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REPORT ON THE

**TASK FORCE MEETING
OF THE
“TUBERCULOSIS”
SUB-GROUP**

**ITALY, NAPOLI
6-7 FEBRUARY 2002**

REPORT OF THE
SUB-GROUP OF TUBERCULOSIS TASK FORCE
MEETING IN NAPLES, ITALY, 6-7 FEBRUARY 2002

Participants: J. Ferris (Chairman),
Members of the tuberculosis Sub-group except UK and Greece,
E. Stifter and F. Reviriego for the Commission,
Representatives of the Italian Ministry of Health, Veterinary
Laboratories in Padova, Brescia and Bologna
Veterinary personnel from the Campania, Lombardia and Piemonte
regions. (see Annex 1)

Agenda: see Annex 2

Location: Naples, ITALY

DAY 1

Mr. Melchionne the Chief Veterinary Officer of the Campania region welcomed the members of the sub-group, the representatives from the Italian Ministry of Health and the local veterinarians. He thanked those that facilitated the meeting and hoped that the findings and recommendations of the sub-group and the Italian commitment to eradication would result in final clearance of from the region. He acknowledged that while the risk from was at present very low with less than one per cent of cattle affected, all the farms and cattle in the region have not been tested due to a chronic shortage of Veterinarians in the region combined with other duties such as BSE, Blue Tongue, FMD and other diseases. He stated that those involved were campaigning for extra staff so as to ensure that all herds and animals are tested within a reasonably short period of time.

The chairman Mr. Ferris thanked Mr. Melchionne and welcomed the delegation of Italian colleagues and on behalf of the sub-group thanked the Italian hosts and especially Mrs. M. Pacciarini for organising the meeting. To those that might have been unfamiliar with the activity of the sub-group, Mr. Ferris provided some background to clarify that the visit was not an inspection mission and that the sub-group was composed of persons who in their own countries worked in the area. The sub-group would try to understand the Italian programme and attempt to provide assistance by suggesting solutions to at least some of the problems being encountered by our Italian colleagues in their Bovine TB Eradication Programme. A number of Member States including Ireland and Greece have already been visited and he anticipated that we would all learn things of mutual benefit in the course of the visit to Italy.

The Commission represented by Mr. Ernst Stifter, introduced the members of the sub-group and asked them to give a brief resume of their experience in TB eradication. Mr. Stifter thanked the organisers of the meeting and updated the meeting on the bovine TB situation in EU.

Mr. B. Fiorito from the Italian Ministry of Health outlined the structure of the Italian Veterinary Service. The Ministry for Health, which deals with human health, has a special Division, which looks after Veterinary Public Health, Food and Nutrition. The Veterinary division is also responsible for various diseases of animals including list A + B diseases. The Central Authorities are in Rome and the country is divided into 21 administrative regions. Each region has a council of the National Health Department and the councillors (Assessori della Sanità) in turn are associated with the central government. Within each region there are a number of Local Health Authority Units which deal with the local perspectives. There are a total of 228 such units in Italy .

The National Institute of Health co-ordinates the activities of 10 “zooprophyactic institutions” which act as the reference laboratories for Central Veterinary Authority and also for the Regional and Local authorities.

In Rome, the Central Ministry of Health has special sections dealing with Veterinary Medicine, any issues that have relevance to human health are covered by the Department of Health and not the Department of Agriculture. Close collaboration maximises the work in each of the Regions. Currently, there is a programme in place whereby responsibility is being transferred to the various institutes in the regions so that the local offices will have greater responsibilities.

Mrs. Bonati from the Italian Ministry of Health described the system of registration of animals and identification of the cattle based on 4 fundamental points – (EU Regulation 1760/2000) – the identification of animals, an individual animal passport, a holding register and a national database.

The local health authority issues the animal passport post-registration. Computerisation of the data on bovines commenced in June '99. From 1.1.2000 all data on animal movement in Italy has been computer recorded. Animals born before 1.1.98 also have passports issued. Imported animals keep the passport of the country of origin. Transfer of animals requires a model form in addition to the passport. Since 2001 the passports of all slaughtered animals are returned to the central authority – the database HQ in Teramo. Three different levels of data collection are provided (1) National (2) Regional (region data collected) and (3) local.

National regulations are also stored on this database and can be assessed by both the Veterinary Services and also by Agricultural and Forestry authorities and other interested organisations.

She outlined the two basic problems experienced with the database such as (1) delays in notifications of births, movements or deaths and (2) slaughter information. Access to the database is not available at each slaughterhouse. The Department Health and the Department Agriculture are collaborating to overcome these problems and Internet access is planned that will allow direct real-time access to data by slaughterhouses.

Mr. Marco Tamba from the CREV of Bologna presented the results of the bovine TB eradication programme in Italy 1995 – 2000. The target is to declare the whole national territory to be TB free.

While the number of herds in Italy is decreasing the herd size is increasing, this is causing problems in clearing infected herds. Herd size in Northern Italy is higher than in Central or Southern Italy. Blue Tongue and other diseases resulted in lower controls in the involved regions. In 2000 only one region had over 1% of herds positive i.e. Sicily with 5.5% of herds restricted due to TB which represents the 50% of the TB infected herds of all Italy. In Italy, herd prevalence is decreasing but in general the time to 'clear' infected herds is not decreasing. The notification of lesions in 'clear' cattle at slaughter is by a standard form 10/33 – notifications in Sicily are increasing. Where applied, the programme has given satisfactory results, in those areas where results have not been achieved, it appears that the programme has not been complied with fully. Enforcement problems have not been communicated to the central authority.

Mr. Ruocco from the Italian Ministry of Health outlined the legislation governing the Bovine TB eradication programme in Italy.

In 1964, compensation was first provided and a voluntary programme was put in place. In 1965 a 'sanitising' plan was approved but participation was voluntary. In this programme bovine identification was achieved by means of tattoo and reactors to the tuberculin test were slaughtered.

In 1968 a second plan was introduced which provided for testing of all bovine animals over 6 weeks of age animals were identified by means of an ear tag. Two consecutive clear herd tests followed by an annual herd test were required to establish the TB free herd status. In 1977, the eradication of in bovine holdings became mandatory. In 1993, it became mandatory to notify the finding of TB lesions at slaughter to the Local Authority responsible for tracing.

In 1995, buffalo farms came under the same controls as cattle farms. This plan established the intention to extend controls within 3 years to all farms. Identification of all farms and cattle was provided for and individual identification of animals over 6 weeks except on farms with animals intended only for slaughter. Isolation of suspects and restriction of movement (except for slaughter) was covered in this legislation. Animals considered positive are marked with an ear T-punch, removed from the herd and require specific authorisation for sending to slaughter. Measures to deal with infected holdings are laid down. Also registration of dealers and keeping of records are required by law. In 1999 Directive 97/12 was transposed into National Regulation, this slightly amended the laws of 1995.

Mr. N. Pozzato, from the CREV (Regional Centre of Epidemiology) of Padova, outlined the development of a homogeneous information system for collection of TB data to obtain a national surveillance programme for Italy. The local Veterinary Office carries out an epidemiological investigation on infected herds in the participating areas, which cover 85% of the cattle population. The resulting data is analysed to produce reports for the eradication programme, to evaluate risk factors and to enable fast decision-making. A common surveillance programme is proposed. He outlined to the group a case-control study on bovine tuberculosis in the Veneto Region of Italy published by S. Marangon *et al* in Preventative Veterinary Medicine 34, 87-95 (1998). This study identified the type of farm enterprise and the introduction of cattle into the herd as the highest risk factors for bovine tuberculosis in that area. He also outlined

the various forms in use to report factory lesions, epidemiological information etc. He outlined the various suggestions that were being considered to improve the epidemiological data and information namely, to build regional epidemiological units where these are not currently present; to provide continuing education programmes and to use a validated and common information system.

Mrs. Maria Pacciarini outlined the diagnostic confirmation methods used, which included pathological and histopathological examination; demonstration of acid-fast bacilli; immuno-histochemistry and culture. In order to reduce processing time of isolation an automated MGIT 960 method is now evaluated in parallel with classical culture method. DNA analysis techniques are actually used together with biochemical and culture techniques for identification of mycobacteria. She then went on to outline some of the Spoligotyping results obtained from the Lombardia and Emilia-Romagna regions. Spoligotypes predominant in Italy are also frequent in France and Spain but not in Ireland or U.K. To date only one isolate has been found with one of the dominant Irish spoligotypes from over 162 M.bovis strains identified in Italy. Mr. Massimo Amadori then went on to outline some of the diagnostic problems encountered at field level –which often lead to stamping out infection; in turn this may be in conflict with EU requirements. He provided some details on the Italian experience using the γ -IFN assay as follows:

- γ -IFN and the intradermal tuberculin test together can identify > 90% infected cattle.
- in controlled field trials, γ -IFN was shown to identify about 20% extra positive animals when compared to the intradermal test
- It is a useful tool to speed up eradication in infected herds

DAY 2

Mrs. Maisto who is responsible for the sanitary planning for the Campania region opened the meeting.

An opportunity was provided to ask questions of the speakers from the previous day in order to clarify various points.

The Chairman asked if there were any practical difficulties encountered in tracing the origin of animals at slaughter. In reply it seems that within a region there are few problems but between regions it is not yet possible to guarantee that all movements can be traced but progress is being made in getting all regions up to the same standard.

Mr. Tamba in response to a query from the UK delegate indicated that there were two main sources of infection (i) recurrence of disease from an earlier outbreak possibly due to a lack of sensitivity of the tuberculin test and (ii) outbreaks occur following movement of animals into a herd or where they have contacted infection when out at pasture. On the relative importance of these two main sources no data is available and on many occasions the origin of infection is rather vague. A uniform method of investigation to standardise the information coming from the local offices is being introduced. The Chairman asked Mr. Tamba if he would agree with the observation

that in most of Italy was not a problem, just being located in various foci in some provinces. Mr. Tamba replied that in the regions with problems the historical background must be taken into consideration. As far as Latio region is concerned the problem is localised to the border area with Campania but is improving. As for Sicily the problem mainly is as a result of having many small breeding farms with difficult access and difficulty in controlling animal movement. There are also difficulties in having reactor animals slaughtered due to a shortage of suitable slaughterhouses. These same problems also exist in Campania and Calabria.

The Spanish delegate asked, in relation to the Provinces with missing data, where the problem lay, was it local offices, slaughter houses, laboratories or elsewhere that were at fault. It seems that the data is usually collected locally, sent to the Regional Office and then transmitted to Rome in a standard format provided by the Central Authority. When Rome gets complete data it sends it on. In some areas it would be the Regional office that had failed to collect data from the local authorities and in other areas it is the local authorities that have failed to collect the information. Mr. Stifter indicated that Italy could lose its EU contribution in part because data had not been supplied, the legal services had confirmed that co-financing depended on provision of data. The Chairman indicated that it appeared that data was not coming smoothly through the system and we would have to look at that area in terms of making a recommendation.

Mrs. Maisto then provided details of the situation in the Campania region in which there are 13 local sanitary units covering Animal Health, Public Health and prophylaxis in 112 districts. In 1998, a regional institute of epidemiology was formed, the flow of new data is standardised from the Veterinarians who collect the information. Certain problems have been encountered in various districts. These basically are as a result of a lack of personnel, local sanitary units without a veterinary centre for epidemiology and problems in computerising the data. The lack of 100% control on all cattle is at the centre of problems in Campania, a specific plan is necessary to reach the objective of clearing infection from each district in turn. Veterinary personnel need to be provided in areas where they are needed. Data from 1997 – 2001 for the Campania region was then provided. It was pointed out that in reality the operation has only worked for 1999 and 2000.

Data is gathered by local veterinary services and sent to the observatory, which checks the data and then sends it to the regional office. The observatory also sends back the information to the districts via the local Veterinary Service. Buffalo herds average 100 head whereas cattle herds on average are much smaller at approximately 10 head/herd. Some provinces have attained almost 100% of animals tested. Others have disimproved in recent years. In those areas where 100% delivery is not obtained, the type of terrain i.e. mountains etc, herd size and number of veterinarians in the territory have been looked at. The prevalence of infected herds has dropped in recent years but in 2001 the % of herds tested also decreased. There is also an excessive time interval between detecting a herd and completing the clearance of this herd. Bovine TB is not a problem in Buffalo, only one TB outbreak was detected in buffalo in 2000 and none in 2001. Procedures to close outbreaks quickly must be put in place and the chronic understaffing problems should be addressed.

The Chairman asked re staffing of the 13 local sanitary units and the ratio of state veterinarians to private contract veterinarians. Mrs. Maisto confirmed that state

veterinary officers were assisted by significant numbers of private contract veterinarians who provided very valuable assistance in the field. The Chairman queried the number of veterinarians at local level and if these were contract or state employees. In effect, everything came down to ratio – the number of animals versus the number of veterinarians and also other duties that have to be performed.

The Chairman asked the personnel from the Campania area what they themselves would do if they had a free hand and went on to summarise the responses engendered. Obviously because there are multiple tasks then to have people dedicated to particular duties would be desirable. The division of duties into categories with a clear outline of duties would help with a backup zootechnic institute. Clarifications of duties between those employed by the central authority and those employed by the district. The central structure, the task of investigation doesn't happen because the human and economic resources are not well defined. In order to optimise the service the availability of a larger number of vets is needed as is administrative support and definition of the economic and human resources.

It appears that the situation in Campania is still developing and the Regional Authority has promised a greater autonomous governing of the local health units. Thus they can organise their own services as they need to, the health problems and duties vary over all the areas. They must establish who should do what and with what resources and then supervise that a proper job is being done.

Mrs. Bonfanti next summarised the position in the Lombardia region, which had an officially free status, but this has been lost in 2001. This withdrawal of status is due to the loss of officially free status of the provinces of Lodi and Pavia. The 1996, the IFN test was introduced to quickly clear infected herds. In 2001 the largest slaughter plant in Europe was opened in this region which resulted in higher numbers of lesions being detected in slaughtered animals. It is clear from the data that cows are the most critical animals. The number of animals detected has given rise to problems and these have resulted in the developing of a plan to look at diagnostic problems. Following the detection at slaughter samples are submitted to the laboratory to confirm the presence of *M. bovis*.

An epidemiological investigation on nine outbreaks from one province, that has experienced particular problems since 1993 was presented. There were 559 holdings containing 120,000 cattle in this province. The province has made good progress in shortening the period of clearance of infection. All test positive infected animals were removed from holdings within 30 days.

In the Lombardia region the 2002 plan has some important new aspects which include,

- (i) A premovement test (30-days) or isolation pending result of post-movement test.
- (ii) The use of γ -IFN assay for diagnosis, it has proved to be a very sensitive tool that can be used to speed up resolution of an outbreak.
- (iii) Stamping out policy is now used when >20% tested animals are detected infected or where a repeated outbreak is detected. It is also systematically applied if in the succeeding 8 months a new outbreak is detected.

- (iv) Link with human health side. Many non-EU nationals are involved in the cattle industry, biennial checks on operators working in the livestock industry are carried out.

The EU commission enquired if the region had a legal basis to use the IFN γ , it transpired that there is a regional decree to this effect.

Mrs. Giuliana Moda then provided details of the situation in the Piemonte region. In Piemonte, the prevalence of bovine TB is higher than the national average. In 1984 the herd incidence was 12% and the animal incidence was 4.6% and in 2000 the herd incidence was 0,6 and the animal incidence 0,2. In a population of 603,800 heads, a total of 1,126 reactor animals were identified. The distribution of TB is confined largely to two provinces in this region, which have relatively high numbers of animals. There are 278 official veterinarians specialising in animal health in the region.

A special programme was drawn up in 2000 for 2001 introducing the use of γ -IFN. The introduction of this programme was slightly delayed in 2001 due to the BSE crisis. The γ -IFN has been used since 1995 and since 2000 in parallel with the intradermal test (positive to either test = positive). Herds are chosen through a risk analysis procedure, which concentrates on infected premises, trade, neighbours and fraud. An information system records the details of the outcome of tests, post mortem and laboratory results.

The γ -IFN – IL2-receptor assay is also being assessed as an auxiliary tool to diagnose TB. The sensitivity and specificity of the γ -IFN were improved with the use of Italian PPD as compared to Australian PPD.

Conclusions and recommendations:

The chairman outlined to the Italian officials that the conclusions and recommendations of the sub-group were essentially based on the information supplied by the presentations of the previous day. He explained the intention was to try reaching a consensus with our Italian colleagues on what was practical and achievable, to draw up and agree a report which would then be presented by the Chairman at a full meeting of the Task Force in Brussels where comments would be invited.

In chronological order the sub-group then looked again at the presentations that had been made to assess their recommendations.

1. The structure of the Veterinary Service

This is somewhat complicated but it seems to work very well in some regions and in others not so well for various reasons.

Starting with Lombardia and Piemonte the situation from the sub-groups perspective seems to be under control. The issue of the γ -IFN assay would be discussed in another forum and the main advocates for this test are in these regions. It is a very technical subject and following discussions the Commission will be in touch with the Member States.

In the Campania region the structures do not appear to work so well. There appears to be personnel problems with some areas appearing to have a heavy workload and others not so. Thus the question of resources must be discussed in this region. There seems to be difficulty in staffing in some of the more remote areas where there are many other official duties to carry out. The sub-group queried if consideration had been given by the authorities for the employment of private Veterinary Practitioners on a fixed-term-contract basis to carry out certain tasks within a time frame on either a part or a whole time basis in problem areas. It was also clear that adequate personnel and financial resources must be available if the eradication was to succeed.

In reply in Campania, it was confirmed that local health authorities had considered the employment of veterinarians on contract in Campania where the situation is improving daily with the employment of additional staff. It was clarified that both the human and veterinary side of the local Health authority, under the Department of Health, must operate from the same budget and human health problems are a priority with Veterinary problems of secondary importance.

The sub-group suggested that a specific plan of region Campania could be considered to ensure that targets are achieved.

The sub-group also expressed concerned about the TB situation in Sicily and Calabria and in particular the high incidence within herds in Sicily and Calabria both areas reporting difficulties.

2. Registration – animal identification and traceability through to slaughter

Italy is moving towards having a system that is timely and intends having a system as good as any Member State but all the usual difficulties are being encountered.

The sub-group requests that this work proceed with all due haste to reach the final goal to improve traceability both from the human and animal perspective. In TB herd breakdowns accurate forward and backward tracing is required including information of the health status of animals from other regions. Thus a good computerised system is necessary linked through the Internet.

3. Epidemiology

The sub-group suggests that a common information system be provided to collect epidemiological information and that part of the data collected would include information on the probable source of infection. At the same time, it is appreciated that an agreed uniform epidemiology format is under development and can assist this task.

The Chairman asked the Italian colleagues if they in turn had any recommendations or requests for the sub-group. In reply they stated that the establishment of a system of bulletins on the data from other Member States which would be readily available would be extremely helpful in field investigations.

The Chairman thanked the Italian hosts and the Chairman of Campania for the hospitality extended and expressed gratitude for the open discussion of the problems in the various regions. He also thanked the field officers for the clarity in outlining the implementation of the Bovine TB eradication programme in Italy. He expressly thanked those that had travelled long distances to attend the meeting and contributed so much to the success of the meeting.

Finally the representative of the Region of Campania highlighted what he felt was a great spirit of collaboration in this meeting and undertook that all recommendations will be seriously considered and hoped that all would reach the desired results for the eradication of bovine TB in all of Italy.