

**CONTROL OF *MYCOBACTERIUM AVIUM* SUBSPECIES *PARATUBERCULOSIS*  
(MAP) IN COWS' MILK**

**Executive Summary**

1. A draft strategy for the control of *Mycobacterium avium* subspecies *paratuberculosis* in cows' milk was presented as an information paper to the Board in December 2001. Consultation on the proposals has now been carried out. The outcome of the consultation, together with a revised strategy, is now presented for Members' information.
2. The paper is for **information** only. **No action** is required.

**Microbiological Safety Division**

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**CONTROL OF *MYCOBACTERIUM AVIUM* SUBSPECIES *PARATUBERCULOSIS*  
(MAP) IN COWS' MILK**

**Issue**

1. The Board is invited to note the outcome of the consultation on the draft strategy to control *Mycobacterium avium* subspecies *paratuberculosis* (MAP) in cows' milk (Annex 1) and the revised strategy (Annex 2).

**Strategic Aim**

2. The strategy relates to the Agency's strategic aims of promoting best practice in the food industry and delivering a measurable improvement in public confidence in the way food safety and standards are managed across the UK.

**Background**

3. This was set out in Paper 01/08/01. In brief, MAP is a bacterium that causes a chronic gastrointestinal infection called Johne's disease in cattle. Some scientists suggest that MAP may also cause a similar disease, Crohn's disease, in humans. A series of recent reviews have concluded that the possibility of a link cannot at present be established, nor can it be ruled out. It may take many years for this question to be resolved but the Agency believes that precautionary action to reduce human exposure to MAP should start now and should not be dependent on waiting for the link to be proved or disproved.
4. MAP is known to be present in raw milk from cattle with Johne's disease and studies to date have tended to concentrate on milk. Other possible vehicles of exposure include dairy products, meat from affected animals, and water contaminated with agricultural run-off. The strategy presented here concentrates on reducing exposure through milk although some of the proposals, i.e. those aimed at reducing disease incidence in animals, will have an impact on all potential food vehicles.

5. MAP has also been shown to be present in pasteurised milk and this appears to confirm laboratory studies demonstrating the relative resistance to heat of this organism and suggesting that MAP will survive normal high temperature short time (HTST) pasteurisation (heating at 71.7°C for 15 seconds).
6. After reviewing this information, the Advisory Committee on the Microbiological Safety of Food (ACMSF) recommended that the Agency should convene an expert group of stakeholders to look at ways to prevent the bacterium from entering milk. The Agency organised a workshop to help gather information on possible controls and the output from this workshop was used to formulate a draft strategy for the control of MAP. This was presented to the Board in December 2001 and then submitted for public consultation, a consultation that included an open meeting, held on 23 January 2002. A summary of the responses obtained is appended (Annex 1).
7. The strategy has been amended in the light of the comments received (Annex 2). The main elements of the strategy remain unchanged, with one exception. The proposal that all dairies should be recommended to extend the pasteurisation time to 25 seconds was questioned by a number of respondents from both industry and the scientific community. At ACMSF, it was observed that more research was needed to assist the understanding of the heat response of this organism before an authoritative view could be given on the efficacy of a 25 second holding time.
8. Although some laboratory work suggested that MAP would not survive a prolonged pasteurisation time, the milk survey carried out by the Food Standards Agency showed that some of the pasteurised samples from which MAP was recovered had been subjected to a 25 second pasteurisation (see Table 1). Whilst some have suggested that the prolonged time is likely to reduce the number of positive samples and the number of organisms in those samples, this cannot be proved from the milk survey or results of research completed to date. Moreover, studies of the thermal tolerance of MAP suggest that 25 seconds at 71.7°C will not completely destroy MAP if it is present at levels above 10<sup>2</sup> cfu/ml. Further information on these studies is provided in the third annex of the strategy.
9. Many of the major dairy producers have already changed to a 25 second pasteurisation time, this increase in the holding time requiring the pasteuriser to be modified. We do not know how much milk is now pasteurised for 25 seconds

but, in the milk survey, which involved a representative sample of dairy establishments, 33% of the dairies were pasteurising for 25 seconds or longer. Further work on the treatment of milk is currently underway to see if there are time/temperature combinations, which destroy MAP in milk undergoing commercial pasteurisation. It is possible that this work could suggest a different time to either 15 or 25 seconds, necessitating a further round of modifications. Pending the outcome of this work, and in the light of the lack of evidence that 25 seconds is superior to 15 seconds, it seems inappropriate to ask dairies that have not already changed their pasteurisation times to do so at this time.

**Table 1: Processing Details for MAP Positive Pasteurised Milk Samples**

Dairy	Sample type	Temperature (°C)	Time (sec)
1	Semi-skimmed milk	72	15
2 (2 samples)	Whole milk and skimmed milk	72	15
3	Semi-skimmed milk	72	14
4	Whole milk	72	15
5 (2 samples)	Semi-skimmed milk and skimmed milk	74	15
6	Semi-skimmed milk	72.2	25
7	Whole milk	74	25 – 26
8	Semi-skimmed milk	75	25

10. In broad terms, the strategy proposes action from farm to dairy, including measures to:

- reduce or eliminate the carriage and shedding of MAP by dairy cattle
- reduce contamination of milk with MAP during the milking process
- make sure that pasteurisation is carried out effectively
- try to discover more effective ways of treating milk in order to eliminate MAP.

### **Timetable**

11. Some of the proposed work is already in hand :

- The measures aimed at improving hygiene practice in milking and control of pasteurisation form part of the action plan to implement the foodborne disease strategy and are already being actioned by the FSA.
- The research on teat cleaning is currently being commissioned.
- The research on effective ways of treating milk to eliminate MAP is underway. The results are likely to be available in 12 to 18 months' time. Since the research has been commissioned jointly by the dairy industry and DEFRA, it is likely that the industry will wish to act promptly upon the results.
- DEFRA have produced a draft advisory leaflet for farmers and have set up a working group of the Surveillance Group of Diseases in Animals to look at MAP surveillance.

12. The rest of the work can be divided into actions that fall within the Food Standards Agency's areas of responsibility and those relating to DEFRA responsibilities. Annex 2 to the strategy provides an action plan, divided into short term (within 1 year), medium term (1-5 years) and longer term (more than 5 years) actions.

13. The timetable for other on-farm control measures needs to be developed by DEFRA and will, to a large extent, be contingent upon the results of the survey of MAP infection in the UK herd and on the prioritisation of further research work. The incorporation of guidance on the control of MAP infection into farm assurance and herd health schemes should provide the basis for the wider adoption of good practice. However, such schemes are likely to take many years to effect a significant reduction in the incidence of MAP in animals. A similar length of time is likely to be required if it is decided that the development of new vaccines is required. It remains to be seen if elimination is a practicable goal but, if it is, the timetable is likely to be decades rather than years.

### **Impact**

14. Much of the work that will fall to the Agency was already planned as part of the overall foodborne disease strategy. Therefore funding has already been made available and there will be minimal additional costs for the Agency in implementing the strategy. It is envisaged that the manpower requirement for

monitoring progress by further surveys of MAP in milk will be found from within existing resources.

15. A number of the measures proposed in the strategy may not have a significant financial impact on the milk industry, as only minimal changes to general hygiene and farm management practices may be required. However, the actual costs of such changes will not become known until these measures have been further developed.

16. Other measures proposed in the strategy as currently drafted would have cost implications for DEFRA and the milk industry. These are difficult to quantify, especially as the data on the extent of Johne's disease in the UK is so sparse. What data is available suggests that a control measure such as vaccination might cost in the region of £10million a year, over and above any cost of developing a more effective vaccine. However, there are a number of caveats to this figure as it is based on a number of assumptions, not least the lack of clear evidence as to just how effective such a control measure would be in controlling Johne's disease in the UK dairy herd.

### **Implementation**

17. The Agency will be setting up a consultative group to bring together those responsible for DEFRA's Johne's disease control strategy, the industry and other major stakeholders.

### **Monitoring progress**

18. An implementation programme will be developed after the first meeting of the consultative group so that there are specific milestones with measurable progress targets. The overall measure will be the strategy's success in reducing the incidence of MAP in pasteurised milk so we will repeat the milk survey at regular intervals, possibly every 5 years. Since the link to human illness has yet to be established and since, if it exists, it may account for only a proportion of cases, we do not consider that the monitoring of Crohn's disease would be an appropriate measure of the success or otherwise of the strategy.

19. A progress report will be presented to the Board in November and subsequently at annual intervals.

**Board Action Required**

20. The paper is for **information** only. **No action** is required.

## RESPONSES TO PUBLIC CONSULTATION ON THE FSA'S DRAFT MAP STRATEGY

### Introduction

This consultation took place between December 5<sup>th</sup> 2001 and March 1<sup>st</sup> 2002 and included an open meeting in order that the strategy could be presented and discussed with stakeholders. As well as being advertised on the Agency's website and in the FSA news, consultation letters were also sent to interested stakeholders, including consumer groups. Approximately 40 written responses were received and these, along with comments from the open meeting, are summarised below. A more detailed summary of the responses will be made available on the FSA website at a later date.

### General comments

In general there was widespread support for the strategy. Some stakeholders were concerned about the additional pressure that would be put on the UK milk industry by measures suggested in the strategy, and the possibility of foreign imports flooding the market. However, it was also noted that many of the measures suggested would result in overall improvements in the quality of milk.

Issues regarding labelling of dairy products were also raised with some consumers wishing to be aware of the length of time milk was pasteurised for, but it was also noted that this may be misleading as MAP can survive pasteurisation for 25 seconds.

There was concern that the strategy did not address other sources of MAP infection (e.g. water supply, meat, wildlife) but it was generally felt that it was best not to wait until this information was available before putting measures to prevent MAP from entering milk in place.

Suggestions were received that a stakeholder steering group should be set up to monitor implementation of the strategy and the Agency intends to follow this recommendation.

### Control in cattle

Many comments were received supporting research into the production of a vaccine, although it was recognised that this might take years and other measures should be put into place first. It was also noted that research into more accurate tests for MAP is essential in order to help farmers work towards Johne's disease free herds in the future.

The production of guidance for farmers at the general farm and milking parlour levels was a major topic of discussion with suggestions that the FSA should liaise with the National Dairy Farm Assurance Scheme (NDFAS) in the production and dissemination of leaflets. The role of the Dairy Hygiene Inspectorate (DHI) was considered, with many respondents believing that their advisory and enforcement activities should be extended. Many stakeholders believed that education and training of dairy farmers needed to be emphasised in the strategy. The setting up of a husbandry panel, consisting of farming and veterinary experts, to oversee a control programme for Johne's disease was also discussed. Comments were made that there should be co-operation with existing farm assurance and cattle health schemes when considering the control of paratuberculosis.

In addition, animal welfare concerns were raised relating to the proposed withdrawal of calves from their dams.

### Control during milking

Issues relating to the role of the DHI and guidance for farmers were again raised here. Comments were also received that better tests for faecal contamination in milk are necessary and that a test for MAP in raw milk should be developed. Many stakeholders felt that teat cleaning was an important area to address and more research, plus a review of current research, is needed in order to give the correct advice to farmers in relation to all diseases.

### Control during pasteurisation

The Dairy Industry Association Limited's (DIAL)<sup>1</sup> and NFU's recently published codes of practice for pasteurisation were generally welcomed. Several stakeholders were concerned that smaller on-farm dairies would be put under the most pressure by measures outlined in the strategy and, that these should not be singled out for

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<sup>1</sup> Formerly the Dairy Industry Federation, now merged with the National Dairymen's Association

criticism, as many improvements have been made in recent years. However, there was still a view amongst some respondents that these dairies pose the greatest hygiene risk.

A number of comments were received that there is little scientific evidence to suggest an increase to 25 seconds of pasteurisation will have any effect in reducing MAP levels in milk. Recommendations were also received that control measures for post pasteurisation contamination should be included in the strategy and that quantitative testing of phosphatase should be introduced.

It was also suggested that a survey of MAP in UHT treated milk should be carried out in order for the agency to review its existing recommendation that no dietary change is necessary.

### Stakeholder comments

Those who took part in the open meeting and written consultation were mainly representatives of the dairy and farming industry, veterinarians, researchers and charities representing Crohn's disease patients.

The dairy industry welcomed the strategy and was particularly keen to emphasise the work that it had been doing in recent years to improve standards, in particular the Codes of Practice issued by DIAL and the NFU. There were a few concerns including issues relating to pressures on smaller pasteurisers, and the adoption of quantitative testing for phosphatase.

The farming industry expressed more concerns, particularly about the costs they might incur in carrying out measures in the strategy. They felt disinclined to act upon the strategy without a link between MAP and Crohn's disease being proven and thought that other diseases were of more immediate importance.

Veterinarians, researchers and charities expressed a variety of views in all areas. Veterinary experts' main interests were in ways to tackle Johne's disease, for example the planned national survey, issues surrounding vaccination and husbandry issues. Researchers were interested in the development of rapid tests for MAP, in cattle and in milk, and establishing levels of MAP present in the wildlife reservoir and general environment. Crohn's disease patients were concerned about the labelling

of pasteurised milk, the benefits of UHT milk and increased funding for research into MAP, particularly the development of a more effective vaccine.



**STRATEGY FOR THE CONTROL OF  
*MYCOBACTERIUM AVIUM* SUBSPECIES  
*PARATUBERCULOSIS* (MAP) IN COWS MILK**

DRAFT

Objective:	Paragraph 1
Background:	Paragraphs 2-4
The strategy:	Paragraphs 5-28
Action plan:	Annex 1
Summary of research on MAP:	Annex 2
Review of research on the heat resistance of MAP:	Annex 3

# STRATEGY FOR THE CONTROL OF *MYCOBACTERIUM AVIUM* SUBSPECIES *PARATUBERCULOSIS* (MAP) IN COWS MILK

## Objective

1. The Food Standards Agency (FSA) is developing a strategy to reduce the likelihood of consumers being exposed to MAP when consuming cows' milk. Other potential routes of exposure exist but are not considered here. In setting this objective, the Agency has put on one side the question of whether or not there is a link between MAP and Crohn's disease. The Agency believes that precautionary action to reduce human exposure to MAP should start now and should not be dependent on waiting for the link to be proved or disproved. The intention is that the strategy should be an evolving document, which will be revised regularly.

## Background

2. Crohn's disease is a chronic inflammatory bowel disease of humans that can be severe, prolonged and debilitating. The cause of the disease is unknown, although one suggestion which has received a lot of attention is a link with *Mycobacterium avium* subspecies *paratuberculosis* (MAP), a bacterium that causes a chronic gastrointestinal infection called MAP infection in cattle and other ruminants. The evidence for and against such a link has been examined by the Advisory Committee on Dangerous Pathogens (twice), by the European Union and, more recently, was the subject of a review produced on behalf of the Food Standards Agency. All of these pieces of work reached a similar conclusion, which is that on the basis of the available information, a link between MAP and Crohn's disease can neither be proved nor disproved.

3. Nevertheless, the FSA considers it important to take the possibility of such a link seriously since a survey commissioned by the Food Standards Agency found MAP in approximately 2% of samples of pasteurised milk in the United Kingdom. The results of this survey were reported to the Advisory Committee on the Microbiological Safety of Food in September 2000. The Committee noted that the risk to human health had not yet been established and did not recommend any change in the current advice regarding the consumption of milk, i.e. that on the basis of the current evidence there is no need for anyone to change their dietary habits.

4. The Committee did however recommend that, given differing views on possible links to human illness which are unlikely to be resolved in the foreseeable future, the Agency should convene an expert group of stakeholders to consider ways of reducing exposure to MAP in milk. The Agency accordingly organised a stakeholder workshop in May 2001 to help gather information on possible controls to reduce or eliminate MAP in milk. The output from the workshop<sup>2</sup>, along with information gathered from other sources, has been used to prepare the strategy.

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<sup>2</sup> Workshop report available on the FSA website - [www.food.gov.uk/science/sciencetopics/microbiology/mapinmilk/mapconf](http://www.food.gov.uk/science/sciencetopics/microbiology/mapinmilk/mapconf)

## The Strategy

5. The various elements of the strategy cover the whole milk production chain and predominantly relate to general hygiene issues. Some of the elements can be put in place relatively quickly, whilst others will take time and should be seen in the context of this being a long term strategy. Although the Agency prepared the strategy, there has been strong input from DEFRA. The responsibility for implementation will fall to both Agriculture Departments and the Agency.

### *Control in Cattle*

6. A long-term aim should be to introduce control measures that would stop MAP at source. This would require reducing or eliminating MAP infection in dairy cattle in the UK, which would not be an easy task. There are problems to be confronted; for example, there are no accurate data on the level of Johne's in the national herd. This needs to be addressed in order to establish the extent of the disease and to have a baseline against which to assess the effectiveness of any future intervention measures. Whilst a survey of MAP infection is seen as a priority, its reliability will be dependent on ensuring that suitable detection methods are used. Some methods are available but they do not detect all infected cattle and their use in the UK requires further validation.

7. There is uncertainty over the extent of survival of MAP in the environment and research has indicated that the organism can be found in a variety of animals (both farmed and wild). The existence of possible reservoirs outside the cattle population raises doubts about the feasibility of eradication and questions about some of the possible control measures. For example, a control strategy for cattle based on the introduction of animals testing negative for MAP infection (acknowledging the limitations of testing) to a farm, would not be fully effective if these animals were then able to acquire MAP from the environment or from other animals on the farm.

8. Despite the above problems, it is judged that preliminary control measures on farm can and should be introduced. Other countries have developed control programmes for MAP infection and these have been reviewed in a report by the Scottish Agricultural College<sup>3</sup> for DEFRA, to assess what features of the programmes might be applicable to this country. There are already certain initiatives within the UK to control the disease, including various cattle health schemes, limited vaccination and veterinary advice to farmers. It does need to be recognised, however, that some of the measures that are most effective in reducing the transmission of MAP from cow to calf, such as the early removal of calves from their dam and the withholding of pooled colostrum, have implications for animal welfare and may also increase the susceptibility of calves to infection with other agents. These consequences must, therefore, be taken into account when considering such measures as part of a control strategy and should be discussed with the farm's veterinary surgeon before deciding on a course of action. The effectiveness of control programmes also needs to be evaluated, since they have not yet been in operation long enough for their effectiveness to be established.

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<sup>3</sup> Executive summary available on FSA website - [www.food.gov.uk/science/sciencetopics/microbiology/mapinmilk/execsumdefra](http://www.food.gov.uk/science/sciencetopics/microbiology/mapinmilk/execsumdefra)

9. The production of guidance which brings together all the available information and helps farmers understand what action they can take now to control MAP infection in their herds would be a worthwhile first step to the introduction of a concerted programme to control the disease on the farm. This should contain practical information on husbandry, basic hygiene and biosecurity measures.

10. Dissemination and implementation of guidance may have some early effect in starting to reduce the level of MAP infection. However, this is unlikely to provide a complete solution and there is a need to consider other options. In the long term, vaccination is seen as having the greatest potential although further research is needed as the efficacy of the currently available vaccine has been questioned.

11. In summary, the strategy for control in cattle contains the following elements;

- **assessment and validation of current methods for detecting MAP infection in cattle.**
- **a survey of MAP infection in the UK dairy herd.**
- **production of guidance for farmers on the control of MAP infection which could be included in farm assurance or herd health schemes.**
- **prioritisation for further research, including development of vaccines against MAP infection.**

#### *Action to Implement the Cattle Measures*

12. A DEFRA funded detailed review of surveillance and control options for Johne's disease in farm animals in Great Britain has been completed by the Scottish Agricultural College (SAC). An expert sub-group of the Surveillance Group on Diseases and Infections of Animals (SGDIA) has been convened to produce a surveillance strategy for MAP in animals and to advise on the validation of the most appropriate detection method/methods, using the SAC review as a basis.

13. DEFRA has issued for consultation a draft advisory leaflet on controlling Johne's disease in dairy herds. This leaflet covers both advice on measures that may be taken to try to keep MAP infection out of the herd and in instances where MAP infection has been confirmed, measures that may be taken to reduce prevalence.

14. It should be noted that advice on MAP infection has been included with other diseases in a leaflet "Golden rules for a healthy herd – Advice to farmers restocking cattle herds" that has been sent to all cattle farmers following the Foot and Mouth outbreak. In addition to information on prevention of introduction of the disease there is information on industry led health schemes which include testing for MAP infection. It is accepted that on the basis of currently available tests for MAP infection there are relatively few Johne's negative herds in the UK from which to source replacements but it is hoped that this will increase.

### *Control During Milking*

15. Minimising the amount of faecal contamination in raw milk is a key part of the Agency's foodborne disease strategy. Control measures during milking, using the application of HACCP principles, are thus already being actively promoted through initiatives to promote good milking hygiene in general. This area of the strategy primarily relates to generic hygiene measures aimed at the reduction of all potential pathogens in raw milk, not specifically MAP.

16. MAP may be secreted directly into the milk in the udder, however the main source is thought to be faecal contamination. Hygiene during milking is therefore fundamental to control and should minimise the likelihood of consumers being exposed to MAP, as the lower the level in raw milk the smaller chance that it will be present following pasteurisation.

17. One important area, which has been identified as requiring attention, is teat cleaning prior to milking. Opinion differs on how best to carry this out in order to reduce faecal contamination of the milk and farmers currently use a variety of different practices. Since teat cleaning is a crucial step in reducing the level of faecal contamination (and consequently could be a crucial step for reducing MAP) there is a need for research to determine best teat cleaning practice, recognising that this may vary depending upon farming practices and the time of year.

18. In summary, the strategy for control during milking contains the following elements which are ;

- **a review of current advice on hygiene practices during milking with a view to issuing consolidated guidance.**
- **a review of the ways of disseminating advice on hygiene practices during milking so as to optimise future delivery.**
- **research into teat cleaning practices and subsequent publication of advice.**

### *Action to Implement the Milking Measures*

19. In England and Wales, the Dairy Hygiene Inspectorate (DHI) assesses milk production holdings for compliance with the Dairy Products (Hygiene) Regulations 1995 and enforces these Regulations on behalf of the FSA. In Scotland the Local Authorities assess all milk production on holdings for compliance with the Dairy Products (Hygiene) (Scotland) Regulations 1995 on behalf of FSA Scotland. In the course of this work, the DHI provide advice to milk producers on an unofficial basis. The role of the DHI is under review as part of the foodborne disease strategy in relation to the need to reduce the risks of faecal contamination of milk during milking. It will be considered whether the DHI's unofficial advisory role function should be clarified and expanded in order to benefit public health. The issues in relation to controlling MAP in milk will be considered in the context of this review.

20. A call for proposals to carry out research on teat cleaning practice was included in issue 7 of the Agency's Research Requirements document published in December 2001. Once the research has been completed guidance will be issued to farmers.

### *Control After Milking (Pasteurisation)*

21. Post-milking controls currently depend upon pasteurisation and the avoidance of subsequent cross contamination. Whilst there is evidence that MAP can survive pasteurisation, it is also clear that pasteurisation significantly reduces the number of viable bacteria. Therefore it is essential to ensure that dairies are carrying out pasteurisation correctly. Any failure, either not pasteurising at the correct time/temperature combination or post-pasteurisation contamination, would increase the likelihood of the presence of MAP in milk sold to the consumer. In view of the importance of pasteurisation as a control measure for pathogens such as *Salmonella* and *E.coli* O157, dairies should already have effective means of ensuring that the process is being carried out correctly, i.e. own checks procedures. However, it is known that problems do occur from time to time and there is the need for a greater awareness of current guidance and a more active programme of inspection and enforcement. Such guidance needs to review and consolidate what has previously been produced.

22. When information first showed the presence of MAP in pasteurised milk, most of the large dairies changed their process conditions by increasing the pasteurisation time from 15 to 25 seconds. There was no direct evidence to prove that such a change would be effective in eliminating MAP, but laboratory work did indicate its possible effectiveness.

23. However, the 1999/2000 FSA milk survey found MAP in some samples of milk that had been pasteurised for 25 seconds, indicating that the extra 10 seconds of heating does not guarantee the complete elimination of MAP. Therefore it is suggested that current pasteurisation procedures should be maintained until the outcome of research on the pasteurisation conditions required to eliminate MAP is known.

24. In summary, the strategy for control during milk pasteurisation contains the following elements;

- **production of pasteurisation guidance for dairies (this should be aimed particularly at small dairies and on-farm pasteurisers).**
- **measures to improve inspection and enforcement (particularly in relation to on-farm pasteurisers).**
- **a recommendation that current pasteurisation procedures should be maintained until the outcome of research on the pasteurisation conditions required to eliminate MAP**
- **research to find effective ways of treating milk to eliminate MAP.**

### *Action to Implement Measures After Milking*

25. Both the Dairy Industry Association Ltd (DIAL)<sup>4</sup> and the National Farmers Union (NFU) published Codes of Practice on HTST (high temperature short time)

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<sup>4</sup> Previously The Dairy Industry Federation now merged with the National Dairymen's Association

Pasteurisation in January 2002. The NFU code is specifically aimed at on farm processors of milk. The Agency welcomes such industry initiatives and will investigate ways of ensuring that their contents become as widely known as possible. For example, in Scotland the Scottish Dairy Association will circulate and recommend the DIAL Code of Practice to their members.

26. With respect to the enforcement of pasteurisation requirements the Agency is reviewing, as part of the foodborne disease strategy, responsibility for and the approach to enforcement of dairy products hygiene legislation at approved establishments pasteurising milk on farms. The aim will be to determine how the enforcement of pasteurisation requirements in these establishments can be enhanced.

27. A LINK project (partially funded by DEFRA) investigating the pasteurisation conditions and technologies required to eliminate MAP from milk, is currently taking place. The full results of this project will be available in January 2003 and it is planned that information from this study should be utilised when considering future action on MAP.

#### *Evaluation of the Strategy*

28. The strategy consists of a number of elements. Some of these are already being implemented, others can be put in place relatively quickly, whilst others are longer term options requiring further investigation. As the strategy develops and is implemented it will be essential to have some mechanism by which it will be possible to assess whether it is working. At this time, it is considered that the most appropriate way of doing this will be to repeat the milk survey that the Agency undertook in 1999/2000. This will provide information on the levels of MAP and faecal contamination in raw and pasteurised milk and details of pasteurisation times and temperatures.

## **ANNEX 1: ACTION PLAN**

### **SHORT TERM: within next 12 months**

- assess and validate current methods for detecting MAP infection in cattle.
- produce guidance for farmers on the control of MAP infection, which could be included in farm assurance or herd health schemes.
- conduct research into teat cleaning practices and publish advice.
- recommend that dairies maintain their current pasteurisation procedures until the outcome of research on the pasteurisation conditions required to eliminate MAP is known.
- conduct research to find effective ways of treating milk to eliminate MAP.
- set up a consultative group to bring together those responsible for DEFRA's Johne's disease control strategy, the industry and other major stakeholders.

### **MEDIUM TERM: 1 – 5 years**

- conduct a survey of MAP infection in the UK dairy herd.
- review current advice on hygiene practices during milking with a view to issuing consolidated guidance.
- review ways of disseminating advice on hygiene practices during milking so as to optimise future delivery.
- produce pasteurisation guidance for dairies (to be aimed particularly at small dairies and on-farm pasteurisers).
- implement measures to improve inspection and enforcement (particularly in relation to on-farm pasteurisers).

### **LONG TERM: 5 years plus**

- repeat of 1999/2000 FSA survey of MAP in raw and pasteurised cows' milk.
- development of a better vaccine against MAP for use in cattle.

## ANNEX 2: SUMMARY OF RESEARCH ON MAP IN THE UK

### COMPLETED

#### FUNDED BY MAFF/FSA

Title	Contractor	Start date	End date	Summary of findings
Testing food for MAP and pathogenic atypical mycobacteria using DNA probe assays	St George's Hospital Medical School	3.12.90	2.12.93	MAP genetic material was found in 22 (7%) of 312 samples of commercially pasteurised milk collected between 1991 and 1993. No viable cells were able to be cultured, even after many months/years.
Heat sensitivity of MAP in milk at pasteurisation temperatures  Effect of HTST pasteurisation on MAP in milk	Queen's University, Belfast  Central Veterinary Laboratory	1.9.93  25.8.94	31.8.94  31.3.95	The projects aimed to establish the efficacy of commercial pasteurisation of milk for the destruction of MAP. Raw milk spiked with high numbers of MAP ( $10^4$ and $10^7$ CFU/ml) was pasteurised by both holder and HTST methods. Queen's University used the Franklin plate method, CVL used a small scale pasteuriser. Surviving MAP were isolated after holder and HTST pasteurisation from milk samples spiked with both $10^4$ and $10^7$ CFU/ml before heat treatment. In contrast, when <i>M. bovis</i> ( $10^6$ CFU/ml) was spiked into raw milk and subjected to HTST pasteurisation no viable cells were recovered, i.e. HTST pasteurisation effectively inactivated <i>M. bovis</i> but not MAP. The organism exhibited a tailing effect and there was some evidence that this may be due to clumping of the bacteria.
Investigation of the thermal death of MAP at pasteurisation temperatures	Queen's University, Belfast	1.9.94	31.8.95	Further investigations were carried out to determine whether the shape of the thermal death curve was: (1) simply an artefact of the heating method employed; (2) unique to MAP or also exhibited by other <i>Mycobacterium</i> spp.; (3) due to some effect of the milk constituents; (4) due to the presence of a

				heat-resistant sub-population; or (5) due to clumping of cells. Some evidence was obtained that MAP cells existing in clumps of cells remained viable for longer periods during heating than single cells and so it was concluded that the natural tendency of MAP cells to exist as clumps may in some way aid its survival during pasteurisation.
Thermal inactivation of low levels of MAP in milk by HTST pasteurisation	Queen's University, Belfast	1.9.95	31.10.96	The HTST pasteurisation experiments were repeated using the same 10 strains of MAP added to raw milk at lower levels ( $10^3$ , $10^2$ and 10 CFU/ml and 10 CFU/50 ml). Surviving MAP were isolated from pasteurised milk samples originally inoculated with $10^3$ and $10^2$ CFU/ml. However, survival of MAP was never observed when raw milk was spiked with $\leq 10$ CFU/ml before pasteurisation (which would equate to 5000 CFU per 50 ml of milk). The combined results of the high and low inoculum level pasteurisation experiments showed that MAP may survive current HTST pasteurisation (i.e. 72°C for 15 s) if present in milk at levels $\geq 100$ CFU/ml.
Investigation of PCR methods for MAP in milk	Laboratory of the Government Chemist	1.11.96	30.4.97	The project aimed to validate the PCR based method described by Prof. Hermon-Taylor of St George's Hospital Medical School, to investigate alternative sample processing methods appropriate for use when analysing milk using PCR and to assess the overall suitability of PCR as a method for the large scale surveillance of retail milk for the presence of MAP.
Characterisation of non-linear thermal inactivation kinetics observed with MAP in milk	Queen's University, Belfast	1.11.96	31.10.00	In an effort to identify a time/temperature combination that would ensure the complete inactivation of high numbers ( $10^6$ CFU/ml) of MAP spiked into raw milk, experiments were carried out to investigate the effect of higher pasteurisation temperatures (75, 78, 80, 85 and 90°C for 15 s) and longer holding times at 72°C (20 and 25 s) on the destruction of MAP. Three of the most heat resistant MAP strains identified during previous studies were subjected to each of the above time/temperature combinations. Survival of MAP after HTST pasteurisation was found to be sporadic, but not impossible, at temperatures up to 90°C. A longer holding period at 72°C proved to be more effective in inactivating MAP than a higher pasteurisation

				<p>temperature. These findings suggest that the duration of heating is more important for the inactivation of MAP in milk than the intensity of heating. The thermal inactivation curve for MAP heated in milk at holder pasteurisation temperature (63°C) was found to be non-linear and exhibited “tailing”. In the early stages of heating (0-10 min) rapid cell inactivation occurred but in the latter stages of heating low numbers of MAP survived for extended periods (10-30 min). A number of possible explanations for “tailing” were investigated and results indicated that this phenomenon was not simply an artefact of the heating method, nor due to some effect of the milk constituents, nor due to a heat-resistant sub-population. By means of a viability stain, viable MAP cells were only observed within clumps of predominantly heat-killed cells at heating times corresponding to the “tail” region. Furthermore, clumped MAP cells have been shown to be twice as heat resistant as declumped (single) MAP cells and macrophage-engulfed MAP cells were more heat resistant than freely suspended cells. These findings provide circumstantial evidence that the non-linear thermal inactivation kinetics exhibited by MAP in the laboratory studies are due to the existence of cells as tight clumps.</p>
<p>Survey of the incidence of MAP in cows, sheep and goats milk in England, Wales and N. Ireland</p>	<p>Queen's University, Belfast</p>	<p>1.4.97</p>	<p>31.10.00</p>	<p>MAP was detected by IMS-PCR in one sample of goats' milk but not isolated by culture from any of the 14 raw sheep and 90 raw goats' milk samples tested. MAP was isolated by culture and detected by IMS-PCR in 1.7% and 10.4% of cows' milk samples, respectively. Viable MAP was isolated from 4 (1.6%) raw and 10 (1.7%) pasteurised milk samples, seven of which had been heat treated at 72-74°C for 15 s and the remainder at 72-75°C for the extended holding time of 25 s. It was concluded that MAP is capable of surviving commercial HTST pasteurisation of milk on occasion and, therefore, pasteurised cows' milk does represent a potential vehicle of transmission of MAP to humans.</p>

## FUNDED BY DEFRA

Title	Contractor	Start date	End date	Summary of findings
Assessment of surveillance and control of Johne's disease in farm animals in Great Britain	Scottish Agricultural College	January 2000	March 2001	<p>The purpose of the report was to assess the surveillance and control of Johne's disease in farm animals with a view to recommending appropriate systems of surveillance and control for Great Britain. This was carried out by considering not only what had been achieved in this country but also taking into consideration the international situation.</p> <p>Current passive surveillance systems are capable of demonstrating changes in the annual trend of diagnoses but cannot provide information on which to base an estimate of national prevalence. Such an estimate is necessary in order to determine which form of control is appropriate and to calculate the resource to be allocated. Once tests have been adequately validated a national survey should be carried out repeated at five-year intervals.</p> <p>Vaccination has been shown to reduce the number of clinical cases in an infected dairy cow herd and to deliver a positive cost benefit. No study has demonstrated that vaccination is of value in beef cow herds. However vaccination does not significantly reduce the number of cattle that are infected in all herds and vaccinated animals that are sold to other herds will remain an effective route for the spread of the disease.</p> <p>For the control of the disease, similar methodology to that used in USA and Australia was recommended i.e. programmes based on annual testing of adult stock to demonstrate absence of disease, supported by biosecurity systems in the form of management rules on hygiene, the prevention of feeding calves milk or colostrum from cows other than their dam and the control of added animals.</p> <p>Average current losses for an infected 100 cow dairy herd were estimated to be £2600 per annum and £1617 per annum for the average 100 cow beef herd. This gives annual losses due to paratuberculosis of £9.8 million for the dairy herd and £3.1 million for the beef herd.</p>

## ONGOING

### FUNDED BY FSA

Evaluation of the effectiveness of different teat cleaning regimes prior to milking. (Project proposals currently being appraised)

### FUNDED BY DEFRA/DAIRY INDUSTRY

<b>Title</b>	<b>Contractor</b>	<b><u>Start date</u></b>	<b><u>End date</u></b>	<b>Aims</b>
FQS14: Reduction of risk associated with contamination of raw milk by <i>Mycobacterium avium</i> subspecies <i>paratuberculosis</i>	Hannah Research Institute	3.1.01	2.1.03	<p><b>Phase 1:</b> Carry out pasteurisation trials using a response surface methodology approach to assess the effect of various time, temperature and homogenisation conditions on the inactivation of MAP in milk.</p> <p><b>Phase 2:</b> Carry out further trials using more defined time/temperature conditions derived from Phase 1.</p> <p><b>Phase 3:</b> Verify that the optimum pasteurisation conditions identified during Phase 1 and 2 achieve a consistent minimum 5-decimal reduction in viable MAP using a variety of strains and naturally infected milk (if available).</p> <p><b>Phase 4:</b> Investigate the effect of centrifugation on MAP removal using laboratory simulation and pilot scale plant.</p> <p><b>Phase 5:</b> Investigate the effect of microfiltration on MAP removal using laboratory simulation and pilot scale plant.</p> <p><b>Phase 6:</b> Investigate the nature of MAP clumping.</p> <p><b>Phase 7:</b> Analyse and collate experimental data and prepare final report.</p>

FUNDED BY SEERAD and EU

SAC project on MAP infection in rabbits and whether the species can maintain the infection in the absence of domestic ruminants.

**FUTURE RESEARCH AREAS**

- Surveillance of UHT and certain milk products (e.g. powdered milk) for the presence of viable MAP.
- Vaccine development
- Timing and levels of MAP shedding in faeces and directly into milk.
- Survival of MAP in the environment



## Evidence relating to the thermal resistance of MAP in relation to conventional HTST pasteurisation and HTST pasteurisation at higher temperatures and/or for longer times

### Introduction

1. The strategy for reduction of MAP in milk is premised, to a large extent, on evidence suggesting that conventional HTST pasteurisation (15 secs at 71.7°C) cannot be relied upon to remove all MAP from milk. Whilst there is controversy about the degree of heat resistance and its explanation, there is general agreement that MAP is more heat-resistant than the other organisms (including other *Mycobacteria*) likely to be present in raw milk. Current pasteurisation standards are based on the destruction of *Coxiella burnetii*, which is more heat resistant than *M. bovis*, *M. tuberculosis*, *Brucella* spp. and *Streptococcus* spp.
2. The purpose of this annex is to summarise the various strands of evidence and to consider whether, if conventional commercial HTST pasteurisation does not eliminate MAP at levels found or likely to be found in raw milk, there is adequate evidence that changing pasteurisation conditions will achieve this. In particular, the question of extending the pasteurisation holding time to 25 seconds will be considered.
3. There are three types of evidence that bear upon the question of the heat resistance of MAP:
  - laboratory studies of heat resistance based on spiked milk samples
  - laboratory studies of heat resistance based on naturally infected samples
  - surveys of MAP in milk following commercial pasteurisation.

### Laboratory studies of heat resistance based on spiked samples

4. Seven published studies of laboratory pasteurisation using spiked milk samples have been identified<sup>1-7</sup>. Most have investigated both low temperature pasteurisation (at temperatures around 63°C) and HTST pasteurisation. Concentrating on the latter results alone, four of the studies show reductions in bacterial counts in excess of 4 logs (ten thousand-fold), whilst the other three show much more modest reductions in the order of 1-3.7 logs. Preliminary information from three other groups is also available<sup>8</sup>, two supporting the higher figure, the other tending to confirm the lower.
5. The variation in results is almost certainly a result of different methodologies and there is considerable debate as to which methodology provides the truest results. These issues are covered in two recent review papers<sup>8,9</sup> and will not be discussed further in this annex.

6. Only three of the published papers provide D values, which indicate the time taken for a 1 log (10 fold) reduction in the bacterial count, but only two of these provide values for 71/72°C. Data on D values at 72°C is also available from one other unpublished study. The two published studies provide a good measure of agreement, with values of 12 and 14 seconds respectively. The unpublished study suggests a much lower D value of less than 2 seconds. However, this study also gives a D value of 15 seconds at 63°C, which is at odds with the range of 1-3 minutes found in 4 other studies, suggesting that the method for recovering organisms used in this study was not sufficiently sensitive.
7. Comparing the data available on the thermal sensitivity of MAP with the 72 studies on which a review of the thermal sensitivity of *E. coli* O157 was based<sup>8</sup>, there is clearly a need for further studies based on an agreed methodology. However, for the purposes of this paper, it does not seem unreasonable to conclude that the D value at 72°C could be around 12 seconds, or possibly longer. If that is the case, a pasteurisation time of 23 seconds would only be sufficient to effect a 2 log (100 fold) reduction in the bacterial count. Therefore, MAP might well survive pasteurisation if present at levels in excess of 100 cfu/ml. Moreover, on the basis of this data, the difference in effectiveness between a pasteurisation time of 15 seconds and one of 25 seconds is likely to be less than 1 log and is therefore unlikely to be very significant. In theory, only if counts in raw milk were consistently in the order of 100 cfu/ml would there be a situation in which MAP survived 15 seconds but was not found in samples pasteurised for 25 seconds.
8. There is relatively little data on actual MAP counts in milk and these tend to be based on samples of milk from individual animals, probably taken under conditions that eliminate or markedly reduce any possibility of faecal contamination. Levels measured in this way tend to fall well below 100 cfu/ml. However, the count in commercial bulked milk will depend not only upon the amount shed by individual animals and the proportion of the herd that is shedding organisms but also upon the level of faecal contamination (since MAP can be present at levels of  $>10^8$  cfu/g in faeces), together with possible dilution through bulking with milk from herds with a low prevalence or no Johne's disease.

### **Milk survey results**

9. Milk survey results are considered at this stage as they were the next finding in historical order. Interim results of this survey, with initial MAP findings, were presented to the Advisory Committee on the Microbiological Safety of Food in September 2000<sup>10</sup> and further details were provided to those attending the open meeting on 23 January 2002<sup>11</sup>.
10. A total of 2042 samples of milk were examined in the study, of which 814 samples were tested for MAP (244 raw milk samples, 567 pasteurised and 3 UHT). MAP was found in 1.6% of raw milk samples and in 1.8% of pasteurised milk samples. Of the 10 pasteurised samples in which MAP was detected, 3 had undergone a prolonged holding period of 25 seconds, one at 72°C and two at higher temperatures. Neither results of testing for other organisms nor

phosphatase results suggested inadequate pasteurisation and no evidence was found of post pasteurisation contamination of the positive samples.

11. At a recent meeting, colleagues from Belgium reported finding MAP in retail milk. We have not yet seen this result in print and so do not have further information about pasteurisation conditions but it does support the UK finding of MAP in pasteurised milk.

### **Laboratory studies of heat resistance based on naturally infected milk samples**

12. There is just one very recently published study of naturally infected raw cows' milk<sup>12</sup>. In this study samples were pasteurised with a commercial-scale pasteuriser. Viable MAP was recovered from 6.7% of 60 raw milk samples and from 6.9% of pasteurised milk samples. Since there is no method for accurately enumerating MAP in naturally contaminated samples, it was not possible to investigate the numbers present in raw milk when positive results were found after pasteurisation. However, information from the number of positive samples per batch and the strength of the PCR signal provided some indication of a particular occasion on which the load in the raw milk was particularly great. On this occasion MAP was isolated from samples pasteurised both for 15 seconds and for 25 seconds, with or without homogenisation. One other samples pasteurised for 25 seconds was also found to be positive and the overall conclusion was that the extended 25 second holding time was no more effective at killing MAP than the standard 15 second holding time.
13. Phosphatase testing was carried out to verify that pasteurisation conditions had been achieved but it is not clear which method was used. No tests for other microbiological parameters were carried out. However, the results appears consistent with the findings from the UK milk survey in finding similar proportions of positive samples before and after pasteurisation and in finding positive samples after extended holding times of 25 seconds.

### **Conclusions**

14. There is a relative paucity of laboratory studies of spiked milk samples. However, the information that is available suggests that the D value of MAP could be in the order of 12-14 seconds. On theoretical grounds, therefore, MAP could survive pasteurisation for 15 seconds if present at levels greater than 10cfu/ml and at 25 seconds if present at levels greater than 100cfu/ml.
15. A large survey of UK milk demonstrated the presence of MAP in milk pasteurised at holding times of both 15 seconds and 25 seconds and a study of naturally contaminated milk has recently suggested that 25 seconds holding time is no more effective than 15 seconds in killing MAP.
16. The weight of evidence is currently against there being any demonstrable benefit in increasing pasteurisation holding times to 25 seconds if the aim is total elimination of MAP from drinking milk. It could have a benefit if there was a threshold level of exposure associated with human disease but, as the link to human disease remains to be established, the question of a threshold cannot be determined.

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