ACM/1261

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

INFORMATION PAPER

Mycobacterium bovis – Risk assessment related to exposure via meat and meat products

- The Committee reviewed a draft risk assessment prepared by the FSA relating to *M. bovis* exposure via meat and meat products at its meeting in January 2017. A small group of members agreed to work with the secretariat to agree a form of wording to reflect the Committee's discussions. The assessment has now been finalised and is attached as Annex A.

- The Committee is asked to note this paper for information.

Annex A

Mycobacterium bovis – Risk assessment related to exposure via meat and meat products

Statement of purpose

- To assess the risk to consumers from *Mycobacterium bovis (M. bovis)* via meat and meat products.

Hazard Identification

1. Bovine tuberculosis results from infection by *M. bovis*, a Gram positive, acid-fast bacterium in the *Mycobacterium tuberculosis* complex of the family Mycobacteriaceae. The aetiological agents of tuberculosis in mammals, classified as members of the *M. tuberculosis* complex, include *M. tuberculosis, M. bovis* and *M. africanum*. (The Centre for Food Security and Public Health, 2009).

2. Bovine tuberculosis is a chronic bacterial disease of cattle that occasionally affects other species of mammals including humans. Animal species reported to be spillover hosts include sheep, goats, horses and pigs. Little is known about the susceptibility of birds to *M. bovis*, although they are generally thought to be resistant (The Centre for Food Security and Public Health, 2009). Given that *M. bovis* is more markedly prevalent in UK cattle in comparison to other meat producing animals, bovine meat will be the focus of this risk assessment though other food producing animals will be acknowledged.

3. *M. bovis* is a zoonotic agent that can be transmitted to humans, typically by the inhalation of aerosols or the ingestion of unpasteurised milk (The Centre for Food Security and Public Health 2009).

Exposure assessment

4. **Transmission in humans** – Human infection with *M. bovis* in the UK has been largely controlled through pasteurisation of cows' milk and systematic culling of cattle reacting to compulsory tuberculin tests. The majority of cases of human TB reported in the UK are due to *M. tuberculosis* acquired directly via person to person transmission (de la Rue Domenech, 2006).

5. Most cases of zoonotic TB diagnosed in the UK are attributed to either reactivation of long-standing latent infections acquired before widespread adoption of milk pasteurisation, or *M. bovis* infections contracted abroad (de la Rue Domenech, 2006).

6. *M. bovis* accounts for 1-3% of human clinical cases of tuberculosis reported each year in the EU (EFSA, 2013). Between 1999 and 2015, *M. bovis* case notifications in the UK ranged from 15 to 42, with the majority of cases being reported in England (Source:PHE). Reported data show 0-3 cases per year in the 0-14 age group, 1-15 cases per year in the 15-44 age group, 2-15 cases per year in the 46-64 age group and 7-23 cases per year in the over 65 age group (Source:PHE). These data support the view that most cases of human TB caused by *M. bovis* are likely due to reactivation of latent infection acquired prior to widespread milk pasteurisation and implementation of compulsory TB control programmes in cattle. Possible person to person transmission of M. bovis has also been reported (Mandal *et al*., 2011)

7. In 2014, Hungary acquired officially tuberculosis free (OTF) status, therefore was added to the list of OTF countries. In 2014, these were Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, five regions and seventeen provinces in Italy, Latvia, Luxembourg, the Netherlands, all administrative regions within the superior administrative unit of the Algarve in Portugal, Poland, Slovakia, Slovenia, Sweden, Scotland in the United Kingdom, Norway and Switzerland, in accordance with EU legislation (Decision 2014/91/EU36). Bulgaria, Croatia, Cyprus, Greece, Ireland, Italy, Lithuania, Malta, Portugal, Romania, Spain and the United Kingdom did not achieve country-level OTF status (ECDC, 2015). The equivalent report for 2016 data show the situation across the EU still remains heterogeneous.

8. Traditionally, the failure to detect any tuberculous lesions in tissues and organs at post mortem meat inspection was considered sufficient evidence that meat was safe. However, McIlroy *et al*., (1986) demonstrated that failure to detect visible lesions at post mortem meat inspection does not necessarily allow an assumption to be made that *M. bovis* is not present in tissues (ACMSF, 2003).

9. In 2013, the European Food Safety Authority (EFSA) prepared an opinion in relation to the public health hazards to be considered during meat inspection. During the current *post-mortem* meat inspection process in the EU, a number of lymph nodes are routinely palpated/incised with the aim of detecting lesions indicating infections. Overall, the conclusions of this opinion are consistent with previous EFSA opinions showing a negative impact on tuberculosis detection if palpation and incision of relevant organs (lung, respiratory tract lymph nodes) were to be removed from inspection tasks. To avoid decreasing the overall sensitivity of surveillance, the experts concluded that these inspection tasks, aimed at the detection of bovine tuberculosis, should be retained in the meat inspection system.

10. The opinion highlighted that for cases where abnormalities on lymph nodes are visually observed, lymph nodes must be removed and subsequently the lymph nodes and, if necessary, corresponding organ tissues should undergo further examination and testing, including by palpation/incision separately from the main slaughterline. However, it was also acknowledged

that routine incision of the lymph nodes could have detrimental effects on bovine carcass meat safety by encouraging cross-contamination with hazards such as *Salmonella* spp. and pathogenic *E. coli* (e.g. VTEC) which were identified by EFSA as being notable hazards related to meat-borne transmission.

11. Only a limited number of studies have been published reporting the presence of *M. bovis* in bovine meat and organs. In 2003, the Committee reviewed results from an FSA-funded study (ACM/652) investigating the presence of *M. bovis* in edible tissues of salvaged cattle carcases that had been demonstrated to be positive to the tuberculin test. The study showed that, 4.5% (19 out of 110) of cattle with no visible lesions yielded viable *M. bovis* from carcasses or edible offal lymph glands, while 4% (1 from 25) of animals with a single visible lesion and 5.5% (1 from 18) of animals with two or more visible lesions also yielded viable *M. bovis* from the carcass or edible offal lymph glands. The Committee agreed that the results from the research did not alter the outcome of its 2002 risk assessment which concluded that the risk was very low. However, it supported the report's recommendation that enhanced surveillance of human *M. bovis* infection should be maintained to alert the Agency to any significant indications that eating meat from *M. bovis* infected cattle constituted a health risk (ACM/1122, Swift *et al*., 2016).

12. Human infection with *M. bovis* is traditionally associated with the consumption of *M.bovis* contaminated raw cows' milk, or occupational exposure to *M.bovis* by direct contact or aerosols in meat plants or while handling infected animals. There is also a possibility of person to person transmission (Mandel *et al*., 2011). In countries where milk is pasteurised or otherwise heat-treated, and the eradication of *M. bovis* is nearing an end, the aerosol route of infection, while very rare, has become more important for humans than the oral route (ACMSF 2003). For immunocompetent individuals, person-to-person transmission is rare, but *M. bovis* has occasionally been transmitted within small clusters of people, particularly alcoholics or HIV-infected individuals. Rarely, humans have infected cattle via aerosols or in urine (The Centre for Food Security and Public Health 2009).

13. In 2013, EFSA highlighted that in relation to the potential for meat-borne transmission, only two very old studies (M'Fadyen, 1890; Francis, 1958) reported transmission of tuberculosis to fur animals or experimental laboratory animals following feeding with meat or meat juice from tuberculous bovine animals. The opinion highlighted that presently, there is a consensus in the published literature that there is no evidence of transmission of *M. bovis* to humans through consumption of bovine meat or meat products. Given that the prevalence of reported *M. bovis* infection in other meat producing animals is markedly lower than in cattle in the UK (see below section relating to transmission in other animals), it seems reasonable to adopt a similar assumption for other meat.

14. However, EFSA did consider that this evidence should be considered in light of difficulties in designing experimental studies to further investigate this situation in Europe. EFSA BIOHAZ panel has therefore highlighted that some studies have considered that meat borne transmission of *M. bovis* is possible. The relevant reports however estimate the risk as very low or negligible, and are linked to consumption of uncooked or undercooked bovine meat (EFSA, 2013).

15. Although a small amount of *M. bovis* contaminated meat may enter the food chain, the actual level of consumer exposure to *M. bovis* from eating less than thoroughly cooked meat or cured meat remains an **uncertainty (medium).** Specific tissues (namely lymph nodes, liver, spleen, kidney and mammary gland) which do not show visible signs of tuberculosis lesions at *post mortem* may carry *M. bovis* (FSAI, 2009). Thorough cooking of meat and meat products such as sausages etc. will effectively destroy any viable *M. bovis*. The possibility of cross-contamination from meat infected with *M. bovis* via unhygienic or inappropriate handling either in the slaughterhouse or in a domestic or catering environment cannot be excluded and the level of *M. bovis* contamination in infected meat is also unknown though likely to be low given the frequency of contamination is likely to be low; therefore the impact of cross-contamination on *M. bovis* transmission can be flagged as an **uncertainty (medium).**

16. EFSA (BIOHAZ panel) compiled a shortlist of biological hazards that can be transmitted to humans through bovine meat in the EU and can be present in bovine animal carcasses post-chill. On the basis of the review carried out by EFSA, *M. bovis* was not included on that list. Furthermore, EFSA concluded that currently, there is no evidence that *M. bovis* is a meat-borne hazard for humans in the EU, despite a number of EU countries not having OTF status (EFSA, 2013).

17. **Transmission in animals** – Bovine tuberculosis is usually maintained in cattle populations, but most species are spillover hosts. Populations of spillover hosts do not maintain *M. bovis* indefinitely in the absence of maintenance hosts but may transmit the infection between their members (or to other species) for a period of time (The Centre for Food Security and Public Health, 2009). However, herd size, history of bovine TB in the herd and the presence of infected wildlife are risk factors. Infection in spillover hosts occurs when challenge levels are relatively high, but infection cannot be sustained in these populations in the absence of infected cattle or a wildlife reservoir. Spillover hosts are capable of transmitting infection to humans and other animals. (APHA, 2017).

18. *M. bovis* is currently endemic in cattle in most of Northern Ireland and large tracts of south west England and South and Mid-Wales. Between 2008 and 2014, reports of new TB breakdowns in cattle herds in the UK (new TB infections) were as follows (Source: PHE):

    2008- 6285
    2009- 5892

2010- 5883
2011- 6293
2012- 6868
2013 -6253
2014 -6045

19. For cattle, *M. bovis* can be shed in respiratory secretions, faeces and milk, and sometimes in the urine, vaginal secretions or semen. In the later stages of infection, large numbers of organisms may be shed. Infection can also be asymptomatic. In most cases, *M. bovis* is transmitted between cattle in aerosols during close animal to animal contact. Some animals become infected via ingestion of *M. bovis* and could imply acquisition from faecal or urine contaminated pastures including for non-calves. Ingestion as a transmission route may be important in calves nursing from infected cows. Bovine tuberculosis is not necessarily transmitted by all infected cattle (The Centre for Food Security and Public Health, 2009). The virulence capability of different *M. bovis* strains or the particular breed of cattle may have a part to play in transmission. Wright *et al.,* 2013 reported that the distribution of lesions varied among genotypes of *M. bovis* and with cattle age and there were also subtle differences among breeds. Age and breed differences may be related to differences in susceptibility and husbandry, but reasons for variation in lesion distribution among genotypes require further investigation according to the authors.

20. Goats can be infected with *M. bovis* and act as spillover hosts. (APHA, 2017). The escalation in the number of cattle cases infected with TB is not mirrored in goats. Two sporadic TB outbreaks were confirmed in goats in 1981 and 1996. In 2007, there was an incident of bovine TB on a small goat holding in Wiltshire and one single incident in 2007. In 2008, there was an extended outbreak of TB in golden Guernsey goats in West Wales (Harwood, 2014). In 2016 there was an outbreak of TB in a large goat herd in Somerset.

21. Although rare, sheep can also become infected with *M. bovis*. Between 1997 and 2013, incidents of *M.bovis* infection in sheep ranged from 0 to 35 per year, with most years reporting between 1 and 3 incidents (Baker, 2015).

22. Pigs can also serve as spillover hosts for *M. bovis*. Between 2007 and 2011, nearly all *M. bovis*-infected pigs originated from farms in the South West and West Midlands areas of England. Data suggest that pigs bred outdoors or on holdings with poor biosecurity may be more vulnerable to infection with *M. bovis* (Bailey *et al*., 2013). Bailey *et al*., (2013) reported that in the majority of cases, the same strains of *M. bovis* were found in pigs and cattle, although direct contact between these species was rarely observed. Genotyping and geographical mapping data indicated that some strains found in pigs may correlate more closely with those present in badgers, rather than cattle. Between 1997 and 2013, incidents of *M. bovis* infection in pigs ranged from 0 to 44 per year (Baker, 2015).

23. Ingestion has been reported to be a primary route of *M. bovis* transmission in pigs. Aerosol transmission has also been documented to be the most likely route of transmission between badgers and *M. bovis* has been detected in urine and faeces of badgers. (The Centre for Food Security and Public Health, 2009).

Hazard Characterisation

24. Symptoms in cattle - Early infections are mostly asymptomatic. In countries with eradication programs, most infected cattle are identified early and symptomatic infections are uncommon. In the late stages, common symptoms include progressive emaciation, low–grade fluctuating fever, weakness and inappetence. Animals with pulmonary involvement usually have a moist cough and may have dyspnea or tachypnea. In the terminal stages, animals may become extremely emaciated and develop acute respiratory distress (The Centre for Food Security and Public Health, 2009).

25. The symptoms of bovine tuberculosis normally take months to develop in cattle. Infections can also remain dormant for years and reactivate during periods of stress or in cattle old age (The Centre for Food Security and Public Health, 2009).

26. Bovine tuberculosis is characterised by the formation of granulomas (tubercles) where bacteria become localised. Granulomas are usually yellowish and caseous, caseo-calcareous or calcified and frequently encapsulated. In cattle, tubercles are found in the lymph nodes, mainly those of the head and thorax. They are also common in the lung, spleen, liver and the surfaces of body cavities. In disseminated cases, multiple small granulomas may be found in numerous organs (The Centre for Food Security and Public Health, 2009).

27. Dean *et al*., 2005 demonstrated that 1 CFU of *M. bovis* is able to cause bovine tuberculosis in cattle. 1 CFU was found to contain between 6 and 10 viable bacilli. Infection with just 1 CFU resulted in pathology with an equivalent severity to that seen in animals which received far higher doses (up to 1,000 CFU).

28. In June 2015, the Committee received a presentation from relating to work carried out at APHA to assess the risks to public health of the possibility of CattleBCG vaccine being present in the food chain and, in particular, in milk and beef products. The risks (per serving) to the healthy population was estimated to be negligible for beef, negligible to very low risk for regional BCG disease due to consumption of beef slaughtered less than 3 months post-vaccination and negligible risk after more than 3 months post vaccination.
https://acmsf.food.gov.uk/sites/default/files/acm_1181_slides.pdf

29. Symptoms in humans - Not all *M. bovis* infections progress to TB disease and infected individuals may remain asymptomatic. Symptoms of TB

disease caused by *M. bovis* are similar to the symptoms of TB caused by *M. tuberculosis* and can include fever, night sweats, and weight loss. Other symptoms might occur depending on the part of the body affected by the disease. For example, disease in the lungs can be associated with a cough, and gastrointestinal disease with abdominal pain and diarrhoea. Untreated TB can be fatal (CDC, 2012).

30. No reports are available on human dose response following ingestion of *M. bovis* but extrapolation from animal studies (on sheep, cattle and guinea pigs) suggest that the human infectious dose of *M. bovis* by the gastrointestinal route is in the region of millions of organisms (ACM/1047a).

31. Several mitigating factors against *M. bovis* transmission via meat have been identified (De la Rua-Domenech, 2006). For example, lesions in skeletal muscle are rare and observed only in animals with advanced infection and such carcases are likely to be condemned following post-mortem inspection. Additionally, *M. bovis* is slow growing and will not replicate outside the living host. *M. bovis* is relatively heat sensitive and any residual contamination in muscle meat should be destroyed by cooking, providing further reassurance for thoroughly cooked meat and meat products. Finally, for humans, ingestion is a markedly less efficient route of infection than inhalation.

32. Cressey *et al*., (2006) briefly reported on the viability of *M. bovis* in meat products. No viable cells remained after the test meat products reached 60°C. This was below the temperature needed to control the MAI complex *(M. avium-M. intracellulare*) found in swine, therefore, controls for that group of micro-organisms should also easily control *M. bovis* (Merkal and Whipple, 1980). In meat products the D value at 61^{o}C was one minute, while at 55^{o}C it was approximately 10 minutes. There was no evidence of a difference in heat tolerance between bovine and porcine derived *M.bovis* isolates (Merkal and Whipple, 1980).

33. The UK is one of the EU countries with the highest prevalence of bovine tuberculosis in cattle. The number of human TB cases due to *M. bovis* infection is closely monitored by Public Health England, Public Health Wales and Health Protection Scotland. Human TB caused by *M. bovis* accounts for less than 1% of the total TB cases diagnosed in the UK every year (PHE 2015).

34. The majority of those *M. bovis* cases were in people over 65 years who had consumed unpasteurised milk in the past, or those of any age who had acquired the infection abroad (EFSA, 2013). Recent UK epidemiological studies reporting on *M. bovis* tuberculosis did not find an increase in the number of human cases despite an increase in cattle cases (EFSA, 2013).

35. Exposure to *M. bovis* through bovine meat that has been inspected and deemed fit for human consumption cannot be excluded, because the sensitivity of meat inspection for detecting cases is not 100 % and may allow for *M. bovis* positive carcasses to enter the food chain (EFSA, 2013).

However, despite the significant burden within the UK cattle population, the number of human cases remains low and there is no evidence for meat-borne transmission.

Risk characterisation

36. This risk assessment uses the EFSA risk level classification in order to describe the output. Further details can be found in Appendix 2.

37. To characterise the level of risk of *M. bovis* infection via meat and meat products, the following information has been considered:

- The consensus in literature and a recent comprehensive review by EFSA is that there is no evidence of meat borne transmission of *M. bovis* to humans.

- Slaughterhouse meat inspection procedures are highly effective in controlling *M. bovis* infected cattle from entering the food chain, but do not provide 100% reassurance that this does not occur.

- *M. bovis* has been isolated from a small percentage of infected animals that do not exhibit visible lesions at post mortem but the Committee did not view this as sufficient evidence to alter its earlier risk estimation several years ago. (4.5% (19 out of 110) of cattle with no visible lesions yielded viable *M. bovis* from carcasses or edible offal lymph glands).

- Although a small amount of *M. bovis* contaminated meat may enter the food chain, the actual level of consumer exposure to *M. bovis* from eating less than thoroughly cooked meat or cured meat is likely to be very low but but remains an **uncertainty (medium).** Thorough cooking of meat and meat products such as sausages etc. will effectively destroy any viable *M. bovis*. The possibility of cross-contamination from meat infected with *M. bovis* via unhygienic or inappropriate handling either in the slaughterhouse or in a domestic or catering environment cannot be excluded and the impact of cross-contamination on *M. bovis* transmission can be flagged as an **uncertainty (medium).**

- Despite the increasing numbers of cattle infected with *M. bovis* in certain parts of the UK, there is no apparent mirroring of an increase in human cases, most of which are acquired abroad or are a result of reactivation of latent infection in the older population; acquired in days prior to milk pasteurisation and stringent TB control measures.

- While exposure to unpasteurised milk has been documented as a possible route of transmission of *M. bovis* to humans (EFSA, 2015), the risk level assigned and agreed by the Committee using EFSA's risk level classification system was still very low. Given that evidence suggests that the risk of *M. bovis* infection via meat and meat

products appears to be lower than the risk via drinking unpasteurised milk, the level of risk assigned in this assessment should therefore be negligible. Two key uncertainties relating to the level of exposure to *M. bovis*, from rare, raw or cured meat products and as a result of cross-contamination of contaminated meat or meat products have been flagged and can be considered as medium level uncertainties[1].

Overall risk

The overall risk of *M. bovis* infection via meat and meat products can be considered as **negligible** with a medium level of uncertainty, on the basis of existing TB controls including post mortem examination. Sufficient legislative reassurance exists in terms of *ante* and *post* mortem inspection requirements to assign the same level of risk for meat produced in the UK, other EU countries and third countries importing to the UK. It is important to clarify that although the risk level appears lower than the Committee's earlier assessments of "very low risk", the apparent change is the result of adopting a different risk assessment terminology (EFSA's risk level classification) rather than reflecting a real change in the level of risk.

Uncertainties

Two key uncertainties associated with this assessment are outlined in Appendix 1.

[1] Uncertainties have been identified as medium level on the basis of limited information relating to level of exposure to M. bovis from eating contaminated rare, raw or cured meat and the inability to exclude potential cross-contamination from M. bovis infected meat as a route of transmission. This information was balanced against relatively robust information to suggest that meat borne transmission of M.bovis is not significant.

Appendix 1: Key uncertainties

- Exposure Assessment – Despite rigorous slaughterhouse checks and *Ante mortem* checks, a small amount of *M. bovis* contaminated meat may still enter the food chain. While cooking meat thoroughly will help to keep any risks of *M. bovis* transmission via ingestion as low as possible, the level of consumer exposure to *M. bovis* via rare, raw and cured meat remains an uncertainty (medium).

- Exposure Assessment - The possibility of cross-contamination from meat infected with *M. bovis* via unhygienic or inappropriate handling either in the slaughterhouse or in a domestic or catering environment cannot be excluded and the potential impact of cross-contamination on *M. bovis* transmission can be flagged as an uncertainty (medium).

Appendix 2: Risk estimation

Risk Level Classification

Probability Category	Interpretation
Negligible	So rare that it does not merit to be considered
Very Low	Very rare but cannot be excluded
Low	Rare, but does occur
Medium	Occurs regularly
High	Occurs very often
Very High	Events occur almost certainly

Table from EFSA (2006) modified from OIE (2004)

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