

Raw milk got a raw deal from Food Standards Australia New Zealand

In 2009 Food Standards Australia New Zealand published a damning assessment of the safety of raw milk. Using simulations and other modelling, FSANZ warned of widespread disease outbreaks if raw milk sales were permitted. The FSANZ report became the go-to 'scientific' source supporting enforced pasteurisation of all cow milk for human consumption.

Strangely, the fate of Australia's dairy farming families, many of whom drink raw milk, was not mentioned. Why is sickness not rife among them? Why are they allowed to drink raw milk?

A recent technical analysis of this report was carried out for the Australian Raw Milk Movement by an international risk assessment consultant. This critique reveals that FSANZ's 2009 report relied on low grade science and systematic bias. Input data and assumptions were of poor quality and largely lacked independent validation. Sound published information was ignored. Health risks were exaggerated wildly.

Since 2009, international research breakthroughs in the microbiology, benefits, and risks associated with raw milk have revealed additional serious deficiencies in FSANZ's approach that were not evident at the time.

FSANZ considered the four major pathogens that need to be managed in milk: *Campylobacter*, Shiga toxinogenic *E. coli*, *Listeria monocytogenes*, and *Salmonella*. ARMM's new critique probes the data that FSANZ used for its study, highlights reliable scientific evidence available to FSANZ in 2009 but ignored, and summarises highly significant recent developments which invalidate many of FSANZ's assumptions.

We note that FSANZ did not investigate raw milk quality and safety at any dedicated raw milk dairy anywhere in the world. FSANZ listed seven data gaps and areas for further research on page 41 of its report, covering the supply chain from farm to table. It did not mention study of specialised raw milk producers as a missing or desirable contribution. Is FSANZ averse to testing its findings by actually looking at carefully produced raw milk?

ARMM calls on FSANZ to scrap its shoddy report, and revise the Standard by following the science with integrity. Our critique, produced by Ms Margaret Coleman of Coleman Scientific Consulting, provides guidance on how FSANZ can lift its game. The critique is now available, together with a companion database report [here](https://www.ausrawmilk.org/):

<https://www.ausrawmilk.org/>

Please follow the rules

FSANZ ignored widely agreed principles and guidelines for microbial risk assessment, which were approved in 1999 by the Codex Alimentarius Commission. These rules stipulate that such studies should be soundly based on science, and should be transparent. FSANZ did not choose high quality data. Rather, it selected studies that supported preconceived biases.

FSANZ's assumptions are at best weakly supported and largely unvalidated by independent experimental evidence. The impacts of alternative assumptions are not provided, thus limiting transparency for the data and models, and confidence in the outputs of the models.

Broth cultures reveal little about microbial growth in raw milk

Microbial growth in raw milk was calculated from laboratory broth cultures, which is indefensible scientifically and suggests potential bias by FSANZ, which excluded a study of

the growth of *E. coli* in raw milk published more than ten years earlier. In fact, those earlier authors noted that faster pathogen growth in broth media under optimal conditions may be due to lack of competition from raw milk microbes.

Considerable evidence from studies of predictive microbiology was not cited by FSANZ. These studies documented pathogen growth, not only in pure culture broth systems, but also in raw and pasteurised milks. Inappropriate assumptions applied by FSANZ about the growth of bacterial pathogens at temperatures typical of refrigeration, and higher temperatures typical of refrigeration breakdowns, should be re-considered by FSANZ in updating the 2009 report, along with pathogen growth studies that include the dense, diverse natural microbe communities of milk. In growth studies of pathogens, our critique stresses the importance of selecting initial pathogen counts that reflect levels actually observed in raw milk produced for human consumption.

How to make raw milk look risky

FSANZ hugely overestimated risks for raw milk consumers by applying a series of worst-case assumptions. Modelling by FSANZ was particularly superficial and overly conservative, likely resulting in substantially exaggerated estimates of risk for each pathogen.

The application of highly conservative assumptions biased the simulation models, and grossly underestimated uncertainties in the underlying data. Plausible alternative assumptions were excluded. Thus, FSANZ's simulation results overstate the robustness and reliability of its models, due to extremely weak and indirect scientific data, as well as limited statistical and biological relevance of the data and models chosen.

These failings are not surprising, as some studies reporting large uncertainty and variability for the data and models available at the time were excluded from the report. Because of these weaknesses, FSANZ's risk estimates for Australian raw milk consumers were not based on sound science. Its conclusions are untenable in 2021.

In summary, FSANZ got many things wrong. It put dubious data into its models, and ignored much better information that was readily available. It dramatically exaggerated the risks of illness, and uncritically accepted its unverified modelling results, which reflected opinions, not valid scientific evidence.

Microbes as partners

Since publication of the FSANZ report in 2009, the development of new genetics-based study methods has led to a 'microbiome revolution,' leading to major advances in our understanding of microbe populations in various parts of the human body, and in mammalian milks. The microbiome revolution fuelled an explosion of knowledge and delivered profound insights into symbiotic partnerships of microbes in mammals.

There is broadening acceptance that humans are 'superorganisms,' which are 'completed' by microbial communities ('microbiota') forming partnerships in health, rather than as 'insurgents for eradication,' based on germ theory. As understanding of mammalian superorganisms continues to advance, emerging evidence challenges long-held assumptions about microbial communities of humans and natural foods such as milk.

For example, one such outdated assumption, now disproven, is the sterility of mammary tissue in humans and cows. By 2015, when the European Food Safety Authority reviewed studies of raw milk, including the FSANZ report, this expert body included a section on the milk microbiota. Since then, hundreds of peer-reviewed manuscripts on the cow milk microbiota have been added to the scientific literature, including microbes found in raw milk, which was previously believed to be sterile.

Numerous 21st century studies of the microbiota of milks are inconsistent with assumptions used by FSANZ, which appear to be based on 20th century science: that milk should be sterile and the microbes present are the result of contamination by faeces. For example, one study concluded that microbe populations in raw cow milk are different from those in faeces (and different again in feed, rumen fluid, and water). This finding contradicts the common notion that bacteria present in milk are faecal contaminants. Contrary to FSANZ's view, pathogens in faeces are NOT predictive of pathogen levels in raw milk. FSANZ should abandon its outdated views on faecal contamination.

In any case, as you would expect, specialist raw milk producers take great care to avoid contamination. That's why milking takes much longer on raw milk dairy farms.

Recent research does not support the outdated assumptions that raw milk is inherently dangerous, and that existing hygiene management programs, including Hazard Analysis and Critical Control Points, and Test-and-Hold Programs, cannot ensure a safe, low-risk product for raw milk consumers.

Another view of the FSANZ report

FSANZ concluded on page 46 of its report, that 'The ability to reduce or minimize risks associated with raw milk is considered to be quite limited'. The European Food Safety Authority saw it differently. The Authority concluded that FSANZ's simulations demonstrated that improving on-farm hygiene would reduce the incidence of illness. Apparently FSANZ did not notice that nugget. The Authority also drew attention to serious data limitations in FSANZ's report.

FSANZ came out against test-and-hold, and did not think hygiene could be improved much. According to FSANZ, raw milk is seriously dangerous. Emergency departments would be swamped with 'gastro' cases.

But what actually happens in the real world of raw milk?

Organic Pastures Dairy Company, Fresno California

Strict hygiene controls at Organic Pastures include a Hazard Analysis and Critical Control Points Program, and a Test-and-Hold Program for pathogens, under which milk is held back from sale until test results give it the all-clear.

The Test-and-Hold Program became viable as rapid testing methods were developed over the past decade. How is the Program working?

Organic Pastures is licensed to sell raw milk and raw milk products at retail markets in California. The dairy produced 4,280,922 gallons of raw milk from 2018 to 2020, of which 1,351,684 gallons (31.5%) was bottled for direct human consumption at retail in California. Since no raw milk outbreaks associated with microbial pathogens were reported in California in this period, risk estimates based on the serving sizes for children and adults cited in the FSANZ report are that risk of illness is less than 1 in 9.5 million servings for children, and less than 1 in 12.9 million servings for adults.

These risk estimates are substantially lower than those from FSANZ in 2009. FSANZ's estimates are largely based on unvalidated assumptions and extrapolations, and are not based on sound science. They are indefensible.

Filling FSANZ's data gaps

One of the seven data gaps listed by FSANZ was growth of pathogens in raw milk. To address this gap, a pilot study designed by Ms Coleman and colleagues is under way in an independent laboratory in the USA. ARMM will report on this study when it has been completed, and peer reviewed.

Ms Coleman also suggests studies of the consumption of raw milk by dairy farm families in Australia, as well as looking into the benefits and risks of continuing the prohibition of raw milk for other Australian consumers. Further, the effectiveness of current zero-tolerance policies for potential pathogens in reducing raw milk risks, as well as documentation of their costs, warrants study if Australia's prohibition of raw milk is lifted.

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Suggested reading on standards for producing safe raw milk
<https://www.rawmilk institute.org/common-standards>