

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

DISCUSSION PAPER

REVIEW OF THE RISK LEVEL CLASSIFICATION FOR THE HUMAN HEALTH RISKS ASSOCIATED WITH *MYCOBACTERIUM BOVIS* AND MEAT

Introduction

1. In May 2012, the Committee discussed risk assessment outcomes (ACM/1065) and agreed the most appropriate risk level classification system, method of expressing uncertainty and scale for quality of evidence, for use when assessing risks in the future. The classification system agreed is reproduced in paragraph 12 of this paper.
2. Now that this has been agreed, the purpose of this paper is to invite members to review the risk level classification for the human health risks associated with the consumption of meat from animals with evidence of *M. bovis* infection. The risk level classification of 'very low' was initially agreed by the Committee in 2001 and remained unchanged when reviewed in the light of new evidence in 2003 and 2010.
3. The Committee is invited to consider if the classification previously agreed is still appropriate, using the agreed risk level classification system.
4. Members may also wish to consider if they wish to express the uncertainty in relation to this qualitative risk estimate and their view of the quality of the evidence, using the categories agreed.

Background

5. In September 2000, the Committee was asked to review the possible human health risks associated with the consumption of meat from cattle that had evidence of *M. bovis* infection. The Committee's views were also sought on the level of protection offered to human health by the legislation that was in force. Members were reassured that a marked increase in bovine tuberculosis in cattle had not been reflected in human cases of TB due to *M. bovis*. However, it was agreed that a Working Group would be set up to review the possible health risks associated with the consumption of meat from animals with evidence of *M. bovis* infection and to advise on the adequacy of control measures. The Working Group only considered GB data.
6. The Committee endorsed the Working Group's report and it was published in January 2002. In summary, it was concluded that the risk, if any, from the consumption of meat from animals with evidence of *M. bovis* infection, sold as fresh meat for human consumption following assessment by the Meat Hygiene Service in UK abattoirs, was very low.

7. In September 2003, the ACMSF reviewed results from an FSA funded study to investigate whether *M. bovis* was present in the edible tissues of salvaged carcasses from cattle which had reacted positively to the tuberculin test. The Committee was asked whether the results of the survey might impact on the ACMSF's 2002 assessment of possible health risks to consumers. Key results of this study were that 4.5% (19 from 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 their 2002 risk assessment. However, they supported the Report's recommendation that enhanced surveillance of human *M. bovis* infection should be maintained to alert the FSA to any significant indications that eating meat from *M. bovis* infected cattle constituted a health risk.
8. An EFSA risk assessment adopted in 2003, which took account of the results of the FSA funded research, concluded that the risks to public health through the consumption of meat from TB reactor animals are very low and did not justify any changes to existing meat hygiene controls. In 2003, the Irish Food Safety Authority published their own risk assessment which also identified the public health risk as very low and did not result in recommendations for tighter controls on meat from TB reactor cattle. A second edition was published in 2008.
9. In 2010, the ACMSF reviewed changes in the hygiene regulations and disease incidence in cattle and humans over the last 10 years (ACM/981a, ACM/981b). The Committee subsequently re-affirmed the conclusion of its earlier 2001 risk assessment of the possible health risks to consumers of meat from cattle with evidence of *M. bovis* infection as very low and this was reported to the FSA Board in July 2010 (FSA 10/07/12).
10. In June 2013, the European Food Safety Authority published a Scientific Opinion on the public health hazards to be covered by inspection of meat (bovine animals)¹ which declared the risk of transmission of *M. bovis* to humans by meat consumption as negligible owing to the non-meat-borne nature of the agent (see Annex 1).

Risk assessment outputs

11. In May 2012 a paper was presented to the Committee (ACM/1065) on risk assessment outputs. Most of the Committee's risk assessment outputs tend to be qualitative rather than quantitative and the paper provided some examples of possible approaches given the wide ranging nature of the

¹ <http://www.efsa.europa.eu/en/efsajournal/doc/3266.pdf>

questions which the Committee deals with. Risk assessments and risk outputs should take into account the impact of uncertainty and variability and it was suggested that the Committee considers this to help improve transparency of the risk assessment process.

12. The tables below were chosen as the most appropriate for ACMSF risk level classification and for describing uncertainty. The Chair suggested that applying different combinations of these approaches may be required in different circumstances and they should be applied in practice to see what works.

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)

Qualitative categories for expressing uncertainty in relation to qualitative risk estimates

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data available; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them

Table from EFSA (2006)

GRADE scale for quality of evidence (slightly modified)

High quality	Further research is very unlikely to change our confidence in the assessed risk
Moderate quality	Further research is likely to have an important impact on our confidence in the assessed risk and may change the estimate
Low quality	Further research is very likely to have an important impact on our confidence in the assessed risk and is likely to change the estimate
Very low quality	Assessed risk is very uncertain

Table from Guyatt *et al.* (2008) and modified for risk analysis according to Spiegelhalter & Riesch (2011)

N.B When the above table was discussed it was suggested the text in the low quality classification should be altered from “further research.... is likely to change the estimate” to “further research.... may change the estimate”.

Action

13. Members are invited to:

- apply the risk classification system adopted by the Committee in 2012 and consider which classification for *M.bovis* risk from bovine meat is most appropriate using this system.
- consider if they wish to express the uncertainty in relation to this qualitative risk estimate and their view of the quality of the evidence, using the categories agreed.

References

EFSA [European Food Safety Authority] (2006) Opinion of the Scientific Panel Animal Health and Welfare (AHAW) related with the Migratory Birds and their Possible Role in the Spread of Highly Pathogenic Avian Influenza. EFSA Journal 357, 1-46. <http://www.efsa.europa.eu/en/efsajournal/pub/357.htm>

OIE [World Organisation for Animal Health] (2004). Handbook on Import Risk Analysis for Animals and Animal Products Vol 1 2004, World Organisation for Animal Health.

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Spiegelhalter DJ. Riesch H. (2011). Don't know, can't know: embracing deeper uncertainties when analysing risks. Phil. Trans. Royal Society A(369) 4730-4750.
WHO/FAO [World Health Organisation/Food and Agriculture Organisation of the United Nations] (2009) Risk characterisation of microbiological hazards in foods: Guidelines. Microbiological Risk Assessment Series 17. Rome.

Extract from Scientific Opinion on the public health hazards to be covered by inspection of meat (bovine animals)

EFSA Panel on Biological Hazards

Mycobacterium bovis

M. bovis is a zoonotic agent that can cause a condition very similar to human tuberculosis. The human infection occurs typically through contaminated aerosol inhalation or direct contact with animal mucous membranes (Grange and Yates, 1994; Ashford et al., 2001). The introduction of milk pasteurisation and tuberculin screening of cattle herds has largely eliminated the public health risk from *M. bovis* which in the past was a common cause of milk-borne tuberculosis infections in humans (Grange and Collins, 1997; de la Rua-Domenech, 2006; HPA, 2010).

As indicated above, to determine whether *M. bovis* in cattle should be included in the hazard prioritization list for bovine meat inspection, scientific information to be considered is whether: a) the organism is presently found in bovine meat in the EU; and b) there is a risk of its transmission to humans via the meat-borne route.

To date, only a limited number of published studies have reported on the presence of *M. bovis* in bovine meat and organs. Three recent studies reported on isolation of *M. bovis* from carcass lymph nodes (i.e. both visceral and non-visceral related lymphoid structures) and in offal but not in muscle samples (ACMSF, 2003; Beswick, 2004; Van der Merwe and Michel, 2010). Eight older studies reported on the isolation of *M. bovis*, to different degrees, from bovine muscles (Cohrs and Obiger, 1954; Drieux, 1957; Francis, 1958; Gallo and Guercio, 1956a, 1956b, 1957; Hubert et al., 1975; Meyn and Schliesser, 1954; Tison et al., 1966); however, the large majority of them originated from tuberculin-positive animals or animals showing multiple or generalised tuberculosis lesions at post-mortem inspection.

In relation to meat-borne transmission potential, 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. 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.

However, the reported lack of evidence of the potential for meat-borne transmission of *M. bovis* has to be considered in light of difficulties in designing experimental studies to further investigate whether and to what extent a meat-borne *M. bovis* transmission to humans is possible under the current epidemiological situation in Europe. Hence, some published studies

have considered that meat-borne transmission of *M. bovis* is possible, and thus reflected on the level of public health risk.

M. bovis is recorded as accounting for 1–3% of clinical cases of human tuberculosis reported each year in the EU (EFSA and ECDC, 2011, 2012b, 2013), although it is not known if infected-but-asymptomatic individuals exist and, if so, how many. Recent analysis of published information and data reporting on *M. bovis* tuberculosis in the United Kingdom (Hill et al., 2013), which is one of the countries with the highest prevalence of bovine tuberculosis (bTB) in cattle in the EU, indicated that out of 9,153 reported human cases of tuberculosis in 2009, less than 50 (i.e. <0.5% of all tuberculosis cases) were due to infection with *M. bovis*. 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 picked up the infection abroad (HPA, 2010). Recent epidemiological studies, carried out in the United Kingdom did not find an increase in the number of human cases despite an increase in cattle cases in the same country (Jalava et al., 2007; Stone et al., 2011). Furthermore, exposure to *M. bovis* via bovine meat inspected and deemed fit for human consumption can not be excluded. This is because the sensitivity of meat inspection for detecting cases is not 100 % (as discussed with detail in the Animal Health and Welfare related Appendix of this Opinion), thus allowing for *M. bovis* positive carcasses entering the food chain. Thus, for example, despite the significant burden within the cattle population (>1% of herds are infected), the UK Health Protection Agency classifies the current risk to human health from food-borne *M. bovis* as negligible (HPA, 2010).

Other reports, theoretically addressing – should it be possible - the meat-borne *M. bovis* risk, qualify the risk as ‘very low’ or ‘negligible’, and linked to consumption of uncooked or undercooked bovine meat (ACMSF, 2003; de la Rua-Domenech, 2006; Francis et al., 1973; FSAI, 2008; Moda et al., 1996; NZFSA, 2006; O'Reilly and Daborn, 1995; Pritchard, 1988; Roberts, 1986; Thoen et al., 2006). Quantitative estimates are not available in the literature. Therefore, current control measures for bTB in slaughterhouses in the EU (i.e. mandatory cutting of lymph nodes and partial or full condemnation of carcasses at meat inspection) are not actually based on public health risk; rather, they are based on the intention to and the belief that they: a) prevent (presently not documented) potential meat-borne transmission of the disease; and b) provide information for the effectiveness of applied animal health controls and are an important element of national bTB eradication programmes, as described in the animal-health related Annex of this Opinion.

Summarising, it can be concluded that, currently, there is no evidence suggesting that *M. bovis* is a meat-borne hazard for humans in the EU.