

TB in cattle

An Audit of the TB 99
Epidemiological Questionnaire
Process and Defra's Response

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Executive summary

The TB 99 questionnaire study was set up to assess which factors could influence the propagation of TB in cattle. The auditor was asked to audit the whole process from data collection to computer data handling. The TB 99 team gave its full support throughout the audit activities. The findings and recommendations are based on a visit to a selected sample of Animal Health Divisional Offices and farms, as well as on a review of data handling at the VLA.

The findings are related both to the complexity of the questionnaire and to a lack of coordination of the project, leading to too much individual interpretation when completing the questionnaire and when dealing with data management. For example, when a field of information is not completed it is not always clear whether this is due to missing information, oversight or a decision to leave the field blank.

In both Animal Health Divisional Offices (AHDOs) the staff visited were keen to do a good job. In Truro, systems are in place to track questionnaires and to answer the queries they generate. In Stafford there were difficulties in finding out what the actual status of the questionnaires were (how many had gone to data entry, what had happened to controls, answers to data management queries). According to the team, this was due to the fact that although such systems had been in place, staff had changed and everyone had their own system.

The approach to the completion of the questionnaire varied. The ADAS consultants (2) were more questionnaire oriented, perhaps more neutral, more used to the interview approach and to filling in questionnaires, giving equal weight to all questions. The VOs (2) were more scientifically oriented, perhaps more enthusiastic and concentrating essentially on the questions that were more of interest to them.

Caution should be drawn to the interpretation of the findings mentioned above as only a very small sample of the trial has been reviewed.

In terms of data management, criteria for data entry, although already defined and applied according to procedures, should be more detailed. Data entry personnel should make no assumptions. Anything that is missing, incorrect or inconsistent should be queried. A number of cross consistency checks ought to be run, especially with regard to questions related to premises and housing, as some inconsistencies are missed at present.

Measures should be put in place to ensure a consistency of approach to the whole process, a close coordination of the project. More support should be given to the AHDOs. There could be monitors visiting the AHDOs to follow the process, to monitor the forms, to give quick feedback to avoid systematic errors. The more attention that is given at the beginning (at the source of the data), the less work is required further down the process.

Another possibility would be to have a revised, simplified questionnaire with a small dedicated team that was appropriately managed.

In view of these findings and the recommendations made, the auditor suggests that the whole process should continue to be audited.

Part I An audit of the TB 99 questionnaire September 2003

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Key words: Personal contact, communication, coordination, consistency, documentation, interaction, no assumption, and no interpretation

1. Introduction

The Independent Scientific Group (ISG) appointed to advise Defra on the TB 99 questionnaire have made it clear that they wish to see all aspects of the Randomised Badger Culling Trial (RBCT) audited. The audit of the TB 99 questionnaire therefore forms part of the wider audit of the whole of the RBCT.

TB 99 was preceded by TB 49, a management tool for controlling a TB incident; this form gave insufficient epidemiological information for a meaningful analysis. TB 99 was designed to collect epidemiological data on risk factors as well as assisting the SVS to manage the TB incident. Originally TB 99 was extremely broadly based with a view to giving a hierarchy of TB risk factors. It had been hoped to reassess TB 99 after 100 case control pairs (400 forms) had been completed; it was thought this would occur after one year of the project. Due to other factors and priorities, the requisite number of controls has only just been achieved. Hence, the audit is now taking place.

2. Rationale

The rationale is to have reasonable assurance that the conclusions or recommendations which will be made at the end of the trial are based on the analysis of data collected which is as complete, accurate and reliable as possible.

3. Material and Methods

3.1 *Material*

All pertinent material was available for the auditor.

Defra provided:

- The various versions of the questionnaire (1999, 2001 and 2002).
- The appendix J1, which are the instructions on how to complete the questionnaire.
- The three reports of the Independent Scientific Group on Cattle TB.

- Action notes related to the various changes that took place throughout the study.
- The content of a training session for ADAS consultant.

VLA provided:

- Two folders that contained, amongst other documents related to data entry and allocation of controls, a quality control document.

3.2 Method

Because the questionnaire has changed over time the audit concentrated on examining the later TB 99 questionnaires (versions 2 and beyond.). This was done so that any findings can be used to make improvements to the current form. It does, however, mean that the quality of data relating to questions that have been dropped since TB 99 was initially established, has not been ascertained.

a) What could be done

The documents provided were briefly reviewed. The standards against which the audit was carried out were:

- For data management.
- The procedures in place, the quality control document and good data management practices. Computer data validation and data safety were not assessed, as the auditor does not have the competence to do it.

VLA was visited twice

- For the Animal Health Divisional Offices (AHDOs) and the visit to the farms.
- Processes in place to ensure the proper completeness of the questionnaires in terms of both quantity and quality (including queries handling).
- Processes of filling in the questionnaire according to the instructions and the way of assisting the farmers in filling in the questionnaire.

Two AHDOs were visited as well as four farms. In three of them the AHDO representative completed the questionnaire with the farmer in front of the auditor. In the fourth farm, the questionnaire had already been completed but the VO went through it again with the farmer for the benefit of the auditor.

An assessment of the consistency of the approach could be carried out.

b) What was originally planned and could not be assessed yet

- A training session of the Veterinary and Animal Health Officers who assist the farmers in completing the questionnaires. The material used for it was given to the auditor but the auditor did not follow the actual session until now, as none took place.

- A comparison between source data and the questionnaire has not taken place yet. There has not been sufficient time to do this yet and, what constitutes source data had not been identified clearly. (ie all the booklets kept by the farmers) until the visits to the farms.

4. Findings

4.1 Visits to VLA

Two visits to VLA took place until now.

a) First visit

During the first visit, the auditor noted a number of points, which led to the recommendations, which have already been distributed to the ISG. These can be found at the end of this report in Attachment 1.

In summary the findings were related to the changes in data handling over time which should be documented in writing (queries, 10% quality control, reason for rejecting controls). The data entry procedures should be more detailed and more precise to avoid personal interpretation. There should be more interactions between the different members of the TB 99 team.

Comments/recommendations

Following the recommendations:

VLA has developed an action plan that should be implemented in the autumn. The auditor recommends an audit towards the end of the year (December) to assess how the corrective measures have been implemented.

Defra has provided the auditor with additional documentation including action notes. These documents showed that changes are documented.

In addition, during the first visit to VLA the AHDOs to be visited were selected. All Animal Health Divisional Offices (AHDOs) data were looked at in terms of contribution, number of queries raised by the questionnaire, reasons for not accepting a control. The auditor concentrated on the culling trial areas.

Stafford was selected because it was a more recent contributor to the trial and also because it was a high contributor in terms of number of questionnaires completed. Truro was chosen because it was a well-established trial area and also because it was a high contributor in terms of number of questionnaires completed.

b) During the second visit

The data administrators were absent. One was on holiday and one was sick. Therefore, the 10% quality control check procedure could not take place.

The visits to the AHDOs were organised. The auditor looked at the number of officers having filled in the questionnaire, the number of queries per officer. The data for the two lead VOs for TB 99, who were present at the time of the visit, were looked at including the queries their questionnaires generated. A number of printouts were generated which constituted the basis for some of the discussions in the AHDOs.

4.2 Visit to the AHDOs and to the farms

a) In Stafford

In the AHDO

Present: Official A (EO), Official B (AO), Official C (VO)

Absent Official D (EO) and Official E (AO).

Processing of TB 99 questionnaires

A document describing the procedures for the processing of breakdown and controls TB99s had been prepared for the auditor. It is a succinct and comprehensive document that the AO described in details.

Point 5 of the document: *Contiguous testing*: At present animals are out so a contiguous testing could take at least 3 months.

Comments

- *Therefore, in Stafford they accept a control without waiting for the contiguous test result, whereas in Truro they do wait for the contiguous test results before accepting a control.*

Tracking procedures

Every year there has been another AO taking care of the tracking of the questionnaires. At the time of the visit the AOs were not actually able to trace all questionnaires sent to VLA, as they have no logging system.

Comments

- *There at least should be a system, even if not uniform throughout the AHDOs, to be able to track what has been sent to VLA.*

- *Truro had actually identified this as a job that required doing (Official F/2 days per week). He had developed spreadsheets to keep track of the status of TB 99s.*

Recommendations

- *It might be worth suggesting that other AHDOs could consider using his system, if they have not yet developed their own method.*

Filing

In the files, per questionnaire, are succinct hand written notes, map, a print out of 1 km radius search and the original of the questionnaire.

Comments

- In Stafford, the original of the questionnaire is kept in the AHDO. In Truro, the original is sent to VLA.

Recommendations

- There should be a uniformity of approach throughout the AHDOs.

Queries

The pertinence of some of the queries was discussed.

The VO was not aware of the fact that queries related to the questionnaires he had filled in had been sent back to the AHDO for response.

Comments/ recommendations

- One way to improve the completion of the questionnaire is to have a quick turn over of queries. Apart from answering the query, this has an educational effect. It helps to avoid repeating the same mistakes time over time (provided the queries are relevant). At the same time, it was also apparent that there is a need for close interaction and direct contact between VLA and AHDOs to discuss and agree on what constitute sensible and valid queries.

Acceptance or refusal of proposed controls

In Stafford in 24 instances (at the time of the visit), the farmers had refused to become controls. They either said already no when contacted by phone or they refused when they got an information paper on the questionnaire feeling it was too complex.

In the database a number of controls allocated have been neither rejected nor accepted yet. The person in charge of dealing with the controls was not present at the time of the visit so no one could give any explanation.

Comments

- There were at least three people who had done the 'control job'. There seemed to be a lack of continuity in the way in which they had gone about it.

Staff having completed the questionnaire

In Stafford: Until now 24 TB officers have contributed to the completeness of the questionnaire. The VO did not have a list of who attended the training course for completing the questionnaire.

General comments and recommendations

- The staff were committed and keen on doing a good job. They were asking a lot of questions of the TB 99 database manager. It was clear that the whole project would benefit from more interactions by direct contact between VLA and AHDO. The TB database manager could identify some of

the practical needs of the AHDO because he saw for the first time how they actually worked in practice.

Example of questions asked: Date when incident starts: Is it the date when the reactors goes down or the date in VetNet? There was a detailed discussion as to what constituted a start date of incident as defined by TB 99.

On the farms (Stafford)

The TB 99 questionnaire may be referred to as the form.

Case: Farm 1, Questionnaire number: 3525

Present: Official C (VO), the TB database Manager (VLA, data management responsible), the auditor and Farmer 1

The visit took place on Thursday 10 July 2003.

The questionnaire had been completed earlier.

The comments below refer to specific questions and how they were handled.

1.5: Movements off

Q: How many reactor animals were disclosed as a result of tracing from this incident?

A: F/R

Q: How many confirmed herd incidents were disclosed as a result of tracing from this incident?

A: F/R

Comments

- Further report (F/R) should not be used. It was agreed in a TB 99 working party meeting before the new version was implemented that initial report and final report are only sent after a breakdown is closed. This decision was not minuted but in fact, this is specified in the update of how to fill in the form (Appendix J).

1.7: Herd health over past 12 months

Source data was available for this question. The farmer has a medical record booklet.

Comments

- Only disease codes known as present and ticked as such (yes answer) are entered in the Database. All the others, although ticked as no in this form, are not entered in the database. Data management assumes that all fields not ticked as yes are no, not making any difference between the ones

truly answered as no (presumably checked) and the ones left blank, which in fact could have even been an error when filling in the form, or could have been truly missing.

2.3: Details of premises where cattle from the reactor farm have been kept from the 12 months prior to the start of the incident

A “field data sheet movement book” was the source data for this information.

Comments

- There is no mention of reactor in the instructions as opposed to the form title that mentions the word reactor. According to the TB Database Manager there has been agreement between all (VLA and AHDOs) that this question should refer to all premises, ie the form is wrong and the instructions are right. However, if some AHDOs are interpreting the instructions on the form literally, this could have serious data implications.

2.4 Details of cattle accommodation (including grazing) where reactor cattle were kept during the 12 months prior to the start of the incident

This information is based on a diary kept by the farmer (source data).

Comments

- The form was wrongly complete. In the 'premises No' column, cow and calf are mentioned. In addition, the reactors have only been on one premise (2.3) and here three premises are mentioned. The next column for 'house No', was not completed at all.

There was a major misunderstanding regarding Q 2.4. It had not been realized that you needed to define housing at this question (in fact, the VO incorrectly thought that version 2 of the form did not refer to housing). Because the later part of the questionnaire relies on the correct identification of housing where the reactors had been present, the errors in 2.4 meant that the answers to 2.11, 2.12, 2.13 & 2.14 were also incorrect.

2.7.a: Contiguous herd contact

Comments from the farmer

'direct contact is not necessarily equal to contiguous'

But for data management, it is the same. This information is used for the allocation of controls.

2.10.a Boundaries

Comments

Data was entered for premise number 5. There was no premise number 5.

Comments from the VO

- Point i and ii. Approximate total length of all internal and external boundaries is impossible to answer (the same comment was made by the VO in Truro).

2.13. Housing

Comments

The whole section is wrong as he only talks about 1 house yet he has 3 houses.

2.15. Wildlife seen on reactor premises, time element

Comments from the farmer

'It was unclear as to over what time period this question referred to.'

The farmer mentioned having a badger in a house, but this was well over a year previously. The VO entered this data. The instructions page 21 say "at any time during the year preceding the date of the TB incident".

General comments

- Following the visit to the farm the VO was asked to show us which version of the instructions for completing the questionnaire he was using. He showed us a paper copy of the initial instructions dated 1999. But after seeing our surprise, he added that if he should have any doubt or query about a question he would look in the intranet.

General recommendations

- Indicated above a number of pieces of information in the form are derived from "original source data". In the instance of this farm: medical records booklet, field data sheet movement book, herd composition, movements off and on, movements of cattle within farm and crop details. In future audits the data on the form could be checked against source data and the database to check the accuracy and the completeness of the information.

Control: Farm 2.

Questionnaire number: 4079

The breakdown date of the incident case was 13/05/02.

Comment

- This control case is taking place over a year after the breakdown date of the incident.

The visit took place on Friday 11 of July 2003

Present: Official C (VO) Official G (ADAS Livestock Consultant.) Farmer 2 and the auditor.

1.6: Testing history of contiguous herds, proposed action and results of testing of contiguous premises

Comment from the ADAS representative
- *Why is this page there at all?*

1.7: Herd health over past 12 months

The question was overlooked by Official G, but was noted by the VO present.

2.4: Details of cattle accommodation (including grazing) where reactor cattle were kept during the 12 months prior to the start of the incident

Comments

- *The ADAS person was making the same mistake as the VO mixing premises and houses. In fact in 2.4 he did not fill in the column on 'house No.' which again has consequences for all the questions related to premises and housing. The VO noted this.*

General comments.

- *Official G had his own map of the area with him. In the Action Note 2002/84 chapter 23 it is said page 3 of 4 that "he or she must be provided with a map (GIS) of suitable scale...." Official C will make sure that this happens in future.*

Apart from the points mentioned above the ADAS representative was taking his time, explaining what he was asking. He did not at anytime push for the answers. He gave enough time for the farmer to answer. He was professional and supportive.

b) In Truro

In the AHDO:

Present: Official F (VO), Official H (AO), Official J (VO), TB Database Manager (data management responsible) and the auditor.

Absent: Official K: (AO).

Processing of TB 99 questionnaires

The procedures were described to the auditor. According to Official F who does the initial check when there is a breakdown, there are numerous premises in Cornwall. He first checks that the breakdown is in the trial area, then whether the reactor has grazed in the trial area. Then a map is prepared. Part 1 of the questionnaire is filled in.

The maps the VO takes out with him are already prepared for the coming visit. Contiguous premises are worked out from the map.

Movements are generally filled in in the AHDO. Movement's records are photocopied (book of record generally taken from the farmer, photocopied and sent back).

Tracking procedures

A system is in place that allows follow up of the present status as well as TB99s sent to VLA. This system is up dated on an on-going basis and the same person is doing this work (Official F).

Filing

The file of each case contains a map of the farm and surrounding area, all preceding records and actions taken, an epidemiological form related to the case and for local use.

Comments

- In Truro they have there own epidemiological form, they say that they do not use section 3 "manuscript part of TB 99".

Queries

First the VO said that all VOs were taking care of the queries related to the forms they had filled but in fact there is one person who deals with the queries first and then consults the VOs if necessary. This person (Official K) was absent on the day of the visit.

Acceptance or refusal of allocation of controls

In four instances (at the time of the visit), farmers had refused to be controls. The reasons were in two instances movement restrictions, and in the two others the farmers did not want to participate.

In the database, there are a number of pending cases (controls neither rejected nor accepted yet). The person in charge of dealing with the controls Official H was present at the time of the visit and because the tracking system is in place, she could check whether this was correct or whether there was a data entry problem. This work is still in progress.

Comments

- Since the time of the visit. Official H has commented on the list left with her and has sent it back to VLA. According to TB Database Manager, who has not yet studied it in detail, Official H says that they never received some of the allocation, or they were invalid. This issue is pending and needs to be addressed further.

From a methodological point of view, the auditor believes that it is important to have a "clean and complete" database on the controls, particularly recording reasons of accepting or refusing to participate to the trial.

Staff having completed the questionnaire

In Truro, over 30 persons have completed the questionnaire. The VO did not have a list of who attended the training course for completing the questionnaire.

Comments and recommendations

- In Truro, the staff have greater experience with TB. Their computer tracking system seems to be in place (the system was shown but there was in fact no time to assess the accuracy of the information computerised). Their individual files (cases) contain a lot of information (past and present).

In Truro, they wait for contiguous test results if not tested in last 3 months. The choice of a contiguous control is only made after the results of contiguous tests are negative. This is different to Stafford where staff, as mentioned earlier, allocate controls at once without waiting for any results of contiguous tests.

Case: Farmer 3, Farm 3,

Present: Official J (VO), TB Database Manager (VLA, data management responsible) the farmer and the auditor.

The visit took place on Tuesday 15 July 2003

The VO started the questionnaire at 1.7.

1.7 Herd health over past 12 months

There was a lengthy discussion between the VO and the farmer about the disease and the severity of the disease.

Comment

*- The VO started the question by "I expect..." which is already leading to the answer. The question on the form is straight "disease known to be present" but in the instructions it mentions " **significant** problem".*

2.1 Description of whole farm

The herd was established in 1964 and the farmer has been on the farm since 1987.

Comment from the VO

- How do you answer the question about the time the herd has been established. There was confusion between farm and herd.

Comment

- In the questionnaire it asks how long has the herd been established. In the instructions it asks how long has the herd been established at this premise.

2.2 Usual herd composition

Comment from the VO

- What time period do we refer to? Is it last 12 months? How long do you go back? On this farm, they have always had a breeding dairy bull but not at present. Nevertheless, this data was entered as being present.

Comments

- There is no advice in the instructions about the timing. The previous 12 months are mentioned for 2.1 and 2.3 but not for this question.

2.3 Details of premises where cattle from the reactor farm have been kept from the 12 months prior to the start of the incident

Comment

- The VO decided to enter this farm as a single premise although there were lands spatially separate and used for different purposes.

Comments

- If one decides to treat it as one premise it simplifies the answers to all questions related to premises.

The instructions (Appendix J) are not clear on how to define premises. “**Premises**” means an area of land fragmented, which may or may not include buildings and yards. One or more premises will make up a **holding** which is synonymous with “occupier”, and the holding will be identified by a “main premises” and may or may not have a number of subsidiary premises.”

Recommendations

- The auditor suggests to look over time if VOs who have filled in a number of questionnaires have simplified their answers to this question. The statistician was also asked to look if over time the number of premises had gone down. This has not been the case.

2.4 Details of cattle accommodation (including grazing) where reactor cattle were kept during the 12 months prior to the start of the incident
In this question, the VO also mentions only one premise.

2.5 Epidemiological group of cattle

For group 7, the VO answered yes and no for the question on whether the reactors were ever in this group or not.

Comment

- The reason for this was that she had filled it in before the farmer had had a chance to answer the question. The VO assumed which epidemiological group the reactor cattle had been in.

2.6 Other species of domestic and farmed animals on the holding

Comments

- The VO asked all the questions but when the answer is not present it is not entered as no it is left blank so in this instance the work is done but there is no way of knowing that it was done as it is not recorded. This information could have been missing as nothing was entered. In addition further down the process “no” is not entered in the database.

2.7 Contiguous and other herds

2.7c Indirect contact

Comments from the VO and the ADAS consultant

- *This question is irrelevant.*

2.7d Other domestic/farmed species

Comments

- *The VO only asked about contiguous contact. She left out the non contiguous and the indirect contacts. They think this question is impossible i.e. they mentioned things like how are they meant to know all the farms that water goes through, before it reaches the farm they are on.*

2.8 Crops

Comments

- *VOs find this question confusing. According to the TB database manager this question has always led to confusion. The problem is where the same piece of land is used for multiple purposes i.e. for hay and grazing. Version 2 tried to overcome this by having two subtotals, total grass and total tilled, which should add up to the area of the farm, but he is not convinced that this is working.*

2.9 Environment

2.9 a: Land cover classification

The VO was prompting the answers.

2.10a: Boundaries

Comments from the VO

- *Point i. and ii. Approximate total length of all internal and external boundaries is impossible to answer (the same comment was made by the VO in Stafford).*

2.14.2: Supplementary feedstuffs used on reactor premises

Comments

- *The VO did not make it clear that it was on reactor premises.*

Part 3

Comments

- *The VO filled in a TB epidemiological form, which is a local one for Truro.*

General comments

- *The VO had a tendency to prompt answers and not let the farmer express himself. She spent mainly time on questions of interest to herself.*

Control: Farm 4 Questionnaire number 4058

The breakdown date of the incident case was 27/12/02.

Comment

- *This control case is taking place six months after the breakdown date of the incident.*

The visit took place on Monday, 14 July 2003.

Present: Official L (ADAS Livestock Consultant.), TB database manager (VLA, data management responsible), Farmer 4 (farmer) and the auditor.

The map of the control farm and the immediate vicinity area of the control was provided by the AHDO.

The ADAS consultant went directly from question 1.3 to question 1.6. Questions 1.4 and 1.5 are about movements. He decided to take the book of movements with him, photocopy it and send it back. This appears to be the procedure in Truro. It saves time and allows the person completing the TB 99 to concentrate on the other questions.

1.6: Herd health over past 12 months

This was filled in based on the farmer's memory: He had no records.

2.3: Details of premises

Comments

- *There were three premises run as one unit entered as one premise.*

2.4: Details of cattle accommodation on each premise where the selected control cattle were kept during the past 12 months

This was filled in based on the farmer's memory: He had no records.

2.5 Epidemiological groups of cattle

Group condition

This was filled in without looking at the animals' actual condition which is in accordance with the instructions.

2.6 Other species of domestic and farmed animals on the holding.

Do they have contact with cattle?

Comment

- *This question was not asked.*

2.7b and 2.7c Non contiguous contact and indirect contact

These were not filled in.

Comments

- *The ADAS consultant said he knew the answer to these two questions was zero, from the work he had done at the start with the map. But in fact, surely this only identified contiguous herds?*

2.7d: Other domestic/farmed species

Comments

- *The ADAS consultant did not ask further than contiguous contact. The VO had done the same.*

2.15 Wildlife seen on control premises

Comments

- *The ADAS consultant in Stafford spent much more time on this question.*

General comments

- *The ADAS person was precise and succinct. He did not spend much time discussing other issues than the questionnaire. He went straight to the point. He has experience in completing questionnaire. He did not prompt any answers. The farmer was not influenced by the ADAS person in his reply.*

4.3 Comparison between questionnaire, database and queries raised

Two questionnaires completed in Stafford were selected to compare the data on the form with the data in the database and to check which data (missing, inconsistent) actually raised queries.

Form 2210

Paragraph No	Questionnaire: completion by the VO	Database (DB)	Query raised	Comments
1.2 (a) Incident details	Date restrictions served and date that herd restrictions: corrected by hand	Entered		Correction by hand (not known by whom, nor when) Information from VetNet. AHDO informed
1.3: Reason for slaughter	first animal: entered as R	first animal: entered as IR		IR in Vet Net
1.4 (a, b) movements on	Data missing	matching	Yes	
1.5 (a, b) movements off	Data missing	matching	Yes	
1.6: Testing history of contiguous herds	Some data pre printed corrected by AO	1.6 not entered in DB		
1.7: Herd health over past 12 months	Completed for all disease codes (yes and no answers)	Only yes answers have been entered,	No	no answers although ticked as no are not entered in the DB

Comments: As mentioned earlier, this is an example where all data from VO are not entered: It means that for this question on herd health one would not know if what is not entered in the database (although filled in the questionnaire) is yes, no, not known, or could be yes but not asked. In this instance, the VO had done a complete job by ticking all disease codes. Data management at present assumes that a blank in DB is no. it seems a pity that when data is available it is not processed and that one makes assumption that a blank is a negative answer. In addition, the VO had only followed the instructions.				
Paragraph No	Questionnaire: completion by the VO	Database (DB)	Query raised	Comments
2.3: details of premises	Premise 2 and 3: type of premise ticked in 2 boxes (grazing rented and outlying farm) OS map reference missing	DB only accepts one tick so grazing (rented) was entered Matching	Yes	DB does not match the questionnaire
2.4: details of cattle accommodation	Premise 2 house 1: presence of reactor: No month ticked	Blank	No	Should have raised a query
Comments: In this question the VO mentions only 2 premises where the reactor has been but in 2.3 he mentions 3 premises where the reactor has been. This could be flagged as an inconsistency and raise a query if there were cross consistency checks between the 2 questions. The same applies to grazing: In the previous question he says that the reactor has been grazing on 3 premises and he only ticks grazing in 1 premise in this question. The VO has difficulties with 2.3 and 2.4. This has an additional impact on the answers from 2. 10 onwards.				
2.5: Epidemiology group	Cattle type. BBA entered for group 2, Hrfx entered for group 3	Not entered	Yes: No such cattle types exist	
2.7 (a)	Contiguous herd contact: 1 st line, code: other Restricted since tracing date: empty	Entered as not known Matching	Yes	Data entry error?
2.8	Crops: data	Matching		
2.9	Environment: data	Matching		
2.10(a) grazing: boundaries	Completed, incorrect	Matching	No	Inconsistency: Has been grazing in premises 1, 2 and 3 (2.3). yet in 2.10a grazing ticked for premises 1 and 2: This did not raise a query: i.e. no cross consistency check between 2.10(a) and 2.3
2.10(a) approximate total length of int./ext. boundaries	Not answered	Matching	Yes	
2.10(b) grazing systems	Answered for the 3 premises	Matching		No cross consistency check between 2.10(a) and 2.10(b)
2.11: management of cattle.	Completed	Matching		
2.12: source and delivery of drinking water....	Completed	Matching		
2.13.2(b) source and delivery of drinking water to the reactor cattle while housed....	Were any water troughs for house cattle located outside the house answered no for a third house yet only 2 houses mentioned in 2.4	No not entered		
Comments: "No" is probably an error made by the VO when filling in the questionnaire, but it is on the form. It was neither entered in the database nor queried.				
2.14.1 Mineral supplement	Completed	Matching		

2.14.2 (a) feeding of cattle outdoors	Other: trough or feeder: height: 0 cm	Entered as 60 cm		Data entry error or assumption
2.14.2(b) Feeding of cattle: inside buildings	Green foods: height: 0 cm	Not entered	No	Green foods present answered yet height not entered did not raise a query
Paragraph No	Questionnaire: completion by the VO	Database (DB)	Query raised	Comments
2.16: possible association with TB	Completed for yes answers, not completed for no yet questions asks Y/N	matching		
2.17: TB prevention	Completed	Only enter yes answer for 1 premise: others answered as no but not entered as such		

General Comments

- A number of mistakes especially inconsistencies were made when filling in the form by the VO. If these had been identified at an early stage, it could have been used as a training process for this particular VO. Monitoring of the form or a quick data entry with a program capturing all inconsistencies could have helped prevent the repetition of errors in subsequent forms.

Form: 2517

Paragraph No	Questionnaire	Database	Query raised	Comments
1.3: homebred or purchased location of lesions	Left blank N/A	Homebred blank	No	Assumed or data entry error? Why no query?
1.4 (a, b)	Data missing	matching	Yes	
1.5 (a, b)	Data missing	matching	Yes	
1.7: Herd health	Completed for all disease codes	Only yes answers are entered,		no answers although ticked as no, are not entered (see comments for 1.7 above)
1.12 Were cattle on the farm slaughtered for the purpose of FMD control during 2001	Answered no	Not entered	No	Should have raised a query
2.1: description of whole farm	Completed	Matching		
2.2. usual herd composition	Completed	Matching		
2.3: parish testing interval/years CPH number OS map reference	Missing Only provided for 1 premise Missing	Matching Matching Matching	Yes Yes Yes	
2.4: details of cattle accommodation	Missing for 2 premises	Matching	Yes	
2.5 :Epidemiology group	BBA entered for group 2, Hrfx entered for group 3	Not entered	Yes: No such cattle types exist	

2.7(a) contiguous herd contact	1 st farm: restricted since tracing date entered as no	Left blank	No	Data entry error? Should have raised a query anyway?
Paragraph No	Questionnaire	Database	Query raised	Comments
2.7 (d) other domestic farmed species	2 nd farm restricted since tracing date not answered	Matching	Yes	In this instance a blank raised a query, inconsistency with 2.7 (a) where a blank did not raise a query
2.8 crops	Completed	Matching		
2.9 (a, b, c, d), environment	Completed	Matching		
2.10(a) grazing: boundaries	Completed for 3 premises	Matching		
2.10(b) grazing systems	Answered for 2 premises only	Matching		No cross consistency between 2.10(a) and 2.10(b)
2.11: management of cattle: manure	Incomplete	Matching	Yes	
2.12: source and delivery of drinking water....	Completed	Matching		
2.13 Housing	Completed	Matching		
2.14.1 Supplementary feeding of the reactor cattle: Mineral supplement	Completed only for 1 premise yet 3 premises where reactor cattle has been	Matching	No	No cross consistency checks with 2.3
2.14.2(b) Feeding of cattle: inside buildings	Missing, not answered	Matching	No	Did not raise a query
2.15: wildlife seen on reactors premises	Badgers: elsewhere on farm, Foxes: also elsewhere on farm	Not entered Not entered	No	Did not raise a query yet field is blank for badgers
2.16: possible association with TB: risk factor	Present on farm: Completed for yes and no answers	Only yes answers entered		
2.17: TB prevention	Completed	Only enter yes answer for 1 premise: others answered as no but not entered as such		

General comments

- The review of these two forms showed that some work is required to improve the query program. It also emphasizes the importance of having a quality control check. The 10% data check must be carried out as a priority and reviewed on a regular basis. Although based on a small sample it seems that more data entry errors were made towards the end of the form (i.e. 2 15). More forms ought to be checked to be able to draw any conclusions on this issue.

4.4 Training

The auditor could not attend any training session as none is taking place at present. The documents presented at a training session, which were given

to the auditor for review, are clear and succinct but the auditor cannot comment further at this stage.

Comments

- In the two AHDOs visited, as mentioned earlier, no one could provide the auditor with a list of the persons who attended the training session. This is unfortunate as in Stafford 24 persons completed the form and in Truro 32 persons (You said over 30 elsewhere). Some of them have only completed one form but nevertheless it raises the question as to how have all the staff been trained in completing it. Of course, only the ones who have completed most forms could bias the results. The auditor has asked VLA to produce a list per AHDO of all the persons who have filled in the questionnaire as well as how many they filled in.

In Truro, they are now keeping a record of the training courses in general but this is a recent initiative.

4.5 Recommendations

a) On the questionnaire

The questionnaire is overly complex. It requires simplification. In future, any questionnaire used should be simpler and shorter.

It is difficult to capture the attention of the person being interviewed for over 2 hours. It is equally difficult for the interviewer to concentrate for over 2 hours.

The questionnaire and the instructions must match. The instructions should be simple and user friendly. An annotated questionnaire could be useful.

The questionnaire should have a case identification number on each page. At present, if the hard copies are not attached together one does not know to which case a single page refers to.

b) On the people “in the field”

Possibly too many people are going out to farms (on average 25 to 30 persons in each AHDO have gone to visit farmers to complete the questionnaire at least once). It would be better to have as few interviewers as possible, but they should be well trained and capable of following cases including correcting the questionnaires if needed.

The persons filling in the questionnaires should do it in a professional way. They should be neutral when asking the questions. They should avoid being emotional. They should not influence the answers. They should go thoroughly through all the questions.

c) On data management

As mentioned earlier the data the analysis is based on should match the original source data. If it does not, there should be written documentation available that explains why it does not match. When handling the data

(data entry and analysis) no assumptions should be made, no interpretation should take place. If one allows these to take place, each person will have his own interpretation or assumption and this will introduce bias. There has to be consistency within individuals and across individuals when dealing with the data, hence the importance of documenting in detail what is being done for each field of information. The credibility and the reliability of the data depend on this.

In addition, a number of cross consistency checks should be carried out for the data already entered and corrective actions (including correcting the data on the questionnaires together with the AHDO representative) should take place.

d) On the whole process

A much more proactive and unified approach would improve quality.

There should be a project coordinator who is aware of the whole situation and who has sufficient time to supervise all the phases of the process. This would also overcome the problem of local decision making that leads to inconsistencies across AHDOs.

There should be more active monitoring in the field. There should be more interactions between all parties. It is in the field that the data is generated. More attention should be given to this aspect of the trial. The more attention that is paid in the early stages of the process the less work there will be thereafter and there will be more chances of improving the quality of the data.

In addition, changes in the process must be documented in such a way that an “outsider” should be able to follow what has happened by himself without further oral explanation from any of the TB 99 team.

e) In terms of audit activities

The findings at the AHDOs and on the farms are only based on a small sample which may or may not be representative of what is happening elsewhere. Nevertheless, they raise a number of issues, which should be investigated further. For the immediate future, the auditor recommends extending the visits to the main AHDO’s contributors, and to visit some farms with the most active AHDOs representatives.

The implementation of corrective measures taken by VLA following the first recommendations made by the auditor should also be checked. The 10% quality control check procedures should still be assessed.

A random sample of data recorded in the form should be compared to source data, which has now been clearly identified. This would also add to the credibility of the data.

The auditor also should review the minutes of the TB 99 working groups meetings, which have taken place in the last 2 years.

5. Conclusion

All staff involved from Defra, VLA and the SVS gave their full support and cooperation to the auditor. Official M (Defra) provided all the documentation required. He also organised the visits to the field. In VLA the data management team was available at all times and fulfilled all the auditor's requests. TB database manager (VLA) accompanied the auditor in her visits to the AHDO and his knowledge of the questionnaire was of great help and both facilitated the understanding of the process and prevented misunderstanding and misinterpretation. In the AHDOs, everyone was keen to find ways to improve the quality of the data.

The approach to the completion of the questionnaire varied. The ADAS consultants were more questionnaire oriented, perhaps more neutral. The VOs were more scientifically oriented, perhaps more enthusiastic and therefore having a tendency to prompt the answers. But caution should be drawn to the interpretation of these findings as only a very small sample of the trial has been investigated.

In terms of data management, a number of inconsistencies, missing or incorrect data is not queried at present.

The questionnaire in its present form is very long and not structured enough. Therefore, the data on the form and in the database is not necessarily an accurate reflection of the data on the farm.

For the future one set of options would be:

- Revise the existing form, with account being taking of both the preliminary analysis and the findings of this audit. The revised form should be shorter, targeted and more structured. The people responsible for the revision should take into account: interviewers, data manager, statisticians, quality assurance staff and selected farmers.
- Target a sample of representative farms.
- Have the project run by a project manager with a small, dedicated team.
- Ensure ongoing audit activities/trouble shooting and quality assurance procedures are put in place, to assess whether a consistent approach is taken at all times.
- Encourage personal contact/exchange of information/feedback.
- Obtain feedback from the main contributors, to capitalise on the lessons learnt so far.

In the meantime, given the findings of the auditing activities so far, the auditor recommends that auditing activities should be ongoing.

Attachment 1

Recommendations following the review of the data management process in VLA, Weybridge (11 June 2003, already distributed to the ISG)

These recommendations follow a review of the process of data management in VLA. This review is still ongoing. A full report will be available after another visit to VLA as well as a visit to some animal health divisional offices and farms. Nevertheless, these recommendations are issued at this stage so that they can be implemented as soon as possible.

Rationale

The rationale for these recommendations is that one should always be able to trace data. The data the analysis is based on should match the original source data. If it does not there should be written documentation available that explains why it does not match. When handling the data (data entry and analysis) no assumptions should be made, no interpretation should take place. If one allows these to take place each person will have his own interpretation or assumption and this will introduce bias. There has to be consistency within individuals and across individuals when dealing with the data, hence the importance of documenting in detail what is being done for each field of information. The credibility and the reliability of the data depend on this.

In addition, changes in the process must be documented in such a way that an "outsider" should be able to follow what has happened by himself without further oral explanation from any of the TB 99 team.

To be implemented sometime in the near future:

A history of what has happened over the years should be put together.

History of the changes

The TB 99 questionnaire has been modified (version 99, 2001 and 2002). It is not enough to have the questionnaires available; one should describe in a chronological order what has happened and how and why the questionnaire was modified.

History of data handling. Some decisions have been made, which should be documented in writing, such as:

- Query program implementation: when did it start, what has happened to data entered prior to the implementation, was that data queried too?
- The reason for rejecting a control was not entered prior to June 2001.
- The criteria for the 10% check of data entry were changed in June 2002.

There should be clear statements which take up the various points and give precise dates as to when certain policies were introduced, which data they do affect and which data they do not. The dates of introduction of these policies can be found quickly in the computer in different programs but there should be a concise summary of all of them.

To be implemented as soon as possible:

In principle, a questionnaire should be complete and accurate. If it is incomplete, it should be queried. If it is not accurate or if it is inconsistent, it should be queried.

Data entry procedures

Empty fields. All empty fields do not appear to have the same meaning: for some it is acceptable for them not to be filled in, others are empty because the information is missing, unknown, or not applicable. This must be documented. The significance of this information must be discussed between data management and the statisticians

Fields filled in by hand but data not entered in the computer. An explanation as to why one decides not to enter the information should be given. In principle, all data recorded "at the source" should be either entered in the database as such or queried if necessary.

The data entry procedures should be more detailed. The persons actually doing the data entry should review the document and complete it. The above mentioned items must be developed in this document. As mentioned earlier, this will help achieve consistency for each data entry person as well as between data entry persons.

From a methodology point of view and to be beyond criticism it is much better to define these things now in a prospective fashion rather than retrospectively when the analysis is carried out.

At present, it is not easy to assess the amount of "true" missing data.

The validation programs (validation constants, form control validation document version 2 and query database).

These programs should be reviewed and updated on an ongoing fashion. This is a dynamic process. For example, when a data entry person identifies an inconsistency in the way the questionnaire is filled in, and the computer still allows this data to be entered, without querying it, this person should discuss this within the group and see whether the program could flag these inconsistencies. This at present is not the case for all consistency checks.

A series of computer based queries (consistency checks) that can be run at regular intervals by the administrative staff should be developed.

There must be more interaction between all the parties involved (see below).

The 10% quality check of the questionnaire

The delay in carrying out this check (30 pending/271 checked on June 5th 2003) should be overcome. This 10% check should be a good indicator of the data quality. The results of this check should be reviewed regularly within data management to assess the reasons for the errors. For example, are they: errors occurring at source in the field that have been allowed onto the database due to possible weaknesses in the program (error not flagged), or are they data entry (transcription) errors.

Interaction between working parties

The group in VLA needs the input of Defra to be able to flag information entered in the DB which is of scientific significance and which would require further clarification from the field. Defra should also give its input in the "boundary checks" which have been entered in the program to check whether they are complete and whether the limits given are appropriate.

The statisticians need to work in close collaboration with data management. No "executive decision" should have to be made by the statisticians. (for example the significance of empty fields).

These recommendations were discussed and reviewed with TB database manager.

General comments concerning VLA at this stage

- The team in VLA gave its full support to the auditor. The team was available, cooperative and had a constructive and positive attitude. The group is not only just interested in carrying out the work but also keen to improve the quality. More interactions within the team to identify the weaknesses and how to improve the quality would be beneficial but at present the TB 99 administrators are extremely busy just carrying out data entry and control allocation. To give a higher priority to the various quality initiatives recommended above may not be that easy.

- The quality control document is of good quality but it still needs to be reviewed for completion. The auditor plans to go through it in details with the team during her next visit.

- The auditor followed the control allocation procedure together with the administrator. The process runs according to the procedures. Control allocation can take time.

- All data required by the auditor was available at once. Programs were written on the spot.

- The team should get into the habit of dating and signing their documents (authors).

- A delegation of responsibility sheet could be developed indicating who is taking part in data management: name, function, time period in the project, sample of initials. The auditor will provide examples of such sheets.

- Corrections or changes to the TB 99 questionnaire should be dated and initialed. Only authorised persons should be allowed to correct the questionnaire, and they should do so only if they have proper documentation supporting their corrections.

Conclusion

The recommendations made are to ensure that at any time in the future, whoever has access to the data understands what happened and why certain procedures were introduced at certain time. A trail of the events must be kept. All the steps mentioned above will improve the quality of the data on an on going basis but they do require additional time and support.

In addition, communication and coordination are of utmost importance at this stage of the trial.

Although still checking the process in VLA in the coming weeks, the auditor recommends already at this stage that another visit should take place to VLA in the autumn (September-October) to assess how the recommendations have been implemented.

Part II The Government Response

Audit of the TB 99 questionnaire (September 2003) - Summary of Recommendations and Conclusions with Defra's responses in italics (December 2003).

Recommendations

1 On the questionnaire

1.1 The questionnaire is overly complex. It requires simplification. In future, any questionnaire used should be simpler and shorter.

1.2 It is difficult to capture the attention of the person being interviewed for over 2 hours. It is equally difficult for the interviewer to concentrate for over 2 hours.

1.3 The questionnaire and the instructions must match. The instructions should be simple and user friendly. An annotated questionnaire could be useful.

1.4 The questionnaire should have a case identification number on each page. At present, if the hard copies are not attached together one does not know to which case a single page refer too.

Reply: Defra agrees with all these points. A working group to develop a shorter and more user friendly epidemiological report form has now been established. The group involves representatives of those who use the current TB 99 form in the field, process the data received and analyse the data. The Independent Scientific Group on Cattle TB (ISG) is also represented, and the progress and results of the group's work will be reviewed by the TB 99 auditor at appropriate intervals.

2 On the people "in the field"

2.1 Possibly too many people are going out to the farms (on average 25 to 30 persons in each Animal Health Divisional Office (AHDO) have gone to visit farmers to complete the questionnaire at least once). It would be better to have as few interviewers as possible who should be well trained and capable of following the cases including correcting the questionnaires if needed.

Reply: Defra understands the auditor's point of view and the inherent advantages, from a data collection angle. Defra feels it will be possible to ensure the completion of control reports is done by a small team of operatives but there would be practical barriers to doing so with case forms. As the TB 99 is also used for managing TB incidents, it is felt that the application of case TB 99s is best handled by Veterinary Officers (VOs) who already have a rapport established with the farmer. It should be

recognised, however, that the limitation of TB 99 application for 2004 to three triplet areas will mean only three AHDOs being involved and that fewer interviewers than in previous years will, naturally, be involved in 2004 TB 99 data collection. Defra accepts the validity of the auditor's concerns for correcting forms and filling in missing data and will seek to cover this through improved training and advice.

2.2 The persons filling in the questionnaires should do it in a professional way. They should be neutral when asking the questions. They should avoid being emotional. They should not influence the answers. They should go thoroughly through all the questions.

Reply: Agreed, Defra recognises the value of interviewers maintaining a neutral demeanor for the collection of good quality data. This will be covered through improved training and advice.

3 On data management

3.1 The data, which the analysis is based on, should match the original source data. If it does not, there should be written documentation available that explains why it does not match. When handling the data (data entry and analysis) no assumptions should be made, no interpretation should take place. If one allows these to take place, each person will have his own interpretation or assumption and this will introduce bias. There has to be consistency within individuals and across individuals when dealing with the data, hence the importance of documenting in detail what is being done for each field of information. The credibility and the reliability of the data depend on this.

Reply: Defra accepts the validity of the comments made and the need for improvement in the consistency and accuracy of the data being recorded. It is felt that a modified questionnaire with an improved layout will assist in the improvement of data quality, particularly with regard to consistency between individuals with responsibility for field application of the form.

3.2 A number of cross consistency checks should be carried out for the data already entered and corrective actions (including correcting the data on the questionnaires together with the AHDO representative) should take place.

Reply: Defra has provided additional funding to the State Veterinary Service (SVS) for TB work which should ensure there is sufficient resource available for TB99s to be checked, and missing data added, before being sent to the Veterinary Laboratory Agency (VLA) for input.

4 On the whole process

4.1 A much more proactive and unified approach would improve quality. There should be a project coordinator who is aware of the whole situation and who has sufficient time to supervise all the phases of the process. This

would also overcome the problem of local decision making that leads to inconsistencies across AHDOs.

Reply: With the introduction of a Programme Management working approach to the Animal Health and Welfare Directorate General, a formal project with an owner will be established.

4.2 There should be more active monitoring in the field. There should be more interactions between all parties. It is in the field that the data are generated. More attention should be given to this aspect of the trial. The more attention that is paid in the early stages of the process the less work there will be thereafter and there will be more chances of improving the quality of the data.

Reply: Defra agrees there is value in issues being identified early, communicated and addressed. The T 99 working group will include representatives from the ISG, VLA, SVS and the veterinary and administrative arms of the Animal Health and Welfare Directorate General (AHWDG). The working group, therefore, should provide a suitable forum, not just for the discussion of modifications to the TB 99 for use from 2005, but also for the application of the form in 2004 and the identification of key aspects of the questionnaire's use, pressure points in the process and solutions to any challenges to effective application. The working group, through its members, should provide linkage for wider communication between the different units involved.

4.3 In addition, changes in the process must be documented in such a way that an "outsider" should be able to follow what has happened by himself without further oral explanation from any of the TB 99 team.

Reply: Defra agrees this is important and all the meetings of the TB99 working group will be minuted formally, and all changes to the TB99 process be documented fully, and clearly.

5 In terms of audit activities

5.1 The findings in the AHDOs and on farms are only based on a small sample which may or may not be representative of what is happening elsewhere. Nevertheless, these raise a number of issues, which should be investigated further. For the immediate future, the auditor recommends extending the visits to the main AHDO's contributors, and to visit some farms with the most active AHOs representatives.

Reply: Defra agrees that auditing of the existing TB99 report should be carried out in the year 2004, and is willing to re-appoint the existing auditor to recommend and carry out a programme of such auditing work that is agreed.

5.2 The implementation of corrective measures taken by VLA following the first recommendations made by the auditor should also be checked. The

10% quality control check procedures should still be assessed. A random sample of data recorded in the form should be compared to source data, which have now been clearly identified. This would also add to the credibility of the data.

Reply: Defra agrees, and the auditor will be invited to work with the VLA data manager to implement this recommendation.

5.3 The auditor also should review the minutes of the TB 99 working groups meetings, which have taken place in the last 2 years.

Reply: Defra has now supplied copies of the minutes of past TB 99 working group meetings to the auditor for her to do this.

6. Conclusion

6.1 All staff involved from Defra, VLA and the SVS gave their full support and cooperation to the auditor. Official M (Defra) provided all the documentation required. He also organised the visits to the field. In VLA the data management team was available at all times and fulfilled all the auditor's requests. TB database manager (VLA) accompanied the auditor in her visits to the AHDOs and his knowledge of the questionnaire was of great help and both facilitated the understanding of the process and prevented both misunderstanding and misinterpretation. In the AHDOs, everyone was keen to find ways to improve the quality of the data.

Reply: Defra is pleased to see this recognition of the positive effort that staff from VLA, SVS, ADAS and the Animal Health and Welfare Directorate of Defra, including the Veterinary Adviser who coordinates the project, contributed toward facilitating the auditor's work. It is intended that the work planned to modify the TB 99 form will result in a more user friendly questionnaire that will generate a positive response from all involved in its use, and provide quality data.

6.2 The approach to the completion of the questionnaire varied. The ADAS consultants were more questionnaire oriented, perhaps more neutral. The VOs were more scientifically oriented, perhaps more enthusiastic and therefore having a tendency to prompt the answers.

Reply: Defra realises that the familiarity and knowledge that a VO may have with individual farm businesses, allied to the fact that they are responsible also for managing the incident, might mean they find it harder to conduct the TB 99 interview in a neutral manner than, for example, ADAS staff. This is something Defra will seek to address through training and/or guidance.

6.3 Caution should be applied to the interpretation of these findings as only a very small sample of the trial has been investigated. In terms of data management, a number of inconsistencies, missing or incorrect data are not queried at present. The questionnaire in its present form is very long

and not structured enough. Therefore, the data on the form and in the database are not necessarily an accurate reflection of the data on the farm.

6.4 For the future one set of options would be:

Revise the existing form, with account being taking of both the preliminary analysis and the findings of this audit. The revised form should be shorter, targeted and more structured. The people responsible for the revision should take into account: interviewers, data manager, statisticians, quality assurance staff and selected farmers.

Reply: The TB 99 working group will be meeting throughout 2004 to develop a modified and shorter TB 99 epidemiological report form for use from 2005. It should be noted that it was always the ISG's intention to revise, and try to shorten the TB 99 form in the light of experience of its use and the data it provided.

Target a sample of representative farms.

Reply: The collection of 2004 data is being restricted, with ISG agreement, to a limit of 100 cases with accompanying control forms.

Have the project run by a project manager with a small dedicated team.

Reply: The establishment of a programme management approach in the AHWDG generally will lead to a formal project with an owner being established.

Ensure ongoing audit activities/trouble shooting and quality assurance procedures are put in place, to assess whether a consistent approach is taken at all times.

Reply: The auditor has been approached and has agreed to continue audit activities for 2004/2005.

Encourage personal contact/exchange of information/feedback.

Reply: Defra intends the TB 99 working group will facilitate this.

Obtain feedback from the main contributors, to capitalise on the lessons learnt so far.

Reply: Members of the TB 99 working group will be asked to act as conduits for their units to enhance the provision of feedback.

6.4 In the meantime, given the findings of the auditing activities so far, the auditor recommends that auditing activities should be ongoing.

Reply: Defra agrees and (as above) has taken steps to arrange this.

Concluding response

Defra is grateful to the auditor for her work on the audit and her report. A number of positive suggestions that will help Defra improve the application of the questionnaire in the field and the quality of data collected have been made. Defra intends, within the context of available resource, to use the recommendations to improve and focus the TB 99 for future use from 2005. Defra has taken steps to ensure audit work on TB 99 continues and that the auditor is consulted on the work to modify the form without compromising her independence.