

Review of Evidence for Health Benefits of Raw Milk Consumption

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Preamble

The Office of the PMCSA was requested by the Minister and DPMC to review the advice given to her regarding the sale and supply of raw milk, given the distinct positions held over the issue. The purpose of this review is to provide an independent assessment of the reports provided by MPI along with the available scientific evidence for health benefits and potential risks of raw milk consumption, as compared with consumption of pasteurised milk, to determine whether any claimed benefits have been scientifically validated.

The analysis therefore includes a review of Ministry for Primary Industries (MPI) Technical Papers^{*} and their data sources on the relevant science, as well as subsequent studies, in order to ensure that no validated claims have been discounted.

The review also discusses the relative risks of consumption of raw vs. pasteurised milk.

Methodology

As base information we accessed three MPI reports and were provided MPI briefing notes on issues that Officials considered could be relevant. Websites from advocates for raw milk were scanned to identify claims that would need evaluation. The review involved broad searches in Medline, EMBASE, the Cochrane library database, Scopus, and Web of Science databases to identify relevant studies in the *peer-reviewed* scientific literature relating to the claimed health benefits and /or dangers of raw milk, and the impact of pasteurisation on the beneficial qualities of milk. Data sources that served as the basis for the conclusions in the MPI Technical papers were reviewed, and searches for missing and subsequent studies were carried out.

^{*} MPI Technical papers:

^{1.} Ministry for Primary Industries. Assessment of the microbiological risks associated with the consumption of raw milk. June 2013 (No: 2014/12)

^{2.} Ministry for Primary Industries. An Assessment of the Effects of Pasteurisation on Claimed Nutrition and Health Benefits of Raw Milk. October 2013; (No: 2014/13)

^{3.} Ministry for Primary Industries. The sale of raw milk to consumers. May 2014 (No: 2014/22)

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1. Background - raw milk consumption in New Zealand

Cow's milk has long been recognised as an important source of nutrients in the human diet in many populations. Milk is an important source of calcium and protein, but also provides carbohydrates, iodine, magnesium, potassium, phosphorous, zinc and vitamins A, B2 and B12. Most milk sold in New Zealand is pasteurised to eliminate illness-causing microorganisms, and homogenised to prevent separation of cream and extend shelf life. However, raw (unpasteurised) milk is commonly consumed within farming families and there is a continuing and perhaps growing interest in its presumed benefits among proponents of raw and minimally-processed foods. Such proponents generally believe that raw milk is healthier than pasteurised milk. Informal channels for purchasing raw milk beyond the farm gate are increasingly being utilised.

The access and demand for raw milk must be considered against the increased risk of illness resulting from microbial contamination of milk on one hand and the claims for benefit from raw milk ingestion on the other. As in any situation of this type where beliefs, values, science and public interest collide, passionate views are inevitable amongst those who values are in conflict with the scientific and public health consensus. In such situations it is important to understand the validity of claim and counter claim so that the policy decision is informed as to the benefits and risks of any decision.

There have been a number of infectious diseases linked to the consumption of unpasteurised milk, including campylobacteriosis, salmonellosis, Escherichia coli (E. coli) O157:H7 infection (Shiga-toxin producing E. coli; STEC), listeriosis, tuberculosis, brucellosis, yersiniosis, staphylococcal enterotoxin poisoning, and streptococcal infections. [1] Healthy cattle are reservoirs of E. coli in New Zealand, [2] and bacterial contamination is an inevitable consequence of the milking process. A 2012 study across the main dairying regions (Northland, Waikato, Taranaki/Manawatu, Canterbury and Southland) detected the recognised human pathogens E. coli O157:H7 (STEC), Campylobacter, Listeria and Staphylococcus aureus (S. aureus) in raw milk randomly sampled from bulk farm tanks. [3] The prevalence and concentration of the pathogens were generally lower than those found in many of the studies from other countries, which was attributed to New Zealand farming practices of grass feeding and cattle living outdoors. Nonetheless, the risk of infection by the identified pathogens is considered to be significant in the absence of pasteurisation. Raw milk testing alone is not sufficient to eliminate all risk for exposure because test results only reflect the conditions at the time of sampling.

On the other hand, proponents of the use of raw milk have made claims for health benefits associated with its digestibility, its nutritional and immune qualities – all of which have been claimed to have health promoting or therapeutic value. The validity of these claims is one point of contention that many reports [4-7] and the work of MPI has had to consider.

The issue of raw milk sales for human consumption in New Zealand has been under review by MPI. This document aims to assist the Minister in decision making about regulatory controls on raw milk sales, based on the scientific assessment of potential benefits and risks of raw milk consumption. It does not consider other issues that may be material to the decision.

2. Findings of the MPI Technical papers

The Ministry for Primary Industries has recently conducted a number of reviews relating to the issue of raw milk safety, public demand, and potential benefits. These documents are briefly reviewed below.

2.1 <u>MPI Technical Paper No: 2014/12</u>: Assessment of the microbiological risks associated with the consumption of raw milk.

This report was published in June 2013 and is based on information available to MPI prior to February 2013. [8] It provides a thorough microbiological risk assessment of the risk to New Zealand consumers from drinking raw milk, and the possible impact of extending sales beyond the farm gate. The report models risk scenarios based on analysis of New Zealand data (where available) on the occurrence of pathogens in raw milk and the impact of critical farming practices on levels of contamination.

The epidemiological evidence indicates that *Campylobacter* spp. and STEC are the pathogens of most health concern, and that children are affected disproportionately by milkborne illness. Salmonella also presents a risk associated with raw milk. The risk of tuberculosis (TB) is considered low but not nil; bovine TB still present in New Zealand but cows/herds must be TB free for 5 years before being used for milking. The risk assessment indicates that an appreciable number of cases of illness would occur in New Zealand as a result of access to raw drinking milk. The risk to the urban population for campylobacteriosis was determined to be five times greater than for on-farm residents who may have acquired immunity, and the risk of pathogenic contamination increased with increasing duration between production and consumption of raw milk.

The epidemiological evidence from New Zealand, and risk assessments based on these data, are consistent with those from the USA and other countries. Thus the public health consensus in many developed countries is that raw drinking milk represents an ongoing, significant risk to public health that is proportional to the extent of raw milk availability. The report did not assess the potential benefits of raw milk consumption, or how this might impact on the perception of this clearly significant risk. These issues were addressed in a subsequent report, discussed in section 2.2.

2.2 <u>MPI Technical Paper No: 2014/14</u>: An Assessment of the Effects of Pasteurisation on Claimed Nutrition and Health Benefits of Raw Milk

This report was published in October 2013 and is also based on information available to MPI prior to February 2013. [9] The information was derived from a literature search of the peer-reviewed scientific literature and published reports of international regulatory authorities. The report forms the basis for our current review, which is focused on assessing whether any of the claims of benefits of raw milk are supported by scientific evidence.

The report highlights four claimed benefits of raw milk:

- Claim: Raw milk has higher nutritional value than pasteurised milk.
 Conclusion of the report: The nutritional profile of raw milk is not substantially different from that of pasteurised milk. The heating
 - (pasteurisation) of milk has:
 - no significant impact on the digestibility or nutritional value of milk proteins,
 - minimal impact on the concentration of vitamins (relative to their contribution from milk to the Recommended Dietary Intake (RDI),
 - no impact on milk mineral content or bioavailability, and
 - no effect on milk fat composition.
- Claim: People with lactose intolerance can drink raw milk
 Conclusion of the report: There is no evidence of a significant association between lactose tolerance and raw milk consumption, based on the fact that:
 - lactase is not present in milk, and
 - lactase-producing bacteria (which would be killed by pasteurisation) are inactive at refrigeration temperatures, and
 - participants in a case-control study reported symptoms after consumption of both raw and pasteurised milk, with no difference in severity of symptoms
- 3. Claim: Pasteurisation destroys/inactivates beneficial antimicrobial systems and enzymes

Conclusion of the report:

• Pasteurisation reduces the number or bacteria in milk, including those of potential antimicrobial benefit, but this has minimal effect on milk quality because these bacteria are only present at low levels (high levels indicate poor farm hygiene),

- Antimicrobial enzymes are not present in raw milk in sufficient quantities to be affected by pasteurisation.
- Overall there is little evidence that "good bacteria or other components reduce pathogen numbers.
- There is no evidence for a physiological role of milk enzymes in human digestion.
- 4. Claim: Consuming raw milk helps the development of a strong immune system and prevents the development of allergies, asthma and atopy. People with these conditions will have worse symptoms if they drink pasteurised milk. Conclusion of the report: although several epidemiological studies suggest that early life exposure to raw cow's milk, together with other factors (farm exposures), may reduce the risk for developing asthma, allergies, or atopy, they do not identify any cause-effect relationships and data are insufficient to allow recommendation of raw milk as a preventive measure for allergic disease.

2.3 <u>MPI Technical Paper No: 2014/22</u>: The sale of raw milk to consumers

The third report is a consultation paper that examines the problems with the current situation regarding sale/availability of raw milk to the public. [10] The report reviews data from the previous two MPI Technical Papers on risks and benefits of raw milk, and outlines options for regulating raw milk sales to consumers, based on the assessment that existing laws are not suited to current situation (they were established for rural populations previously unable to access pasteurised milk). The report includes a survey for stakeholders.

The options presented are based on the observation that the incidence of milk-borne illness in New Zealand is rising, and on the assumption that no control levels will eliminate all of the risks associated with raw milk drinking.

The review of possible risks and benefits concluded that:

- pasteurisation does not substantially alter the nutritional value of milk for consumers,
- pasteurisation (or lack thereof) has no impact on lactose tolerance,
- there is little evidence of 'good bacteria' in raw milk, and
- the science is inconclusive on whether drinking raw milk at young age reduces allergies/asthma most studies cannot control for confounding farm exposures

Overall, the risk assessment "reaffirmed raw drinking milk as a high-risk food" and recommended that options for its regulation must provide sufficient controls to protect public health, while allowing access for people who are made aware of, and are willing to accept, the risks involved.

3. Further assessment of the claimed benefits of raw milk by the Office of PMCSA

The MPI Technical Paper No: 2014/14 discussed in section 2.2 (and to some extent, MPI Technical paper No: 2014/22 – section 2.3) assessed four broad claims of benefits attributed to raw milk by its proponents [9] and the popular literature also focuses on these same four areas.

After reviewing the MPI documents, a further search of the scientific literature was conducted, both tracing back to verify the data sources and conclusions of the MPI report, and searching forward to identify any subsequent studies not included therein. The scientific literature and the internet were also searched for additional claims of beneficial affects of raw milk consumption irrespective of the source of that claim.

The findings, where they expand on or alter the conclusions of the MPI report, are described below.

3.1 Claim: Raw milk has more nutrients than pasteurised milk

Our review confirmed the findings of the MPI reviews. Raw milk is claimed to be a better source of essential amino acids, bioactive peptides, vitamins, and minerals, and has a better fat content than pasteurised milk. For most nutrients, this claim is unsupported by scientific evidence, or where there is a small difference it is of negligible biomedical or nutritional significance given the sources of nutrients in a mixed diet.

3.1.1 Vitamins

With regard to vitamins, the MPI review relied primarily on a meta-analysis of studies available up to 2009 [11] which indicated that the concentration of most vitamins in milk was not significantly affected by pasteurisation. No additional studies have been identified which address this issue.

Milk contains the fat-soluble vitamins A, D, E, and K, the content of which depends on the fat content of the product. Reduced fat milk therefore contains lower concentrations of these vitamins than whole milk, whether or not it has been pasteurised. Comparing whole pasteurised milk with raw milk, the meta-analysis found that vitamin A concentration is increased, rather than decreased by pasteurisation. Milk is considered an important source of vitamin A. [11]

The available literature allowed only qualitative assessment of the effect of pasteurisation on vitamin B12 levels and suggested that the small observed reduction would have negligible impact on typical adult daily intake. As vitamin B12 is found only in animal products, milk (both pasteurised and raw) could be considered an important source of this nutrient for vegetarians who consume dairy products. [11]

Pasteurisation causes a statistically significant reduction in the concentration of vitamin C in milk, but because milk is not a major source of this vitamin in a diet, the decrease has negligible impact on daily intake.

Levels of vitamin B2 (riboflavin) in milk are reduced by pasteurisation. [11] Although dairy products (including pasteurised milk) are a significant source of vitamin B2, many other foods also contain this vitamin (e.g. meat, eggs, fish, nuts and seeds, green leafy vegetables) and insufficiency is extremely rare in New Zealand. Thus the impact of restricting raw milk is not significant provided there is a balanced diet.

3.1.2 Minerals

Minerals in milk are stable under conditions of pasteurisation, and therefore show similar content and bioavailability between raw and pasteurised milk. The calcium content in particular, which is the most important dietary component provided by milk, has been shown to be the same in both milk types. [12, 13] No recent studies have added to this conclusion.

3.1.3 Proteins and essential amino acids

Milk is a source of essential amino acids, and pasteurisation (including UHT) appears to have negligible effect on their concentration. [4] Very small losses of lysine (1-4%) have been reported, but this is not considered to be significant given the multiple sources of amino acids in any diet.

The major proteins in bovine milk are caseins (milk-specific phosphoproteins) and whey proteins (including immunoglobulins, α -lactalbumin, β -lactoglobulin, bovine serum albumin, immunoglobulin, lactoferrin and transferrin). Caseins are heat stable, and therefore are not affected by pasteurisation. Whey proteins are more sensitive to heat, but are not significantly affected at normal temperatures used for pasteurisation. They are, however, denatured by ultra-high-temperature (UHT) pasteurisation. [14]

3.1.4 Conclusion

Overall, the evidence does not support the claim that raw milk as a better nutritional profile than pasteurised milk. The major nutritional components of milk (protein, minerals [calcium]) that contribute to an individual's recommended dietary intake remain substantially intact after pasteurisation.

3.2 Claim: People with lactose intolerance can drink raw milk

The claim that raw milk is digestible for people with lactose intolerance is refuted by the scientific literature. This claim assumes that raw milk contains "beneficial" (probiotic) bacteria that produce lactase, an enzyme that breaks down lactose, and that these bacteria are inactivated by pasteurisation. However, raw milk does not naturally contain probiotic bacteria. In fact, the presence of probiotic Bifidobacteria (which colonises the bovine intestine), in milk indicates bovine fecal contamination and is a sign of poor farm hygiene. [15]

In a randomised, double-blind trial, subjects who claimed to have hypersensitivity to processed milk reported the same (subjective) experience of milk 'tolerance' with both raw and pasteurised/homogenised milk. [16] In people with diagnosed lactose intolerance, raw and pasteurised/homogenised milk elicited the same responses of intolerance. [17]

As concluded in the MPI report, there is no compelling evidence that enzymes or bacteria in raw milk play a role in digestion or gastrointestinal health. [4]

3.3 Claim: Pasteurisation destroys/inactivates beneficial antimicrobial systems and enzymes

The literature review did not reveal further information on this claim, and supports the conclusion of MPI that raw milk does not contain a high enough concentration of microbial compounds or bacteriocidal/bacteriostatic microorganisms to have an effect on the safety of raw milk compared with pasteurised milk. The major antimicrobial compounds found in milk (lactoferrin, xanthine oxidase, lactoperoxidase, and lysozyme) are all relatively stable at pasteurisation temperatures. [18-20]

3.4 Claim: Consuming raw milk helps the development of a strong immune system and prevents the development of allergies, asthma and atopy.

Raw milk is claimed to contain molecules that enhance immune system function, such as immunoglobulins, and also components that prevent the development of allergies, asthma and atopic conditions such as eczema, while at the same time being less immunogenic – i.e. having fewer components that cause allergy.

3.4.1 Immune-enhancing molecules

The concentration of immunoglobulins is low in milk, and considered to be physiologically insignificant to humans. The effect of pasteurisation, if any, is considered to be beneficial, as heat-induced aggregation can increase the binding affinity of immunoglobulins for receptor sites. [21]

Transforming growth factor- β (TGF- β) is a potent immunoregulatory molecule present in raw human and bovine milk. It has been shown to survive manufacturing processes and remain biologically active in pasteurised milk. [22] Athough other known immunomodulatory factors have been identified in bovine milk (e.g. IL-1 β , IL-6, IL-10, TNF- α) they are present in very low amounts and their activities have not been clearly defined. [23] Further, the physiological significance of such factors in milk is not clear.

The data on the immunoregulatory properties of milk proteins does not support claims for benefits of raw milk on immune-mediated diseases including Crohn's disease and cancer.

3.4.2 Preventive effects for asthma/allergies

As indicated in the MPI review, [9] a number of epidemiological studies have suggested a protective effect of early-life exposure to raw milk on the development of asthma and allergies. However, these studies are all confounded by multiple farm-life exposures, including contact with animals, straw, feed, grass, etc.

There is a substantial body of evidence indicating that farm children have a lower incidence of these disorders than children raised in an urban environment, but the exact components that contribute to this effect have not been definitively identified. For example, in the GABRIEL Advanced Study, exposures to cows, straw, and farm milk were protective for asthma, but the strongest association was with straw and not milk. Early life contact with grain was shown to be inversely proportional to atopy in farm children in Poland, but consumption of farm milk was not significantly associated. [24] Exposure to a wide range of environmental microorganisms on farms in early life may explain a substantial fraction of inverse relationship between farm life and asthma. [25] A high concentration of grass pollen during feeding in cowsheds (and the accompanying increase in fungal and actinomycetal levels) combined exposure to pollen and microbes may also initiate allergic tolerance in farm children. [26] Such findings are compatible with the 'hygiene' hypothesis, which suggests that exposure to multiple antigens early in life reduce the risk of allergy and these broader factors are more likely to be relevant in a farm environment than raw milk exposure.

Results of the PARSIFAL study in Europe [27] appeared to show an inverse relationship between 'farm milk' consumption and asthma and allergy that was independent of farm exposure. However, no objective confirmation of the raw milk status of the farm milk was reported, and in fact much of it was boiled. A small study in New Zealand found that consumption of unpasteurised milk as part of an infant diet was inversely associated with all allergic diseases (except hay-fever), and was particularly strong for atopic eczema/dermatitis syndrome and allergic rhinitis. [28] However, unlike most other studies, the farm children in NZ otherwise had more hay-fever, allergic rhinitis, asthma, wheeze, and atopic eczema/dermatitis. [28] A recent study involving the PASTURE birth cohort in rural areas of Austria, Finland, France, Germany and Switzerland suggested that unprocessed cow's milk "protects" infants from common respiratory infections, but only relative to feeding with UHT-treated milk (not pasteurised milk). "Protection" against fever was observed for both raw and pasteurised milk when compared with UHT milk. However, the authors appropriately comment that raw milk can confer life-threatening infectious disease, particularly in infants, and is therefore not recommended for infants. [29]

Overall, there are some weak epidemiological data suggesting that raw milk exposure in early life may be associated with some reduction in the development of allergic disorders and asthma, but the evidence is not strong and exposure to raw milk in this age group is particularly risky given the susceptibility of this age group to infection. The evidence does not warrant a recommendation promoting raw milk consumption in children who are at risk of allergic disorders.

3.4.3 Lower allergenicity of raw milk vs pasteurised milk

A related claim to that of the protective effect of raw milk on the development of allergy is that raw milk is itself less allergenic than pasteurised milk. Loss et al. [30] suggested that the protective effect of raw milk correlated with the presence of nondenatured whey proteins in raw milk. Thermal processing may result in covalent protein modifications that could either increase or decrease the antigenicity of food components, [31] but the evidence of this occurring in milk is equivocal. It is known that high-temperature (UHT) pasteurisation causes denaturation of whey proteins, but denaturation appears to be minimal at typical pasteurisation temperature. Contrary to the conclusions of Loss et al. [30] a study of allergy provocation in children demonstrated that heat treatment of raw milk actually reduces (but does not eliminate) the antigenicity of milk proteins. [32] Another animal study showed very slight increase (>5%) in allergenicity of caseins in cow's milk after pasteurisation, but substantial decrease after boiling or sterilisation. [33]

The contradictory results from such studies do not allow conclusions to be drawn about possible effects or mechanisms relating to the allergenicity of raw and pasteurised milk components, but again suggest that any effect, if indeed there is one, would be minimal.

4. Conclusions

The reports provided to the Minister by MPI are of high quality and we find little to add to them or to qualify.

Although not reviewed extensively here, the evidence that raw milk can be a vehicle for serious and sometimes life-threatening foodborne illness is very well documented, and such disease outbreaks are on the rise in New Zealand and elsewhere where raw milk has been gaining popularity as a "health food". A recent study in Minnesota (USA) found that the number of illnesses ascertained as part of documented outbreaks likely represents a small proportion of the actual number of illnesses associated with consumption of raw milk. [34] The number of sporadic, laboratory-confirmed cases was 25 times greater than the number of reported raw milk-associated outbreaks. Among recorded cases, children are disproportionately affected, and are also among the most vulnerable to serious adverse outcomes (along with pregnant women, the elderly, and immune-compromised individuals).

The claimed health benefits of raw milk compared with pasteurised milk are for the most part not backed by scientific evidence, making the risk:benefit ratio very high for this food product, particularly among the vulnerable groups. Even if consumers recognise that the consumption of raw milk may carry some inherent risk, they might not appreciate the potential severity of the hazard, particularly for young children. It seems prudent to advise that at a minimum, a detailed warning label be required for the sale of raw milk, to allow consumers to make a more informed decision. It may be

appropriate to consider whether such a label should indicate that raw milk should only be provided to young children under the advice of a medical practitioner.

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