

**Paper FSA 00/05/04
FOR DISCUSSION**

Safety of Raw Milk

Executive Summary

1. The attached paper, produced by Advisory Committee member, Dr David Casemore, provides a background discussion paper and literature review on the public health issues related to retail bottled raw milk.
2. The paper should be considered in conjunction with Paper FSA 00/05/04.
3. The committee is asked to
 - Consider the paper.
 - Comment upon whether further information is required in order to assist the committee in reaching a conclusion on the safety of raw milk.

Food Standards Agency Wales
Contact:

Helen George, Secretariat

Tel: 029 20678907

**Public Health Issues Related to
Retail Bottled Raw (Green top) Milk.**

Background discussion paper and literature review.

**Prepared by:
Dr David P Casemore PhD FRCPATH
Senior Research Fellow, CREH
Member, Food Standards Agency Advisory Committee for Wales**

"The infection of milk constitutes one of the most frequent factors in the causation of infant mortality." International Congress of Hygiene, 1891.
"The general means of prevention of diarrhoea will probably consist in -6. Great care in the storing and transmission of milk, and cleanliness of cows and dairies..."

In: Russell. Epidemics, Plagues & fevers - their causes and prevention. 1892.

"... this failure to introduce universal heat treatment of milk throughout the United Kingdom may prove to be a costly mistake in terms of human health."

Galbraith NS* et al. Communicable disease associated with milk and dairy products in England and Wales, 1951-80. Br Med J 1982; 284:1761-5.
(* Director at that time of PHLS CDSC.)

"Meaningful differences in nutritional value between pasteurized and unpasteurized milk have not been demonstrated, and other purported benefits of raw milk consumption have not been substantiated. Conversely, the role of unpasteurized dairy products in the transmission of infectious diseases has been established repeatedly. To effectively counsel patients attracted by the health claims made for raw milk, practising physicians must understand both the rationale used by proponents of raw milk and the magnitude of the risks involved in drinking raw milk."

Potter et al.* Unpasteurized milk. The hazards of a health fetish. J Am Med Assoc 1984; 252: 2050-54.

***Division of Bacterial Diseases, Centers for Disease Control, Atlanta, Ga, USA.**

"...the continuing availability of unpasteurized milk on retail sale constitutes an unacceptable risk to public health."

De Louvois & Rampling. Brit Med J 1998;316:625

"If the cow had been designed with HACCP for the dairy industry in mind it is unlikely that the udder would have been placed where it is."

DP Casemore: Discussion, this paper.

Raw milk - definition

Green top milk is farm-bottled, unpasteurized milk, the retail sale of which is still permitted in England and Wales (SI 1995), but not in Scotland. Standards for raw milk intended for retail sale or for the production of other dairy based products, are defined in the Statutory Instrument (1995).

Laboratory Criteria for Milk

Initial quality and keeping quality are measured by means of several tests, including somatic cell count, microbial count (syn. plate count, TVC or TBC) and, historically, by an indirect measure of microbial content, the methylene blue reduction test (Wilson 1935). Current regulations specify the following criteria for raw milk to be sold direct to the consumer:

- Plate count at 30°C - < 20,000/mL
- Coliforms* - < 100/mL
- Pathogens/toxins - not present in quantities to affect health of the consumer.

* An indication of faecal contamination of milk is the presence of *Escherichia coli*, part of the normal gut flora of both humans and animals (the regulations specify only the broader term coliforms). The presence of *E. coli* is an indication of faecal contamination and thus for the potential presence of enteric pathogens, including pathogenic variants of *E. coli*.

General improvements in dairy hygiene in the UK means that the bulk of milk produced here is generally significantly better than is required under UK and EU regulations, particularly with regard to plate count. This is partly as a result of tying payment to the farmer to TBC (Keceli & Robinson 1997; Neaves 2000; Williams and Neave 2000). Good hygiene indicators (e.g. TVC) cannot be relied upon to suggest an absence of pathogens (McEwan 1988).

Pasteurization of milk - usually at 71.7°C for 15 seconds, or similar combination of temperature and time (Dairy Products (Hygiene) Regulations 1995) - kills or reduces numbers of many vegetative organisms that may be present, but not generally spores or other thermotolerant organisms. Effective pasteurization depends to some extent on the numbers of organisms present, i.e. results in a proportional reduction (log reduction, e.g. 99.9% kill) (Russell et al 1992). Thus, large inocula may permit the survival of a small percentage that may still represent an infective dose. Vegetative organisms in raw milk may include normal microbial flora and pathogenic organisms (see below). Organisms present in milk may be derived from the udder, from the skin of the cow (including faecal material) during milking, and from post-milking contaminants from the environment. Numbers of organisms present may increase with inappropriate storage temperature, although some pathogens and spoilage organisms are able to multiply at refrigeration temperatures.

In some areas this paper includes reference to outbreaks or risks associated with pasteurized, or putative pasteurized milk, or dairy products, that results from faulty

pasteurization processes, contamination during processing, or post processing, and are thus representative of the risk associated with milk retailed as raw (green top) milk.

Potential pathogens

A wide range of pathogens has been reported in milk, or infecting persons where milk consumption has been implicated epidemiologically (Anon 1985; Archer & Young 1998; Barrett 1989; DeLouvois & Rampling 1998; Djuretic et al 1997; Galbraith et al 1982, 1987; Galbraith & Pusey 1984; Humphrey et al 1998; Sharp 1986,1987; Sharp et al 1986, 1987; Rampling 2000; Tacket et al 1984). These include:

- Aeromonas species
- *Bacillus cereus*
- Campylobacter*
- Cryptosporidium*
- *Corynebacterium diphtheriae* and *C. ulcerans*
- *Coxiella burnetii* (Q fever)
- Dysentery organisms (e.g. *Shigellae*)
- *Esch coli* O157*
- Haemolytic streptococci (including scarlet fever; *Streptococcus zooepidemicus*)
- *Listeria monocytogenes*
- Mycobacteria (Tubercle bacilli), bovine and human, ?*M. paratuberculosis*
- ? Toxoplasma
- Typhoid and Paratyphoid
- Non-enteric fever Salmonellas*
- Staphylococci (e.g. enterotoxin producing *Staph. aureus*)
- Yersinia species (e.g. *Y. enterocolitica*)
- Unidentified causal agents (probably microbial toxins and or viruses, including newly emerging pathogens).
- Viruses (SRSV, hepatitis, etc)

- Multiply drug resistant bacteria

* Currently most common or problematic

Background

The process of pasteurization (low temperature heat treatment) is named after Louis Pasteur, who introduced the process for the treatment of beer and wine to extend their keeping quality and to prevent "off" flavours developing. Its use was extended to milk with the realization of its effectiveness for killing milkborne infectious agents, particularly tubercle bacilli (primarily the bovine type of *Mycobacterium tuberculosis*) and those associated with gastroenteritis especially the fatal infantile form. These were seen even then as significant public health problems. The process was also designed to improve keeping quality, especially in the days prior to refrigeration (Russell 1892; Sims-Woodhead 1891; Wilson 1935; Wilson & Miles 1966).

Between 1938 and 1982, 318 outbreaks of milkborne infection were reported, comprising an estimated 14,783 cases with, in addition to an estimated 33,000 cases with 19,000 deaths due to bovine TB; there were 17 deaths due to other infecting agents (Anon 1985). These figures are a significant underestimate, partly due to under-detection and under-reporting of outbreaks, but the difficulty of identifying sporadic (endemic) cases. However, these figures hide a considerable reduction in incidence over time because of a variety of factors, including improvements in animal health, dairy hygiene, including pasteurization, and distribution and refrigerated storage of milk, and the decrease in some human pathogens that could be transmitted via milk handlers.

Infective agents in milk may be derived in various ways:

- Active infection of the udder (mastitis) - should lead to withdrawal of cow from milking herd and/or disposal of milk but this may actually be included. This may then cause (i) contamination of rest of bulk milk, (ii) failure of milk (if tested) through raised cell count, or (iii) undesirable presence of antibiotic substances. Common causes of mastitis in cows include *Staphylococcus aureus*, *E. coli*, *Salmonella*, *Campylobacter* and *Listeria monocytogenes* (Johnston 1991);
- by the bacteraemic (haematogenous) route;
- through ascending infection of the teat canal, including faecal and environmental organisms;
- as a result of faecal contamination during milking or bulk storage (probably the most common route) - the presence of faecally derived enteric pathogens is not necessarily reflected in the general microbial quality of the milk because relatively small numbers of pathogens may be required to cause infection in consumers;
- Inappropriate storage conditions permitting bacterial multiplication to unacceptable levels.

Relevant Legislation and Regulatory Framework

Following the moves to reduce or eliminate milkborne tuberculosis and brucellosis (see below) various regulations were introduced, with regard to the provision of milk for human consumption, including raw milk, and the production of milk-based products. These include measures intended to improve general hygiene within the dairy and of the milk itself. One or two other regulations that might be relevant to foodborne infection are included. Regulations (not exhaustive) include:

- The Milk and Dairies (General) Regulations 1959 (SI 1959 No 277). Requires the registration of all dairy farms and other premises used as dairies. Registration is conditional upon appropriate structural and hygienic standards, including safe water supply, etc, and appropriate routines.
- Milk (Special Designations) (Scotland) 1980. SI No 1866 (S186). (NB Regulations introduced in Scotland to prohibit the retail sale of raw milk from 1983).
- Milk (Special Designations) Regulations 1989 (SI 1989 No 2383). This applies to the licensing of premises to carry out procedures such as pasteurization, etc.
- The Zoonoses order 1989 (SI 1989 No 285) - designates salmonella and brucella (see below) as risks to human health.
- The Food Act 1984 (section 35) prohibits the sale of milk from cows with acute mastitis or infection of the udder, or any other infection or disorder that is likely to transmit disease to man.
- Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988 provide for the formal notification (and hence investigation) of food poisoning. These were due to be updated to include a system for reporting (as opposed to Notifying) and a consultation paper issued in 1989.
- General Food Hygiene Regulations 1995.
- Food Safety Act 1990 (especially Section 40) and 1995.
- Council Directive 92/46/EEC includes microbiological criteria for milk-based products and drinking milk, including raw milk.
- The Dairy Products (Hygiene) Regulations 1995 (SI 1995 No 1086). This revokes or incorporates various earlier regulations. Amongst other matters, this document incorporates general hygiene standards and microbiological and other criteria for various forms of milk including raw milk. ADAS, MAFF and PHLS (Greenwood & Rampling, 1995) guidance notes are available.
- The Dairy Products (Hygiene) (Amendment) Regulations 1996. (various mainly minor amendments to the wording of the 1995 SI.).
- EC Council Directive 96/90/EC. Milk and dairy products. Earlier Directives, to which this refers, lay down health rules, *inter alia*, for the production and placing on the market of raw and heat treated milk.

MILKBORNE INFECTIOUS DISEASES

Milkborne tuberculosis

The recognition of the problem of transmission of tuberculosis by milk goes back to the time of Robert Koch, the discoverer of the tubercle bacillus (*Mycobacterium tuberculosis*), in the late 19th century (Sims-Woodhead, 1891; Brock 1988). Initially Koch erroneously thought that both human and bovine TB were due to the same organism. They were, however, proved to be due to different organisms, bovine mycobacterium, thought at first to be a distinct, stable biological variant known as *M. tuberculosis var bovis*, now regarded by many as a separate species, *Mycobacterium bovis* (Gallagher & Jenkins 1998).

Koch's studies led him to believe, disastrously, that the bovine type could not be transmitted to humans via milk. This was because bovine TB in humans usually causes a non-respiratory illness such as infection of the glands of the neck, stomach, mesentery, bladder or bone. His refusal to accept publicly the evidence (c.f. more recent problems with BSE, etc) related more to the problems of damaging his own reputation and German beef sales (Brock 1988)!

Eventually, in 1935, tuberculin testing and the Attested Herd Scheme, with a slaughter policy for reactors, were introduced (delayed because Koch's view carried such weight). In 1946, 30-35% of cows in Great Britain reacted to the tuberculin test. Between 1938 and 1979 there were an estimated 33,000 cases of milkborne tuberculosis with 19,000 deaths, most of the cases occurring prior to the 1950s although a small outbreak occurred as recently as 1961 (George & Payne 1961). The scheme led to the virtual elimination (rate in cattle estimated at 0.16% in 1960) of bovine TB in the UK by the early 1960s (Wilson & Miles 1966; Cruickshank 1969).

The potential for reintroduction from badgers should not be under-estimated

Although bovine TB is now an uncommon sporadic disease, 90% of that is believed to be associated with badgers (Gallagher & Jenkins 1998) and there has been a considerable upsurge in badger numbers in recent years. The spurious arguments introduced to the debate by wildlife enthusiasts ignore the evidence that (i) the badger is fully susceptible to tubercular disease involving bladder, respiratory tract, etc, (leading to infected excreta), and shown to carry *M. bovis* (Anon 1979) (ii) it helps maintain the cycle of bovine infection in endemic areas, and (iii) a tuberculous badger is a sick animal in which the disease needs to be controlled, the only effective means being selected culling.

Milkborne Brucellosis

The public health driven scheme to eliminate bovine TB was followed by the Brucellosis (Accredited Herds) Scheme of 1967 and the Brucellosis Incentives Scheme in the 1970s. In cattle the disease causes abortion "storms" in affected herds, which provided much of the impetus for the scheme because of the economic impact of the disease in cattle.

In humans, brucella is the cause of a pyrexial illness that may become chronic - a debilitating condition known as undulant fever, which may last for years. It is acquired by contact with infected animals and by consumption of raw milk. Prior to eradication there were estimated to be some 200-500 reported cases per year with about 60-70% believed to be derived from consumption of raw milk. (Dalrymple-Champneys 1960; Bell & Palmer 1983; Galbraith & Pusey 1984; Plommet et al

1998). Consumption of infected milk by farming families in the past often led to a long term debility, a disabling condition that was often left undiagnosed, sometimes leading to a suicidal tendency (Casemore, personal observation). Most cases are sporadic although outbreaks have occurred (Galbraith & Pusey 1984).

The Incentives Scheme, although dependent on farmers shouldering the cost of slaughter of reactors, led to virtual eradication of the disease in cattle. As with bovine TB, it is possible for it to be reintroduced although a veterinary vaccine (S19) exists. Cases in humans declined to virtually nothing following the introduction of the eradication scheme.

Milkborne gastroenteric infections

With the apparent virtual elimination of the above largely historical problems, the benefits of pasteurization were seen to be largely a matter of keeping quality and prevention of the transmission of food poisoning organisms. Salmonella had long been recognized as causing milkborne infection. Subsequently Campylobacter, Cryptosporidium, *E. coli* 0157, etc, emerged as significant pathogens. Milkborne infection is particularly associated with the consumption of raw milk, sold as green top bottled milk or unmarked. In addition, milk sold as pasteurized but in which heat treatment had been inadequate or failed is indicative of the risks associated with raw milk. The descriptions following outline some of the problems encountered currently with the most problematic of milkborne gastrointestinal infections. Following that is a list of less common pathogens.

Salmonella

In the UK and elsewhere milk has long been recognized as a source of salmonella infection (salmonellosis), which can be serious with systemic involvement and sometimes death, especially among the very young or elderly. The prevalence has increased with the more general increase in the prevalence and variety of types (serovars) and other sub types (phage types) of salmonellas, but especially with *S. typhimurium* (Casemore 1987; Galbraith & Pusey 1984; Humphrey et al 1998; Sharp 1987; Werner et al 1979). Outbreaks sometimes involve multiply-drug-resistant strains (Tacket et al 1985). There were 179 outbreaks of milkborne salmonellosis in England and Wales between 1938 and 1982, comprising nearly 4,000 cases with 7 deaths. Of these outbreaks, 172 were due to raw milk consumption. In England and Wales between 1992 and 1999 there were 12 outbreaks of gastroenteritis attributed to raw milk consumption, of which 5 were due to salmonella (see tables, Appendix 1), and an indeterminate (but probably large) number of undetected cases in outbreaks, and sporadic cases (see Epidemiology section below).

Salmonella may be present in milk by several routes (see above) but most commonly from faecal contamination during milking (Humphrey et al 1998; Giles et al 1989; McEwan et al 1988). Cattle may be asymptotically infected, both in the enteric tract and in the udder, for prolonged periods (Giles et al 1989). In one instance, an outbreak in North Wales with raw milk borne *S. st paul*, intensive veterinary investigation revealed intermittent excretion from one quarter of the udder of one cow in the herd that showed no clinical signs of infection (Casemore, personal observation). In 1987 a country wide outbreak of *Salmonella ealing* infection in

infants was traced to extremely low level contamination of milk used to prepare infant formula feed, probably because plant had previously been used to dry raw milk (Rowe et al 1987). A number of other similar outbreaks have been described, including those involving salmonella, staphylococci, and *Clostridium perfringens*.

A number of outbreaks have been attributed to pasteurized milk although, given the thermal sensitivity of the organism this is likely to be due either to treatment failure or post-treatment contamination with either raw milk or faecal contamination (see Appendix 2). A massive outbreak with 16,000 cases, following consumption of purportedly pasteurized milk occurred in the USA (Ryan et al 1987; Sharp 1987).

In Scotland the retail sale of raw milk was seen as a particular problem; between 1970 and 1982, 50 outbreaks affected over 3,500 persons while there were 109 outbreaks in England and Wales affecting 1495, reflecting the wider consumption of the product in Scotland (Sharp 1986; Sharp et al 1985). In 1983 the retail sale was banned in Scotland but not in England and Wales and community outbreaks of milkborne salmonella infection virtually disappeared. However, smaller outbreaks affecting farming families, who were permitted to consume raw milk, continued (with a high infection rate calculated at 112 per 100,000 in an at-risk population of about 30,000).

Campylobacter

In 1977, Skirrow described infection with a previously little recognized human pathogen, *Campylobacter*, in particular *C. jejuni*. The organism is fastidious with regard to its cultural requirements, it does not usually multiply in the environment, having an optimum growth temperature of $\approx 40^{\circ}\text{C}$ (probably reflecting an avian origin), with reduced oxygen levels. In conventional bacterial culture it is readily overgrown by less fastidious species. With the publications of suitable methods its role as a major foodborne pathogen rapidly became clear. It is widespread among animals and birds and is commonly present in surface waters. The gastroenteric infection, most commonly an enterocolitis, caused by this organism is often associated with severe stomach cramps and bloody diarrhoea (Pebody et al 1997; Skirrow 1998).

C. jejuni has been most commonly associated with poultry but has also been associated with consumption of raw milk - 4 of 12 outbreaks in the years 1992-99. The majority of cases occur as sporadic (endemic) infection (Barratt 1989; Johnston 1991; Orr et al 1995; Palmer & Biffin 1989; PHLS Communicable Disease Reports; Pebody et al 1997; Roberts 1991; Sharp 1987; Skirrow 1998; Rampling 2000). The organism may be present in milk as a result of faecal contamination or because of active infection of the udder (Orr et al 1995). In a survey of 985 bottles or cartons of retail raw milk and 153 bulk samples, by Humphrey & Hart (1988), *C. jejuni* was isolated from 5.9% while another survey yielded 1.7% from 1097 bottles (De Louvois & Rampling 1998).

Following the introduction of legislation banning retail sale of raw milk in Scotland community outbreaks of milkborne infection virtually disappeared; one outbreak of campylobacteriosis resulted from illegal sale (Sharp et al 1986). Mixed infections occur, especially with *Cryptosporidium*, associated with consumption of raw milk (Casemore et al 1986; Casemore 1990).

The consumption of raw or inadequately treated cows milk has been associated with a number of outbreaks, the largest of which affected 3000, including about 2,500 children, while in the USA 26 outbreaks accounted for 7600 cases. Between 1992 to 1996, five outbreaks of campylobacter infection in the UK affecting a reported 262 people, were associated with milk consumption (Djuretic et al 1997). Unpasteurized milk was involved in four and the other with milk for which the pasteurization had failed. CDSC data and published reports tend to concentrate on outbreaks so will considerably underestimate the size of the problem. It has been estimated that 2.5-12.3% of bulked raw milk contains campylobacter and that **the consumption of raw milk carries up to a ninefold increased risk of infection** (Skirrow 1998).

A large outbreak in North Wales in 1987 involved some 346 students from Merseyside staying at a rural outdoor activities centre. They were supplied with either milk produced at the associated farm or pasteurized milk bought in to supplement the farm's supply; all those becoming ill had consumed the farm's product. At a large music festival in the south west in 1994, involving 70,000 visitors, milk was supplied from two farms which had temporary producer licences. It was estimated that several hundred cases occurred, of which 72 were confirmed and were linked epidemiologically to the consumption of raw milk. Other such outbreaks were seen during the 1990s.

Two outbreaks have been reported recently in Europe; Kalman et al (2000) reported on an outbreak in Hungary in 1998 where 5-600 visitors to a farm sale consumed unpasteurized milk, of which 52 were known to have become ill and 34 were confirmed to have campylobacteriosis. In Germany two outbreaks, affecting some 93 identified cases, mostly secondary school children, occurred in April 2000 associated with consumption of raw milk (Anon 2000).

One curious phenomenon noted has been the occurrence of an increased prevalence of non-linked cases in spring that has been attributed to birds pecking the foil tops of milk bottles left on door-steps. The birds are believed to have had their beaks contaminated when probing in cow-pats for grubs (Palmer & McGuirk 1995; Rampling 1998).

***Escherichia coli* and *E coli* O157**

The species of gut inhabiting coliform, *E coli*, is effectively a universal indicator of faecal contamination and is not usually pathogenic by ingestion. Its presence is taken, however, as an indication of the potential presence of pathogenic species. A UK survey carried out by ADAS in a 12 month period, 1995-96, looked at 1674 samples taken from 60 dairy farms and 714 raw milk producers; *E. coli* was present in 62% of milk samples tested (Rampling 2000). In a similar PHLS study during a 12 month period, 1996-97 (see table Appendix 1), 1097 bottles of raw milk from 242 retail outlets, were tested; 41 yielded pathogens (salmonella, Campylobacter, *E coli* O157, *S. aureus*, and haemolytic streptococci), (DeLouvois & Rampling 1998).

Despite the usual non-pathogenicity of *E. coli* a variety of sub-types (antigenic types) of *E. coli* have been known for many years to be pathogenic, including historically, the cause of infantile enteritis (summer diarrhoea of infants) often associated with

marked mortality (Casemore 1987). The last outbreak, among neonates in a hospital in the north-east, occurred as late as the 1960s with more than a dozen infant deaths. Known as Entero-pathogenic *E coli* (EPEC), these could be further divided into a number of stable sero-types (i.e. antigenic subtypes). Subsequently, other varieties emerged such as Enterotoxigenic *E coli* (ETEC), including vero-cytotoxin-producing *E coli* (VTEC), first recognized in 1977. Of the latter, the most important is the serotype 0157:H7, which is widely prevalent among cattle (Chapman et al 1997; Clark et al 1997; Nelson et al 1998; Rahn et al 1997).

E coli 0157 infection may be associated with uncomplicated diarrhoea, or with haemorrhagic colitis sometimes leading to systemic symptoms such as the haemolytic uraemic syndrome (HUS). This is now the commonest infective cause of kidney failure and that may also result in serious CNS (brain) damage. HUS occurs in about 10% of VTEC infections and carries a case fatality rate of 3-7% (Nelson et al 1998; Trevena et al 1999). The commonest source of VTEC is the faeces of domestic animals, especially cattle (Chapman et al 1997; Keene et al 1997; Trevena et al 1999). The first outbreak was recognized in the USA in 1982, associated with beefburgers, and the first in the UK in East Anglia in 1985 was associated with contaminated raw vegetables (Galbraith & Barrett 1987). At least seven outbreaks in the UK have been associated with milk consumption, either retail raw or inadequately pasteurized (Clark et al 1997; Nelson et al 1998; Rampling 2000).

In the USA a number of outbreaks have been reported associated with raw milk consumption. In one protracted outbreak the significance of raw milk as the vehicle of transmission was only found by detailed follow up of apparently unrelated cases (Keene et al 1997). The link between cases and putative source was confirmed by molecular studies. **The outbreak is of interest in that (i) outbreaks with low attack rates can be difficult to detect and may be missed, (ii) cases occurred despite public warnings and newly introduced labelling.** The authors commented that without restrictions on distribution of raw milk outbreaks can continue intermittently and unpredictably.

In November to December 1996, an outbreak in East Lancs resulted in 12 laboratory confirmed cases; three children and one adult were admitted to hospital and one child developed HUS (Bolton, 2000). Infection was linked to consumption of milk from a dairy farm that they had visited. An outbreak in Cumbria in February to March of 1999 affecting 114, with 88 laboratory confirmed cases, of which 28 were admitted to hospital and three children developed HUS. The outbreak was linked to farm bottled "pasteurized" milk (Bolton, 2000). Both these incidents involved farms with a history of problems with their pasteurization process and equipment. At least 25 cases of HUS in the UK have been associated with milk consumption (Bolton, 2000).

Cryptosporidium parvum

The enteric protozoan parasitic organism, *Cryptosporidium parvum*, causes a fluctuating or chronic (=> 1 month) gastro-enteritis that can be particularly severe and even fatal in the immunocompromised. It causes a protracted (ca 3->14 days), and often severe but self-limiting gastroenteritis in otherwise healthy subjects, especially children (Casemore 1987, 1990; Casemore & Warrell 1997; Current 1998). The parasite has a complex life cycle that it completes within a single host. Oocysts, the

transmissible stage, survive for prolonged periods in a cool moist environment but do not multiply there (Casemore 1987; Current 1998; Fayer 1997). Oocysts are readily killed by pasteurization (Casemore 1990; Coop et al 1998; Harp et al 1996). Cattle and sheep are almost universally infected; it causes scours (enteritis) in young calves, which are not protected by colostrum (Coop et al 1998; Scott et al 1995). It is probable that milk becomes infected through faecal contamination during milking but it is thought that ascending infection of the milk ducts also occurs (Coop et al 1998). This protozoal infection shares some epidemiological features with *Campylobacter*. It has been associated particularly with transmission by water, direct contact with farm animals and person-to-person transmission, and with food including raw milk consumption (Archer & Young 1988; Casemore 1987, 1990; Coop et al 1998; Friedank & Kist 1987; Laberge et al 1996; Palmer & Biffin 1989; Rose & Slifko 2000; Petersen 1995; Smith 1993; Wright et al 1986, 1998).

An outbreak of cryptosporidiosis among school children in 1995 was attributed to inadequately pasteurized milk from a small farm producer with poor hygienic standards (Gelletlie et al 1997).

Many cases of cryptosporidiosis (other than those associated with waterborne outbreaks) are sporadic (endemic), particularly in rural areas, and are mainly confined to children (Casemore 1990; Casemore et al 1997). Many of those drinking raw milk, largely in rural areas, are probably widely exposed to *Cryptosporidium* from other sources (direct and indirect animal contact, private water supplies). This will reduce the likelihood of outbreaks because of acquired immunity that is regularly boosted by frequent exposure. As with campylobacteriosis, it is difficult to know how many sporadic cases are attributable to consumption to milk consumption but investigation of numerous such cases suggests this is not uncommon (Casemore 1990; Palmer & Biffin 1989).

Other infections transmissible by raw milk.

Various reviews (see reference list) have listed or described milkborne infection with a wide variety of other organisms, as follows:

- *Aeromonas* sp. has been reported from some parts of the world as an enteric pathogen, and can be found in milk (Kirov et al 1993).
- *Bacillus cereus*. This causes organoleptic changes ("bitty cream") and thus is not commonly a problem although it has been the cause of infection in the past.
- *Clostridium perfringens*. An outbreak of *Cl. perfringens* gastroenteritis involving 77 cases occurred in 1981.
- *Corynebacterium diphtheriae* (historical only - none since 1947; attributed to human-derived direct contamination of milk by dairy workers); *C. ulcerans*, causing sore throat with exudate - eight outbreaks since 1975 associated with raw milk consumption.
- *Coxiella burnetii* (Q fever). Various outbreaks - 24 cases in an outbreak in the Midlands in 1967 associated with raw milk consumption; 1975-80 PHLS records showed 12 of 640 cases associated with raw milk consumption (most associated with direct or indirect (environmental) contact with livestock). Has the potential to cause severe pneumonia and chronic heart lesions.

- Dysentery organisms (e.g. *Shigellae*). Numerous outbreaks historically (mainly pre-1950). Attributed to human-derived direct contamination of milk by dairy workers or of water used in dairy.
- Haemolytic streptococci, including *Strep pyogenes*, *Streptococcus zooepidemicus*. 12 reported outbreaks of milkborne scarlet fever or streptococcal sore throat between 1938-82, many associated with infected carriers in dairy. An outbreak of *Strep. zooepidemicus* affecting 23 people was reported in 1984 and another affecting four in 1994.
- *Listeria monocytogenes*. Attention has focused on *Listeria* mainly in association with consumption of cheese prepared from unpasteurized milk although it is widely present in milk and milk has been shown to be the likely vehicle of infection (Flemming et al 1985; McLauchlin & van der Mee-Marquet 1998; O'Donnell 1995; Rampling 1998). The organism is commonly present in raw milk but it is not clear how significant this is in public health terms from consumption of milk. Infection with *Listeria* is often only mildly symptomatic or asymptomatic in otherwise healthy people but can be especially severe in pregnant women and her foetus/neonate, the elderly and the immunocompromised. Given the varied incubation period and insidious clinical onset, it is often difficult to ascribe a particular source and the frequency with which milk is involved is unknown. An area of concern is the increasing recognition of *Listeria* as a cause of gastro-enteritis (Anon 1997; Dalton et al 1997). It is unknown how widespread this is as *Listeria* is not normally looked for in the examination of clinical samples from diarrhoeal patients.
- *M. avium subspecies paratuberculosis* (Johne's bacillus). There is current concern that this relatively heat-resistant organism might be associated with chronic bowel disorders, including Crohn's disease (Blanchfield, pers comm; Collins 1997; Herman-Taylor 2000; IFST 1998; Lund et al 2000; McDowell & McElvaine 1997). While studies on the role of this potential pathogen in Crohn's disease, and its heat inactivation, much of the industry has voluntarily extended heat treatment (Muir 2000).
- *Streptobaccillus moniliformis* (rat-bite fever of Haverhill fever) has been attributed occasionally to consumption of raw milk contaminated by rats.
- Toxoplasma. This parasitic infection may cause a variety of symptoms from mild febrile illness to serious defects in the foetus. The usual route for acquiring toxoplasmosis is through ingestion of soil contaminated with cat faeces or consumption of raw meat (Casemore 1990; Dubey 1998). Evidence has been published, however, describing infection associated with consumption of raw goats' milk. It is not known if this occurs with cows' milk (Dubey 1998; Sacks et al 1982; Riemann et al 1975). For a number of reasons, evidence for acquisition from milk is difficult to obtain.
- Typhoid and Paratyphoid. Numerous outbreaks historically, mainly pre-1950 although there have been occasional outbreaks since (see reviews cited). Usually attributed to human-derived direct contamination of milk or of water used in dairy although outbreaks have occurred when cattle have become infected from contaminated pasture or water, including an outbreak in North Yorkshire in the late 1960s.
- Staphylococci (e.g. enterotoxin producing *Staph. aureus*). Various outbreaks described of staphylococcal intoxication associated with milk, most recently in the 1960s (see reviews cited).

- *Yersinia* species (e.g. *Y. enterocolitica*). This may cause a variety of signs and symptoms, including febrile illness, gastroenteritis, and infection of the abdominal glands (mesenteric adenitis) that may lead to unnecessary surgery. Both pathogenic and non-pathogenic strains of *Yersinia* may be found in milk and are able to multiply at refrigeration temperatures. Large outbreaks have been described, particularly in North America but not in the UK (see reviews cited; Tacket et al 1984).
- Unidentified causal agents. Outbreaks of infection with unidentified agents epidemiologically associated with milk consumption have been described. These are probably mainly due to viruses and toxigenic bacteria.
- Viruses (SRSV, hepatitis, etc) - probably due to human-derived direct contamination of milk or of water used in the dairy.
- Multiply drug resistant bacteria. There is concern that multiple drug-resistant bacteria (not necessarily pathogenic themselves) present in milk may transmit their resistance to human bacterial bowel flora (Ryan et al 1987; Tacket et al 1985).

Epidemiological aspects.

The data shown refer primarily to outbreaks, a term which refers to a wide range of case numbers from as few as two to hundreds or even thousands. Cases may be linked by place and or time, as well as common exposure to a putative risk factor - source, reservoir or vehicle of infection - and infection with a single identifiable strain (Casemore 1994; Palmer & Swann 1991). In many cases there may be more than one potential risk factor. For example, those consuming raw milk often live in rural areas, be exposed to livestock, and perhaps use a rural private water supply, as well as other recognized food vehicles. Where an unusual strain of an organism is involved, especially using modern molecular techniques, it may be possible to detect outbreaks involving only a few cases. Isolation of an indistinguishable strain from the suspect source obviously strengthens the link. The more cases there are the easier it becomes generally, to carry out an analytical (case-control) study and to demonstrate a statistically meaningful result (usually expressed as a 'p' value based on a $\geq 95\%$ probability of an association). This can never, however, provide absolute proof of causation. In addition, case numbers generally represent only confirmed (and sometimes clinically diagnosed but unconfirmed) cases. The figures under-estimate the size of an outbreak by a factor variously estimated at 1/10 to $<1/100$ of actual cases numbers (Casemore 1994; Mead et al 1999; Palmer & Swann 1991; Wall et al 1996; Wheeler et al 1999).

For sporadic (endemic) cases it is usually much more difficult to adduce clear evidence of such an association and many such cases remain undetected, or if detected get only a descriptive epidemiological investigation, which at best provides a presumptive link, and may not be notified. Even published figures on outbreaks are lower than they might be the case because of failure to report them centrally. Thus the incidence of milkborne infection is undoubtedly underestimated.

The presence of acquired immunity in frequently exposed populations, such as farm families, may hide the true level of risk to those who might be exposed but who do not share that immunity, such as guests and other visitors.

Discussion

If the cow had been designed with HACCP for the dairy industry in mind it is unlikely that the udder would have been placed where it is. (NB there is an evolutionary argument in favour of that arrangement for the offspring in that the mother's own normal gut flora is ingested, along with the colostrum, to initiate the normal intestinal flora of the calf. The occasional calf might succumb if a pathogen breaks through the colostrum antibody cover but most calves would survive.) Direct infection within the udder, faecal contamination during the milking process, and subsequent environmental contamination of raw milk are inevitable.

Where transmission to human consumers is concerned, several factors have to be taken into consideration in assessing levels of risk (Bryan 1996; Friedman et al 1997; Heathcock et al 1998; ILSI 1996; Majewski 1992; Rose et al 1995; Simpson 1996). Determining the risk requires knowledge of three key factors:

- hazard (the inherent potential for causing harm of any pathogens present);
- risk (the probability of that hazard being expressed, including likelihood and level of exposure);
- the impact (seriousness) of the outcome of infection.

These factors are often unknown or difficult to assess for particular organisms. For the equation to be calculated it is necessary to know, *inter-alia*:

- the pathogenicity, virulence and infective dose size of the organism involved;
- ubiquity, environmental robustness of the organism, etc;
- the size of the exposed population (number consuming product);
- public awareness of the hazard;
- control measures in place;
- effect of variable population immunity levels;
- volume of food consumed, manner of consumption, etc.

With regard to hazard, some major diseases transmissible by milk have declined in prevalence generally while others have emerged. The effect of uncomplicated gastroenteritis in an otherwise healthy subject is one largely of an unpleasant few days illness and inconvenience. Only a minority of such patients has a sample sent to the laboratory to determine the cause of their illness (Casemore 1994; Wheeler 1999). The assessment of impact has, however, to take into account the total burden (in terms of health and social costs), which collectively can be large for any outbreak (Sockett, Roberts 1991). The impact of the cost to the individual and to society as a whole for something as serious as HUS is large even for a single case. The potential cost should human infection with bovine TB return would be huge and very damaging, especially to the farming industry. Other old pathogens may re-emerge; new or newly recognized pathogens may emerge.

Various public health/medical scientists, from the 19th century onwards, have pointed out the dangers of milkborne disease and urged improving hygiene, including moves towards the mandatory pasteurization of all public milk supplies. The scientific evidence adduced is irrefutable. The numbers of cases of milk-borne infection are but a small proportion of all cases of foodborne infection. Relative to the size of the exposed population, however, the risk (i.e. the attack rate) is unacceptably high. Attempts have been made to estimate the true size of outbreaks and the cost of confirmed cases (Cohen et al 1983; Mead et al 1999; Sockett & Roberts 1991; Wheeler et al 1999). These include direct and indirect medical/pharmaceutical costs, sick leave, lost production, etc. These illustrate the major impact of such preventable disease.

What are the arguments in favour of raw milk? These are primarily:

- the perceived organoleptic superiority of the raw product;
- health and nutritional benefits (that heating destroys beneficial nutrient factors);
- that raw milk has inherently improved keeping quality or anti-bacterial properties;
- freedom of choice.

Firstly, freedom of choice is a political, philosophical or emotional, matter that largely ignores the evidence of hazard and risk. Appreciation of risk is often poor among the public, even among those who are especially susceptible (Heathcock et al 1998). Various analogous situations exist in relation to food safety where freedom of choice is restricted for the benefit of individuals and society as a whole. Many are a matter of common sense, such as the use of restrictions on or need for control regarding hygienic production, storage, transport, shelf life, etc. Why should milk be any different?

The argument regarding organoleptic quality is clearly a subjective one on which society and parliament must make a cost-benefit judgement.

Regarding nutritional factors, there is evidence for a loss of some nutritional factors but these are readily available from alternative sources in the normal diet, without the need for supplementation (Potter et al 1984).

The relative differences in keeping quality and any anti-bacterial affect are a scientific curiosity that have little relevance with modern production, cold storage (in production, distribution and domestic), and transport, provided that adequate attention is paid to optimizing these using HACCP, etc. Better attention to these, as well as improvements to testing supposedly pasteurized milk (see appendices) is undoubtedly required (Rampling 2000).

Some have argued that because milkborne infection is only a small proportion (about 1.6%) of the total of foodborne infection, the need for introducing legislation banning it is unnecessary (Neave 2000; Williams & Neave 2000), but this ignores the smaller at-risk population. There are, however, indications of a growing "niche" market for "green" or what are perceived or sold as "health foods" (Neaves 2000). In Wales there are currently 26 suppliers of raw milk, mainly dairy farms. It is unclear how many customers this represents. There is an argument that withdrawal of their doorstep supply will create difficulty, given that alternative supplies may not be readily available in the rural areas concerned. It might be argued that they mainly comprise individuals with enhanced immunity giving protection against much milkborne infection. However, the acquisition of that immunity reflects exposure and infection at some time in their life and may mask the real risk. It does not prevent infection with newly emerging strains, for example of salmonella and other pathogens to which they have not been previously exposed.

Other indirect outlets must also be considered. Farmers and regular raw milk consumers generally believe that raw milk is better than heat treated milk and that it does them no harm; they may even appreciate that they are "immuno-logically privileged" because they have grown up with it. In an ongoing epidemiological survey of zoonoses in farming families in the Preston, Hereford and Norwich areas (Thomas & Salmon 1997), raw milk consumption was noted in 82.2%, 32.7% and 18.6% respectively. This variation largely reflects the type of farming, with nearly 100% of dairy farmers reporting consumption. Additionally, farmers may take in both paying and non-paying guests. If registered to provide accommodation (e.g. B&B, farm holidays) they are required to notify guests (who may be more susceptible to the risk) that raw milk is used. Such regulations are not always observed and raw milk

may be consumed unwittingly by them, and by non-paying guests, from unmarked containers.

The risk has been highlighted scientifically by numerous outbreaks reports and investigative studies (see above) and several reports and editorials have recommended banning the sale of retail milk (e.g. Anon, 1981; Barrett 1986; Boor 1997; Campbell et al 1997; Cohen et al 1983; DeLouvois & Rampling 1998; Deutz A et al 1999; Djuretic et al 1997; Galbraith et al 1982; Headrick et al 1998; Holsinger et al 1997; Keene et al 1997; O'Donnell 1995; Orr et al 1995; PHLS 1997; Potter et al 1984; Rampling et al 1987; Sharp 1985, 1986, 1987; Sheppard 1998; Steele et al 1997; Trevena et al 1999; Werner 1979). **Can the UK continue to ignore the scientific evidence that raw milk consumption imposes an unacceptable preventable burden on public health? Reliance on risk-warning labeling is unlikely to prevent such transmission and may serve merely to shift responsibility to the consumer who may well not fully understand the nature or level of risk.**

Appendix 1

Tables:

The following tables give an assortment of data relevant to the above reports. CDSC data represent only include cases officially notified by a clinician or public health physician as foodborne and thus under-represents the actual numbers of cases occurring.

From Epidemiology Division, PHLS CDSC.

General outbreaks of Infectious Intestinal Disease associated with unpasteurised milk.

England & Wales, 1992 - 1999.

Table 1. Gastrointestinal Disease (IID) Outbreaks by year

Year	All outbreaks IID (foodborne)	Dairy product Associated (%)	Raw milk Associated
1992	373 (232)	7 (1.9)	1
1993	454 (243)	4 (0.9)	3
1994	490 (238)	5 (1.0)	3
1995	837 (231)	6 (0.7)	1
1996	733 (198)	6 (0.8)	2
1997	591 (245)	8 (1.4)	1
1998	609 (141)	2 (0.3)	1
1999	514 (117)	6 (1.2)	0
Totals	4601 (1645)	44 (0.96)	12

NB: Outbreaks can be a mixture of foodborne and those where it is not possible to distinguish between foodborne and person-to-person transmission; more than one food vehicle can be reported for each outbreak. The above figures for dairy products or raw milk are from outbreaks where at least one of the foods reported was milk or other dairy product (column 3) or raw milk (column 4).

Table 2. Morbidity & mortality (outbreaks 1992-99)

	Affected*	Hospital-ised**
Number Of		
Outbreak Reports	12***	10***
Min number of cases	3	0
Max number of cases	72	7
Sum	198	19
Average number of cases per outbreak	17	2

* Indicates size of outbreaks (known cases) reflecting restricted size of exposed population.

** indicating the severity of infections, significantly more frequent than in other food poisoning outbreaks,

*** Number of reports in which this information is given

Table 3. Implicated organisms (raw milk outbreaks 1992-99)

Organism	Number of outbreaks
Salmonella (mainly S. typhimurium)	5
Campylobacter	4
<i>E. coli</i> O157	3
Total	12

Table 4. Details of 10 Outbreaks associated with "pasteurized"* milk, 1992-99.

Organism	Number of outbreaks
Salmonella	3
Campylobacter	2
<i>Esch coli</i> 0157	4
<i>Cryptosporidium</i>	1

* Post-pasteurization contamination - 3; Pasteurization failure - 7

**Table 5
Enteric pathogens in retail raw (green top) milk
PHLS study 1996-97**

- Samples examined 1097
- Salmonella positive 5 (0.5%)
- Campylobacter positive 19 (1.7%)
- *Esch coli* 0157 positive 3 (0.2%)

Appendix 2

"Pasteurized" milk

A separate but relevant issue that needs to be considered by FSA is milk sold as pasteurized which may be insufficiently treated or otherwise potentially unsafe (Casemore, unpublished observations; Clark et al 1997; Djuretic et al 1997; Fahey et al 1995; Gelletlie et al 1997; Keceli & Robinson 1997; Rampling et al 1987, 1998, 2000; Sharp 1987; Tacket et al 1984). This may occur because of failure or partial failure of the pasteurization process, post pasteurization contamination, or raw milk contamination of bulk pasteurized milk. This problem applies particularly though not exclusively, to smaller producers such as farm dairies.

Raw milk contains, *inter alia*, the enzyme alkaline phosphatase, which is inactivated by pasteurization. Milk that has been pasteurized according to the regulations may still contain approximately 0.1% raw milk and yet achieve satisfactory results in the phosphatase test (Rampling 2000). Other more sensitive indicators are available (Bolton, 2000; Brandl 1997; Holsinger et al 1997; Rampling 1998, 2000;)

Problems with pasteurization arise because of a number of factors:

- equipment used is old and not designed the purpose for which it is being used (e.g. designed for producing pasteurized whole milk when demand has increased for skimmed and semi-skimmed).
- poor temperature control;
- poor dwell time control in heating unit;
- pin holes in the heat treatment unit;
- faulty plumbing with the back-pressure relief valve (in the event of blockage of the in-line filter) being fed forward to the bottle filler unit rather than back to the raw milk bulk tank;
- overriding of the automatic system, using the manual wash-cycle of the pasteurization unit to speed up flow;
- leaving open manually operated valves linking raw and treated milk parts of the system (used during cleaning);
- Log-reduction factors (numbers of pathogens initially present).
- This may be further compounded by problems with the phosphatase test (false pass) that detects an enzyme that is inactivated by pasteurization, especially with skimmed milk (see above) and is known to be unreliable with non-bovine milk.

This indicates the need for stricter criteria for suitability for licensing, and more stringent quality control, particularly of smaller farm units.

Appendix 3

Other dairy products

Another issue that needs to be considered by FSA is that of dairy products such as cheese and yoghurt made from raw milk, and milk and dairy products made from non-bovine milk, such as that from goats and sheep, for which there is an increasing "niche" market. Numerous cases and outbreaks of infection have been attributed to consumption of dairy products made from raw milk (Abdel-Aziz et al 2000; Goulet et al 1995; Keceli & Robinson 1997; Klinger & Rosenthal 1997; Neaves 2000; Quinto & Cepeda 1997; Rampling 1998, 2000; Riemann et al 1975; Roberts 1985, 1991; Sacks et al 1982; Sharp 1986, 1987). Milk quality control methods, particularly the phosphatase test may be unsuitable for non-bovine milk.

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