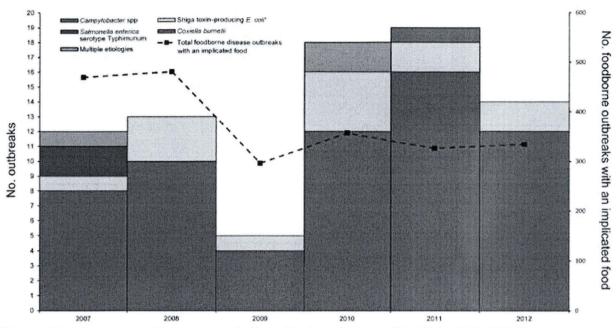
During 2007–2012, a total of 81 outbreaks associated with nonpasteurized milk were reported from 26 states. These outbreaks resulted in 979 illnesses and 73 hospitalizations. No deaths were reported. The causative agent was reported for all outbreaks. Of the 78 outbreaks with a single etiologic agent, Campylobacter spp. was the most common pathogen, causing 62 (81%) outbreaks, followed by Shiga toxin-producing E. coli (13 [17%]), Salmonella enterica serotype Typhimurium (2 [3%]), and Coxiella burnetii (1[1%]) (Figure 1). Three outbreaks were caused by multiple pathogens (Figure 1). The number of outbreaks increased from 30 during 2007-2009 to 51 during 2010-2012. During 2007-2009, outbreaks associated with nonpasteurized milk accounted for  $\approx 2\%$  of outbreaks with an implicated food; during 2010-2012, this percentage increased to 5%. The number of outbreaks of Campylobacter spp. infection also increased, from 22 during 2007-2009 to 40 during 2010-2012 (Figure 1).

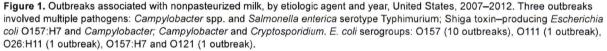
Information about the age of patients was available for 78 outbreaks (Figure 2). For 59% of outbreaks, at least 1 patient <5 years of age was involved (Figure 2), and 38% of illnesses caused by *Salmonella* and 28% of illnesses caused by Shiga toxin–producing *E. coli* were in children 1–4 years of age (Figure 2).

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#### DISPATCHES





How milk was obtained was reported for 68 (84%) outbreaks. Nonpasteurized milk was obtained from dairy farms (48 [71%] outbreaks), licensed or commercial milk sellers (9 [13%]), cow- or herd-share arrangements (8 [12%]), and other sources (3 [4%]) (Table). Of the 81 outbreaks, 66 (81%) were reported from states where the sale of nonpasteurized milk was legal in some form: Pennsylvania (17 outbreaks), New York, Minnesota (6 outbreaks each), South Carolina, Washington, and Utah (5 outbreaks each) (Table). A total of 15 (19%) outbreaks were reported in 8 states in which sales were prohibited (Table). Among these outbreaks, the sources of nonpasteurized milk were

reported as a dairy farm (6 outbreaks), cow or herd share (4 outbreaks), and unknown (5 outbreaks) (Table).

#### Conclusions

Within this 6-year period, the number of outbreaks associated with nonpasteurized milk increased. The number of outbreaks caused by *Campylobacter* spp. nearly doubled. The average number of outbreaks associated with nonpasteurized milk was 4-fold higher during this 6-year period (average 13.5 outbreaks/year) than that reported in a review of outbreaks during 1993–2006 (3.3 outbreaks/year) (4). This increase was concurrent with a decline in the number

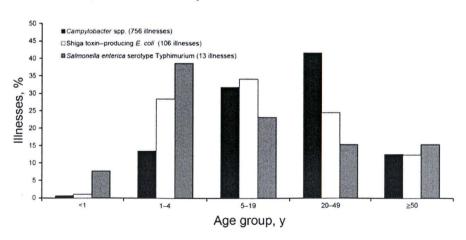


Figure 2. Percentage of patients affected by outbreaks associated with nonpasteurized milk, by age and etiologic agent, United States, 2007–2012.

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#### Outbreaks Associated with Nonpasteurized Milk

	Obdice where mik was purchased of obtained						
			Licensed or				
Legal status of raw milk sales			commercial	Cow or		Not	
(no. states)	State (no. outbreaks)	Dairy farm	milk seller	herd share	Other‡	reported	Total
Allowed on farms and at retail	Pennsylvania (17), Washington	21	7	1	3	6	38
stores separate from farms	(5), Utah (5), South Carolina (5),						
(legal, 12 states)	California (3), Idaho (1), Arizona						
	(1), Connecticut (1)						
Restricted to farms (legal, 14	Minnesota (6), New York (6),	16	2	1	0	2	21
states)	Wisconsin (3), Kansas (2),						
	Massachusetts (1), Nebraska (1),						
	Missouri (2)						
Allowed on farm and at retail	Vermont (4)	4	0	0	0	0	4
stores if standards met (legal, 1							
state)	0	0	0	0	0	0	0
Only at farmer's markets (legal, 1	0	0	0	0	0	0	0
state) Prohibited but allows cow or herd	Colorado (3)	1	0	2	0	0	3
share (1 state)	Colorado (5)	1	U	2	0	0	5
Prohibited, including cow or herd	Ohio (4), Michigan (4), North	6	0	4	0	5	15
share (illegal, 20 states)	Dakota (2), Iowa (1), Indiana (1),	0	0	-	0	5	15
share (megal, 20 states)	Georgia (1), Alaska (1),						
	Tennessee (1)						
On-farm sales allowed only from	0	0	0	0	0	0	0
farms with 2 producing cows, 9	-	-		-			
producing sheep, and/or 9							
producing goats (legal, 1 state)							
Total		48	9	8	3	13	81
*Data for this analysis were downloade	d on June 6, 2013.				_	_	
+Cow milk in 77 outbrooks goat milk in	1 outbrooks						

Table. Source of milk in outbreaks associated with nonpasteurized milk, by legal status of state sales, United States, 2007–2012\* Source where milk was purchased or obtained†

†Cow milk in 77 outbreaks, goat milk in 4 outbreaks.

‡Bed and breakfast lodging (1 outbreak), flea market (1 outbreak), raw milk buying club (1 outbreak).

of states in which the sale of nonpasteurized milk was illegal, from 28 in 2004 to 20 in 2011 (7–9) and with an increase in the number of states allowing cow-share programs (from 5 in 2004 to 10 in 2008) (8,9). The decision to legalize the sale of nonpasteurized milk or allow limited access through cow-share programs may facilitate consumer access to nonpasteurized milk (5). The higher number of outbreaks in states in which the sale of nonpasteurized milk is legal has been reported elsewhere (4).

The legal status of nonpasteurized milk sales in 1 state can also lead to outbreaks in neighboring states. In a 2011 outbreak of *Campylobacter* spp. infections associated with nonpasteurized milk in North Carolina, where sales of this product were prohibited, milk was purchased from a buying club in South Carolina, where sales were legal. Another outbreak of *Campylobacter* spp. infection in 2012 implicated nonpasteurized milk from a farm in Pennsylvania, where sales are legal; cases from this outbreak were reported from Maryland, West Virginia, and New Jersey, all of which prohibit sale of raw milk (*10*). All patients residing outside Pennsylvania had traveled to Pennsylvania to purchase the milk (*10*).

Outbreaks associated with nonpasteurized milk continue to pose a public health challenge. Legalization of the sale of nonpasteurized milk in additional states would probably lead to more outbreaks and illnesses. This possibility is especially concerning for vulnerable populations, who are most susceptible to the pathogens commonly found in nonpasteurized milk (e.g., children, senior citizens, and persons with immune-compromising conditions). Public health officials should continue to educate legislators and consumers about the dangers associated with consuming nonpasteurized milk; additional information can be obtained at http://www.cdc.gov/foodsafety/rawmilk/ raw-milk-index.html. In addition, federal and state regulators should enforce existing regulations to prevent distribution of nonpasteurized milk.

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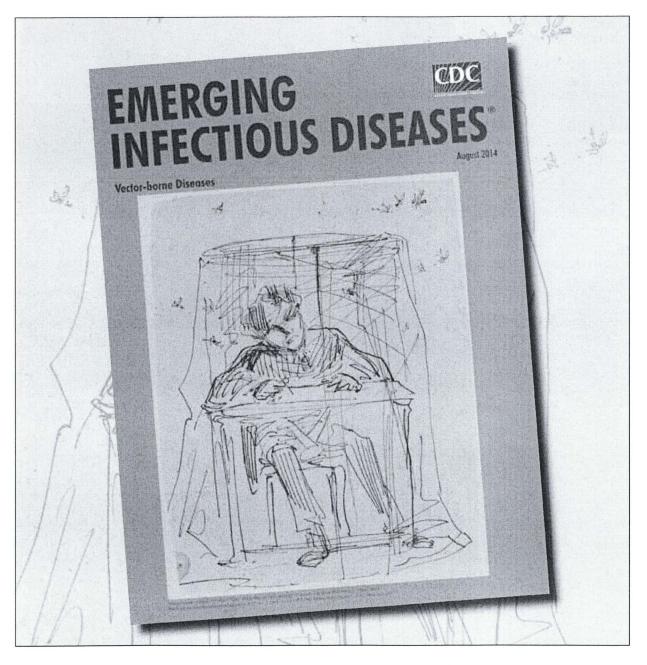
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Most Up-to-date Statistics Human gastrointestinal illnesses in USA

217,973,045 Total diarrheal episodes annually USA: (2008) [CDC]

**48,000,000** Total Foodborne illnesses annually USA: (1 of 6 people)

**1,937,561** Annual foodborne infections from the 4 "pathogens" (all foods)

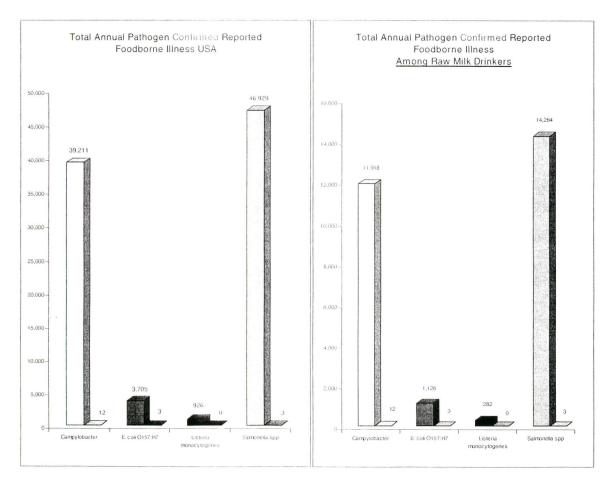
<u>Average</u> annual illnesses attributed to investigated incidents of <u>fluid raw milk consumption</u>:

**42** people reported ill per year (Dr. Beals, 1999 – 2011)

27 people reported ill per year (Drs. Oliver et al, 2000 – 2008)

## 9,385,864 Total consumers of raw milk in USA: (2010)

(3.04% of the US population from very large phone survey by FoodNet )



In each pair, the left is all food, the right those attributed to drinking fresh unprocessed whole milk

## Salmonella spp.

- Where does it like to grow?: Inside animal cells. But also in food and feed with high protein content when stored warm.
- Most common SOURCE: Infected humans and animals; Animal feeds, re-warmed foods that have been contaminated.
- Most common Reservoir: Contaminated water
- Things that increase risk to drinkers: Inadequate refrigeration
- Things that decrease risk to drinkers: Eliminate sources
- Overall human public health impact: The most common foodborne illnesses
- Specific public health impact of drinking raw milk: CDC estimates an annual average of more than 1 million (1,027,561) people in the USA had domestically acquired diarrhea caused by food contaminated with Salmonella; on average 3 were attributed to drinking raw milk.

## Listeria monocytogenes

- > Where does it like to grow: can alternate between two growing modes:
  - 1) grows within animal cells
  - 2) or can switch to growing in decomposing plant materials.
- Most common SOURCE: Poorly managed silage. Infected animal products of conception. Processing plants & their equipment.
- > Most common Reservoir: The environment, particularly if cool, wet and undisturbed
- > Things that increase risk to raw milk drinkers. Not a risk
- > Things that decrease risk to raw milk drinkers: Not a risk

S

- Overall human public health impact: Severity of systemic disease. The most serious public health risk:
  - Ready-to-eat PROCESSED foods particularly meats.
  - > Specific public health impact of drinking raw milk: CDC estimates an annual average of
  - 1 ½ Thousand (1,591) people in the USA have systemic infections caused by food contaminated with *Listeria monocytogenes;* there have been NO cases attributed to drinking raw milk in the last 12 years.

## Shiga Toxin producing E. coli (E. coli O<sub>157</sub>:H<sub>7</sub>)

- > Where does it like to grow: Intestinal tract of warm blooded animals
- Most common SOURCE: Infected humans (fecal)
- Most common Reservoir: Cattle/cows that are shedding colonized virulent subtypes
- Things that increase risk to drinkers: Things that increase risk to drinkers: Dairy animals contaminated with feces from high-shedding animals. Milk handlers shedding during and after infection
- Things that decrease risk to drinkers: Closed herds, keeping people that are shedding away from milk processing and herds.
- Overall human public health impact: Small but highly publicized because of hemolytic uremic syndrome
- Specific public health impact of drinking raw milk: CDC estimates an annual average of more than Sixty three thousand (63,153) people in the USA had domestically acquired diarrhea caused by food contaminated with *E. coli* O<sub>157</sub>:H<sub>7</sub>; on average 5 were attributed to drinking raw milk.

## Campylobacter jejuni

- Where does it like to grow: Grows only inside living animal cells
- Most common SOURCE: POULTRY

(they are not sick, they are "carriers", feces & meat) People with diarrhea from virulent forms of campylobacter

- Most common Reservoir: Water contaminated from poultry manure (if shedding)
- Things that increase risk to drinkers: Drinking <u>really</u> fresh milk.
- Things that decrease risk to drinkers: Storage time, exposed to air. Keeping poultry and people that carry campylobacter, away from milk processing
- Overall human public health impact: Second most common cause of all foodborne illness. There are extremely rare severe complications.
- Specific public health impact of drinking raw milk: CDC estimates an annual average of more than Eighthundred thousand (845,024) people in the USA have domestically acquired diarrhea caused by food contaminated with Campylobacter jejuni; on average 34 were attributed to drinking raw milk.

# The most common virulent pathogen currently associated with raw milk outbreaks

3rd International Raw Milk Symposium, 2011

#### NEW STUDIES CONFIRM: RAW MILK A LOW-RISK FOOD

Posted on June 11, 2013 Via <u>www.realmilk.com</u> January 24, 2016

WASHINGTON, DC-Three quantitative microbial risk assessments (QMRAs) recently published in the *Journal of Food Protection* have demonstrated that unpasteurized milk is a low-risk food, contrary to previous, inappropriately-evidenced claims suggesting a high-risk profile. These scholarly papers, along with dozens of others, were reviewed on May 16, 2013 at the Centre for Disease Control in Vancouver, BC (Canada), during a special scientific Grand Rounds presentation entitled "Unpasteurized milk: myths and evidence."

The reviewer, Nadine Ijaz, MSc, demonstrated how inappropriate evidence has long been mistakenly used to affirm the "myth" that raw milk is a high-risk food, as it was in the 1930s. Today, green leafy vegetables are the most frequent cause of food-borne illness in the United States. British Columbia CDC's Medical Director of Environmental Health Services, Dr. Tom Kosatsky, who is also **Scientific Director of Canada's National Collaborating Centre for Environmental Health**, welcomed Ms. Ijaz's invited presentation as "up-to-date" and "a very good example of knowledge synthesis and risk communication."

Quantitative microbial risk assessment is considered the gold-standard in food safety evidence, a standard recommended by the United Nations body Codex Alimentarius, and affirmed as an important evidencing tool by both the U.S. Food and Drug Administration and Health Canada. The scientific papers cited at the BC Centre for Disease Control presentation demonstrated a low risk of illness from unpasteurized milk consumption for each of the pathogens *Campylobacter*, Shiga-toxin inducing *E. coli, Listeria monocytogenes* and *Staphylococcus aureus*. This low risk profile applied to healthy adults as well as members of immunologically-susceptible groups: pregnant women, children and the elderly.

Given that these QMRAs appear to contradict a long-held scientific view that raw milk is a high-risk food, Ms. Ijaz noted (in line with United Nations standards) that it is important to confirm their accuracy using food-borne outbreak data. The accuracy of recent QMRA findings was scientifically demonstrated using a combination of peer-reviewed data and Ijaz's own recent scholarly working paper, which analysed U.S. outbreak data for raw milk using accepted methodologies.

1

Peer-reviewed outbreak data confirming a negligible risk of illness from *Listeria monocytogenes* in raw milk was particularly notable, and demonstrates the inaccuracy of a high-risk designation given to raw milk in an older U.S. government risk assessment for *Listeria*. The forty-year worldwide absence of listeriosis cases from raw milk presented in a 2013 scholarly review, and affirmed in the QMRA results published in 2011, is attributed by European reviewers to the protective action of non-harmful bacteria found in raw milk.

"While it is clear that there remains some appreciable risk of food-borne illness from raw milk consumption, public health bodies should now update their policies and informational materials to reflect the most high-quality evidence, which characterizes this risk as low," said Ijaz. "Raw milk producers should continue to use rigorous management practices to minimize any possible remaining risk."

Ms. Ijaz used extensive high-quality evidence to further deconstruct various scientific myths from both raw milk advocates and detractors. As Ijaz pointed out, increasing evidence of raw farm milk's unique health benefits to young children, as well as the possible detriments of industrial milk production practices, will need to be carefully considered in future risk analyses. She recommended an honest, evidence-informed dialogue on raw milk issues between producers, consumers, advocates, legislators and public health officials.

"The BC CDC should be commended for recognizing this important research on raw milk safety," said Sally Fallon Morell, president of the Weston A. Price Foundation, a non-profit nutrition education foundation that provides information on the health benefits of raw, whole **milk** from pastured cows. "I look forward to productive discussion with the US CDC and Food and Drug Administration in light of this new scientific evidence."

#### ####

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Tel: 301-807-5063

References and interviews: http://www.bccdc.ca/About-Site/Documents/UBC-CDC/RevisedPresentationJuly8Rawmilkmythsandevi denceNadineljaz\_PROTECTED.pdf

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Life-Changing Success From Raw Milk

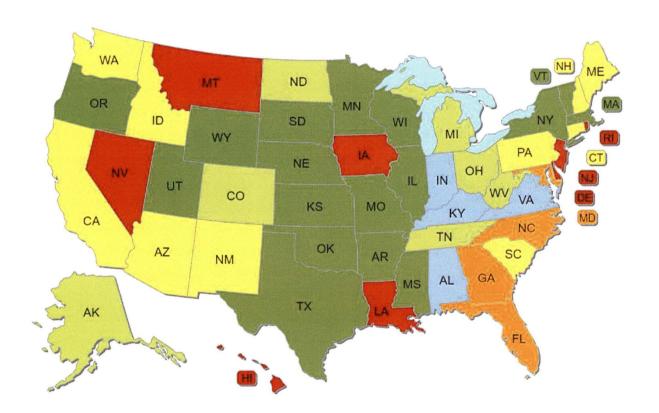
Ronnie Johnson, Williston ND. Watch the story of transformation at:

http://realfoodnd.com/success









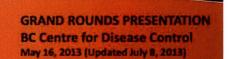
### State-by-State Review of Raw Milk Laws



### www.farmtoconsumer.org

# Unpasteurized milk: myths and evidence

Nadine Ijaz MSc Copyright 2013



## Purpose

- To review evidence around health and safety claims for raw milk
- To deconstruct myths propagated on various sides of the debate
- To consider how evidence relates to current regulatory frameworks in Canada





# Why raw milk?

### Raw milk consumers give importance to scientific ('health benefits', 'safety') as well as other criteria

- > Taste (Headrick et al 1997, Hegarty et al 2002, Katafiasz & Bartlett 2012)
- Convenience and lower cost (amongst farmers) (Hegarty 2002, Jayarao 2006, Kaylegian et al 2008)
- Preference for 'natural', 'local', 'traditional' foods (Enticott 2003b, Hegarty 2002)
- Food sovereignty values (Berg 2008, Paxson 2008)
- Concerns with dominant industrial food production systems (Berg 2008, Enticott 2003a, Kaylegian et al 2008)
- Low confidence in dominant scientific and public health models (Berg 2008, Enticott 2003a, 2003b; Katafiasz & Bartlett 2012, Paxson 2008)

# Myth #4: Raw milk is a high-risk food

Consumption of nonpasteurized dairy products cannot be considered safe under any circumstances.

~(Langer et al 2011: 390)

Drinking raw (untreated) milk or eating raw milk products is *"like playing Russian roulette with your health."* 

~ (J. Sheehan, US FDA, in Bren 2004: 29)



http://www.realmilk.com/press/new-studies-confirm-raw-milk-low-risk-food/

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# What kinds of evidence do we need?

- International food safety standards for microbial risk assessment have been established by the United Nations (Codex 1999)
- Canada is committed to science-based microbial risk assessment with respect to food safety (Health Canada 2007)
- 'Gold standard' method is to undertake 'Quantitative Microbial Risk Assessment' (QMRA) studies

## Recent raw milk QMRAs published

- Escherichia coli 0157 and Campylobacter jejuni related to consumption of raw milk in a province in Northern Italy. J Food Prot. 75:2031-2038. (Giacometti et al 2012a)
- Quantitative risk assessment of listeriosis due to consumption of raw milk. J Food Prot. 74:1268-1281. (Latorre et al 2011)
  - Methodology improved upon a previous 2003 U.S. government assessment (US FDA, FSIS et al 2003)
- Quantitative microbial risk assessment for S. aureus and Staphylococcus enterotoxin in raw milk. J Food Prot. 88:1219-1221. (Heidinger et al 2009)
- As yet, no high-quality QMRAs for Salmonella spp. and raw milk
   Major methodological weaknesses in an older assessment for Salmonella dublin (Richwald 1988)



## Raw milk and Listeria monocytogenes

\*Low risk QMRA calculation: 2011 QMRA risk per serving estimates (Latorre et al 2011) across all demographic groups (including perinatal and elderly) fall within range designated by US FDA as indicative of low risk (US FDA 2003)

#### No confirmed illnesses over last 40 years:

- Despite *L. monocytogenes* prevalence rates in UPM being comparable to known causes of illness (*Campylobacter, Salmonella, STEC*)
- Claeys et al 2013: report but do not cite two 'non-European' cases which I have unsuccessfully tried to locate
- US FDA, FSIS *et al* 2003: cite two 'European' cases which, when checked do not bear out

#### Listeria QMRA results (low risk) = reasonable

- Low significance attributed to high infectious dose + competitive exclusion from UPM commensal flora (claeys et al 2013)
- Contradicts 'very high risk' estimate in previous U.S. government QRA (US FDA, FSIS et al 2003)

# \*Raw milk and Campylobacter risk

Notably lower risk than home-cooked chicken: Per-serving QMRA figures contrast with chicken QMRA risk estimates, suggesting significantly lower risk profile for raw milk

Exposure type	Risk per serving	Location/Source	Comparative risk estimate
Unpasteurized	1.23 x 10 <sup>-6</sup> -	Northern Italy,	Reference figures
milk (UPM)	6.64 x 10 <sup>-7</sup>	Giacometti <i>et al</i> 2012	
Home-cooked	6.99 x 10 <sup>-5</sup>	Denmark,	~57 – 105 x higher
chicken		Rosenquist <i>et al</i> 2003	than UPM figures
Home-cooked chicken	7.84 x 10 <sup>-4</sup>	Belgium, Uyttendaele <i>et al</i> 2006	~637 - 1,181 x higher than UPM figures

 Per-consumer UPM QMRA risk figures (Giacometti et al 2012) corroborated by outbreak figures in working paper (Ijaz 2013)





# \*Raw milk and E. coli 0157 risk

- QMRA results (Giacometti et al 2012) estimate risk per-serving of hemolytic uremic syndrome (HUS) from *E. coli* 0157 via UPM consumption for best and worst storage conditions
  - <u>Age 0 5</u>:  $1.08 \times 10^{-7}$  (best)  $4.99 \times 10^{-7}$  (worst)
  - <u>Age 5+</u>: 2.16 x 10<sup>-8</sup> (best) 9.97 x 10<sup>-8</sup> (worst)
- Notably lower HUS risk than home-cooked hamburger? Compared to QMRA per-serving risk estimates for HUS from homecooked beef patties (Cassin et al 1998), raw milk risk appears lower by a factor of 7 - 34 x for children aged o - 5
  - Figures ideally need validation with epidemiological data



- 10% of symptomatic STEC cases typically result in HUS: (Giacometti et al 2012, Cassin et al 1998) Multiplying per-serving raw milk HUS risk estimates (age 5+) by 10 allows comparison with QMRA estimates for STEC 0157 cases from other exposure types (such as leafy greens)
- Notably lower STEC 0157 illness risk than salad greens? Compared to QMRA per-serving risk estimates for leafy greens consumed at salad bars (Tromp et al 2010), Franz et al 2010), raw milk (upscaled) STEC 0157 risk from QMRA (Giacometti et al 2022) appears <u>6 – 28 x lower</u>
- Raw milk STEC/HUS risk may be yet lower: Comparison of perconsumer STEC 0157 UPM risk estimates based on U.S. outbreak data (upscaled for underdiagnosis) in working paper (Ijaz 2013) with QMRA estimates (Giacometti et al 2012), suggests raw milk QMRA-based risk estimates used above may be too high





### \*Raw milk and Staphyloccocus aureus

• QMRA calculation:

 "Based on the 99.9th percentile cutoff frequently assumed to represent a reasonable risk, raw milk servings do not appear to pose a significant health risk from [S. aureus enterotoxin] intoxication" (Heidinger et al p. 1651).

- Zero associated cases internationally (Claeys et al 2013) despite high S. aureus prevalence in UPM samples (Oliver et al 2009)
  - QMRA estimates therefore reasonable
  - Low significance attributed to:
    - Limiting action of UPM commensal flora (Claeys et al 2012)
    - Large # of *S. aureus* organisms required to produce dangerous # of enterotoxins (Claeys *et al* 2013)



- History: How / why have we framed raw milk as a high-risk food?
- **Implications:** What does this mean for public health policy?





# Raw milk risk history

- 1938: 25% of U.S. foodborne outbreaks from raw milk (Weisbecker 2007)
- 1938: Province of Ontario was the first sizeable jurisdiction worldwide to make milk pasteurization mandatory (CHPA 2009)
- Today: 1 6% of foodborne outbreaks across industrialized nations attributed to dairy products (Claeys et al 2013)
- > Easy to draw an incomplete conclusion...

# **Changing pathogens**

- Milk-borne pathogens circa 1938: included human tuberculosis and brucellosis (Claeys et al 2013)
  - Largely eradicated in industrialized nations today
  - Detectable for culling via regular testing
- Milk-borne pathogens of concern today: generally cause self-limiting gastrointestinal illness
  - Rare severe health outcomes
  - Risk higher for susceptible groups





# Inappropriate extrapolations from lesser evidence

- Three primary types of evidence extensively used to support raw milk's characterization as a high-risk food:
  - Type 1. Individual outbreak reports Type 2. Pathogen prevalence data Type 3. Comparative risk assessments
- Each evidence type has notable limitations in terms of accurately characterizing foodborne hazards, risks, rates
- Over-extrapolations have produced scientific bias against raw milk



# **Typical outbreak report messaging**

Consumers can never be assured that certified unpasteurized milk is pathogen-free, even when from a seemingly well-functioning dairy. The only way to prevent unpasteurized milk-associated disease outbreaks is for consumers to refrain from consuming unpasteurized milk.

~(Longenberger et al 2013)





## Contrast with...

 2013 U.S. CDC study: Green leafy vegetables the most frequent cause of foodborne illness in the U.S., causing 20% of all cases (1998-2008) (Painter et al 2013)

"Most meals are safe," said Dr. Patricia Griffin, a government researcher and one of the study's authors who said the finding shouldn't discourage people from eating produce.

~(Associated Press 2013)

### Type 3. Comparative risk assessments

- Overview: Comparative epidemiological data analyses associate raw milk (vs. pasteurized) with:
  - $\,\circ\,$  a notably higher rate of foodborne outbreaks per serving
  - a higher hospitalization rate per outbreak

a younger affected demographic (under age 20)
 (Langer et al 2011, Gillespie et al 2003)

### What these analyses DO tell us:

- For foodborne illness, pasteurized milk is safer
- Pasteurization remains an effective mitigator
- Younger people appear more vulnerable



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### What these analyses DO tell us:

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- Pasteurization remains an effective mitigator
- Younger people appear more vulnerable

### Type 3. Comparative risk assessments

### What these analyses DON'T tell us:

- <u>Anything much about standard food safety parameters!</u>
  - Risk per serving, risk per consumer
  - · Rate of morbidity, hospitalization (severity), mortality
  - · Risks and rates for susceptible populations
  - · Significance of risk (low, moderate, high)

### Comparative risk assessments widely cited as 'reliable evidence' of raw milk's 'high risk profile'

- Are an inappropriate evidence type for making such conclusions
- Such studies simply demonstrate pasteurization's efficacy as a mitigator, but do not determine raw milk risk profile *per se*





# Myth #4 SUMMARY: High risk?

### High quality evidence affirms UPM's low risk

- Recent QMRA data
- Relevant epidemiological data
- Raw milk today  $\neq$  high risk food

### Reliance on limited evidence types has supported high-risk 'myth'



# High Quality Evidence Affirms Unpasteurized Milk's Low Risk



Rep. Luke Simons Testimony on HB 1433 – Senate Ag Committee.

Hello, I'm Luke Simons and I'm the prime sponsor of this very simple, yet important, legislation.

HB 1433 3/17

#1

Thank you Mr.Chairman and members of the Senate Agriculture Committee for the opportunity to share a few words with you.

We have before us a very common sense bill. Essentially, it is a cottage food law. This bill represents a noble tradition.

For most of America's history, farmer-to-consumer direct commerce was the norm. Food producers have become increasingly ensnared in a regulatory system which has contributed to a decline of family farms and self-sufficient communities.

Even today in North Dakota, many farms struggle as younger generations leave home. With HB 1433, we can help reverse this trend.

This bill will give North Dakotans greater economic opportunity and consumer choice.

It will allow thousands of North Dakota families to buy and sell the same types of farm fresh and homemade products that they already produce and consume every day.

It will help both our small rural communities as well as our urban food producers.

It will diversify the economy.

It will encourage young farmers to stay on the farm.

This is an economic development bill that will give thousands of families supplemental income and help many determine whether or not food production is the type of work they wish to pursue.

Ladies and gentlemen, I urge a Do Pass recommendation on House Bill 1433.

While I'm happy to answer questions, I will be here throughout the hearing and I want to make sure all the folks who've traveled across the state can get a chance to testify.

They may answer some of your specific questions in their testimony. They'll be discussing specific language in the bill, economic development opportunities, the differences between home and commercial kitchens, as well as folks representing farmers markets and a home baking business.

Again, Mr. Chairman and members of the Senate Agriculture Committee, I thank you very much for your time.

HB1433 3/17 #2 pg.1

**TESTIMONY** for HB 1433 Senate Hearing By Jared D. Hendrix

#### WHAT IS THIS?

HB 1433 lovingly referred to by its supporters as the North Dakota Food Freedom Act, is a "cottage food" law. Simply put — If you grow or create a food product in your home or on your farm, under this law you may sell that item to an informed end consumer for home use only. Producers must inform consumers that the product or food item is not inspected, permitted or regulated.

At school bake sales, church potlucks or block parties, we trust North Dakota citizens to decide for themselves if they wish to purchase or consume a product. This legislation simply allows families the opportunity to legally make extra income buying and selling the foods we eat everyday in our homes, safely and responsibly.

Very soon it will be legal in North Dakota to sell medical marijuana -- but still criminal to sell homemade chicken noodle soup to your neighbor. Currently, you can legally grow carrots, you can cook noodles and you can butcher up to 1000 chickens on your own farm and sell those products separately to the consumer. However, you cannot mix the ingredients to make chicken noodle soup and sell it. You would be an outlaw.

By opening markets and allowing rural and urban food producers to sell products to friends and neighbors, we keep local dollars in local communities. This legislation removes impediments to free market commerce for small producers who do not have the production volume necessary to make commercial kitchen facilities feasible, thus allowing people the chance test the market before investing.

#### **BREAKDOWN OF BILL**

Now, I'd like to take the opportunity to quickly give a rundown of the bill, line by line.

#### Section 1, Lines 6-13 (page 1) - Eggs

Current law says only chicken eggs may be sold directly to consumers. But buyers are seeking a variety of eggs. This bill allows egg sales from any domesticated poultry such as ducks, geese, ostrich or guinea fowl.

#### Lines 17-9 (page2) - Definitions

"An informed end consumer"

A producer may be someone living on a farm raising poultry, a large garden and having some animals. A producer could also be someone in town who has excess garden products which they wish to sell or process into jam, jelly, salsa, etc. The key phrase is "individual who harvests or produces."

### Lines 10-14 (page2) - Health Districts

Simplifies & codifies the buying and selling process so all food producers are playing by the same rules across all of North Dakota's 28 independent local public health units. Puts government agencies in the role of helpers and educators versus regulators and makes it easier for producers and consumers to ask questions without fear or the stigma of prohibition.

HB 1433 3/17 #2 pg.2

### Lines 15-18 (page 2) - Where can transactions occur? Lines 19-31 (page 2) - CANNOT OCCUR

Fully compliant with federal law, including USDA-inspected meats, which makes the distinction between poultry and red meat processing. Only the first 1,000 birds in a year are exempt. Essentially, these items are for home use only and cannot be resold. (Line **5 - restaurants exception**) The only exception is what is already legal, which is that right now restaurants may purchase fresh, unprocessed fruits and vegetables. Restaurants are NOT allowed to purchase uninspected poultry or unpasteurized milk or milk products. Nothing will change for these businesses.

Lines 1-2 (page 3) - Disclaimer Lines 3-4 (page 3) - Animal health issues

### FOOD SAFETY

Now let us address the elephant in the room — food safety. Those in opposition to this bill may suggest the potential risks of negligence are too high. Specifically, the greatest concern seems to be from canned foods. Obviously, the proper containers, heating and pressure must be applied in the canning process in order to ensure foods do not become toxic. The truth is that homemade and farm fresh foods are consumed daily by hundreds of thousands of North Dakotans without incident and thus do not present a systemic danger to citizens at large.

State law requires that incidents of foodborne illnesses be reported to the Health Dept. There is an array of criteria in order for an outbreak to be determined, as well as a range of epidemiological, laboratory and environmental analysis. The Health Dept. has a report cataloging foodborne illnesses from 1988-2014, indicating their likely cause. Commercial inspected restaurants and other regulated food sources were among the top culprits, not foods consumed at private homes. According to that data, 4,088 people became ill. 270 of those (6.6%) were linked to food in private homes or at private parties. There was no notation on the report if the food was all prepared in the home or purchased cooked or partially cooked. That's an average of 10 cases a year. 100 of those ill occurred at a private business during a single incident in 2002.

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In that 27 year span outlined by the Health Dept. – there was only ONE case where the suspected food was home canned – a jar of zucchini relish. Only one person became ill from botulism. Many of the causes and suspect foods were listed as unknown. Of those known, there was only 1 instance where baked goods were listed as the suspected food. We know from many other sources, including the CDC, that the largest and most common pathogenic outbreaks of foodborne illnesses occur from commercially available and inspected food products from large food producers. This is simple mathematics. Large food producers produce such high quantities and in such a manner that outbreaks are simply much more possible. However, no rational person is suggesting that we ban products at Dan's supermarket.

None of us want anyone to get sick. Producers under this bill know their livelihood is on the line with every sale. Risk is practically minimized by the small scale of production. We all appreciate the work and efforts put forward by the Health Dept. However, there comes a certain point where we must acknowledge that government should not restrict our choices through onerous standards in an attempt to achieve the impossible objective of eliminating all risk.

#### RELATIONSHIP

This brings me to the most important aspect of this bill, which are the relationships it will form between producer and consumer. Products will often be sold directly to friends, neighbors, or others. This is an exchange of goods between willing buyers and sellers who both must exercise good judgment. Out of this relationship will come information, carefulness, customization of products and, perhaps most importantly, trust.

The bond is such that buyers are going to generally be more informed about what they're buying directly than over many products in retail stores. Transactions could include buying a cream pie or salsa from your neighbor's kitchen, who can tell you exactly what ingredients were used. This unique arrangement increase access to products for home consumers who wish to buy local and try artisanal products.

In some instances, the producer may want to label their product for marketing. This bill allows the producer to label their products as they wish. Consumers then use their common sense to decide if there's enough information to make a purchase, or if a particular producer label or private brand has developed an intrinsic trust.

#### EDUCATION

The final major component to this is education. One might ask - will the Department of

Health and Department of Agriculture have a role in this? The answer is 'yes' except that they will be educators instead of regulators. Removing the regulatory hammer makes discourse between producers and agency personnel more friendly. By eliminating the fear factor of regulatory penalties, producers are more likely to seek assistance and to freely attend workshops, conferences, etc. where their sales are openly discussed.

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There is no fiscal impact on the state, because the Health Dept. and Ag. Dept. already have individuals on staff to help in these areas. However, we believe that most of the education will come through private avenues. Right now, we have a highly engaged social media campaign and website, which we fully intend on maintaining for the foreseeable future.

#### FUTURE OF FOOD IN NORTH DAKOTA

Agriculture is number one in North Dakota. Therefore, you all sit on one of the most important committees in the Capitol. This legislation will unleash the entrepreneurial spirit of small farmers, and urban food producers and enliven our small towns and big city farmer's markets with greater variety of products. In conclusion, I just want to reiterate the importance of this historic legislation. It goes to the essential core of what it means to be the purveyors of our own economic destinies.

I urge the members for a 'Do Pass' on HB 1433 and I'm happy to take questions. Thank you very much.

Respectfully,

Jared D. Hendrix

Please contact me anytime. 701-712-1487 libertyhendrix@gmail.com www.ndfoodfreedom.com

#### HB1433

HB 1433 3/17 #3 pg.1

### Howdy committee members,

My name is Bonnie Munsch I am a member of both the Capital Farmers Market and North Dakota Farmers Market and Growers Association. I am the secretary/treasurer of the Capital Farmers Market and one of my responsibilities is to make sure all the market members know the local regulations. Regulations are currently governed by the local health districts of 53 counties, which can vary greatly, some have none and some have pages. Some cities also have their own rules. It is very hard to keep up with all of them. The Capital Farmers Market has venders from a 75 mile radius around Bismarck and some vendors have different rules where they live and I have to inform them of the Burleigh County and Bismarck city rules. This can cause frustration and confusion among vendors.

The Capital Farmers Market has members that are also members of the Mandan farmers market and when I first joined the market back in 2002 the rules between the two differed greatly. Bismarck could not sell eggs, Mandan could. Bismarck could not sell canned goods, Mandan could. Bismarck could not sell baked goods, Mandan could. There was no law or regulations against it. It was the judgement call of the administrator of Bismarck's local health unit. The gentleman retired and his successor now allows Bismarck to sell eggs, baked and canned goods at farmers markets in Bismarck. One other difference is Mandan specifies what type of jar is used for canning, Bismarck does not.

This bill would enable an individual who has grandma's best secret recipe for pickles to be able to market and test it on a local level without a lot of investment. A vendor usually knows within the 1<sup>st</sup> or 2<sup>nd</sup> year whether they have a blue ribbon or Grandma's Pucker Pickles. This bill would allow that person to find out without the expense of permits, kitchen certification or inspections.

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HB1433 would allow people to sell fudge, caramels, peanut brittle, kuchen, popcorn balls, caramel rolls, and candies at bake sales. Bake sales use to be a very popular way for clubs and schools to raise money. Too many different rules, regulations and fear of lawsuits are some of the reasons why they don't use bake sales as a fundraiser anymore. HB1433 could help bring them back.

If HB1433 is passed I can do my job better as the Sec/Treasurer when it comes to the rules and regulations. I plan to educate the vendors and customer on the responsibilities of each. It will be posted on the Capital Farmers Market Facebook page, available at the market or if someone just gives me a call, text or e-mail, I will be able to inform with confidence what is required. I plan on making a short video for the Capital Farmers Market on the subject.

I would like to thank the committee members of allowing me to state my views on why I recommend a **DO PASS ON HB1433**.

Bonnie Munsch

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Bismarck, ND 58503

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3/17

# #4 pg.1

### Testimony House Bill 1433 Senate Agriculture Committee March 17, 2017; 9:30 a.m. North Dakota Department of Health

Good morning Chairman Luick and members of the Senate Agriculture Committee. My name is Julie Wagendorf and I am the Director of the Division of Food and Lodging for the North Dakota Department of Health (NDDoH). I am here today to testify that the department would support House Bill 1433 if amended. The department is agreeable to the intention of House Bill 1433 as a statewide "Cottage Food Law" and offers suggestions for further amendments in order to set standards that protect public health while still allowing producers an opportunity to profit from locally-grown foods.

Currently in North Dakota, under the Food Handler's Education Act NDCC Chapter 23-09.2, certain low-risk food items that are home-processed, home-canned and home-baked are allowed for direct sale from the producer to the consumer at county fairs, nonprofit and charitable events, public-spirited celebrations, farmers markets and roadside food stands. A list of food items currently allowed for sale at the venues mentioned, prepared in a home kitchen in the absence of a license and inspection by the NDDoH, are referenced on the attached NDDoH *Fact Sheet for Certain Home-processed, Home-Canned & Home-Baked Foods*.

Foods defined as approved 'cottage food products' are considered lower risk because these products do not require time or temperature controls for safety. These types of food items are naturally acidic (pH 4.6 or lower) or have been 'pickled' or acidified, either by a fermentation process or addition of acids to the recipe such as vinegar, ascorbic acid, etc. Low-risk food items also have a low water activity (0.85 or less). Food products with these properties – high acidity and/or low water activity – make it difficult for bacteria to survive and to sustain growth at high enough numbers to cause illness in humans. NDDoH recommends only using approved recipes of high-acid and acidified foods that have been tested with a calibrated pH meter to ensure a pH level of 4.6 or lower as a final pH level.

Food items considered to be higher risk (low-acid foods) are not currently recommended as cottage food products by the NDDoH because refrigeration and additional processing controls are required to protect consumers from dangerous

1

HB 1433 3/7 #4 pg.2.

bacteria. Children, pregnant women, the elderly and people with compromised immune systems are most susceptible to infections and severe complications caused by harmful bacteria and toxins. Food products that are lower in acid content and higher in water activity require time and temperature controls for safety to limit growth of harmful bacteria and to prevent bacteria from producing dangerous, heat-resistant toxins. These food items must be held under proper temperature controls, such as refrigeration at 41 degrees F, to prevent the growth of bacteria that may cause human illness. A high-risk food product contains protein, moisture (water activity greater than 0.85), and is neutral to slightly acidic (pH between 4.6 -7.5).

Proper processing of certain low-acid foods and the temperatures needed to kill heat-resistant spores, such as those produced by the bacteria that causes botulism, cannot be attained by canning in a boiling water bath. Pressure cooking is required for processing low-acid foods in order to offer a kill step for harmful bacteria and heat-resistant spores. Because these types of foods are at a higher risk for contamination with harmful bacteria, they are not currently recommended to be processed in a home-kitchen and offered for sale..

Using the current department fact sheet and guidance as a foundation, as well as considering similar Cottage Food Laws in other states, the NDDoH offers proposed amendments in the attached supplement. The proposed amendments provide clarification about which food products are included under this bill as opposed to which food products require a licensed and inspected kitchen or commissary. The proposed amendments are attached.

Chairman Luick and members of the committee, thank you for listening to my testimony. I am happy to answer any questions you may have.

HB 1433-Wagendorf -2017-03-17

# HB 1433 3/17 #4 pg. 3

# FACT SHEET

# for certain homeprocessed, home-canned & home-baked foods

This fact sheet addresses recent issues relating to certain home-processed, home-canned and home-baked foods.

Products covered are pickles, vegetables or fruits having an equilibrium pH value of 4.6 or lower and non-temperature-controlled baked goods that do not require refrigeration.

The food products can only be sold at community and nonprofit events or farmers markets located in North Dakota. This includes such events as: county fairs, nonprofit and charitable events, public spirited and/ or community celebrations and farmers markets and roadside stands.



#### It does NOT include:

Craft shows, food festivals, or other for profit events nor sales to other businesses; interstate or Internet sales, or sales from one's home or business.

The individual who is selling home-processed, homecanned and home-baked foods under this exemption should have available, upon request of the regulatory authority, the product's recipe and/or pH results.

The seller must display a sign or placard at the point of sale which states:

### These canned goods/baked goods are homemade and not subject to state inspection



Persons producing and selling these products are urged to have the recipe and manufacturing process reviewed by a person knowledgeable in the food canning/ processing industry and recognized as a process authority.

#### Labeling requirements:

Each food container and/or food item sold must include the following statement using a font size that is prominent, conspicuous, and easy to read.

"These food products were produced in an uninspected home kitchen where major food allergens may also have been handled and prepared, such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish."

If you have questions, please contact your local health unit or:

#### KENAN BULLINGER, DIRECTOR

Division of Food and Lodging North Dakota Department of Health Call: 701.328.1291 or Toll Free: 1.800.472.2927 http://www.ndhealth.gov/DoH/contact.htm HB 1433 3/7 #4

# Home-Processed & Home-Canned Foods

### You may not sell

Foods that require refrigeration

Fresh-processed (not canned) foods that require refrigeration such as fresh salsa, pesto, etc.

Foods that are home-processed or home-canned such as home-canned fish, pickled eggs and meat.

**NOT ALLOWED:** Certain foods are not allowed to be sold under these rules.

Any non-acidified foods processed by either the use of a boiling water bath or by the use of a home pressure cooker.

Some foods naturally have a pH of 4.6 or greater.

# These foods are not allowed unless the pH of these foods is reduced to pH 4.6 or less.

These foods include:

artichokes asparagus beans (lima, string, kidney, Boston style, soy, waxed) beets broccoli Brussels sprouts cabbage cauliflower carrots horseradish sweet corn egg plant mushrooms peas most peppers squash potatoes vegetable soups spinach

# **Home-Baked Foods**

**ALLOWED:** Home-baked foods may include but are not limited to lefse, bread, rolls, fruit pies, candies/ confectioneries, and cookies & bars.

**NOT ALLOWED:** Foods that require refrigeration may not be sold under this ruling.

These foods include home-baked foods such as custards, custard-filled pastries, meringue-topped pies or pastries, kuchen, pumpkin pies, cream pies or other pies, pastries or baked goods that are considered potentially hazardous or require temperature control.

### Products not covered under this rule

Certain foods fall under regulatory jurisdiction and are not exempted by this ruling. *YOU MAY NOT SELL:* 

- fish
- dairy
- poultry
- meat products including: smoked fish
  - butter
  - raw milk
  - jerky

potentially hazardous products such as garlic and oil mixtures or other flavored oils.

### You may sell

**ALLOWED:** Foods that have a natural pH of 4.6 or less and acidified foods which have acid(s) or acid food(s) added. *The final pH of the food must be 4.6 or less.* 

Home-canned high acid foods such as:

- sweet or dill pickles
- tomatoes
- salsa
- apples
- cherries
- grapes
- plums
- peaches,
- flavored vinegars
- naturally fermented foods such as sauerkraut pickles and KimChi

# When in doubt check it out!

Please contact your local health unit or: **KENAN BULLINGER, DIRECTOR** Division of Food and Lodging North Dakota Department of Health Call: 701.328.1291 or Toll Free: 1.800.472.2927 www.ndhealth.gov/DoH/contact.htm

### House Bill 1433 North Dakota Department of Health Proposed Amendments

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- Placement of this legislation, if passed, may be better served as a new chapter in statute such as 23-09.5 Health and Safety. Currently, as a section within North Dakota's Food Drug and Cosmetic Act (NDCC 19-02.1), which is modeled after the Federal Food Drug and Cosmetic Act, creates a conflict of interest since food products covered in 19-02.1 offer consumers an assurance that controls (laws) are in place to prevent adulteration and misbranding.
- In Section 2 on page 1, line 16: Replace the word "foods" with "cottage food products".
- In Section 2, page 1 and 2: Include the following definitions:

"cottage food products" means baked goods, jam, jellies and other food products produced at a cottage food operation that does not require time or temperature control for safety. Although not all inclusive, the following list of examples provides for most types of approved cottage foods:

- Baked goods that do not require refrigeration, such as cakes, cupcakes, rolls, biscuits, cookies, bars, loaf breads, and pastries (no custards, meringues or cream fillings, etc.)
- Candy (including chocolate, chocolate-dipped pretzels, chocolate-dipped Oreos, cotton candy, etc.)
- Coated and uncoated nuts
- Canned jams, jellies, and preserves
- Fruit pies (including pecan pie)
- Dehydrated fruits and vegetables, including dried beans
- Popcorn and popcorn snacks
- Cereal, including granola
- Dry herbs, seasonings and herb mixes
- Vinegar and flavored vinegars
- Roasted coffee or dry tea
- Farm flock eggs\*
- Pickles, salsas and other acidified foods where the final pH level has been reduced to 4.6 or less and verified using a calibrated pH meter.
- Naturally fermented foods such as sauerkraut and KimChi where the final pH level has been reduced to 4.6 or less and verified using a calibrated pH meter.

\*Farm flock eggs may only be sold by cottage food operators who are licensed egg dealers approved by the North Dakota Department of Agriculture under Administrative Code Article 7-11.

Other food items which present a food safety risk and are not considered approved cottage foods include low-acid canned foods (e.g., green beans, peas) as well as the following examples:

- Bakery goods which require refrigeration such as cream, custard, meringue-toppings, cheesecake, cream cheese icings or fillings, etc.

HB 1433 3/17 #4 pg.6

- Focaccia-style breads with vegetables and/or cheeses
- Garlic in oil or other flavored oils
- Fresh or dried meat products including jerky
- Poultry
- Fish, smoked fish or shellfish products
- Milk or dairy products, butter, hard or soft cheeses, cottage cheese and yogurt
- Cut fresh fruits and/or vegetables
- Food products made with cut fresh fruits or vegetables
- Food products made with cooked vegetable products
- Barbeque sauces, ketchups and/or mustards
- Fresh fruit dipped in candy or chocolate (for example, chocolate covered strawberries or caramel apples)
- Juices made from fresh fruits or vegetables
- Ice and/or ice products
- Raw seed sprouts

"cottage food operator/operation" means a person who produces and/or packages approved cottage food products only in a private-home kitchen that:

- o Sells directly to an informed-end consumer at the individual's home-based kitchen,
- farm, ranch, farmer's market, farm stand or a municipal, county, or nonprofit fair, festival or event.
- Delivers products to the informed-end consumer at the point-of-sale location designated by the consumer.

"private-home kitchen" means a kitchen designed and intended for use by the residents of a home but that is also used by a resident for the production of cottage food products.

• In Section 2 on page 2, line 10:

The seller must display a consumer advisory printed legibly on the label and/or on a separate sign or placard at the point of sale notifying the informed end consumer, "This product is made in a home kitchen that is not inspected by the state or local health department."

A legible, printed food label shall be required on all pre-packaged cottage food products displaying:

- o common or usual name of the product
- $\circ$   $\,$  city, state and zip code of the food processor  $\,$
- $\circ$  list of ingredients
- major food allergens
- In Section 2 on page 2, line 30 include language to clarify :

Except for whole, unprocessed fruits and vegetables, food prepared at a cottage food operation may not be sold or used in any food service establishment, food processing plant, or retail food

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store. Cottage food operators are not allowed to transport or ship cottage food products across state lines or conduct sales by internet, mail, phone order or consignment.

Include mandates that address:

- Only potable water from a properly constructed, on-site well or municipal water systems can be used. Annual testing of a private, noncommunity water system is necessary in order to ensure the water supply is potable. Backflow prevention is needed on potable water connections.
- An approved, onsite wastewater system properly permitted and evaluated by the local health department is recommended in order to ensure the adequacy of the private home system and that it can handle additional load.
- A cottage food operation must comply with all applicable county and municipal laws and zoning ordinances that apply to conducting a business from one's home residence.

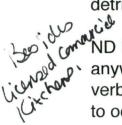
Good morning,

My name is Jennifer **Counter**. I own a cake shop in my local community that would be adversely affected by HouseBill 1433. The passing of this bill would be detrimental to small businesses such as mine...

HB 1433

3/1- # 50

pg.1



one hand

ND Food and Health code currently disallows food transactions to occur anywhere except for farmer's markets and non-profit events. With the new verbiage under Section 2 and bullet point 3, HB1433 would allow food exchanges to occur without inspection or licensing from private homes, farms, ranches and home kitchens.

This would mean that food products would be exposed to illnesses, spoiled or improper handling of food and unregulated temperature control, pet hair, and dander, countertops, dishes, utensils and work surfaces that are not sanitized, possible cross contamination of food products and filtnesses and etc. A US Public interest research group recently published a report that warned approximately 48 million Americans get sick every year from tainted food including things such as bad or improper cooked eggs in bakery items, putrid peanut butter, frozen berries and cheese. This is on the rise and will become widespread should HB1433 pass. A food law and policy clinic study done by Harvard concluded that "food production is almost always required to take place in a certified commercial kitchen to be safe". If you would eat and drink in the production area of a licensed kitchen, or have pets, or wash and rinse everything in the same sink, my health inspector would fine me in a heartbeat or even close me down. These are the very things that happen in people's homes and what this bill would be opening the floodgate to.

In reference example, I've scouted out a few current "illegal" home bakers that have pages up on Facebook and I'd like to point out hazards that can be seen with the naked eye. (show photos) An additional example, of which I was not able to print, is a home baker that had posted on her personal page about having a flea infestation in her home all the while listing photos of cakes that she had been making during that time. This is also the same cake maker that I had seen a photo of her toddler sitting in a diaper only on her work surface next to the cake she was decorating.

Some may argue that allowing home kitchen baking would stimulate small business growth when in fact, it would diminish already existing small businesses that have spent thousands of dollars to comply with the current state health code laws in order to pass and maintain health inspections **(b)** to be licensed. This would mean that while I am struggling to maintain my business to support my family, a home baker down the street that likes to bake for a hobby would be allowed to take business from me and other licensed bakeries at a fraction of the price because he or she would be able to undercut me as they did not have to pay the expense of installing a commercial kitchen up to code nor pay the overhead to run a business including carrying a hefty liability insurance in the event a client should become ill from a good produced in my cake shop. With the current popularization of baking and cooking thanks to channels and shows on The Food Network, TLC and many others, everybody thinks that they can bake a marketable product. I would how to follow staff halfh (ode fo produce the same plocult that such that they can bake a marketable product. I would how to follow staff halfh (ode fo produce the same plocult for the same plocult for the same back for this show the block produce the same plocult for the same back for this show the block

HB 1433 3/17 #50 pg.2

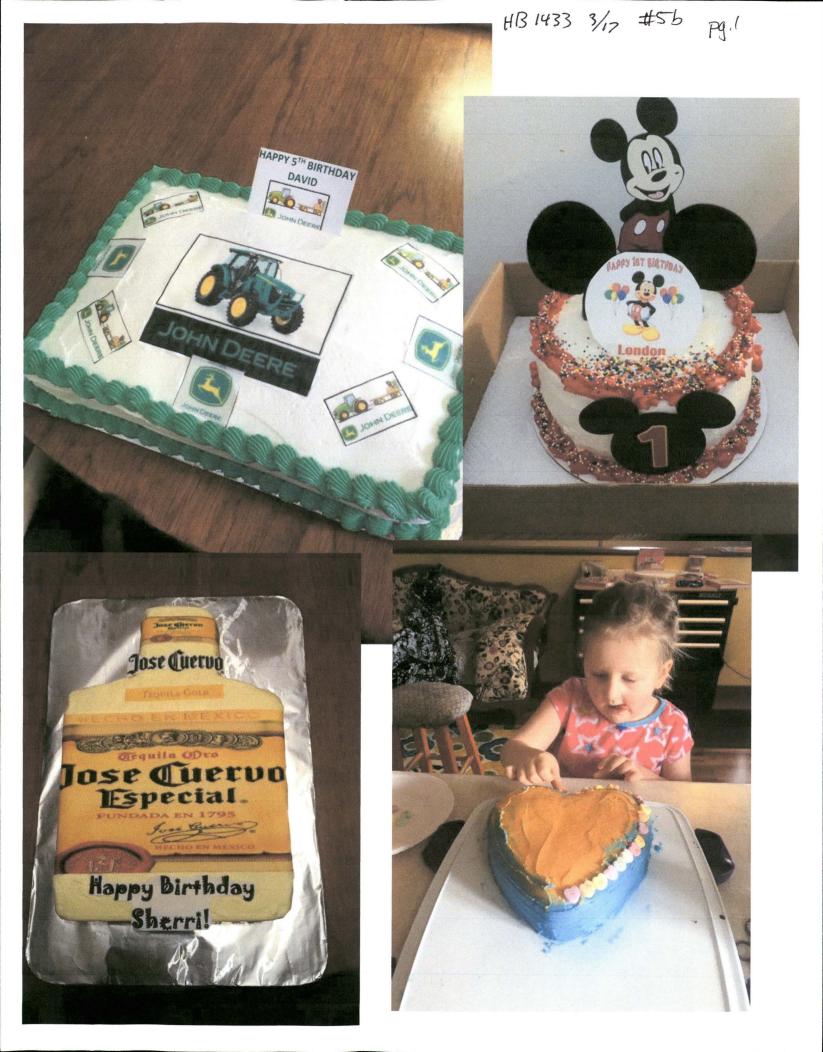
This would also be disastrous for Pride of Dakota, whom a large portion of it's business members are food and beverage small businesses who are also required to be fractive licensed and heath inspected.

In addition to this, from a straight forward business standpoint, I and every other business, are required to report all earnings for state and federal income tax purposes. It highly probable that these home bakers will not be reporting the income they would petentially be making. So in addition to business being taking away from me and decreasing my income, the state of North Dakota's revenue would also be affected from a decrease in taxes being paid in.

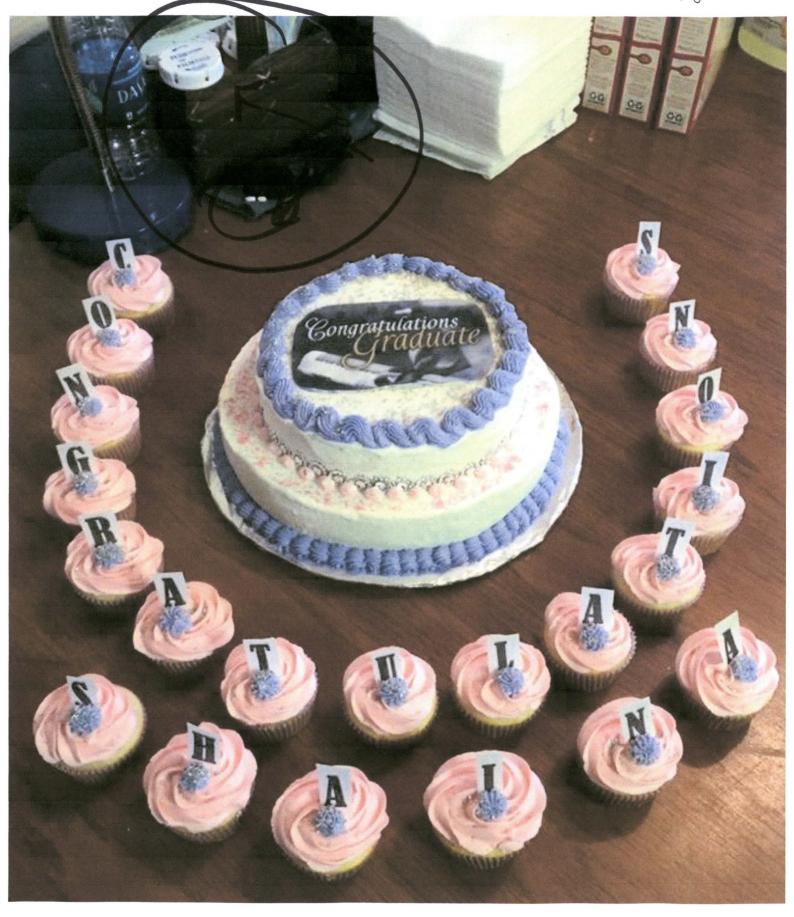
I urge you, for the sake of the safety of the general public, for current business owners and our families, to please remove the ability of direct producer to consumer sales of goods from farms, ranches, and private home kitchens from House Bill 1433 and leave it as it currently stands based on existing ND code.

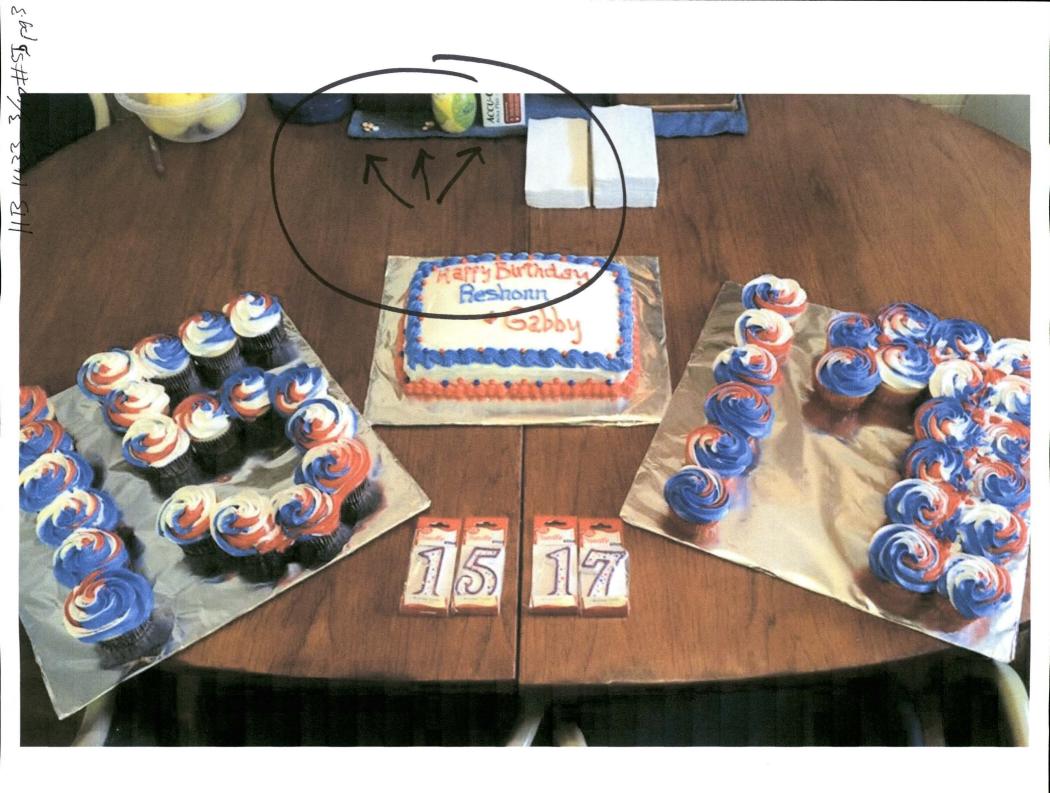
This bill is not only unfair to anybody that has ever started a food business and played by the rules and followed the law, it is downright dangerous to the general public. These laws are mostly in place to protect the consumer, but also the business owner.

Thank you for your time.



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HB 1433 3/17 #5C pg.1

Good Morning,

My name is Kate Halvorson. I am currently pursuing a small bakery and deli business in our local community that would be affected by HB1433. In reading HB 1433, I am noting several areas I feel that affects the small business entrepreneur and has a great potential to affect the "informed end consumer". The new added verbiage created, into 19-02.1, Direct Producer to Consumer Sales of Foods, has the greatest concerns to me personally. Section 2. Notwithstanding any other provision of law, a state agency, or political subdivision may not require licensure, permitting, certification, inspection, packaging, or labelling that pertains to the preparation, serving, use, consumption, or storage of foods or food products under this section.

I ask to you, why would we, the consumers of these food products, not want the food to be viably safe? In reading of this section, this beginning section, "notwithstanding any other provision of law, a state agency, or political subdivision" means that no matter what laws have already been created shall not mean anything, anymore, in regards to food safety. That alludes to me that the ND Health Department's warnings and concerns put forth in Century Code 33-33-04-01 & <u>33-33-04-02</u> do not have any strength or power anymore to ensure food safety for human consumption.

<u>33-33-04-01</u> Definitions – 35 c. "Food establishment" does not include #4. A kitchen in a private home if the food is prepared for sale or service at a function such as a religious or charitable organization's bake sale. <u>33-33-04-02</u> General Care of Food Supplies –

3. Food shall be safe, unadulterated and honestly presented – A). Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

4. Food prepared in a private home may not be used or offered for human consumption in a food establishment.

In reading these three specific areas of the food and lodging portion of the century code, my understanding is that a private home is not equal to a "food establishment". Yet, in the bill 1433, this new addition to 19-02.1 will create a confusion that these home cooks will have nearly equal rights to sell their products anywhere. As the definition, 'transaction' in the new addition to Bill 1433 means the exchange of buying and selling. The subsection to transactions is further described as" transactions under this section must be directly between the producer and the informed end consumer and be only for home consumption. Transactions may occur at a farm, ranch, farmer's market, farm stand, home-based kitchen, or any other venue not otherwise prohibited by law or through delivery."

However, according to the health department's food and lodging century codes, a home-based kitchen is not equal to a food establishment and is not allowed to sell anywhere they want for a good reason. They are not regulated. If this Bill continues to move forward, written as is, then any person who chooses to sell home-cooked foods from their home and sell to the informed end consumer may do so without following certain health department century codes. For example: *Century Code 19-02.1-21 Inspection* –

Examinations – The department has free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose of inspecting such factory, warehouse, establishment, or vehicle to determine if this chapter is being violated and to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such samples.

As the Bill is written currently, these home-based kitchens will not be regulated, will not be inspected, and will not pay into State or Federal taxes as it may. Home-based kitchens have never been regulated. However, this bill is expanding the definition of what a home based kitchen is and how they can sell their products.

Please refer to the Fact Sheet from NDHealth.gov. ND Health defines home-based kitchens very clearly and the expectations posed upon them. FOR "CERTAIN" HOME-PROCESSED, HOME-CANNED AND HOME BAKED FOODS.

The food products (pickles, vegetables, or fruits with a pH value of 4.6 or lower, & non-temperature

controlled baked goods) can only be sold at COMMUNITY and NONPROFIT EVENTS or FARMER'S MARKETS located in ND. Such as: county fairs, nonprofit & charitable events, public spirited and/or community celebrations & farmer's markets & roadside stands.

Does not include: Craft shows, food festivals, or other for profit events nor sales to other businesses, interstate or internet sales, or sales from one's home or business.

Cannot Sell – foods requiring refrigeration, fresh processed foods requiring refrigeration, and certain foods home-processed or home-canned (such as fish, pickled eggs, and meat).

HB 1433 5/17 #50

Pq.2

I feel that the ND Health Department has researched the home based kitchen idea thoroughly and feel that areas that should be removed from this Bill directly involve the wording of notwithstanding any other provision of law, a state agency or political subdivision. I do feel that a home-based kitchen should remain under the current terms set forth by the ND Health Department under Foods and Lodging Century Codes. I do not feel that the home-based kitchen should be allowed to sell from their home to the "informed end consumer" anywhere or anyway they choose. I do feel they should be held accountable regarding risks to the informed end consumer.

This does not help the small business person in many ways.

- 1. Home based kitchens are not held to the same standards as the "food establishment" that must follow rules and regulations and pay into State taxes.
- 2. Home based kitchens are taking business away from the business owner and producing product that may or may not be safe to the "informed end consumer" without retribution, fines, or penalties.
- 3. Home based kitchens are taking money from the state by not being forced to provide documentation of income earned from sales, nor paying State or Federal taxes where appropriate.

Please reconsider Bill 1433 before passing at this stage. As a hopeful, soon-to-be, bakery and deli owner, I implore you to understand my stance. Why would I bother to start a business, by health-related standards, and become a food establishment, if the home baker down the road, can sell her product for the same price or less and not follow the same rules as I would need to follow?

1433 3/17 #6



(701) 787-8100 Fax (701) 787-8145 151 South 4th Street, Suite N301 Grand Forks, ND 58201-4735 www.grandforksgov.com/publichealth

TESTIMONY ON HOUSE BILL 1433 Senate Agriculture Committee Senator Larry Luick, Chair Grand Forks Public Health Department March 17, 2017

Chairman Luick and Members of the Agriculture Committee:

I am writing to express opposition to House Bill 1433 on behalf of the Grand Forks Public Health Department. If this bill is to pass, it should be amended to limit food types to low risk foods, as determined by the Food and Lodging Division of the Health Department, that do not need refrigeration for safety, such as home baked goods, pickles, and jams and jellies. This would provide uniformity reduce confusion about where people can sell these low risk foods instead of limiting them to farmers markets.

The bill, as written, goes too far and would allow many high risk food products and specialized processes that could endanger the health of our citizens. Specialized processes such as cook/chill and vacuum packaging need to incorporate methods to limit the growth of listeria and clostridium botulinum to prevent illness. Even the simple process of cooling properly food to limit bacterial growth is difficult in a domestic setting because residential refrigerators are not designed to adequately cool food in larger quantities. Keeping foods adequately refrigerated to the point of sale/delivery would also be difficult. Foods with special processes or that require refrigeration for safety should be excluded from the bill for the safety of our citizens.

Each year 1 in 6 Americans gets sick from eating contaminated food or beverages according to the Centers for Disease Control. They estimate that roughly 48 million people get sick from foodborne illness each year, 128,000 people are hospitalized, and 3,000 people die. It would be prudent to limit direct food sales to low risk food products to protect North Dakota citizens from foodborne disease.

Thank you for your time.

Respectfully,

Javin Bedard Environmental Health Manager Grand Forks Public Health Department 701/787-8100





# HB 1433 3/17 pg. l NORTH DAKOTA ENVIRONMENTAL HEALTH ASSOCIATION

March 17, 2017

To: Senator Luick, Chairman Senate Ag committee members

Re: HB #1433 – Concerns and support as amended

Dear Representative Luick,

On behalf of the North Dakota Environmental Association (NDEHA), I would like to convey our concerns and support for the amendments to House Bill #1433. The amendments by the North Dakota Department of Health (DOH) have been proposed to promote the health and safety of the end consumers.

The NDEHA board, and its membership, asks for your consideration to amend the following concerns:

- Our primary concern with HB #1433 is that the bill currently includes all type of 'foods', meaning any food or drink, could be produced and sold to the end consumer. We support the DOH's amendment to limit the type of foods to low risk products currently listed in the DOH's guidelines for farmers markets.
- The current bill also does not include requirements for labeling and consumer advisory information. We support the DOH's proposed amendment detailing the type of product labeling, to include allergen identification, as well as proper consumer advisory information verifying the food related products have not been produced under inspection by the Health Department.
- The current bill also does not specify the requirement for a producer to utilize and/or verify a potable water source. We support the DOH's amendment to require the use and/or verification of a potable water source for any facility used by a producer.
- The current bill also does not specify the requirement for a producer to be either connected to a municipal wastewater system or a permitted onsite sewage treatment system. We support the DOH's amendment to require the producer to be either connected to a municipal wastewater system or a permitted onsite sewage treatment system.

If you have any questions or would like additional information, please feel free to contact me.

Respectively submitted,

Grant Larson, President North Dakota Environmental Health Association (701) 241-1388





# HB 1433 $3_{17}$ #7 pg. 2 NORTH DAKOTA ENVIRONMENTAL HEALTH ASSOCIATION

March 17, 2017

To: Senator Luick, Chairman Senate Ag committee members

Re: HB #1433 – Concerns and support as amended

Dear Representative Luick,

On behalf of the North Dakota Environmental Association (NDEHA), I would like to convey our concerns and support for the amendments to House Bill #1433. The amendments by the North Dakota Department of Health (DOH) have been proposed to promote the health and safety of the end consumers.

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- The current bill also does not specify the requirement for a producer to be either connected to a municipal wastewater system or a permitted onsite sewage treatment system. We support the DOH's amendment to require the producer to be either connected to a municipal wastewater system or a permitted onsite sewage treatment system.

If you have any questions or would like additional information, please feel free to contact me.

Respectively submitted,

Grant Larson, President North Dakota Environmental Health Association (701) 241-1388





# HB 1433 <sup>3</sup>/17 pg. 3 #7 NORTH DAKOTA ENVIRONMENTAL HEALTH ASSOCIATION

March 17, 2017

To: Senator Luick, Chairman Senate Ag committee members

Re: HB #1433 – Concerns and support as amended

Dear Representative Luick,

On behalf of the North Dakota Environmental Association (NDEHA), I would like to convey our concerns and support for the amendments to House Bill #1433. The amendments by the North Dakota Department of Health (DOH) have been proposed to promote the health and safety of the end consumers.

The NDEHA board, and its membership, asks for your consideration to amend the following concerns:

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- The current bill also does not specify the requirement for a producer to be either connected to a municipal wastewater system or a permitted onsite sewage treatment system. We support the DOH's amendment to require the producer to be either connected to a municipal wastewater system or a permitted onsite sewage treatment system.

If you have any questions or would like additional information, please feel free to contact me.

Respectively submitted,

Grant Larson, President North Dakota Environmental Health Association (701) 241-1388



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HB 1433

#/ pg.1 3/23

## FIRST ENGROSSMENT

Sixty-fifth Legislative Assembly of North Dakota

**ENGROSSED HOUSE BILL NO. 1433** 

Introduced by

Representatives Simons, Rick C. Becker, Johnston, Kiefert, B. Koppelman, Magrum, Olson, Schatz, Toman

Senators Kannianen, O. Larsen

- 1 A BILL for an Act to create and enact a new section to chapter 19-02.1 of the North Dakota
- 2 Century Code, relating to the direct sale of <u>food</u>cottage food products by the producer to a

3 consumer; to amend and reenact sections 19-07-01 and 36-24-06 of the North Dakota Century

4 Code, relating to the sale and production of animal-based products.

# 5 BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

- 6 SECTION 1. AMENDMENT. Section 19-07-01 of the North Dakota Century Code is
- 7 amended and reenacted as follows:

## 8 **19-07-01. Eggs to be graded - Exemption.**

9 All eggs sold or offered for sale to an ultimate consumer in this state must be candled,

10 graded, and labeled with the correct grade designation. "Eggs" in this chapter means eggs in

11 the shell which are the product of the domesticated chickenpoultry. A producer of eggs when

selling only eggs of the producer's own flock production is exempt from the provisions of thischapter.

SECTION 2. A new section to chapter 19-02.1 of the North Dakota Century Code is created
 and enacted as follows:

# 16 Direct producer to consumer sales of foodscottage food products.

# 17 <u>1.</u> <u>As used in this section:</u>

- 18
   a.
   "Cottage food operator" means an individual who produces or packages cottage

   19
   food products in a kitchen designed and intended for use by the residents of a

   20
   private home.
- 21
   b. "Cottage food product" means baked goods, jams, jellies, and other food

   22
   products produced by a cottage food operator.

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1		C.	"Delivery" means the transfer of a cottage food product resulting from a
2			transaction between a producer cottage food operator and an informed end
3	1		consumer.
4		<del>b.</del> d.	"Farmers market" means a market or group of booths where farmers and other
5			producers cottage food operators sell cottage food products directly to
6	Í		consumers.
7		<u>с.е.</u>	"Home consumption" means food consumed within a private home or food from a
8			private home consumed only by family members, employees, or nonpaying
9	I		guests.
10		d.f.	"Informed end consumer" means an individual who is the last individual to
11			purchase a cottage food product and has been informed the cottage food product
12			is not licensed, regulated, or inspected.
13		<u>e.</u>	"Producer" means any individual who harvests or produces any product that may
14			be consumed as food or drink.
15		f.g.	"Transaction" means the exchange of buying and selling.
16	<u>2.</u>	Not	withstanding any other provision of law, a state agency or political subdivision may
17		not	require licensure, permitting, certification, or inspection, packaging, or labeling that
18		per	tains to the preparation, serving, use, consumption, or storage of foods or food or
19		sale	e of cottage food products under this section. This section does not preclude an
20		age	ency from providing assistance, consultation, or inspection, upon request, of a
21		pro	ducer.
22	<u>3.</u>	Tra	nsactions under this section must be directly between the producer cottage food
23		ope	rator and the informed end consumer and be only for home consumption.
24		Tra	nsactions may occur at a farm, ranch, farmers market, farm stand, home-based
25		kitc	hen, or any other venue not otherwise prohibited by law or through delivery.
26	<u>4.</u>	Tra	nsactions under this section may not:
27		<u>a.</u>	Involve interstate commerce;
28		<u>b.</u>	Be conducted over the internet or phone, through the mail, or by consignment;
29		C.	Include the sale of uninspected products made from meat, except as provided
30			under subdivision ed; or
31		<u>e.d.</u>	Include the sale of uninspected products made from poultry, unless:

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1		(1)	The producer cottage food operator slaughters no more than one thousand			
2			poultry raised by the producer cottage food operator during the calendar			
3			<u>year;</u>			
4		<u>(2)</u>	The producer cottage food operator does not buy or sell poultry products,			
5			except products produced from poultry raised by the producer cottage food			
6			operator; and			
7		<u>(3)</u>	The poultry product is not adulterated or misbranded.			
8	<u>5.</u>	Except for	or rawwhole, unprocessed fruits and vegetables, food prepared by a cottage			
9	food operator may not be sold or used in any commercial food establishm					
10		the food I	has been labeled, licensed, packaged, or inspected as required by law, food			
11		processir	ng plant, or food store.			
12	<u>6.</u>	The prod	ucercottage food operator shall inform the end consumer that any cottage			
13		food prod	luct or food sold under this section is not certified, labeled, licensed,			
14		packaged	d, regulated, or inspected.			
15	<u>7.</u>	This sect	ion does not change any requirement for brand inspection or animal health			
16		inspection	ns.			
17	8.	A cottage food operator shall label all cottage food products that require refrigeration.				
18		such as b	paked goods containing cream, custard, meringue, cheesecake, and cream			
19	cheese, with safe handling instructions. Safe handling instructions must specify the					
20		product n	nust remain frozen until thawed under refrigeration at forty-one degrees			
21		Fahrenhe	it [5 degrees Celsius] or lower and the product is intended for immediate			
22		consump	tion or should be discarded within seven days of purchase.			
23	9.	A cottage	food operator shall comply with all applicable county and city building and			
24		zoning re	quirements that apply to conducting a business within a residential dwelling.			
25	10.	The state	department of health or a local regulating authority may conduct an			
26		investigat	ion upon suspicion a cottage food operator is in violation of this section or			
27		upon com	plaint of an illness or environmental health complaint.			
28	SEC	TION 3. A	MENDMENT. Section 36-24-06 of the North Dakota Century Code is			
29	amended and reenacted as follows:					
30	36-24-06. Prohibitions.					
31	A <u>Unless otherwise provided in chapter 19-02.1, a</u> person may not:					

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1 Slaughter an animal or prepare an article usable as human food at any establishment 1. 2 preparing articles solely for intrastate commerce, unless the person complies with this 3 chapter; 4 2. Sell, transport, offer for sale or transportation, or receive for transportation, in 5 intrastate commerce any article that is usable as human food and which is adulterated 6 or misbranded or any article that has not been inspected and passed under this 7 chapter; or 8 3. Alter an article that is usable as human food while the article is being transported in 9 intrastate commerce or held for sale after transportation, if the alteration is intended to 10 cause or has the effect of causing the article to be adulterated or misbranded.

17.0559.03001 Title. Prepared by the Legislative Council staff for Senator Klein March 22, 2017

3/23 #2 pg. 1

#### PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1433

Page 1, line 2, replace the first "food" with "cottage food products"

#### Page 1, line 16, replace "foods" with "cottage food products"

Page 1, line 18, after "<u>a.</u>" insert "<u>Cottage food operator" means an individual who produces or</u> packages cottage food products in a kitchen designed and intended for use by the residents of a private home.

> b. <u>"Cottage food product" means baked goods, jams, jellies, and other</u> food products produced by a cottage food operator.

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<u>c.</u>"

Page 1, line 18 after the second "a" insert "cottage food"

Page 1, line 19, replace "producer" with "cottage food operator"

Page 1, line 20, replace "b." with "d."

Page 1, line 21, replace "producers" with "cottage food operators"

Page 1, line 21, after "sell" insert "cottage food"

Page 2, line 1, replace "c." with "e."

Page 2, line 4, replace "d." with "f."

Page 2, line 5, after "a" insert "cottage food"

Page 2, line 5, after "the" insert "cottage food"

Page 2, remove lines 7 and 8

Page 2, line 9, replace "f." with "g."

Page 2, line 11, after the third underscored comma insert "or"

Page 2, line 11, remove ", packaging, or labeling"

Page 2, line 12, replace "<u>, serving, use, consumption, or storage of foods or food</u>" with "<u>or sale</u> <u>of cottage food</u>"

Page 2, line 15, replace "producer" with "cottage food operator"

Page 2, line 21, after "<u>b.</u>" insert: "<u>Be conducted over the internet or phone, through the mail, or</u> <u>by consignment;</u>

с."

Page 2, line 22, replace "c" with "d"

Page 2, line 23, replace "c." with "d."

Page 2, line 24, replace "producer" with "cottage food operator"

Page 2, line 25, replace "producer" with "cottage food operator"

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Page 2, line 26, replace "producer" with "cottage food operator"

Page 2, line 27, replace "producer" with "cottage food operator"

Page 2, line 29, replace "raw" with "whole"

Page 2, line 29, after "food" insert "prepared by a cottage food operator"

- Page 2, line 30, remove "commercial"
- Page 2, line 30, remove "unless the food has been labeled, licensed,"
- Page 2, line 31, replace "<u>packaged</u>, or inspected as required by law" with "<u>, food processing</u> <u>plant</u>, or food store"
- Page 3, line 1, replace "producer" with "cottage food operator"
- Page 3, line 1, after "any" insert "cottage"
- Page 3, after line 4, insert:
  - "8. A cottage food operator shall label all cottage food products that require refrigeration, such as baked goods containing cream, custard, meringue, cheesecake, and cream cheese, with safe handling instructions. Safe handling instructions must specify the product must remain frozen until thawed under refrigeration at forty-one degrees Fahrenheit [5 degrees Celsius] or lower and the product is intended for immediate consumption or should be discarded within seven days of purchase.
  - 9. <u>A cottage food operator shall comply with all applicable county and city</u> <u>building and zoning requirements that apply to conducting a business</u> <u>within a residential dwelling.</u>
  - 10. The state department of health or a local regulating authority may conduct an investigation upon suspicion a cottage food operator is in violation of this section or upon complaint of an illness or environmental health complaint."

Renumber accordingly

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17 0559 03002 Title

#1pg.1 Prepared by the Legislative Council staff for Senator Klein

March 23, 2017

### PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1433

Page 1, line 1, replace "section to chapter 19-02.1" with "chapter to title 23"

Page 1, remove lines 14 through 21

- Page 2, remove lines 1 through 31
- Page 3, replace lines 1 through 4 with:

"SECTION 2. A new chapter to title 23 of the North Dakota Century Code is created and enacted as follows:

### Definitions.

As used in this chapter:

- "Cottage food operator" means an individual who produces or packages 1. cottage food products in a kitchen designed and intended for use by the residents of a private home.
- "Cottage food product" means baked goods, jams, jellies, and other food 2. and drink products produced by a cottage food operator.
- 3. "Delivery" means the transfer of a cottage food product resulting from a transaction between a cottage food operator and an informed end consumer.
- "Farmers market" means a market or group of booths where farmers and 4. other cottage food operators sell cottage food products directly to consumers.
- "Home consumption" means food consumed within a private home or food 5. from a private home consumed only by family members, employees, or nonpaving quests.
- 6. "Informed end consumer" means an individual who is the last individual to purchase a cottage food product and has been informed the cottage food product is not licensed, regulated, or inspected.
- "Transaction" means the exchange of buying and selling. 7.

## Direct producer to consumer sales of cottage food products.

Notwithstanding any other provision of law, a state agency or political 1. subdivision may not require licensure, permitting, certification, inspection, packaging, or labeling that pertains to the preparation or sale of cottage food products under this section. This section does not preclude an agency from providing assistance, consultation, or inspection, upon request, of a producer.

- 2. Transactions under this section must be directly between the cottage food operator and the informed end consumer and be only for home consumption. Transactions may occur at a farm, ranch, farmers market, farm stand, home-based kitchen, or any other venue not otherwise prohibited by law or through delivery.
- 3. Transactions under this section may not:
  - a. Involve interstate commerce;
  - b. Be conducted over the internet or phone, through the mail, or by consignment;
  - <u>c.</u> Include the sale of uninspected products made from meat, except as provided under subdivision d; or
  - d. Include the sale of uninspected products made from poultry, unless:
    - (1) The cottage food operator slaughters no more than one thousand poultry raised by the cottage food operator during the calendar year:
    - (2) The cottage food operator does not buy or sell poultry products, except products produced from poultry raised by the cottage food operator; and
    - (3) The poultry product is not adulterated or misbranded.
- <u>4.</u> Except for whole, unprocessed fruits and vegetables, food prepared by a cottage food operator may not be sold or used in any food establishment, food processing plant, or food store.
- 5. The cottage food operator shall inform the end consumer that any cottage food product or food sold under this section is not certified, labeled, licensed, packaged, regulated, or inspected.
- <u>6.</u> This section does not change any requirement for brand inspection or <u>animal health inspections.</u>
- 7. A cottage food operator shall label all cottage food products that require refrigeration, such as baked goods containing cream, custard, meringue, cheesecake, pumpkin pie, and cream cheese, with safe handling instructions and a product disclosure statement indicating the product was transported and maintained frozen.
- 8. A cottage food operator shall display a consumer advisory sign at the point of sale or place a label on the cottage food product with the following statement:

"This product is made in a home kitchen that is not inspected by the state or local health department."

<u>9.</u> The state department of health or a local regulating authority may conduct an investigation upon complaint of an illness or environmental health complaint."

Renumber accordingly