



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

Veterinary and International Affairs

Unit G5 -Veterinary Programmes.

Brussels,

SANCO/10067/2013

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

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1. Introduction

The purpose of this document is:

- to provide guidelines for the design and operation of eradication and surveillance programmes for bovine tuberculosis;
- to provide a basis for decision-makers to determine appropriate (in addition to the legislation) measures in order to enhance the efficiency of the programmes;
- to provide a basis for Member States (MS)/region/Countries to adapt these measures to the local epidemiological situation;
- to lay out guidelines for quality control;
- to stimulate discussion on future strategy and future changes in legislation on tuberculosis eradication.

The proposed measures must be explored and assessed based on the individual situation in each MS/region/Country running a programme for bovine tuberculosis.

1.1. Definition of bovine tuberculosis (TB)

For the purpose of this document, the definition of bovine tuberculosis (TB) is: “Infection in cattle (including all *Bos* species, and *Bubalus bubalus*) and bison (*Bison bison*) with any of the disease-causing mycobacterial species within the *M. tuberculosis*-complex”. In the future, we recommend that this definition be used generally.

1.2. European Union legal framework

The European Union (EU) legal framework on TB (listed in Annex I) is formed by:

1. Legislation on trade of bovine animals
2. Legislation on EU co-financing of eradication programmes
3. Legislation on animal products for human consumption (meat and milk)
4. Legislation relating to official controls, in particular for the tuberculosis EU reference laboratory (EURL)
5. Legislation related to bovine animals identification and registration.

In addition, the standards of the Terrestrial Code (<http://www.oie.int/international-standard-setting/terrestrial-code/access-online/>) and Manual (<http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/>) of the World Organisation for Animal Health (OIE) have to be taken into consideration.

The EU legislation on trade and the OIE Code that define the country, zone (regions), herd and animal status regarding bovine TB have been frequently used for eradication purposes with the aim of gaining free status as soon as possible. However, as presented in this document, eradication requires more specific measures that need to be adapted to the situation in each MS, country or region.

1.3. Task Force subgroup on bovine TB and EURL.

The task force (TF) for monitoring animal diseases eradication was created in 2000 following recommendations of the White Paper on Food Safety. It was set up with the specific objectives to improve “animal disease eradication” and “the cost-benefit ratio of animal disease eradication programmes co-financed by the Community” and is maintained to assist MSs to implement animal disease eradication programmes which are suitable for meeting set objectives and allowing harmonisation of programmes across different MSs.

Plenary TF meetings are held in Brussels once per year. They are attended by representatives of the 27 MSs, the chairpersons of the expert subgroups and representatives of the European Commission that chair the meeting. Since 2010, the scope of subgroups extends to relevant non-EU countries.

Subgroups give tailored technical assistance to EU countries for some diseases, including TB. Members are MS representatives with an approved programme for TB, other concerned EU countries, independent experts and the Commission.

Meetings are held in a MS with an approved eradication programme and in areas with particular problems by invitation extended by a MS, EU applicant Country or other third countries. This allows discussions with local veterinarians (vets) and possible visits to farms, laboratories, veterinary services, etc.

Full information on the activity and the reports of the plenary TF and of the subgroup is available at: http://s-sanco-europa/food/animal/diseases/index_en.htm

Concerning the TB EURL, Commission Regulation (EC) No 737/2008 designated the Community Reference Laboratory for TB (EU-RL) to the VISAVET Health Surveillance Centre, Universidad de Madrid (Spain). Among the responsibilities and tasks of the EU-RL are: (1) to coordinate, in consultation with the Commission, the methods employed in the member States for diagnosing TB, in particular by a) typing, storing and supplying strains of *Mycobacterium* spp., b) preparing, controlling and supplying reference reagents, c) validating antigens and tuberculins, d) building up and maintaining a collection of strains and a database of strains isolated across Europe, e) organizing periodical comparative tests of diagnostic procedures, f) collecting data about methods of diagnosis used in the EU, g) updating methods to allow a greater understanding of the epidemiology, h) keeping abreast of developments in bTB surveillance, epidemiology and prevention, i) acquiring knowledge about preparation and use of the products of veterinary immunology used to eradicate and control BT; (2) to facilitate the harmonization of techniques the EU; (3) to organise workshops for the benefit of National Reference Laboratories, including training of experts from the Member States; (4) to provide technical assistance to the Commission; and (5) to perform research activities to improve control and eradication of TB.

Representative of the TB EURL is member of the TB TF sub-group.

1.4. TB status of EU Member States

Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds¹ lists the Member States and regions thereof which are declared respectively officially tuberculosis-free, officially brucellosis-free and officially enzootic-bovine-leukosis-free.

A more complete overview is available in the "The Community summary report on trends and sources of zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks in the European Union" prepared by the European Food Safety Authority (EFSA) (www.efsa.europa.eu). More detailed information at MS or regional level may be contained in the eradication programmes of the MSs approved for co-financing which are available in the DG Health and Consumers website (http://s-sanco-europa/food/animal/diseases/index_en.htm).

1.5. Strategies to enhance the effectiveness of TB eradication programmes

The main aspects to be considered, based on the experience, conclusions and recommendations of the TB TF subgroup, are the need for a thorough evaluation of the epidemiological situation in the region or MS (including other domestic and wild reservoirs of infection), correct choice of the relevant epidemiological unit and sound epidemiological parameters. This should be done before a strategy is defined, or an eradication plan is designed and implemented.

An effective surveillance programme with high quality ante and post mortem diagnosis and appropriate measures for confining and wiping out of infection by use of adequately organised veterinary services, competent authorities and stakeholder involvement are prerequisites.

2. Issues to be addressed in a general context

The EU strategy is not intended primarily to support control programmes but is focused on the achievement of the total eradication of bovine TB. To achieve this, the presence of TB in other animal species (domestic and wild) sharing the same environment must be taken into account.

However, effective control of the disease may be essential as a preliminary step towards eradication. The intermediate target is a rapid decrease in the prevalence of infection. This leads to an increase in the percentage of officially free (OTF) herds, and ultimately the recognition of OTF regions, prior to the complete eradication of bovine TB from the territory of the EU.

¹ OJ L 156, 25.6.2003, p. 74.

2.1. Organisation

An adequate organisation of the competent authorities and others involved in the programme is necessary. The flow chart of those involved and their respective responsibilities must be clear.

A legislative framework for the programme must be established.

Collaboration between the competent authorities is essential. There should be continuous exchange of information and knowledge as well as a common goal for veterinary and public health authorities on all administrative levels.

Sufficient and proportionate financial resources must be allocated to the running of the programme.

2.2. Training and education

Continuous training, as appropriate to each participant, in the execution of the programme must be included. Training includes practical training, education and awareness campaigns. Education will also include update on scientific advances and research findings as relevant for the professional category. Participation in training programmes at the appropriate level must be mandatory for all relevant parties. Adequate time for, and quality assurance of, training is important.

Provision of advice and guidance, in addition to awareness campaigns, should also be provided for farmers.

2.3. 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.

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 attitude that could be a constraint for the accelerated elimination of TB.

2.4. Quality control

A system for controlling and measuring all inputs to and outputs from the programme must be in place. For this, standards are necessary. Such standards include the quality control of tuberculin, testing equipment, testing procedure, laboratory kits and procedures. Some of these can be found in international guidelines or in EU legislation but for others standard operating procedures need to be developed.

Quality checks must be documented and would involve on-the-spot checks of e.g. testing performance and testing facilities.

Data collection and management should facilitate evaluation of performance and trends.

2.5. Enforcement

Systems should be in place to promote compliance with the eradication programme and to detect and measure any non-compliance with requirements under the programme.

Enforcement measures must be available for corrective action at all levels. These systems should be audited on a regular basis.

3. Issues to be addressed in a specific context

3.1. Diagnostic tests

Test characteristics are important for all diagnostic components of the programme. There is usually a trade-off between sensitivity (Se, the proportion of infected animals detected by the test) and specificity (Sp, the proportion of non-infected animals cleared by the test).

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 (as determined by e.g. ROC curve) against the background of the prevailing epidemiological circumstances (prevalence).

However, in a regulatory context where the minimum cut-off values are laid down in legislation these should not be changed nor adapted to relax these although more stringent criteria may be used within the context of the relevant rules.

An increase in Se 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 test positive in the short term (including truly infected as well as apparently non-infected but test positive animals), 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.

For tests with a lower Se in individual animals, detection capability may be increased by whole-herd testing. The herd level Se is better than individual Se for all tests used for the detection of TB. Parallel testing/interpretation (combining several tests and regarding any positive test result as a positive animal) also increases Se while serial testing/interpretation (combining several tests and regarding only those animals that test positive by all methods as positive) increases Sp.

Increasing the overall Se of testing reduces the reproduction rate of the disease (i.e. the 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.

If concomitant diseases (e.g. paratuberculosis) are present in the herd, this may affect the accuracy and reliability of diagnostic tools based on immunological reactions. Accordingly, this factor should be taken into account. The predictive values (i.e. the probability of a test result being accurate), Se and Sp of either the tuberculin test or the IFN- γ assay, or both, as well as other tests, may be compromised by the concurrent presence of these other diseases or by exposure to other non-pathogenic mycobacteria present in the environment.

3.2. Definition and application of the epidemiological unit

The primary unit of concern or epidemiological unit for TB is the herd. “Herd” in the legal context of Council Directive 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”. 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 direct or indirect link or contact between them would constitute two (or more) epidemiological units provided proper personnel and/or equipment biosecurity practices were applied, whereas two (or more) groups of animals belonging to two (or more) owners but kept together, or 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, 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.

National 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 or amongst 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/region/Country.

The wide range of cattle industry systems in operation in the EU makes it difficult (or even impossible) to apply an EU-wide definition of “epidemiological unit” for TB eradication purposes. This issue therefore requires to be addressed at the individual MS level in the design of the eradication programme.

3.3. *Post mortem surveillance*

Post mortem surveillance at the slaughterhouse is a unique opportunity to obtain essential information on the situation and changes in trends of TB and other diseases at both the herd and regional level. The information obtained through post mortem 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 needed.

The detection of TB in the slaughterhouse is, among other things, influenced by the stage of infection in the individual animal. Thus, while the detection of tuberculous lesions in test reactors at slaughter is to be anticipated in many instances, such detection can also be made in animals that have not reacted in the field test. When lesions are detected in a non-reactor animal this may indicate lack of sensitivity of field testing or an old, immunologically inactive, case. Thus, it is important to combine detailed information about the findings in the slaughterhouse with data from previous herd testing, epidemiological information and follow-up tests.

The performance of the inspection procedures in place at the slaughterhouse is influenced both by the physical conditions under which inspection is performed, such as lighting, line speed, equipment and number of inspectors. The efficacy of such inspection also depends on the competency and training of the inspectors. These factors are of primary importance and should be competently and continuously supervised and monitored as part of quality control.

It is necessary to perform a detailed ante- and post-mortem inspection of all slaughtered animals. Particular attention should be paid to animals removed under an eradication programme. 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 OTF areas/regions and regions with less than annual field testing as, in this case, herds are not frequently tested and post mortem inspection is the only means available for TB surveillance.

Monitoring and auditing of post mortem inspection by means of a proper assessment of certain key indicators such as submission rates of suspected lesions and detection rates of animals with confirmed tuberculous lesions (per category of animals) should be in place. Moreover, the normal patterns of disclosure of non-tuberculous TB-like granulomatous lesions should be established as a baseline target. The data regularly submitted from slaughterhouses (on a quarterly or more frequent basis) should be in place and assessed as an integral part of the eradication programme. Audit of the slaughterhouse 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 and public health services is essential. The collection and analysis of post mortem inspection findings and of their application, in real time, to the assessment of the current status of herds in an area or region should be regarded as an essential component of the programme of eradication of TB. In those MS/region/Countries 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 so as to guarantee the enactment of effective, formalised protocols that ensure timely communication and reciprocal feed-back on an ongoing and sustained basis.

3.4. Frequency of herd testing

The minimum frequency of tuberculin tests on herds in each MS or region depends on regional prevalence and is set out in EU legislation. In order to accelerate eradication it may be necessary to increase the frequency of tuberculin tests to more than the minimum requirement. Different frequencies are to be considered, as appropriate for the situation.

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

The optimum ratio of herd prevalence and frequency of tuberculin testing on herds, 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.

3.5. Interpretation of the tuberculin test

The Standard Interpretation of the tuberculin test is described in Annex B.2.2. to Council 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.

While the tuberculin test has been an effective tool when applied at herd level, a lack of sensitivity at the individual animal level is a recognised limitation of the tuberculin test. An increase in the Se of the test is achievable by changing the cut-off point of the test by using a more severe interpretation. However, Sp could be lowered when the severe interpretation is used.

It is important that the tuberculin used has passed quality and potency controls to ensure that it's adequate for field use and to ensure optimum Se. The sensitivity of the tuberculin test would be decreased by a decrease in the relative potency of the bovine tuberculin as compared

to the avian tuberculin (for the comparative test), or the potency of the bovine tuberculin (single test).

The single tuberculin test has a higher sensitivity while the comparative test has a higher specificity. In infected herds or areas it is recommended that the single test be used, where specificity is sacrificed in the interest of sensitivity.

3.6. Strategic use of the IFN- γ assay

Parallel testing as prescribed in Annex B.3 to Council Directive 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.

The use of the IFN- γ assay in parallel with the tuberculin test in infected herds 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. The use of parallel testing slightly reduces test specificity but may accelerate eradication of infection from the herd. Furthermore, in herds already deemed TB-positive, the IFN- γ assay should be considered for use at least for 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.

Due to lack of standardisation, the PPD based IFN- γ assay is not at this time suitable for use as a routine screening test. This is supported by a recent scientific opinion from EFSA (<http://www.efsa.europa.eu/en/efsajournal/pub/2975.htm>), that states that the PPD based IFN- γ assay is considered suitable for use as a routine prescribed test for screening only when it is harmonised within the EU.

The additional direct and indirect laboratory-related costs to perform the IFN- γ assay and the logistic requirements linked to the collection of blood samples and their delivery to the laboratory within a specified period represent a constraint in more remote areas.

3.7. Movement control

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, provide some assurance in regard to the risk of introducing TB into herds through the introduction of such cattle from another herd.

The confining of infection by 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.

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 of destination and provides some assurance for the recipient in this regard. It also serves indirectly as an additional assessment of the TB status of the herd of origin. Likewise, the movement of cattle from unrestricted herds in high prevalence regions to herds outside these regions poses a risk of introducing infection to the region of destination.

The use of certain derogations provided for in EU legislation on trade regarding pre-movement tuberculin testing should be considered only for herds in low prevalence regions and in the context of a sound epidemiologically rational approach.

Assessment of the cost-benefit and/or cost-effectiveness ratio of pre-movement testing and any other measures under a programme would be appropriate in order to determine whether or not the particular measure is more or less beneficial on (a) a national basis, or (b) a regional basis in regions of high or moderate prevalence, when compared to other measures, if an exercise of prioritization of measures is undertaken.

Movement restrictions on non-OTF herds resulting from the application of EU legislation are not enough when particular epidemiological conditions prevail. Practices such as transhumance, the use of common grazing areas, the so-called “bed and breakfast”, contract rearing, “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 should be taken into account, especially in areas or regions of high prevalence. Pre-movement testing is recommended under these particular conditions.

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 OTF 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 re-gaining the OTF status under certain conditions. The procedure laid down in EU legislation 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 OTF status is regained, should be applied under certain conditions. These strategies could be applied as a further means of reducing the likelihood of re-infection and movement of infected cattle out of such herds.

In some situations, restricting certain animals (such as inconclusive reactors) for a longer period, or their entire life, may be advisable. This means that such animals may only leave the herd to go directly to slaughter.

Movement restrictions may present major practical or animal welfare problems in particular situations. Derogations are not allowed in the current legislation on eradication. However, after a careful assessment of the individual risk, certain movements may be regarded as of low risk and a reasonable balance between sustaining industry and disease eradication may be achievable. For example, moving negative animals from restricted herds for fattening in a closed herd under particular official supervision and subsequent movement directly to slaughter may not present a high risk. On the other hand, moving animals from several restricted herds into one unit and testing them to regain OTF status represents a risk that is not acceptable. These aspects need to be addressed in future EU legislation.

3.8. Epidemiological data analysis: performance and epidemiological indicators

Basic indicators for the follow-up of the co-financed eradication programmes and reporting of animal diseases are provided in EU legislation. 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 or regional level. Some of these indicators may require additional information to be recorded or analysed.

The EU mandatory reports contain the following three surveillance indicators, on herd and animal level, respectively: percentage coverage of the programme, prevalence and incidence. Moreover, the number of herds with different status (OTF/infected/not OTF) must be reported. For MS without co-financed eradication programmes, only the number of infected herds and the percentage of OTF herds are reported.

Additional indicators to monitor the progress of TB eradication that are recommended are: slaughterhouse submission rate, number (and proportion) of herds detected by post mortem inspection with test reactors on follow-up tests, number (and proportion) of test reactors with visible lesions at slaughter, number (and proportion) of reactors that are confirmed as infected post-mortem, number (and proportion) of positive herds with a history of positive reactors (and/or inconclusive reactors), number of human cases caused by *Mycobacterium bovis* and *M. caprae* or otherwise of zoonotic origin, reproduction rate of the disease.

Coverage: The figures for coverage are calculated as number of herds/animals tested divided by number of herds/animals under the programme. The number of herds/animals under the programme may be different from the total number of animals/herds in the population at risk. In such cases, this figure is less useful as a measure of how well the other indicators reflect the overall situation in the region. In some regions, all herds are not submitted to yearly tuberculin testing, while some herds may be tested more frequently. Thus, the simple calculation for coverage may be misleading. If the frequency of testing is decreased to every 2, 3 or 4 years in some herds, this will affect the overall sensitivity of the surveillance and thereby the reliability of the prevalence and incidence figures.

Prevalence and incidence: Case definition is essential for prevalence and incidence figures. Whether this definition means all positive reactors or only animals with a positive culture or any other definition, will greatly influence the prevalence/incidence. For TB, the difference between prevalence and incidence figures can be used to assess the duration of restrictions in infected herds.

Simple prevalence figures are calculated as number of positive animals/herds divided by number of tested animals/herds. This apparently straightforward approach may however result in the figures from different MS/region/Countries representing different things. The number of tested herds usually includes herds subjected to routine tuberculin tests, whereas the number of positive herds may also include herds detected by post mortem inspection, pre-movement testing, epidemiological investigations and targeted surveys. Depending on surveillance efforts in addition to routine testing, prevalence figures may reflect a good surveillance or a less ambitious one. The same is applicable for incidence figures where the number of new positive herds should be divided by the number of tested herds, for a certain period.

To avoid misinterpretations, especially when comparing regions or assessing the national situation, it may be necessary to use raw data instead of reported prevalence/incidence. This is especially important for countries/regions where only a sample of the population is tested every year. For national purposes, i.e. to allow for a proper evaluation of the situation and make full use of all available information, data from screening should be calculated separately from risk based testing, and slaughterhouse monitoring results, as they will be used for different purposes and to allow for analyses of trends.

Monitoring of *slaughterhouse submission rates* is important to ensure the efficiency of this surveillance component. Even in the absence of TB, a certain number of visible lesions are to be expected due to e.g. parasitic infections and other bacterial infections. A baseline lesion rate should be established (see 3.2. above) for this purpose.

Number of herds detected by post mortem inspection with further reactors: This figure may provide insight into the sensitivity of herd testing. If animals detected at slaughter have old lesions and no further positive animals are found in the herd, this does not give much cause for concern. On the contrary, if many reactors are detected on follow-up testing this indicates a failure to detect herds with active infection by surveillance in the field.

Number of reactors with visible lesions: If many reactors have visible lesions at post-mortem inspection, this may indicate a lack of sensitivity of the testing. This test should ideally identify animals before visible lesions appear, so that infected animals may be removed before they can spread the infection. Conversely, if very few reactors have visible lesions this may indicate a sensitive surveillance in the field or a lack of sensitivity of post mortem inspection.

Number of reactors confirmed as positive: This figure may be important for the confidence in the field test. However, when striving to achieve a high sensitivity of the testing, detected animals will be recently infected and difficult to confirm by post-mortem investigations. It is advisable not to rely too much on confirmatory testing if positive reactors are to be treated as positive cases. On the other hand, if only those reactors or lesion-positive animals that are confirmed as positive on the basis of laboratory tests are to be regarded as cases, then the low sensitivity of confirmatory tests must be taken into account. If a large proportion of reactors with visible lesions are not confirmed, the performance of laboratory tests may be questioned. The number of reactors without visible lesions but confirmed by bacteriology is also of importance as this indicates detection at an earlier stage of infection. However, in order to obtain this figure, resources must be allocated to bacteriological examination of all reactors and not just animals with visible lesions.

Number of positive herds with a history of reactors (reoccurrence): Analyses of testing history in infected herds, especially herds detected at slaughter, will allow for follow-up of test performance, provide a basis for decisions on test interpretation in different situations and indicate the need for more strict eradication measures in some situations.

Human cases: Data on human cases of *M. bovis* (or other *M. tuberculosis complex* species transmitted from animals) infection may provide indications of undetected animal cases as well as a lack of biosecurity in infected herds. The interpretation of such data requires knowledge of the diagnostic methods and case definitions used in human medicine, and collaboration with public health authorities.

Reproduction rate: In this context, this measure may be used for the number of new infected herds generated by each positive herd, or the number of reactors following the detection of each infected animal. The figure may be difficult to obtain, and requires proper follow-up of each infected herd and animal, with thorough epidemiological investigations to trace the infection. If reliable figures can be obtained, this is a very good indicator of whether infected herds are handled efficiently and if control and eradication measures are working as intended.

In some situations indicators related to population demographics, such as the herd ratio of new-born calves per cow, or mortality vs. slaughter may be relevant. Such indicators may be used to validate population registers e.g. if the data quality or compliance with reporting is in doubt. Moreover, indicators related to the quality of test performance, such as testing results for each veterinarian, results of quality assurance monitoring, results of tuberculin potency testing, and test data related to different tuberculin sources could be useful. In areas where wildlife reservoirs present a problem, population data on wildlife are of importance, as well as data on investigations performed in wildlife.

Proper management of each programme requires the assessment of the most suitable information.

Epidemiological analyses of available data may indicate different levels of risk in e.g. different herd types or other risk factors that need to be addressed. Expertise on epidemiology is needed at MS level to identify and provide the most appropriate indicators and analyses for each epidemiological situation. Molecular epidemiology is also needed, in particular towards the final stages of eradication, in order to better determine the sources of infection and routes of spread.

3.9. Management of infected herds

As a basis for the management of an infected herd, a thorough epidemiological investigation is needed. This is important for decisions on test interpretation strategy, application of additional tests, necessary biosecurity measures, removal of in-contact animals and perhaps stamping out of the entire herd. It is also needed for capturing data and assessing risk factors that are useful in future eradication strategies and changes in the programme. Among the important information that can be captured are source and duration of the infection in the herd and epidemiological links that require investigation. In this regard it is important to remark that all countries (regardless of TB status) must as soon as possible notify TB outbreaks that involved cattle possibly infected and exported to another MS.

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 and clarified in guidelines. 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. The decision also involves an assessment of the cost of stamping out versus other means of eradication in the herd as well as protection of certain genetic resources.

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.

After stamping out, the legally required cleansing and disinfection must be applied to a proportionate level taking into account the particularities of the infectious agent.

Restocking involves making sure that appropriate biosecurity is applied so as to reduce the risk of new infections in the herd.

3.10. Reservoirs of infection in wildlife and other animals

There are currently no legislative provisions on EU level for TB eradication in animal species other than cattle (except for milking goats in direct contact with cattle in the context of food safety rules).

An active approach to the removal of TB-infected wildlife, or other species that share the environment with cattle and the development of appropriate means of preventing transmission of TB from these sources to cattle, and *vice versa*, is recommended. This also involves the development and evaluation of diagnostic tests for these animal species.

It has been demonstrated that the persistence of an infected animal 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.

Future prospects for the development of suitable TB vaccines for use in wildlife and other species are promising. However, considerable obstacles remain which makes it difficult to foresee the use of such vaccination on its own, especially in heavily infected populations, as a suitable tool to address the persistence of a variety of infected reservoirs worldwide in the near future. In the meantime, therefore, alternatives to vaccination 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.

Major socio-political resistance 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, banning of feeding of wildlife or game and proper disposal of carcasses and offal from hunted wildlife. All measures directed at other reservoirs must be conducted in association with a broader-based programme of efficiently implemented measures in the cattle population.

3.11. Compensation schemes

Compensation should be adequate but not, in any way, pose an obstacle for the progress and success of the programme. Compensation schemes should be subject to regular review and linked to the herd-owners' compliance.

The compensation scheme should also be aimed at modifying the behaviour of the farmers in a way that they avoid the introduction of the disease and further spread in their herds.

Furthermore, compensation should never be above that of the current market price of comparable healthy animals.

3.12. Future perspectives

Vaccination of cattle against TB is explicitly forbidden in the EU legislation on disease control (Council Directive 78/52/EEC) and implicitly also in intra-Union trade legislation, as vaccination is not compatible with the provisions for testing and herd qualification (Council Directive 64/432/EEC). The main reason for the current vaccination ban is due to the possibility that vaccinated animals are not fully protected against TB infection.

The development of vaccines and new tests for domestic animals as well as wildlife will mean that legislation and guidelines will need to be reviewed and perhaps revised. Before addressing the legislative issues a scientific assessment and field experience in a broader perspective would be needed.

As long as TB is not eradicated from the entire EU, OTF regions/Countries will need to monitor their situation and continuously address risks of introduction and spread of the disease.

4. Conclusions and Recommendations.

- Eradication of TB is the target at EU level and should be feasible in the long term. However different epidemiological situations in the EU pose certain difficulties that should nevertheless be addressed through specific reinforced measures. In particular, certain farming practices and reservoirs of infection in animal species sharing the environment with cattle can be a constraint to progress.
- Requirements of EU 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 tailored measures aimed at addressing the different constraints to eradication in each epidemiological situation.
- The current EU legislation should be urgently revised to reflect scientific progress, changes in the agricultural sector and the experience gained by the implementation of the eradication programmes in the Member States.
- Full involvement and collaboration between all authorities and stakeholders are necessary for the progress of TB eradication.
- Use of post mortem inspection should be optimised as a surveillance component of the eradication programmes.

- All aspects of the programme, including training, should be reviewed, quality controlled and audited on a regular basis.
- Testing strategies should be optimised, taking into account the epidemiological situation and the targets of various components of the programme.
- Epidemiological data analyses and performance/epidemiological indicators should be an integral part of the continuous assessment and consequent enhancement of the eradication programme.
- The measures discussed in this document should be applied as relevant for the epidemiological situation and ranked in order of priority/effectiveness when allocating the funds available for TB eradication. The diversity of the situations means that different emphasis should be made on the various measures in different MS/Countries.

ANNEX I

1. Legislation on trade of bovine animals

- **Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine**

laying down measures on:

- Requirements for trade of bovines based on herd qualification. The procedures for gaining, maintaining, suspending, withdrawing or regaining the Officially Tuberculosis Free (OTF) status (Annex A, I) A Member State or part of a Member State may be declared OTF
- Diagnosis of bovine tuberculosis in cattle (Annex B)

2. Legislation on EU co-financing of eradication programmes

- **Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle.**
- **Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle.**

Council Directive 77/391/EEC which introduced Community measures for the eradication of TB, Brucellosis and EBL in cattle: MSs are obliged to draw up programmes for accelerated eradication (financial contribution Community). Amended and completed by **Directives 78/52/EEC, 82/400 and Decision 87/58/EEC** (provide additional legal framework for the eradication TB, Brucellosis and EBL in cattle.

- **Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field.**

Financial support from the EU for these programmes was also foreseen.

Decision 2009/470/EC lays down the procedures governing the Union financial contribution for programmes for the eradication, control and monitoring of animal diseases and zoonoses. In addition, Article 27(1) of Decision 2009/470/EC provides that a Union financial measure is to be introduced to reimburse the expenditure incurred by the Member States for the financing of national programmes for the eradication, control and monitoring of the animal diseases and zoonoses listed in Annex 1 to that Decision.

- **Commission Decision 2008/341/EC of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses**

This Decision provides that in order to be approved under the Union financial measures, programmes submitted by the Member States must meet at least the criteria set out in the Annex to that Decision.

3. Legislation on animal products for human consumption (meat and milk)

- **Regulation (EC) No 853/2004** of the EP and of the Council: laying down specific hygiene rules for food of animal origin (Annex III, section IX, chapter I).
- **Regulation (EC) No 854/2004** of the EP and of the Council: laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (Annex I, section IV, chapter IX).

4. Legislation relating to official controls, in particular for the tuberculosis EU reference laboratory (EURL)

- **Regulation (EC) No 882/2004** of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

5. Legislation related to bovine animals identification and registration.

- **Regulation (EC) No 1760/2000** of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97.