



**EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL**

Unit 04 -Veterinary Control Programmes.

Brussels, 10/08/2006

SANCO/10200/2006 final

Working Document

on

Eradication of Bovine Tuberculosis in the EU

**accepted by the Bovine tuberculosis subgroup of the
Task Force on monitoring animal disease eradication**

This document does not necessarily represent the views of the Commission Services

1. Introduction

The purpose of this document is:

- to review the general principles that constitute the basis for strategic planning for the future
- to propose short term measures in order to accelerate the progress of eradication programmes
- to draw conclusions on perspectives on eradication
- to stimulate discussion on future strategy

The proposed measures must be explored and assessed based on the individual situation in each Member State (MS) running an eradication programme for bovine tuberculosis.

1.1. Definition

For the purpose of this document, the definition of bovine tuberculosis (TB) is: “Infection in cattle with any of the disease-causing mycobacterial species within the *M. tuberculosis*-complex”.

1.2. Legal framework

The Community legal framework on TB is formed by legislation on trade of bovine animals (Directive 64/432/EEC), legislation on animal products for human consumption (Directive 64/433/EEC, Directive 92/46/EEC and Regulation No. 2004/853/EC) and legislation regarding Community co-financing of eradication programmes (Directive 77/391/EEC and Decision 90/424/EEC).

The first legal initiatives on TB at Community level were aimed at facilitating intra-community trade among the EEC Member States by establishing comparable health requirements. Council Directive 64/432/EEC defined specific requirements for the trade of cattle in relation to TB and defined the officially tuberculosis-free (TBOF) status of bovine animals and herds.

Directive 64/432/EEC establishes that bovine animals consigned from one Member State to another must originate from a TBOF herd and have been submitted to a pre-movement tuberculin test. The pre-movement test is exempted for animals from herds located in a TBOF free Member State or region and for animals sent directly for slaughter. The procedures for gaining, maintaining, suspending, withdrawing or re-gaining the TBOF status are laid down in annex A to Council Directive 64/432/EEC and are based on the results of tuberculin tests at herd level. A key concept of this legislation is that a Member State or part of a Member State may be declared TBOF if certain requirements are fulfilled. Annex B deals with the diagnosis of TB; this annex was thoroughly reviewed in 2002 to incorporate new methods and to align more with the Office Internationale des Epizooties (OIE) health standards.

Council Directive 64/433/EEC establishes the procedures for the post-mortem inspection at the slaughterhouse. Some of these measures are specifically aimed at the detection of lesions of TB. Meat from animals with generalised TB must not be declared fit for human consumption and strict conditions are laid down for the inspection of carcasses of animals that have shown a positive or inconclusive reaction to the tuberculin test.

Community measures regarding milk hygiene are laid down in Council Directive 92/46/EEC and are essentially the same in Regulation (EC) No 853/2004. Only milk from TBOF herds can be used for human consumption without heat treatment. Milk from animals that have

shown a positive or inconclusive reaction to the tuberculin test may not be used for human consumption in any case.

An important further step was Council Directive 77/391/EEC which introduced Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle. Member States were obliged to draft eradication programmes in order to accelerate, intensify or carry through the eradication of TB. Financial support from the Community for these programmes was also foreseen. This legislation was amended and completed by Directive 78/52/EEC, Directive 82/400/EEC and Directive 87/58/EEC and provides a legal framework for the TB eradication programmes.

Council Decision 90/424/EEC on expenditure in the veterinary field lays down Community financial measures on eradication and monitoring programmes aimed at progressively eliminating animal diseases that are endemic in certain areas of the Community. Detailed rules for reporting on the progress of eradication programmes are contained in Commission Decision 2002/677/EC while Commission Decision 2004/450/EC provides a standard format for Community financed programmes.

2. Visions for the future

2.1. Experts' input

Several recent initiatives have been taken at international level and at MS level to address the major constraints to the eradication of TB. In addition, a number of strategies have also been proposed.

Some of the conclusions¹ of the workshops held during the 4th International Conference on *Mycobacterium bovis* provide well focused recommendations that should be kept in mind for the design of future strategies:

1. Epidemiological data analysis and monitoring of the progress of most programmes should improve. For this purpose more refined indicators to measure the level of infection and progress of the programme are required.
2. The tuberculin test performs well at the herd level but has limitations when used at the level of the individual animal. Its performance can be improved by increasing the extent of coverage of the total cattle population and the intensity at which the test is applied. Compliance with 64/432/EEC (trading rule) requirements alone does not provide for an optimal testing regime in order to eradicate the disease because of the diversity of situations in different MSs and regions in which it is used.
3. Extended use of IFN γ test on a strategic basis to supplement the tuberculin skin test.
4. Improve the efficiency of slaughterhouse surveillance by focussed training, improved supervision and ensuring effective communication between the meat inspection services and animal health services.
5. The reservoir of infection within wildlife populations should be effectively addressed.
6. All stakeholders should fully participate at every stage in the eradication programme and should be involved in the development and delivery of an agreed, integrated and sustainable and effective programme. Such a programme should have clear objectives, an operational science-based strategy, sound financial commitment by government, the

¹ Workshop report / Veterinary Microbiology 112 (2006) 383–391

continued availability of other relevant resources and the practical support of the other stakeholders. Such a programme will require constant monitoring of delivery, auditing and assessment in terms of progress in eradication and utilisation of resources including funding.

7. The development of a vaccine for wildlife should be a priority for research.

Strategic planning should consider the following²:

- a) An integrated approach that takes account of the separation of risk assessment and risk management roles.
- b) Improvement of between-herds and intra-herd movement control in order to avoid the introduction or re-introduction of TB.
- c) Improvement of the detection of infected herds by the use of an appropriate interpretation of the skin test, the use of ancillary tests and enhanced meat plant surveillance.
- d) Improvement of the management of infected herds, ensuring that all sources of infection have been removed (e.g. anergic and other non-reactors to tuberculin, including cattle identified on epidemiological grounds, and infected wildlife) and that measures to avoid reintroduction are in place (wildlife-proof fences), by ensuring proper epidemiological investigation of outbreaks to identify the source of infection and the implementation of a well focussed action plan aimed at stamping out infection in these cases.
- e) Improved management of wildlife by strategic removal of infected wild animals.
- f) Public health measures (including enforcement of rules on milk hygiene).

To summarise, there is general agreement on certain general issues and on some specific measures that have been identified as key points that require to be addressed in order to further improve the effectiveness of the eradication programmes. Some of these are measures based on the principles of infectious disease control that in general need sufficient time to be implemented. Horizontal measures, which can also apply to the management, control and eradication of other infectious diseases, require further investment to address the following:

- Research on vaccines and diagnostic tools.
- Efficient and effective strategic planning of an efficient and effective programme that inevitably depends on the participation, commitment and delivery of the support of all stakeholders
- An integrated approach that takes due account of the complementary roles of risk management and risk assessment in the planning and delivery of the eradication programme
- A good organization, administration, coordination and supervision of the activities of the programme and an effective means of interaction and communication between all the parties concerned
- Full enforcement of current legislation along with a review and, where necessary, amendment of the legislation.

Similarly, specific measures related to TB eradication, that are largely in line with the conclusions and recommendations drawn up previously by the Task Force, are also identified. The implementation of most of these specific measures is considered to be feasible in the short term.

² J.D. Collins / Veterinary Microbiology 112 (2006) 369–381

Accordingly, an assessment of additional specific reinforcing measures aimed at increasing the effectiveness and efficiency of current eradication programmes is now appropriate.

Two groups of measures are identified:

- Issues to be addressed in a wider context
- Specific short term measures

2.2. Issues to be addressed in a wider context

Two cornerstones of the eradication programmes have been insufficiently addressed in many of the MS where TB remains as a problem. These are:

- Stakeholder involvement
- Use of meat inspection as an essential surveillance tool.

2.2.1. Stakeholder involvement

It is essential that all stakeholders involved in the eradication programme, independent of their respective roles and responsibilities, actively commit and contribute to the full implementation of all the measures of the programme. Therefore the programme should clearly define the tasks and duties for each one of the players.

Every individual player should be aware of his/her responsibilities and what is expected from him/her in the context of his/her involvement in the programme. This is better attained by adopting a holistic approach to the programme's management and delivery at the level of the farm, private veterinarians, abattoir, official veterinary services and local, regional and national administration. This overall approach should clearly define these responsibilities and ensure the sustained commitment of all concerned parties.

In order to ensure that the stakeholders fully understand their role in ensuring the success of the eradication programme and to obtain the highest degree of commitment, the programme should take into account specific positive stimuli that apply to each participant so as to encourage their sustained participation in and contribution to the progress of the programme. At the same time, sanctions or corrective actions should also be foreseen so as to avoid certain actions or to address any perceptions and attitudes that could be a constraint for the accelerated elimination of TB.

In summary, the authorities in charge of the programme have an opportunity to re-design a programme that incorporates a system of "rewards" and "penalties" aimed at encouraging other stakeholders to take due account of their role in the eradication of TB and to fully cooperate with the implementation of all of the measures contained in the programme.

2.2.2. Use of meat inspection as an essential surveillance tool

The slaughterhouse is a unique facility that provides essential information on the actual situation and changes in trends of TB and other diseases at both the herd and regional level. The information obtained through efficient meat inspection at the slaughterhouse cannot be replaced by information coming from the farm alone. The combination of reliable high quality information from both sources is needed³.

³ Tuberculosis in Bovine Animals: Risks for human health and control strategies. The EFSA Journal (2003) 13, 1-52,

The detection of TB in the slaughterhouse is influenced by several factors related to animal conditions, such as stage of infection, anergy or desensitisation, that should be taken into account. Thus, while the detection of tuberculous lesions in tuberculin-reactors at slaughter is to be anticipated in many instances, such detection can also be made in animals that have not reacted to tuberculin. The performance of the inspection procedures in place at the slaughterhouse is influenced both by the physical conditions under which inspection is performed, and the efficiency of such inspection. These factors are of primary importance and should be competently and continuously supervised and monitored.

In accordance with current legislation, it is necessary to proceed with a detailed ante- and post-mortem examination, especially but not exclusively for animals coming from non-officially tuberculosis-free herds. Inspection protocols should be rigorously followed as an integral part of both the hygiene procedures and the disease eradication programmes for all bovine animals.

Moreover, slaughterhouse surveillance is of particular importance in TBOF herds/areas/regions as, in this case, herds are not regularly tested and abattoir surveillance is the only means available for the detection of TB

Monitoring and auditing of meat inspection by means of a proper assessment of certain key indicators such as suspected lesion submission rates, detection rates of animals with confirmed tuberculous lesions per category of animals and the data submitted from slaughterhouses on a quarterly or more frequent basis should be in place as an integral part of the eradication programme. Audit of the meat inspection services should be considered as addressing the needs of TB surveillance as well as the other needs of public health.

Enhanced co-ordination and collaboration between animal health services and meat inspection services, in which the collection and analysis of meat inspection findings and of their application, in real time, to the assessment of the current status of herds or groups of herds in an area or region, is a particular goal, should be regarded as an essential component of the programme of eradication of TB. In those MSs in which such collaboration is impeded as a result of their separation between the human and/or animal health structures of government, at regional or national level, this impediment should be addressed immediately so as to guarantee the enactment of effective, formalised protocols that ensure timely communication and reciprocal feed-back on an ongoing and sustained basis.

2.3. Specific short term measures

It is necessary to further explore and assess the impact of certain well-defined recommended measures that can be evaluated and incorporated into TB eradication programmes in the short term.

Those deemed appropriate for the current situation in a particular MS should be applied to a relevant degree and, for those deemed inappropriate, a sound explanation for disregarding or modifying them should be provided.

The specific measures are:

- Use of severe interpretation of the tuberculin test in infected herds and herds at special risk
- Strategic use of the IFN- γ assay
- Increased frequency of herd testing
- Implementation of the pre-movement test in areas and regions of high prevalence
- Definition and application of the epidemiological unit of concern

- More extensive use of epidemiological data analysis: indicators
- Stamping out in infected herds: criteria, application and assessment
- Wildlife removal/alternatives.
- Re-appraisal of compensation schemes
- Re-define and strengthen restrictions on animal movements

2.3.1. Severe interpretation of the tuberculin test in infected herds and herds at special risk

The Standard Interpretation of the tuberculin test is described in Annex B.2.2. to Directive 64/432/EEC (trade context). The severe interpretation of the tuberculin test effectively means that the inconclusive reactors as defined in 64/432/EEC are to be considered as positive reactors and are to be removed for slaughter from the herd. Other more severe interpretations of the test can be applied.

The tuberculin test in its various forms is the sole test prescribed in Community legislation. While the tuberculin test has been an effective tool when applied at herd level, a lack of sensitivity at the individual animal level is recognised to be a major limitation of the tuberculin test. An increase in the sensitivity (Se) (identifying fewer false test-negative but infected animals that remain in the herd) of the test is achievable by changing the cut-off point of the test. However, specificity (Sp) of the test could be lowered (more false test-positive but healthy animals are removed from the herd) when the severe interpretation is used.

The cut-off point, or threshold, of a diagnostic test and consequently its Se and Sp can be modified in use. Fixing the optimum cut-off threshold should be based on the overall performance of the test at different thresholds (ROC curve) against the background of the prevailing epidemiological circumstances (prevalence).

In high prevalence areas the application of the severe interpretation of the tuberculin test may present a favourable balance in cost/effectiveness terms as it is more likely to give a more reliable basis for the removal and elimination of infected animals in a shorter time than would otherwise be the case. As this approach gives rise to the elimination of a greater number of tuberculin reactors in the short term, a number that includes a greater number of reactors that are truly infected as well as a greater number of apparently non-infected but tuberculin-reactor animals than would have been identified using the standard interpretation of the tuberculin test, an increase in the costs of the programme in the short term is unavoidable. In the longer term, a reduction in overall costs may be expected.

The herd prevalence level where the severe interpretation of the test is to be used and the ROC characteristic of the skin test are the essential parameters to be considered when making this choice.

2.3.2. Strategic use of the IFN- γ assay

Parallel testing (using the tuberculin test and the IFN- γ assay concurrently) as prescribed in Annex B.3 to 64/432/EEC in order to detect the maximum number of infected animals in a herd or region of high prevalence increases the sensitivity of the diagnostic regime. Optimised use of parallel testing allows the detection of 2 out of every 3 false tuberculin-negative but infected animals that would otherwise have remained in the herd if the tuberculin test alone had been used.

By using the severe interpretation of the tuberculin test in parallel with the IFN- γ assay, it appears that it is possible to increase the Se of the diagnostic regime up to 0.95 or even 0.98 in heavily infected herds⁴.

The use of the IFN- γ assay in parallel with the tuberculin test in these instances results in a considerable increase in Se and this allows the earlier removal of a considerable number of infected animals that would have given a false negative reaction to the skin test and would otherwise have remained unidentified in the herd for an undetermined period. However, the use of parallel testing slightly reduces the Sp to 0.95.

However, if concomitant diseases (e.g. paratuberculosis) are present in the herd or cohort under test, this may affect the accuracy and reliability of either or both of these diagnostic tools. Accordingly, this factor should be taken into account. Nevertheless, the strategic use of IFN- γ in combination with an increased frequency of tuberculin testing in herds in areas or regions of known high prevalence may be a logical approach to TB eradication and should be considered despite the fact that the negative predictive value, Se and Sp of either the tuberculin test or the IFN- γ assay, or both, may be compromised by the concurrent presence of these other diseases.

Some drawbacks are the additional direct and indirect laboratory-related costs to perform the IFN- γ assay and also the logistic requirements linked to the collection of blood samples, their delivery to the laboratory within a specified period and the conditions of incubation of the samples with appropriate reagents which the assay requires represent a constraint in more remote areas.

The IFN- γ assay should not be considered for use as a routine screening test in areas or regions where the herd prevalence is low. On the contrary, its use in parallel with the tuberculin test in highly infected areas is recommended as an effective means of attaining a higher Se for the diagnostic regime. Furthermore, in herds already deemed TB-positive, the IFN- γ assay should be considered for use at the first retest in parallel with the tuberculin test on such herds, after the index test, so as to remove the infection with the maximum Se.

The herd prevalence level at which the IFN- γ test is to be used in parallel with the tuberculin test, and the conditions for its use in herds regaining their TB-free status, needs to be defined.

2.3.3. Increased frequency of herd testing

The minimum frequency of tuberculin tests on herds, i.e. once a year, is laid down in Annex A.I.2.c for regions with herd prevalence greater than 1%. However, in order to accelerate eradication it is recommended to increase the frequency of tuberculin tests on unrestricted herds in high prevalence areas to more than the current minimum requirement. Different frequencies are to be considered, such as twice a year, three times every two years or every 10 months⁵.

An increase in the testing frequency from the annual test reduces the reproduction rate of the disease (i.e. number of animals that acquire infection from an infected animal during a stated period of time). Only when the reproduction rate is substantially below 1 for all sources can eradication of the disease be considered achievable.

A higher testing frequency contributes directly to the reduction of the reproduction rate by enabling earlier detection of infected animals and their early elimination. However, additional

⁴ E. Gormley et al. / Veterinary Microbiology 112 (2006) 171–179.

⁵ D. Cox et al. / PNAS 102, no. 49 (2005) 17588-17593.

testing costs can be anticipated due to the increase in the total number of tuberculin tests carried out in any one year.

The optimum ratio of herd prevalence and frequency of tuberculin testing on herds in regions of high frequency, taking into account the local prevailing conditions, including other reservoirs of the infection, needs to be established and later reviewed in line with the progress of eradication in these regions.

2.3.4. Implementation of the pre-movement test in areas and regions of high prevalence

Movement of infected, yet undetected, cattle provides a well-established means of spreading TB from herd to herd. The performance of a tuberculin test prior to and/or after movement may provide some assurance in regard to the risk of introducing TB into herds through the introduction of such cattle from another herd.

The within 30 days pre-movement (or post-movement) test is considered in Annex A.I.1.c as the rule for all cattle movements in non-TBOF MS. The competent authorities in these MS may derogate for domestic movements.

The application of the pre-movement and/or post-movement test reduces the risk of cattle-to-cattle spread of TB between herds or within the herd (if several parcels are used) where the incidence is not very high and provides some assurance for the purchaser in this regard. It also serves indirectly as an additional assessment of the TB status of the herd of origin. This also applies to the movement of cattle into and between herds in areas or regions of high prevalence. Likewise, the movement of cattle from unrestricted herds in these regions to herds outside these regions poses a relatively higher risk of spread than would otherwise be the case, due to the insidious nature of TB and the limitations of the tuberculin test, in terms of Se, particularly when the test is conducted on single or low numbers of animals. Furthermore, if there is contact with an infected wildlife population in the area, this provides a further means of herd to herd spread of TB, in addition to cattle-to-cattle spread, with this risk being substantially greater in herds in areas of high prevalence.

There are additional testing costs associated with pre-movement and post-movement tuberculin testing. A cost-benefit and/or cost-effectiveness ratio of pre-movement testing would be appropriate in order to determine whether or not this measure is beneficial if introduced as a mandatory measure on (a) a national basis, or (b) a regional basis in regions of high prevalence, when compared to other measures.

The control of animal movements between herds, and in particular, the control of animal movement out of farms or regions known to have a high prevalence of disease is a basic principle of animal disease control and can be highly effective as in the case of brucellosis in cattle. The use of the derogations provided for in EU legislation regarding pre-movement tuberculin testing should be considered only for herds in low prevalence areas and in the context of a sound epidemiologically rational approach. See also Section 3.3.10. below.

The herd prevalence level of the region and the type of movements where the pre-movement test could most usefully be implemented are to be defined.

2.3.5. Definition and application of the epidemiological unit of concern

The primary unit of concern or epidemiological unit for TB is the herd. "Herd" in the legal context of 64/432/EEC is defined as "an animal or group of animals kept on a holding (within the meaning of Article 2 (b) of Directive 92/102/EEC) as an epidemiological unit; if more

than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status”. However, from an epidemiological point of view in the context of TB eradication, the epidemiological unit can be defined as “any number of animals that are held, kept or handled in such a manner that they share the same likelihood of exposure to TB and the control of the spread of infectious disease from the unit can be facilitated”.

In practical terms, two (or more) groups of animals belonging to the same owner but without any other link or contact between them would constitute two (or more) epidemiological units, whereas two (or more) groups of animals belonging to two (or more) owners but kept together, or are in contact with one another, constitute a single epidemiological unit. When production conditions result in frequent contact between animals (or mixing), then the entire group of animals should be considered as one epidemiological unit.

From an epidemiological perspective, the fragmentation of holdings and/or management linkages between farms presents a problem for TB eradication. Therefore it is necessary to define the epidemiological unit in an appropriate and clear way, using the appropriate criteria.

In fact, currently in some cases the herd is not the epidemiological unit of concern for TB eradication. The definition “epidemiological unit” should be formalised with the necessary legislative backing. This definition is a “sine qua non” requirement in order to make it possible for the rest of the measures of the programme to work effectively.

Legislation should empower the veterinary services to make the necessary decisions in order to guarantee that the appropriate epidemiological unit is used as the primary unit of concern for all the measures of the programme. When one considers the significant role of spread of infection between herds kept on contiguous holdings as a serious impediment to TB eradication, herd owners and their representative bodies require to be informed as to why this approach is so necessary in order to effectively address the issue of spread of infection in the context of TB eradication and to have an understanding as to why amendments to current legislation may be required.

This key issue should be addressed, taking into account the prevailing practices used in animal production in each MS.

The wide range of cattle industry systems in operation in the EU does not allow an EU-wide definition of “epidemiological unit” for TB eradication purposes. This issue requires to be addressed at the individual MS level.

2.3.6. Epidemiological data analysis: indicators

Basic indicators for the follow-up of the co-financed eradication programmes are provided in Commission Decision 2002/677/EC. However, when evaluating the progress of the programmes, international ‘trading rules’ are frequently used as the sole or main benchmark. Measuring progress concerns more than simply assessing data that are easy to retrieve. It also requires an evaluation of the effectiveness of the measures currently in place. Therefore, more appropriate, and sometimes more sophisticated, indicators adapted to the needs of each programme, could be developed and applied at MS level.

The use of appropriate indicators to evaluate the individual components of the programme is necessary for a proper assessment of the management of the programme at regional/national level, with a view to identifying how different issues currently posing an obstacle for the eradication can be addressed. However, some of the more relevant indicators may require additional information to be recorded or analysed.

Proper management of each programme requires the assessment of the most suitable information. The “reproduction rate” of the disease (net and or basic) is a good example of an indicator.

Expertise on epidemiology is needed at MS level to identify and provide the most appropriate indicators for each epidemiological situation.

2.3.7. Stamping out in infected herds: criteria, application and assessment

Stamping out is a drastic but very efficient option for the eradication of TB, provided that the infection is removed from the epidemiological unit and that restocking is not a means of re-introducing the infection.

The decision whether to use stamping out or not should be based on a consideration of certain essential criteria that should be defined in advance. The prevalence in the area, the intra-herd prevalence, the persistence of an infected wildlife reservoir, contact with other cattle or susceptible species, the persistence of mycobacteria in the environment under local conditions, the interval before restocking, herd size, enterprise type and the type of husbandry, prevailing bio-security measures, farm security in relation to contiguous holdings (fences) and the ability and willingness of the herdowner(s) to conform with conditions pertaining to the stamping out protocol. Also, account should be taken of additional criteria assessed by the local veterinary services in relation to the decision to proceed with stamping out.

Provided depopulation of a herd is carried out in accordance with a well-defined and appropriate strategy, then there is a reasonable likelihood that the reconstituted herd or epidemiological unit will remain free from the disease. The selection of candidate herds for depopulation involves an assessment of the TB status of contiguous herds and requires some constraints on the selection of replacement stock so as to ensure that these are not themselves a source of infection. At regional level the application of this strategy in regard to the approach to those infected herds remaining towards the end of the programme will enable effective eradication of TB provided other sources of infection, such as an infected wildlife reservoir, do not pose a major risk.

The definition of these criteria and of the strategy for the use of depopulation under specified local conditions is needed.

The decision to adopt a stamping out policy should be formalised in the form of guidelines that identify the criteria to be considered when extensive spread of infection within a herd or group of herds or epidemiological units is diagnosed. Such guidelines would be required to be consulted in detail by local or regional veterinary officers when considering whether or not to apply this option.

Appropriate guidelines that are epidemiologically reliable and which take into account all relevant criteria should be drawn up and formally applied when deciding whether or not to implement herd or regional depopulation as a component of the eradication programme.

2.3.8. Wildlife removal/alternatives

An active approach to the removal of TB-infected wildlife and the urgent development of alternative means of preventing transmission of TB from this source to cattle is proposed.

It has now been reliably demonstrated that the persistence of an infected wildlife reservoir that enters into contact with cattle is a major obstacle to the eradication of TB. This obstacle

should be addressed in tandem with the measures implemented in relation to the cattle population.

While future prospects for the development of suitable TB vaccines for use in wildlife are promising, considerable obstacles remain⁶ which make it difficult to foresee the use of such vaccination on its own as the most suitable tool to use to address the persistence of the variety of infected wildlife reservoirs worldwide in the near future. In the meantime, therefore, alternatives to vaccination, in order to address the role of infected wildlife in the persistence of TB should be implemented without any delay so as to allow the progress of the eradication programmes.

Removal of wildlife, either proactively or reactively following outbreaks, has proven to be an effective ancillary, and in certain situations necessary, measure to control and eradicate TB.

Alternatives to the excessive removal of wildlife populations in high-density areas are based on procedures aimed at the separation of the two populations (cattle and wildlife) by means of effective wildlife-proof fencing. The practicality and effectiveness of such separation of the two populations are frequently jeopardised by the idiosyncrasy of the different types of extensive livestock production and/or the behaviour of the wildlife species involved. Nevertheless, this alternative or complementary approach should always be considered before applying an extensive wildlife removal strategy in the field.

The elimination or reduction of the risk posed by an infected wildlife reservoir enables the other measures contained in the programme to yield the expected results, whereas the persistence of TB in these wildlife populations impedes the effective elimination of the disease.

Major socio-political resistance (lobbyism) against any measure involving the removal of infected wildlife or interventions affecting the environment are to be expected. The additional costs associated with these actions are not likely to be negligible.

Control of infected wildlife species that is based on the strategic removal of members of a selected species in certain areas is nevertheless a necessary and probably unavoidable measure if eradication of TB is to be achieved. Such control measures, however, require to be conducted in parallel with other measures aimed at the separation of these species from local cattle populations and in association with a broader-based programme of efficiently implemented measures in the cattle population.

Strategies to be implemented on wildlife and in particular the removal of infected wildlife need a sound scientific basis and, if applied, should be accompanied by a range of other measures.

2.3.9. Re-appraisal of compensation schemes

The re-appraisal of compensation schemes and their alignment with the level of the herdowner's cooperation with the eradication programme is necessary.

Once adequate compensation is approved, then its payment should be swift. Adequate compensation implies that the compensation does not, in any way, pose an obstacle for the progress and success of the programme.

The compensation scheme should be aimed at modifying the behaviour of the farmers in a way that they do their best to avoid the reintroduction of the disease in their herds.

⁶

B.M. Buddle et al. / Veterinary Microbiology 112 (2006) 191–200

Consequently, a level of compensation that is perceived by the farmers not to be sufficient to allow them to adjust to their new circumstances following the loss of their stock and the imposition of animal restrictions, along with concern associated with the possible reintroduction of the infection, jeopardizes the progress of the programme by engendering an attitude of non-cooperation.

Nowadays, in general, TB does not present with clinical signs in affected animals and the notification of clinical suspicions (passive surveillance) is not the main basis for the detection of the disease but routine testing (active surveillance). Therefore, the level of compensation has no link with the willingness to report clinical signs of the disease by the farmer and should not be aimed at this purpose as is the case for some exotic diseases.

Accordingly, it is extremely important to ensure that the level of compensation is the appropriate and serves to encourage farmers to respond to their situation in an appropriate manner that will prevent or considerably reduce future risk of infection. There is also a case to be made that the compensation is conditional on the herdowner's compliance with stated conditions relating to the prevention of a further outbreak on the holding within a reasonable period. Otherwise, compensation may not be approved, or if approved, would be at a lower rate. Furthermore, compensation should always be at a level below (to a reasonable or, sometimes, significant extent) that of the current market price of comparable healthy animals.

Compensation schemes should be thoroughly and constantly reviewed, taking into account local conditions so as to ensure that the amounts payable are reasonably sound and that the payment is linked to full compliance with stated measures aimed at the prevention of re-infection. Over-compensation should be avoided.

3.3.10. Re-define and strengthen restrictions on animal movements

Movement restrictions result from the application of Directives 64/432/EEC and 78/52/EEC that restrict the movement of animals from herds not qualified as TBOF. These movement restrictions alone are not effective when particular epidemiological conditions prevail. Practices such as transhumance, the use of common grazing areas, the so-called “bed and breakfast” or “flying herds/holdings” or the inclusion of a number of fragments of land as components of one recognised epidemiological unit or unit of concern result in additional difficulties that are not always taken into account when the implementation of the movement restrictions in practice is considered, especially in areas or regions of high prevalence.

Movements of animals that are considered as “intra-herd movements” and which therefore are not restricted in cases in which a tuberculin reactor contained in such a unit has been disclosed or when the TBOF status of the herd has been lost, are of critical importance, as such movement may expose animals in an increased number of contiguous herds to infection.

Another aspect that should be considered is the procedure for a herd/unit re-gaining the TBOF status under certain conditions. The procedure laid down in Directive 64/432/EEC may not be the optimum in all cases. More stringent strategies such as a longer interval (of 90 days or longer) between clear tuberculin tests before this status is regained, or the introduction of an additional clear tuberculin test before TBOF status is regained, could be applied under certain difficult conditions. These strategies could be applied in MS which are not TBOF and in particular, in the case of herds in areas or regions of high prevalence, as a further means of reducing the likelihood of re-infection and movement of infected cattle out of such areas.

Specific procedures for re-gaining the TBOF herd status in high prevalence areas with certain epidemiological conditions or, in restricted herds before the return to trading, may need to be applied.

3. Conclusions

- Eradication of TB is the target at EU level as laid down in Community legislation. Eradication should be feasible in the long term despite the fact that different epidemiological situations in the EU pose certain difficulties that should nevertheless be addressed through specific reinforced measures.
- Requirements of Community legislation are to be considered in the context of the eradication programmes as the absolute minimum level of measures to be implemented. Effective eradication programmes should include additional measures aimed at addressing the different constraints to eradication in each epidemiological situation.
- Full involvement of all stakeholders and optimum use of the abattoir as a surveillance resource that is more fully integrated in the eradication programme should be considered as necessary issues to be specifically dealt with in the context of eradication programmes.
- A set of ten specific short-term measures aimed at strengthening current programmes have been identified. The implementation of some (if not all) of these measures in regions with high prevalence and in which little or no progress has been made in recent years should be addressed. In principle non-implementation of any of these short term measures in areas of high prevalence would require an epidemiologically sound reason, if such a position is to be accepted.
- It would be appropriate for the MS involved to rank the measures in order of priority/effectiveness when allocating the funds available for TB eradication. The diversity of the situations in different MS means that different emphasis must be made on the various measures.