



The TAFS Assessment of Paratuberculosis in the Food Chain

2013

Version 1.0

About the TAFS forum



- **Unique set-up:**
Science, industry, regulators, consumers
- **Leading scientists**
- **Track record in consensus building:**
TAFS solved the stalemate on BSE when the science was not clear.
- **Track record with MAP:**
Position papers, action plan, simulation exercise, regular updates and news
- **Independent organization:**
No political or any other constraints
- **Collaboration with Global Food Safety Initiative (GFSI) and GlobalG.A.P.**

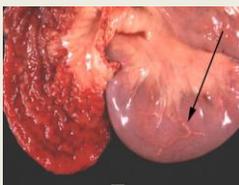
Paratuberculosis in animals: the basics



- Paratuberculosis = Johne's disease
- Infection during the first few months after birth
- Infected animals can stay symptomless for many years
- Affects ruminants: cattle, water buffalo, sheep, goats, deer, antelope, and bison



- Caused by *Mycobacterium avium* ss. *paratuberculosis* (MAP)
- Cannot replicate naturally outside animals
- Relatively resistant to heat, cold and drying
- May be able to form spore-like structures (-> more infectious through wind and dust, harder to kill)



- Diarrhea, rapid weight loss, decrease in (milk) productivity
- Fatal gastrointestinal disease
- Causing massive economic losses

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Why does TAFS address MAP?



Consideration	Assessment of MAP
TAFS' guiding principle: Safe food comes from healthy animals.	Animals with paratuberculosis (caused by MAP) are not healthy.
TAFS' vision: Contributing to justified consumer trust in food safety	Consumers are exposed to MAP through food, putting their trust in food safety at risk.
TAFS is committed to science-based decision making and acting responsibly in the face of hazards.	The scientific evidence on the food safety aspect of MAP is complex and unclear, warranting careful analysis.
Public risks should be addressed publicly.	Few options available for personal risk reduction (e.g., consuming UHT milk). Addressing the risk on farm level, i.e. publicly, is the most effective approach.

MAP is widely spread...



Every country that has tested their susceptible livestock for Paratuberculosis has found cases of infection.*

Source: johnes.org

* potential exception: Sweden (Frössling et al. 2012, Prev. Vet Med 2012 Aug. 14)

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...but many countries report only low numbers or no quantitative data officially



EXAMPLES

	Japan	Korea Rep. of	Germany	Switzerland	China	Chile
# cases in cattle reported to OIE (2010)	456	432	334	14	5	1
	Argentina	Netherlands	USA	Canada	Czech Republic	India
	(yes)*	(yes)*	(yes)**	(yes)**	(yes)**	(yes)***

*: infection present, but no quantitative data

** : clinical disease present, but no quantitative data

***: disease limited to one or more zones

Source: TAFS forum 2012; OIE WAHID

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Yet studies report high prevalences in many countries



EUROPE	
Country	Herd-level apparent prevalences ¹
Belgium	18 %
Denmark	55 %
France	68 %
Germany	42 %
Italy	7 – 65 %
Norway	10 %
Rep. of Ireland	13 %
Slovenia	3 – 12 %
Spain	8 – 10 %
Sweden	0 %
Switzerland	3 – 22 %
The Netherlands	54 %
Turkey	38 %
United Kingdom	17 %

USA	
Percentage of Operations in which at least one environmental sample cultured positive for MAP in 2007 ²	
All operations	68%
> 500 cows	95%
True herd-level prevalence ³	
All operations	91 %
Annual losses to US farmers ⁴	\$US 1.5 billion

Survey findings vary based on the validity of the population sample, diagnostic test and assay cutoff.

Sources:

- ¹ Soran Saxmose Nielsen, Nils Toft A review of prevalences of paratuberculosis in farmed animals in Europe, Preventive Veterinary Medicine, Volume 88, Issue 1, 1 January 2009, Pages 1–14
- ² USDA-VS-CEAH Info Sheet N521.0408, April 2008
- ³ J.E. Lombard et al. / Preventive Veterinary Medicine 108 (2013) 234–238
- ⁴ http://ec.europa.eu/research/biosociety/inco/projects/0062_en.html; based on NAHMS, 1997. Johne's Disease on U.S. Dairy Operations. USDA:APHIS:VS, CEAH, National Animal Health Monitoring System, Fort Collins, CO. #N245.1097.

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Reasons why reported figures often do not reflect the full extent of the disease

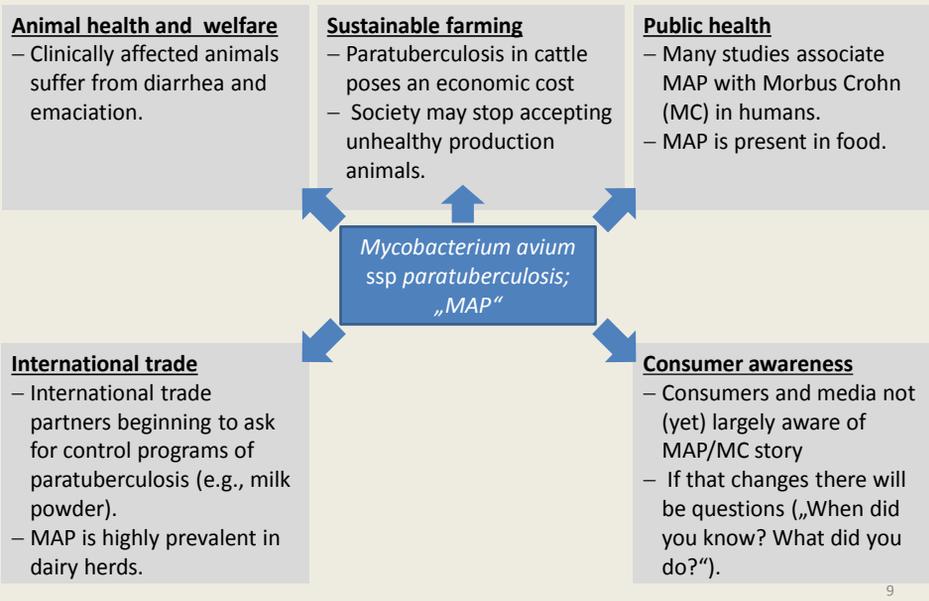


- Surveillance programs in countries may be insufficient to detect the full scale of prevalence. Some countries do not run systematic surveillance for paratuberculosis at all, giving higher priority to other diseases.
- Countries report only presence of disease to OIE without quantitative data.
- Herd level surveillance does not allow conclusions on animal level prevalence.
- The sensitivity of diagnostic tests is insufficient to detect all cases.

Overall, information on the prevalence of paratuberculosis is very poor. Based on the available results no country can claim to be in a better situation than others.

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Why is paratuberculosis a problem?



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Cornerstones of the scientific debate on MAP and human health



- Paratuberculosis and Morbus Crohn (MC) are similar, but not the same.
- MAP is 7 times more likely to be found in MC patients than in normals. MC patients shed MAP in feces and milk.
- Although many people are exposed to MAP, few develop MC.
- A genetic predisposition increases the risk of developing MC.
- The therapeutic value of antimicrobials is disputed.

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Status of the scientific debate on MAP and human health



- It is uncontroversial among scientists that Morbus Crohn is a complex syndrome and that many factors are involved in its development. The effect of any particular factor is hard to single out.
- It is controversial what the exact roles of each contributing factor – including MAP – are.
- There is no clear evidence on either side.
- Future scientific evidence may shift the balance either way.

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Assessment of options to address the paratuberculosis problem



	Downstream processing (food level)	Neglect/non-communication	Farm-level disease control
Animal health and welfare	✗	✗	✓
International trade	✗	✗	✓ / ✗ ²
Sustainable farming	✗	✗	✓
Public health	✓ / ✗ ¹	✗	✓ / ✗ ^{2,3}
Consumer awareness	✓ / ✗	✓ / ✗	✓ / ✗ ²

1 Pasteurisation has been shown to substantially reduce the levels of MAP in raw milk, but there are reports about presence of viable MAP in pasteurized milk.

2 Effect of programs increases over time.

3 Eradication of the disease seems unrealistic at this time, but shedding of MAP can be reduced massively.

Disease control on farm level is the best option to address the problem.

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Requirements to address the problem on farm level are met



- ✓ **Knowledge** about the disease, transmission of the infectious agent and risk management options
- ✓ Sufficiently reliable **tests** (for the first 10 years of a control program, more sensitive tests would then be needed to make further progress)
- ✓ **Vaccines** rapidly reduce shedding (but interfere with diagnosis of bovine TB)
- ✓ Examples of successful **control programs** in Denmark and Canada
- ✓ **Economics:**
cost of control program: 0.003 € / litre of milk*

* Source: von Roermund et al., Development of a milk quality assurance program for paratuberculosis: from within and between herd dynamics to economic decision analysis; Proceedings of 8ICP 2005. [2 Elisa tests p.a., samples taken by farmer]

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But little has been done so far because of major challenges



Not of economic importance on farm

- pTB-related losses are unequally distributed and develop gradually on farms
- The costs of control are (perceived to be) higher than the costs of the disease.
- The disease progresses slowly and hence gets less attention than massive sudden outbreaks.

Communication dilemma

- Acknowledging a problem implies responsibility (for insufficient past action).
- Not acknowledging the problem is the easy way out (only in the short term).

No quick fix

- pTB control programs stretch over many years.
- Past promises of „quick fix“-solutions have led to disappointment and loss of credibility/commitment.

Supply chain disruption

- MAP is so prevalent that mandatory sourcing from certified MAP-free herds would disrupt supply.
- A staged transition is hard to explain (two levels of „quality“).

Delegation of responsibility

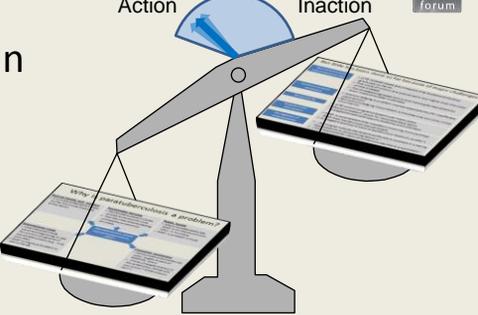
- „As long as nobody declares this officially a zoonosis it is not my responsibility to do anything about it.“
- „The responsibility lies with those who say there is a problem.“

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Some think the balance should lean towards action...

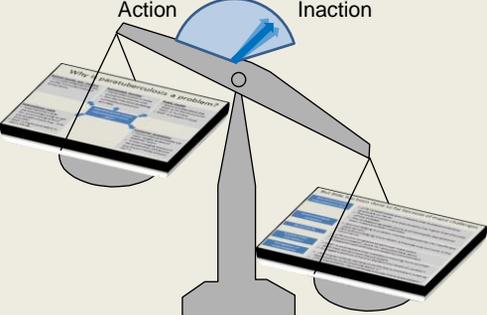
Paratuberculosis control

Action Inaction



Paratuberculosis control

Action Inaction



...but many decision makers see it the opposite way.

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The major discrepancy between the two views is about the aspect of paratuberculosis and human health

1 Controversy on the required level of evidence

Some people say: „MAP has not been proven to be a public health hazard. Once it will be, we will take action. Until then, we don't.“

While others say: “In want of a final proof the precautionary principle mandates action against uncertain risks”.

FACT IS:

- Ultimately, such a proof is difficult to achieve without experimental infection. (In particular with children who are suspected to be most susceptible to infection).
- There is no ultimate proof for other diseases either (including BSE).

TAFS' position

The level of evidence regarding a public health hazard required to justify taking action to reduce the risk should be proportionate to the consequences if the hazard is real.

2 Conflicting evidence

There is evidence supporting either side of the debate. There is no unifying hypothesis explaining and supported by all available evidence.

TAFS' position

It is the rule, not the exception that there is conflicting evidence. This should not block taking action. Action should be based on the balance of evidence.

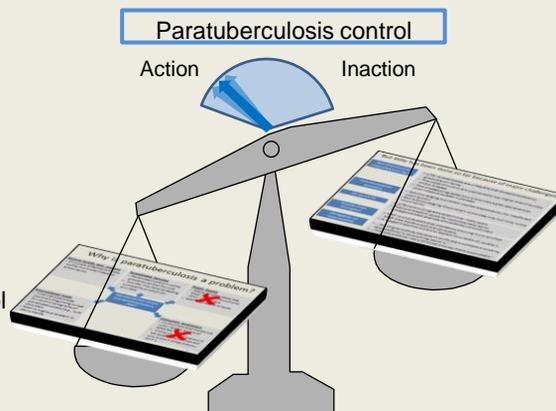
Our view:

Paratuberculosis should be controlled regardless of its human health impact



- Animal health and welfare, sustainable farming and international trade aspects are sufficient to warrant efforts to control paratuberculosis in animals.
- The long-term benefits of such control programs outweigh their difficulties.
- The reduction of human exposure to MAP, resulting from paratuberculosis control programs, would be an important additional benefit.

TAFS VIEW



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The way forward



Guiding principle

Safe food comes from healthy animals.
Animals with paratuberculosis are not healthy.

„One Health“- perspective

Considering the costs of MC, even a 2% chance that MAP from food contributes to causing it economically justifies taking action to control MAP in farm animals.

Managing expectations

Past programs to control MAP in farm animals have failed to meet expectations.
Care must be taken not to raise unrealistic expectations from farmers, industry, authorities or consumers.

Comprehensive participation

The TAFS forum is an established platform bringing scientists, industry, regulatory authorities and consumer representatives together. This set-up will be essential for the success of action steps taken on MAP .

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Summary of TAFS position



- Several reasons warrant enhanced efforts to control paratuberculosis, including animal health, welfare, economics and trade.
- The best option to control paratuberculosis in animals is control on farm.
- Reducing exposure of humans to MAP should not be seen as the ultimate reason to control paratuberculosis in animals, but as an additional benefit without harm.
- Current scientific evidence on the human health aspect of paratuberculosis is unclear and implications are discussed controversially. Future science may or may not remove that uncertainty in either direction.

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Contact:
The TAFS forum
Bremgartenstrasse 109a
3012 Bern
Switzerland

info@tafsforum.org
www.tafsforum.org

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