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Directorate F - Food and Veterinary Office

DG(SANCO)/9194/2003 – MR Final

FINAL REPORT OF A MISSION

CARRIED OUT IN THE UNITED KINGDOM

(NORTHERN IRELAND)

FROM 10 TO 14 NOVEMBER 2003

IN ORDER TO EVALUATE THE BOVINE

TUBERCULOSIS ERADICATION PROGRAMME

"Please note that factual errors in the draft report have been corrected in bold, italic, type. Clarifications provided by the UK Authorities are given as footnotes, in bold, italic, type, to the relevant part of the report."

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

APHIS	The Animal and Public Health Information System (central database of cattle holdings, identification and movement records)
Bed and Breakfast holding	Holding where cattle are temporarily kept by a third person (bed and breakfast principle)
BSE	Bovine Spongiform Encephalopathy
CA	Competent Authority/ies
Conacre	Rented pasture where cattle are temporarily kept
DEFRA	Department of Environment, Food and Rural Affairs (UK)
DARD	Department of Agriculture and Rural Development, Northern Ireland
DVO	Divisional Veterinary Office
FVO	Food and Veterinary Office
NI	Northern Ireland
OIE	Office international des epizooties
OTM Scheme	Over thirty months scheme
PM	Post mortem examination
PVP	Private Veterinary Practitioner
SRM	Specified Risk Materials, as defined in the Annex XI, point 1 (a) of the Regulation (EC) N° 999/2001 of the European Parliament and of the Council
TB	Tuberculosis
TVO	Temporary Veterinary Officer
VO	Veterinary Officer
VSD	Veterinary Services Division (central laboratory)

1. REPORT SUMMARY

The mission was undertaken as part of a series of missions, starting in February 2003, in Member States with co-financed bovine tuberculosis eradication programmes in order to assess progress with the approved programmes for 2001 and 2002.

The tuberculosis eradication programme in Northern Ireland has a legal basis in the national legislation. The regional CA has recognised that the post mortem (PM) tuberculosis requirements as laid down in the fresh meat (hygiene and inspection) Regulations (NI) 1997 have to be brought into line with those of Council Directive 64/433/EEC. Pending the amendment, instructions have been issued since 1 October 2003.

The structure and organisation of the competent authority allows effective communication and co-ordination of activities under the tuberculosis eradication programme. However, at all levels, no high level of commitment to disease eradication was seen.

Despite the fact that the TB eradication programme has been in place for several years, the herd prevalence and animal prevalence has increased significantly, in particular over the last two years. The mission team identified numerous deficiencies such as insufficient control on strict implementation of test regimes, the interpretation of its results, the isolation of reactor and inconclusive animals and movement controls. Therefore, it is highly questionable that the eradication programme in place could lead to the eradication of bovine tuberculosis. Although the programme was reviewed in 2002, no policy has been made for all recommendations given by the "Policy Review Report" and certain questions have not been developed or addressed.

Epidemiological studies of infected herds are carried out, including forward and backward tracing. Due to time constraints, these are often not verified on-the-spot by the regional CA. Epidemiological investigations do not cover the fact that TB infected milk is fed to calves.

Some holdings are not registered, not all animals are moved being properly identified and movements between holdings can take place without being recorded. The number of movements between, and within, herds is high. Animals, which do not undergo annual testing can move without restriction running the risk of not having been tested during their whole lifetime.

Control on movement restrictions imposed within the framework of TB eradication is not satisfactory. The collection of the reactor and inconclusive animals depends more on the logistical plan of the hauliers and slaughterhouses respectively rather than on disease eradication aspects. A number of irregularities were identified in relation to the issuing of movement documents. Removal of reactor animals is too slow and the target set for slaughtering within 15 days is met in only 32% of cases.

The basic principles of Annex A of Council Directive 64/432/EEC are not followed with regard to the annual test of herds, the annual test of individual animals and the follow up test on herds with reactors and inconclusive animals. Testing intervals for annual screening and herd re-testing are not respected and significant delays have been noticed.

The comparative skin test is used with insufficient certainty. Interpretation of test results is not fully in compliance with the requirements as laid down in Annex B of Council Directive 64/432/EEC. As a consequence, not all reactor and inconclusive animals are identified.

Isolation of reactor or inconclusive animals was inadequate and clear instructions on this were missing.

Biosecurity measures are rarely applied at farms, livestock markets and slaughterhouses visited. Cleaning and disinfecting of facilities visited and vehicles seen were inadequate and could not contribute to the prevention of a possible further spread of disease.

*The **Veterinary Sciences Division** of DARD is designated for the statutory investigation/confirmation of M. bovis infection in tissues submitted from abattoirs. This laboratory undertakes research and development work on tuberculosis, which can facilitate the investigation of tuberculosis infections in herds and its spread. The laboratory is in the process of setting up "ring tests" on TB**, for example** with **another Member State** laboratory in the Republic of Ireland.*

*When eradication of reactors takes place, the CA has not calculated in the tuberculosis eradication programme budget for 2004 the amount of the salvage of the carcasses, creating a gap of £5.5 million. **Relating to the amount due in compensation within the framework of the OTM scheme (£1 - £2 million) a question arose if the situation could be the same**. A compensation system is in place, which is based on a daily-negotiated market price between farmer and value and does not lead to a high number of disagreements. In the case of a disagreement, a significant increase in compensation has been noticed. Different figures on compensation and the number of reactors for the year 2002 have been provided in different reports.*

Milk from reactor and inconclusive animals is used for human consumption after heat treatment, which is not in compliance with Article 3 of Council Directive 92/46/EEC. Similar findings have been reported during a mission concerning brucellosis bovis eradication (reference DG(SANCO)/8613/2002) without being addressed in a satisfactory way.

Raw milk from reactor animals was used for the feeding of calves after test results became available on the dairy farm visited.

Fundamental aspects of PM health inspection, as laid down in Annex I, Chapter VIII of Council Directive 64/433/EEC, have not been carried out in a satisfactory way at the operational slaughterhouse visited.

The current system of sanctions does not contribute to either the reduction of TB or behavioural changes.

Confirmation of human tuberculosis (M. bovis) is low and vaccination against tuberculosis is mandatory. However, there is no mandatory surveillance programme for people at risk.

2. INTRODUCTION

The mission took place in the United Kingdom (Northern Ireland) from 10 to 14 November 2003. The mission team comprised 3 inspectors from the Food and Veterinary Office (FVO) and 1 observer from other Commission services.

The mission was undertaken as part of the FVO's planned mission programme.

The inspection team was accompanied during the whole mission by a representative from the CA Department of Agriculture and Rural Development, Northern Ireland (DARD).

An opening meeting was held on 10 November 2003 with the CA, UK Northern Ireland Department of Agriculture and Rural Development. At this meeting the objectives of the mission and the itinerary were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested.

3. OBJECTIVES OF THE MISSION

The mission was undertaken in order to evaluate the progress of the bovine tuberculosis eradication programme. Particular attention was paid to the following areas:

1. Competent Authorities.

2. Farm registration, animal identification and movement controls.

3. The bovine tuberculosis eradication programme.

In pursuit of this objective, the following sites were visited:

COMPETENT AUTHORITY VISITS			Comments
Competent authority	Central	0	
	Regional	1	Dept. of Agriculture and Rural Development, Northern Ireland
	Local	2	DVO
OTHER SITES VISITED			**Comments**
Central laboratory		1	VSD
Slaughterhouses		2	One designated for slaughter of reactor and inconclusive animals under 30 months of age
Holdings		4	Selected on-the-spot
Cattle market		1	
Veterinary practice		2	One selected on-the-spot
Milk processing establishments		2	

4. LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation and, in particular, the relevant provisions of the legislation given in the Annex of this report.

5. OUTCOME

5.1. Legislation

Conclusion

The tuberculosis eradication programme has a legal basis in the national legislation.

The CA has recognised that the post mortem tuberculosis requirements as laid down in the fresh meat (hygiene and inspection) Regulations (NI) 1997 has to be brought into line with those of Council Directive 64/433/EEC concerning the condemnation of reactor carcasses. Pending the amendment, instructions have been issued as from 1 October 2003.

Findings

The main legislative orders regulating the TB eradication programme are "The Tuberculosis Control Order (Northern Ireland) 1999", "The Tuberculosis (Examination and Testing) Scheme Order (Northern Ireland) 1999" and "The Diseases of Animals (Northern Ireland) Order 1981".

The CA has developed tuberculosis staff instructions, of which version 10 came into operation on 17 November 2003. These instructions contain, amongst others, information on the TB scheme, the tuberculin test, the TB scheme, reactor and inconclusive reactor animals, overdue tests and TB fraud.

The regional CA has recognised that the post mortem tuberculosis requirements concerning the condemnation of reactor carcasses, as laid down in the fresh meat (hygiene and inspection) Regulations (NI) 1997 has to be brought into line with those of Council Directive 64/433/EEC. Pending the amendment, instructions have been issued as from 1 October 2003 (see chapter establishments).

5.2. Competent authority performance

Conclusion

The structure and organisation of the competent authority allows effective communication and co-ordination of activities under the tuberculosis eradication programme. However, no high level of commitment to disease eradication was seen at all levels.

Findings

The competent authority structure and services involved in the bovine TB eradication programme are as described in a report on a bovine brucellosis eradication programme (reference number DG(SANCO)/8613/2002).

At local level, Temporary Veterinary Officers (TVO) and Private Veterinary Practitioners (PVP) are responsible for carrying out the tuberculin skin tests on behalf of DVO. Except for the fact that TVOs are employed by contract,

their responsibilities are the same as for Veterinary Officers[1]. The work of PVPs is limited by the conditions laid down in their contract with DARD. Special training programmes have to be followed before tuberculin tests can be carried out. Tuberculin tests are carried out by PVPs in routine herds, whilst TVOs mainly carry out the test in risk herds. However, due to workload, some PVPs also carry out the tests in risk herds.

Control on the performance of PVPs on the tuberculin testing in 2003 resulted in suspension of testing for 8 out of ***18*** controlled PVPs.

Few controls on the implementation of restrictions at farm level are carried out. The CA stated that the eradication of bovine tuberculosis is not its first priority. Prioritisation is given to the brucellosis eradication programme and BSE. Statements at DVO and at farm level confirmed this.

5.3. Holding registration, animal identification and movement controls

Conclusion

The bovine database is fully operational and approved by the Commission Services. The control frequency of cattle herds has been reduced from 10% to 5% despite the fact that many holdings are not registered and animals are moved without being properly identified and movements between holdings can take place without being recorded. The number of movements between, and within holdings, is high.

Control on movement restrictions imposed within the framework of tuberculosis eradication is unsatisfactory. The collection of the reactor and inconclusive animals depends more on the logistical plan of the hauliers and slaughterhouses respectively rather than on disease eradication aspects. A number of irregularities were identified in issuing movement documents.

Animals which do not undergo annual testing, can move without restriction and with a risk of not having been tested during their whole lifetime.

Movement between restricted herds has been allowed when they were considered as one epidemiological unit.

Findings

Bed and Breakfast Holdings and conacres exist. ***Bed and Breakfast Holdings are registered, but conacres not***. ***Most*** movements to and off those ***holdings*** are not recorded. It was stated that for reasons of subsidy premiums, movements to and off these holdings are often not recorded and mixture of herds on these premises, independent of their health status is possible.

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[1] ***In their response to the draft report the UK Authorities noted that "the role of Temporary Veterinary Officers and Veterinary Officers differs: it is true that both are authorised to act as inspectors for the purposes of TB legislation, however the responsibilities of the former are limited to carrying out field tests while the latter are responsible for the management of TB controls at local level (including carrying out field tests, investigation of disease outbreaks, backward and forward tracing, test interpretation and scheduling of tests)".***

The number of movements between holdings is high. The regional CA stated that movements within holdings ***and within herds*** to and from different pastures are also high.

A lot of animals at one slaughterhouse visited arrived without being properly tagged. The team witnessed that animals had been accepted for slaughter with only one eartag and where the second eartag is handed over to the responsible person at the lairage of the slaughterhouse[2].

Movement of reactor and inconclusive animals out of herds is not allowed unless they are being sent for slaughter. In general, designated hauliers collect animals to be delivered to designated slaughterhouses. A movement licence accompanies the animals to the slaughterhouses. This licence is not always completed and sometimes contains incorrect information e.g. name of haulier is missing and date of movement to slaughterhouse is printed, but in many cases the date does not correspond with the actual date of movement. Movement licences get a validation period, but no harmonised approach is applied.

Some animals for slaughter, which had arrived at the slaughterhouse visited, were sent back to the farm of origin[3]. This was particularly the case when the animals were over thirty months old. This procedure is not in compliance with Article 2 of Council Directive 64/432/EEC.

Movement of healthy animals out of restricted herds is not allowed unless animals are sent for slaughter. A movement document accompanies the animals but this was not always correctly filled in. Exceptions are made by DVO for movement of animals between holdings, which are considered as one epidemiological unit.

Movement of animals out of non-restricted herds is allowed using a movement licence M2. No restrictions are in place on animals which did not undergo the obligatory annual test. Moreover, there is a risk that some animals are never tested during their whole lifetime because they could be moved out to another herd each time before annual testing takes place.

No movement restrictions are imposed for movement into herds, independently of their health status.

At the cattle market visited, the entrance control was inadequate. Some animals had been unloaded before the animal health status of the herd of origin was cross-checked against the database. It was stated at the cattle

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[2] ***In their response to the draft report the UK Authorities noted that "this is a problem that particularly affects fattening cattle. Keepers of these cattle are reluctant to segregate fattening cattle for retagging in the months prior to slaughter – this is for fear or injury (to either the animals or their handlers) and concern that handling will result in reduced liveweight gain".***

[3] ***In their response to the draft report the UK Authorities noted that "return of cattle to the farm of origin occurs only in exceptional cases and is subject to strict veterinary controls:***
a. Permission of the Official Veterinarian is required
b. An official movement license is issued
c. the animal is subject to a movement restriction on its return to the farm
d. the animal is allocated TB and (as appropriate) Brucellosis tests".

market that sometimes animals from restricted herds have entered the premises.

The central database for bovine (APHIS) is fully operational and approved by the Commission services. It is connected to the disease surveillance programme. Certain risk factors are not flagged by the system e.g. animals present in TB free herds which were not subjected to annual tuberculosis tests, results of skin test which are not available.

Herd control as required in Commission Regulation (EC) No 1082/2003 (previous Commission Regulation (EC) No 2630/97) has been reduced from 10% to 5%. However, during the mission a number of irregularities were identified relating to herd registration, notification of movements, identification of animals and data input.

5.4. Eradication programme

Conclusion

Despite the fact that the tuberculosis eradication programme has been in place for several years, the herd prevalence and animal prevalence increased significantly, in particular over the last two years. The mission team identified numerous deficiencies such as insufficient control on strict implementation of test regimes, the interpretation of its results, the isolation of reactor and inconclusive animals and movement control. Due to these factors, it is highly questionable that the eradication programme in place could lead to eradication of bovine tuberculosis.

Although the programme was reviewed in 2002, no policy has been made for all recommendations made in the "Policy Review Report" and certain questions have not been developed or addressed.

Findings

A significant increase of herd prevalence and animal prevalence has been observed during recent years. See table below.

Year	Animal prevalence of TB	Herd prevalence of TB	Number of herds with a TB reactor	Number of herds controlled
2001	0.46	8.4	1889	22588
2002	0.62	12.6	3029	23975
2003 (up to September)	0.59	11.1	2576	23187

The TB eradication programme has been established for several years. Despite efforts made, an increase has been noticed during the last few years. A working group was established to review the eradication policy and they finalised their "Policy Review Report" in July 2002. A clear action plan has not yet been defined for all recommendations made in this report. For some

significant recommendations no definitive decisions have been taken e.g. valuation and compensation system.

Moreover, a number of issues have not been developed or addressed, for example:
- to record movements ***within holdings and within herds***;
- risk assessments ***of all hazards*** before any future programme and steps to be taken towards risks identified;
- financial assessments or calculations in support of actions and whether they are effective.

Information on the tuberculosis eradication programme is available for the public on the DARD web-site : http://www.dardni.gov.uk.

Timely notification to the DVO of suspected presence of TB in cattle is compulsory, for the keeper and veterinary surgeon. This was not always the case. In one case a delay was noticed of up to 54 days. The PVP did not send the results of the skin tests to the DVO, which included inconclusive animals.

5.4.1. Testing regime and follow-up

Conclusion

The basic principles of Annex A of Council Directive 64/432/EEC are not followed with regard to the annual testing of herds, the annual test of individual animals and the follow up test on herds with reactors and inconclusive animals. Testing intervals for annual screening and herd re-testing are not respected, significant delays have been noticed. Test type classification is laid down in the tuberculosis staff instructions.

The comparative skin test is used, with insufficient certainty. Interpretation of test results is not fully in compliance with the requirements as laid down in Annex B of Council Directive 64/432/EEC. As a consequence, not all reactor and inconclusive animals are identified

The definition of restricted herd applies both to suspension and withdrawal of official tuberculosis free status.

Findings

The comparative skin test is used in Northern Ireland. The Veterinary Laboratory Agency, Addlestone, Weybridge supplies the avian and bovine tuberculin. The comparative skin test and the interpretation of test results are described in the tuberculosis staff instructions. However, the described interpretation of test results are not in accordance with those laid down in Annex B of Council Directive 64/432/EEC.

Moreover two interpretations of test results are given: standard interpretation and severe interpretation. With regard to the standard interpretation, a positive result is defined as an animal showing a positive bovine reaction “at least 5 mm greater” than an avian reaction instead of “more than 4 mm greater”. With regard to the severe interpretation, animals which would be considered as negative with the standard test might become inconclusive and

inconclusive animals might become reactor animals. This interpretation has to be taken by DVO according to specific instructions.

It is the responsibility of the herd keeper to present his animals for tuberculosis testing to the PVP or TVO and to respect the testing intervals. If no action is undertaken after 14 months, the herd keeper gets a warning to present his animals to the PVP or TVO within one month. If this deadline is not met then the herd is placed under restriction until the skin test gives satisfactory results. This means that animals can only move out of the herd for direct slaughter but animals from non-restricted herds can move into the herd. Significant delays in meeting deadlines have been noticed, see table below. The herd keeper from one large herd stated that the imposed sanction did not interfere with the ongoing trade.

During a visit to a private veterinary practice, the tuberculin was stored in a refrigerator. The injectors for both avian and bovine tuberculin are well marked. During visits to farms, the tuberculin is stored in a cool box of thermos flasks.

The team witnessed the reading of test results in one herd. The following findings were observed:
- the PVP stated not having cleansed the injection sites;
- the PVP does not always measure exactly the skin-fold thickness at the injection site;
- the callipers used have an accuracy of one millimetre. This scale does not allow the measurement of skin-fold thickness of a little bit less than 1 or a little bit more than 4 mm and will miss a certain number of conclusive and reactor animals respectively;
- the PVPs have to work within the limits of their contract with DARD which does not include the control on the use of therapeutic agents which may affect test results by checking of medical records and medical stock on farm.

Annex A of Council Directive 64/432/EEC clearly lays down that all animals on a holding, with the exception of calves under six weeks old, are subject to routine tuberculin testing at yearly intervals in order to retain official tuberculosis-free status. Nevertheless, TB annual herd tests were carried out within the following time intervals:

Target time interval	% within target
12 months (365 days)	46.9%
13 months (395 days)	71.4%
14 months (426 days)	84.3%

5.4.2. Additional movement controls

Conclusion

No additional movement controls are in place.

Findings

Northern Ireland does not require 30 days pre- (or post) movement TB tests to be carried out for animal movements in its own territory. At present trade of live cattle is prohibited.

Movement restrictions in place are described in the chapter on animal identification, herd registration and movement controls.

5.4.3. Removal of reactor animals/herds

Conclusion

Reactor or inconclusive animals have to be isolated from the herd. Isolation of these animals was inadequate and clear instructions on this were missing. Removal of reactor animals is too slow and the target set for slaughtering within 15 days is met in only 32% of cases.

Findings

Reactor animals can originate by disclosure of reactors on the farm or at the slaughterhouse. Reactor animals are notified to the herd keeper, who is instructed to isolate these animals by issuing a special form (BT23).

On this form no specific instructions are provided on isolation procedures and the places where animals are kept in isolation are not recorded. It was also noticed during the visit to a farm that this form referred to NI legislation which is no longer in force.

The lack of clear instructions means that some reactor animals are kept separate, but not isolated from other animals. At one farm visited, the positive animal was kept in a field together with sheep (sheep are susceptible to *M. bovis*) and cattle were grazing in the adjacent neighbouring field. Direct contact with these animals was possible via fences. It is also a known fact that *M. bovis* can survive in bedding, slurry, on wellington boots, etc. for several months in damp conditions and out of direct sunlight. Isolation in fields cannot be considered as an optimal solution[4].

Similar procedures are in place for the isolation of inconclusive animals.

Depopulation of herds is rarely done. It is up to the DVO to decide in which cases depopulation will take place.

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[4] ***In their response to the draft report the UK Authorities noted that "the CA accepts that isolation of suspect animals in fields is sub optimal. However the small size of, and limited housing facilities on many farms in Northern Ireland means that this often offers the best available means of managing the risk of disease spread".***

A target is set to remove reactor animals from herds within 15 days for slaughter. At present, this target is met in only 32% of cases. In general, transport is carried out by designated transporters to designated slaughterhouses (see chapter on herd registration, animal identification and movement control). However, herd keepers still have the freedom to transport their own TB-infected animals to the slaughterhouse of their choice. In this case DARD pays no compensation for the animal and the transport. The regional CA stated that this is a rare occurrence.

5.5. Cleaning and disinfecting procedures

Conclusion

Biosecurity measures are rarely applied at farms, livestock markets and slaughterhouses visited. Although a list of approved disinfectants is available, none were used in the designated slaughterhouse and none at the cattle market. Evidence was present that many vehicles are not cleaned and disinfected before loading of the animals as required in national legislation. During the final meeting the regional CA stated that the Biosecurity Code was being revised.

Findings

The awareness of biosecurity measures at farms, livestock market and slaughterhouses visited is low. The CA has acknowledged this. The CA stated at the final meeting that the biosecurity code was being revised.

The inspection team identified a number of deficiencies:

- At the cattle market visited, no other biosecurity measures were implemented other than the presence of a footbath at one pedestrian entrance. It is not common practice to disinfect the premises at the end of the day. There was no disinfectant present at the cleaning and disinfecting point for vehicles. A livestock vehicle arrived from one of the three designated slaughterhouses for slaughtering of reactor animals, to be cleaned at the market place. Moreover, an eartag was found from an animal which was slaughtered one month before on one of the transporter's trucks. Livestock vehicles arrived at the cattle market without having been cleaned and disinfected before the loading of the animals. No disinfectant bath for vehicles was present at the entrance of the market place.

- At the farms visited no disinfecting facilities were present at the entrance of the farms. One farmer stated that since the slaughtering of his reactor animals he did not have any disinfectants available.

- At the slaughterhouses visited, the cleaning and disinfecting facilities for animals transporters were in poor maintenance and not always in use. In the designated slaughterhouse visited, the lairage is not disinfected, but cleaned with hot water and then only weekly. The disinfectant present for

the slaughterhall, was not approved by the CA for use against TB[5]. It was stated that the cleaning of the slaughterhall with hot water (85°C) is sufficient.

The VO has to advise the herd keepers on cleaning and disinfecting of areas, buildings and equipment. DVO use a special form to indicate which areas have to be cleaned and disinfected (BT33). The advice was in some cases insufficient as not all areas had been identified and equipment was not indicated on the forms. The herd keeper has to notify the DVO on the completion of cleaning and disinfecting by return of a completed BT33 form. Control on cleaning and disinfecting after its completion is rarely carried out which forms the basis for the final relifting of restrictions.

5.6. Laboratory services

Conclusion

*The **Veterinary Science Division** of DARD is designated for the statutory investigation/confirmation of M. bovis infection in tissues submitted from abattoirs. **The TB laboratory of** the bacteriology branch is working towards its accreditation **under ISO 17025** due to be completed in the beginning of 2005. Although good laboratory **has not yet been sought for the TB laboratory,** certain standard operational procedures are in place.*

*The laboratory undertakes research and development work on tuberculosis, which can facilitate the investigation of tuberculosis infections in herds and its spread. The laboratory is in the process of setting up "ring tests" on TB**, for example** with **another Member State** laboratory in the Republic of Ireland.*

Findings

The statutory work of the disease surveillance and investigation branch of ***the Veterinary Science Division*** of DARD comprises, amongst others, the examination of carcasses and tissue specimens submitted under DARD's Bovine Tuberculosis Eradication scheme. In the Bacteriology Branch a significant amount of work is integral to DARD's field tuberculosis eradication programme. Besides the statutory investigation/confirmation of *M. bovis* infection in tissues submitted from abattoirs, research and development work is undertaken.

The TB laboratory has not yet sought external accreditation (e.g. to good laboratory practice standard). However, a number of standard operational procedures have been developed relating to the histological and bacteriological tests on confirmation of *M. bovis* infection in tissues submitted from abattoirs. Furthermore, a new building for the bacteriology branch is planned and is due to be finalised in 2005 and the department is working towards accreditation ***under ISO 17025*** once the move will take

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[5] ***In their response to the draft report the UK Authorities noted that " the slaughterhouse does not use a disinfectant approved by DARD for TB in their slaughterhall as none of those approved are food grade and may, even with rinsing result in taints. However the slaughterhall is cleansed, including the use of detergent foam, and disinfected at the end of each days kill".***

place. The laboratory is in the process of setting up "ring tests" on TB, ***for example*** with ***another Member State*** laboratory in the Republic of Ireland.

Lymph node tissues with visible and non-visible lesions from reactor animals or animals with suspect lesions identified at PM examinations in the abattoirs are sent, together with a sample form, which is generated from APHIS to the laboratory. Once *M. bovis* has been confirmed in a herd samples from other reactor animals within the same herd are no longer sent for confirmation of *M. bovis*. Hard copies of sample forms are not kept ***at the designated slaughterhouse visited***. Sample forms for tissues with non-visible lesions do not contain a request for the type of test to be carried out.

Histological examinations are carried out in the Belfast and Omagh divisions. The bacteriological identification of *M. bovis* (conventional mycobacterial culture and BACTEC) is carried out in the Belfast division only. It was stated that OIE standards are applied for mycobacterial culture. Results of tests are reported in APHIS. However, the veterinary staff at the designated slaughterhouse ***visited***, ***were unable to*** access the results ***at the time of the visit***.

Research and development work on TB is related to epidemiology, vaccines and diagnostic tests with the aim of underpinning and supporting DARD's statutory programme and advise on policy decisions in relation to tuberculosis. The multidisciplinary tuberculosis research programme is funded by DARD, with additional funding by EU, DEFRA and research councils. An important element is the *M. bovis* strain typing in order for it to be used for future determination of the genotype of tuberculosis strains responsible for outbreaks in NI, identifying chains of transmission and to investigate the sources of infection and routes of transmission.

Submissions from tissues to the laboratory:

	2000	2001	2002
Submissions from visibly lesioned reactors	1835	1433	2041
Submission from non visibly lesioned reactors	1134	1091	1970
Submissions from lesions at routine slaughter	1159	1173	1597

5.7. Epidemiological studies of infected herds

<u>*Conclusion*</u>

Epidemiological studies of infected herds are carried out, including forward and backward tracing. Due to time constraints, these are often not verified on-the-spot

Epidemiological investigations do not cover the fact that milk from reactors and inconclusive animals and which was not heat-treated is fed to calves.

Findings

Epidemiological investigations of infected herds are carried out by VO. The herds have to be visited by the VO but due to time constraints the VO initially contacts the herd keeper by phone. On all farms visited mapping was based on oral information by phone. On-the-spot verification was rarely done.

Forward and backward tracing was carried out with related tests on direct contact herds.

A standard report format is available in APHIS for this purpose, but raw input data is not harmonised and incomplete e.g. source of disease on two files reflected the opinion of the herd keeper. In one case the reason given was due to the high incidence in the direct neighbourhood, but it was not taken into account that the animal was recently brought in from a cattle market. In the second case, the reason given was due to the presence of a badger set bordering with two neighbouring fields whose herd had been infected before. The herd keeper and VO could not confirm having seen badgers in the field or that TB has been confirmed in badgers close to the holding. The VO stated that he had not controlled whether proper fences were in place between the herds. Moreover, the animals were isolated in the field.

The use of milk and colostrum from reactors and inconclusive animals for calves is not included in the epidemiological investigations as a risk factor.

Data input is sometimes significantly delayed. VOs stated that data input follows when the herd regains the official TB-free status.

5.8. Compensation system

Conclusions

The estimated amount of salvage of carcasses (£5.5 million) ***has*** *not been deducted from the overall budget claimed for the TB eradication programme.* ***Relating to the amount due in compensation within the framework of the OTM scheme (£1 - £2 million) a question arose if the situation could be the same***[6]*.*

Compensation system in place, which is based on a daily-negotiated market price between farmer and valuer, does not lead to a high number of disagreements. In the case of disagreement, a significant increase in compensation has been noticed.

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[6] ***In their response to the draft report the UK Authorities noted that "the £5.5 million amount in relation to salvage includes the OTM scheme compensation. It is incorrect to state that there is an additional £1-£2 million gap in respect of the OTM scheme".***

Different figures on compensation and number of reactors for the year 2002 have been provided in different reports[7].

Findings

Compensation for reactors and in-contact animals is based on a daily-negotiated market price between farmer and valuer or, if they fail to agree, by an independent valuer. This valuation is legal and binding on both parties. No maximum and minimum prices or other pricing criteria are fixed. Compensation paid for reactor and negative in-contact animals increased yearly and, as mentioned in the policy review report of July 2002, the values obtained from independent valuers have been significantly higher (over 80%) than initial valuations e.g. 1998/1999, 1999/2000 and 2000/2001 87%, 84% and 94% respectively.

The CA does not exclude that some farmers could have a financial interest in having an animal over thirty months of age compensated within the framework of the tuberculosis eradication programme instead of within the OTM scheme.

Target ***is to ensure that all non-query payments are processed within 12 days of slaughter.*** For animals slaughtered in 2002 as a result of bovine tuberculosis, compensation was paid for 13,590 animals within 90 days of slaughter amounting to £11,895,924 compensation. 666 animals were not paid for within 90 days of slaughter, but no statistical analysis of the reasons why are available (amounting to £744.045 of compensation). In Annex VI in a final report on tuberculosis eradication programme for the year 2002, submitted to the Commission, the costs for compensation are broken down as follows: 13,556 reactors and 525 negative-in-contact animals amounting to £12,237,453 and £211,522 compensation respectively[7].

The compensation system, including valuation, is under review. However, no agreement has been reached on a future policy. The compensation system will cover a wider scope e.g. single system for all notifiable diseases.

When a reactor is slaughtered, the value of the carcass is paid back to the CA (salvage). The estimated value of the salvage is £5.5 million per year. This figure is not calculated in the tuberculosis eradication budget.

Furthermore when a reactor over thirty months is slaughtered ***it could not be assessed if*** the compensation paid by the OTM scheme is reflected within the tuberculosis eradication budget for 2004. The estimated additional gap ***could amount to*** £1 - £2 million[6].

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[7] ***In their response to the draft report the UK Authorities noted that "there was no contradiction in the figures presented for 2002. Two different sets of data were requested and supplied. The first report provides information on compensation paid during 2002, including the number of animals which this sum represented. The second report provides details of the total number of animals slaughtered in 2002 and the associated compensation that was paid".***

5.9. Milk

Conclusion

Milk from reactor and inconclusive animals is used for human consumption after heat treatment, which is not in compliance with Article 3 of Council Directive 92/46/EEC. Similar findings were reported during a mission on brucellosis bovis eradication (reference DG(SANCO)/8613/2002) without being addressed in a satisfactory way.

Raw milk from reactor animals was still used for the feeding of calves after test results became available on the dairy farm visited.

Findings

Purchasers of milk are informed monthly of the animal health status of dairy herds. The frequency of the information flow on a monthly basis is too low as daily changes on the animal health status of herds take place. Moreover, this information is not used and herd owners send their milk to the factories without separating it from the milk of of healthy animals from reactor or inconclusive animals. This is not in line with Article 3 of Council Directive 92/46/EEC.

Although not required by national legislation, the regional CA stated that it is general practice in Northern Ireland that milk for human consumption undergoes heat treatment. Their view as outlined in the reaction to the mission concerning brucellosis bovis eradication (reference DG(SANCO)/8613/2002) is that mandatory heat treatment of milk from reactor animals is sufficient to meet concerns about the risk to public health from such milk. It was also noticed that the purchasers of milk are informed but not the collectors of the milk or the establishments which buy from the purchasers.

Two dairy establishments were visited, of which one was a dairy factory producing fresh milk and dairy products. The other establishment produces dairy products. The first establishment collects milk directly from farms on behalf of a cooperative. The second establishment buys raw milk from a cooperative then brings the milk with its own transport to another establishment in order to undergo heat treatment. In both cases, the animal health status of the farm of origin was unknown. In addition to this, the following findings were noticed:

– the management of the first dairy plant visited was not interested in the animal health status of the dairy herds as all the milk used in his factory will undergo heat treatment;

– in this plant when raw milk is rejected after unsatisfactory entrance controls, the milk is sent to the cooperative or to other factories in UK. The milk is accompanied by commercial documents only, not reflecting the health status;

– in the second dairy plant visited, the owner transports the raw milk from the cooperative in order to undergo heat treatment in the other factory and then to his plant with the same means of transport. Following transport of the raw milk, the tank is cleaned and disinfected, however no evidence could be given that the disinfectant used is active against tuberculosis.

On a dairy farm visited, colostrum and milk from positive reactor animals had been fed to the calves on the farm without heat treatment. It was obvious during the visit that the farmer was not aware of the potential consequences.

5.10. Establishments

Conclusion

Fundamental aspects of PM health inspection as laid down in Annex I, Chapter VIII of Council Directive 64/433/EEC have not been carried out in a satisfactory way. Carcasses from reactor animals with localised tuberculous lesions in more than one organ or in an organ and non-associated lymph nodes or in a number of areas of the carcass are rarely condemned, which is not in line with Article 5 of Council Directive 64/433/EEC.

Since 1 October 2003, pending an amendment to the Fresh Meat (hygiene and Inspection) Regulations (NI) 1997, to bring the post mortem TB requirements into line with those of Council Directive 64/433/EEC, instructions have been introduced containing amendments to the operation manual. The VOs have to work accordingly.

Animals not properly identified in accordance with the Regulation (EC) No 1760/2000 of the European Parliament and of the Council are accepted for slaughtering without appropriate action.

Findings

At the time of the inspection visit of the designated slaughterhouse, the PM inspection did not include palpation of lungs and gastric and mesenteric lymph nodes with the risk of missing TB lesions. In the other slaughterhouse visited, the VO stated that intestines are immediately removed from the carcasses and destined as Specific Risk Material. This excludes palpation of gastric and mesenteric lymph nodes with the consequence of not detecting tuberculosis in carcasses.

Whole carcasses from reactor animals are not declared unfit for human consumption when localised tubercules lesions are revealed in more than one organ or in an organ and non-associated lymph nodes or in a number of areas of the carcass. This is not in line with the requirements of Article 5 of Council Directive 64/433/EEC. The regional CA stated at the final meeting that the operational manual has been amended and instructions have been in place since 1 October 2003 pending an amendment to the Fresh Meat (Hygiene and Inspection) Regulations (Northern Ireland) 1997. The instructions should be followed when considering whether meat and offal from animals in which tuberculosis is suspected is fit for human consumption.

Although access to APHIS is available and the animal health status of animals at arrival in the slaughterhouses visited can be checked, in particular related to overdue tests, this information does not pass systematically to the ante mortem and post mortem health inspection.

In the designated slaughterhouse, the team observed that a high number of animals were accepted for slaughter with only one eartag without further action when the second eartag was handed over by the haulier.

In the designated slaughterhouse, reactor animals are slaughtered during the normal slaughter process as a group without having procedures in place to clean and disinfect the slaughterhall in between. This handling is against the DARD instructions which require that the slaughterhall must be subject to full cleaning and disinfecting.

In the designated slaughterhouse, carcasses from suspected animals could not be removed immediately from the slaughterhall to the detained area. They are sometimes kept close to the slaughterline for hours.

In the designated slaughterhouse record keeping was unsatisfactory. The slaughter date of reactor animals did not always match the data on APHIS, the killing list (abattoir report) and the records of the veterinary service (reactor sheet).

In both slaughterhouses visited, facilities for cleaning and disinfecting vehicles were present but were rarely used. For more details see chapter on cleaning and disinfecting.

5.11. Sanctions

Conclusion

The current system of sanctions does not contribute to either the reduction of TB or behavioural changes.

Findings

When test intervals are not respected herds are placed under restriction. No animals may leave restricted herds other than for direct slaughter. However, in-movements are not restricted, it cannot be ensured that vehicles do not enter infected areas. Movement restrictions affect mostly diary farms, but not fattening or finishing farms. Farmers as well as VOs confirmed this during the mission.

5.12. Zoonoses

Conclusion

Confirmation of human tuberculosis (M. bovis) is low and vaccination against tuberculosis is mandatory. However there is no mandatory surveillance programme for people at risk.

Findings

Human tuberculosis is a notifiable disease. All teenagers are vaccinated against tuberculosis in Northern Ireland. Infection of human tuberculosis caused by *M. bovis* is low. There have been no cases since 2001 when two cases of human tuberculosis (*M. bovis*) were confirmed. Both cases occurred in adults of middle to late adulthood and were considered to be reactivation of infection. No veterinary field action was required.

Only mammary tissue involvement is suggested following the post mortem of a reactor animal, the VO should inform the medical authorities. When *M. bovis* is confirmed in a herd, the herd keeper is advised to visit the family doctor.

Other people at risk e.g. employees of slaughterhouses, employees of dairy plants and veterinary staff are advised to visit the family doctor on a regular basis in order to be checked for tuberculosis. This is however not mandatory.

6. FINAL MEETING

A closing meeting was held on 14 November 2003 in Belfast with the regional competent authority, UK Northern Ireland Department of Agriculture and Rural Development. At this meeting, the main findings and conclusions of the mission were presented by the inspection team.

The representatives of the DARD took note of the main findings and conclusions and offered to submit their comments and information on action taken, or to be taken.

7. RECOMMENDATIONS

7.1. To the competent authorities of United Kingdom (Northern Ireland)

7.1.1 To urgently complete the transposition and the implementation of Council Directive 64/433/EEC, in particular the post mortem requirements.

7.1.2 To ensure that all specific requirements of Community legislation on herd registration, animal identification, movement controls and on-farm registers are respected.

7.1.3 To implement the eradication programme as a matter of urgency according to the requirements as laid down in EU legislation and to ensure an adequate control on its implementation, in particular with regard to:

- the test regime and follow-up,
- the removal of reactor animals,
- the epidemiological investigation,
- biosecurity and cleaning and disinfecting procedures.

7.1.4 To review the budget of the TB Eradication Programme for 2004, submitted to the Commission services.

7.1.5 To review the milk policy, in particular:

- to re-consider their view on the implementation of Article 3 of Council Directive 92/46/EEC;
- to address proper solutions in order to minimise the health risk represented by the use of raw milk to feed calves;
- to take action to ensure that all milk produced originates from official TB-free herds. To this end, a system of incentives to such herds should be considered.

An action plan, indicating the actions taken or planned to address the conclusions and recommendations (7.1.1 to 7.1.5) of this report, and including a timetable for completion, should be submitted to the Commission services within one month of receiving the final report.

7.2. To the Commission Services

7.2.1. To continue to monitor all the aspects of the bovine tuberculosis eradication programme in Northern Ireland and to closely monitor the measures taken by the UK competent authorities to address the above conclusions and recommendations.

7.2.2. To take the appropriate actions, if the response is found to be unsatisfactory.

8. ADDENDUM

In their letter of 15 March 2004 the UK Competent Authority responded to the draft report, in which they offered certain comments on the factual accuracy of the report and also some clarifications. Where appropriate, their comments have been reflected in the final report.

Their reply also indicates certain preliminary actions planned or taken by the UK Authorities in response to the mission and recommendations of the mission report. Additionally the UK Authorities consider changing certain procedures regarding TB eradication.

In their response to recommendation 7.1.5 of the draft report, in particular to re-consider their view on the implementation of Article 3 of Council Directive 92/46/EEC, the UK Authorities stated that it is “confident that it is implementing Council Directive 92/46/EEC correctly and that their interpretation of the Directive is valid. It is the opinion of the CA that milk from reactor animals may be sold for human consumption providing it is heat treated, which is the case in Northern Ireland. In the absence of any risk assessment to the contrary, the implementation of Directive 92/46/EEC within the Member State is justifiable, presents no public health risk and therefore there is currently no need to alter our current position."

9. ANNEX

LEGAL BASIS FOR MISSION - GENERAL PROVISIONS	
Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (as amended)	OJ L 121, 29/07/1964, p. 1977-2012
Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market (as amended)	OJ L 395, 30/12/89, p. 13-22
Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (as amended)	OJ L 224, 18/08/1990, p. 19-28
Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market (as amended)	OJ L 224 , 18/08/1990, p. 29-41
Council Decision 90/638/EEC of 27 November 1990 laying down Community criteria for the eradication and monitoring of certain animal diseases (as amended)	OJ L 347, 12/12/1990, p. 27-29
Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States.	OJ L 038, 12/02/1998 p. 10-13
LEGISLATION RELATING TO ANIMAL HEALTH	
Council Directive 97/12/EC of 17 March 1997 amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine (as amended)	OJ L 109, 25/04/1997, p. 1-37
Commission Decision 2000/322/EC of 13 April 2000 laying down standard requirements for the reports submitted for programmes for the eradication and monitoring of animal diseases approved for co-financing by the Community (now repealed by Decision 2002/677/EC)	OJ L 111, 09/05/2000, p. 19-29
Commission Decision 2000/774/EC of 30 November 2000 approving the programmes for the eradication and monitoring of animal diseases and for the prevention of zoonoses presented for the year 2001 by the Member States.	OJ L 308, 08/12/2000, p. 39-44
Commission Decision 2001/853/EC of 3 December 2001 approving the programmes for the eradication and monitoring of animal diseases and for the prevention of zoonoses presented by the Member States for the year 2002 (as amended)	OJ L 318, 04/12/2001, p. 46-53
Commission Decision 2002/677/EC of 22 August 2002 laying down standard reporting requirements for programmes of eradication and control of animal diseases co-financed by the Community and repealing Decision 2000/322/EC (as amended)	OJ L 229, 27/08/2002, p.24-32
Commission Decision 2002/944/EC of 28 November 2002 amending Decision 2001/729/EC on the list of programmes for the eradication and monitoring of animal diseases and on the list of programmes of checks aimed at the prevention of zoonoses qualifying for a financial contribution from the Community in 2002 and Decision 2001/853/EC approving the programmes for the eradication and monitoring of animal diseases and for the prevention of zoonoses presented by the Member States for the year 2002	OJ L 326, 03/12/2002, p. 20-23
Commission Decision 2003/467/CE of 23 June 2003 establishing the officially tuberculosis, brucellosis and leucosis-free status of bovine herds of certain Member States or regions of member States	O.J. L 156, 25/06/2003, p. 74-78
GUIDELINES ISSUED BY THE EUROPEAN COMMISSION	
SANCO/1775/2001 Guide for the achievement of production and control programmes in the veterinary field.	

LEGISLATION ON THE IDENTIFICATION OF ANIMALS AND THE CONTROL OF ANIMAL MOVEMENTS	
Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals	OJ L 355, 05/12/1992, p. 32-36
Commission Regulation (EC) No 2628/97 of 29 December 1997 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards transitional provisions for the start-up period of the system for the identification and registration of bovine animals (as amended)	OJ L 354, 30/12/1997, p. 17-18
Commission Regulation (EC) No 2629/97 of 29 December 1997 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards ear tags, holding registers and passports in the framework of the system for the identification and registration of bovine animals (as amended)	OJ L 354, 30/12/1997, p. 19-22
Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals	OJ L 60, 28/02/1998, p. 78-79
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	OJ L 204, 11/08/2000, p. 01-10
Commission Regulation (EC) No 1082/2003 of 23 June 2000 laying down detailed rules for the implementation of Regulation (EC) No 1760/00 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals	OJ L 156, 25/06/2003, p. 9
LEGISLATION RELATING TO THE PRODUCTION OF FRESH MEAT	
Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat (as amended)	OJ L 121, 29/07/1964, p. 2012-2032
LEGISLATION RELATING TO THE PRODUCTION OF MILK AND MILK-BASED PRODUCTS	
Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (as amended)	OJ L 268, 14/09/1992, p. 01-32