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FINAL REPORT OF A MISSION
CARRIED OUT IN
POLAND
FROM 21 OCTOBER TO 30 OCTOBER 2008
IN ORDER TO
EVALUATE THE BOVINE BRUCELLOSIS AND TUBERCULOSIS ERADICATION
PROGRAMMES

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of an endnote.

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Poland, from 21 to 30 October 2008.

The objective of the mission was to evaluate the implementation of animal health and food safety controls in respect of bovine brucellosis and tuberculosis, as required by Council Directive 64/432/EEC and other Community legislation and contained in the Polish eradication plans for these diseases approved by the Commission.

The report notes the developments that have been made in the organisation and resources of the competent authorities, in the cattle tracing systems, in systems to verify that eradication activities are performed according to plan and in the accreditation of designated laboratories. However, it also identifies shortcomings in the systems in place to ensure that routine post mortem controls and tuberculin skin tests on live animals are performed consistently, in the official supervision of holding register requirements, in the measures taken to ensure that bovine abortions are notified and investigated, in the investigation of bovine tuberculosis outbreaks and in the quality controls applied to the reagents and substrates used within the eradication programmes.

The overall conclusion is that measures to control bovine brucellosis and tuberculosis are generally implemented according to Community requirements and national eradication programmes. However, the control system does not ensure that these measures are applied consistently and effectively, which may lead to delays in the detection of new outbreaks and create obstacles to the eradication of these diseases.

The report makes a number of recommendations addressed to the Polish competent authorities aimed at rectifying the identified shortcomings and further enhancing the control measures in place.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
ARMA	Agency for Restructuring and Modernisation of Agriculture (<i>Agencja Restrukturyzacji i Modernizacji Rolnictwa</i>)
CCA	Central competent authority
CDb	Central bovine database
CFT	Complement fixation test
CID	Comparative intradermal test for bovine tuberculosis
CVO	Chief Veterinary Officer
FBO	Food business operator
FVO	Food and Veterinary Office
GVI	General Veterinary Inspectorate (Central level)
NRL	National Reference Laboratory
OV	Official veterinarian
PVI	Powiat Veterinary Inspectorate (District level)
RBT	Rose Bengal test
SAT	Serum agglutination test
SID	Single intradermal test for bovine tuberculosis
TB	Tuberculosis
VVI	Voivodship Veterinary Inspectorate (Regional level)

1 INTRODUCTION

The mission took place in Poland from 21 to 30 October 2008 to evaluate the implementation of the bovine brucellosis and tuberculosis eradication programmes.

The mission was undertaken as part of the FVO's planned mission programme. The mission team comprised two FVO inspectors.

The mission team was accompanied throughout the mission by a representative of the Central Competent Authority. In addition, representatives of all authorities and control bodies involved in the animal health and, when appropriate, food safety controls were available throughout the evaluation.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the implementation of animal health and food safety controls in respect of bovine brucellosis and tuberculosis, as required by Community legislation and contained in the Polish eradication plans for these diseases approved by the Commission.

In order to address these objectives the following sites were visited:

Competent Authorities - Central - Regional - District	2 (initial and final meetings) 1 4
Agency responsible for the central bovine database (ARMA)	1
Laboratories - National Reference Laboratory - Regional laboratories	1 2
Bovine holdings	3
Slaughterhouse	1
Milk processing establishment	1
Animal collection point	1

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation and, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

The other Community instruments of relevance in the implementation and/or monitoring of the eradication programmes are listed in annex I.

4 BACKGROUND

Council Directive 64/432/EEC highlights the importance of effective control of bovine tuberculosis (TB) and bovine brucellosis. Since 1977, the Community has provided financial support to Member States (MS) with eradication programmes.

The Polish competent authorities carried out annual TB and brucellosis testing programmes for decades prior to the Accession of Poland to the European Union. Only a small number of cases were detected each year and the Polish authorities considered that all regions of the country were officially free of both diseases since 1980. Applications for Community funding to continue these testing programmes once Poland became a Member State in 2004 were approved by Commission Decisions 2003/849/EC, 2004/840/EC, 2005/873/EC, 2006/875/EC and 2007/782/EC. The bovine brucellosis eradication programme was funded between 2004 and 2006 (inclusive). The Commission has approved funding for the TB eradication programme each year since 2004.

Although serological reactors continue to occur, no cases of bovine brucellosis have been confirmed bacteriologically since 1980. A small number of cases of human brucellosis are detected each year and are investigated. However, most cases involve returning migrant workers or chronically affected animal handlers and no acute cases have been traced to a domestic source since 2000.

Mycobacterium bovis was confirmed in 84 cattle herds during 2007. It has also been isolated from deer and wild bison. However, the CAs did not link wild animals to any confirmed outbreaks in domestic cattle and do not consider them to be a significant reservoir of the disease.

Certain aspects of the eradication programmes in Poland were evaluated during FVO mission DG(SANCO)/8169/2006, the report of which is available at http://ec.europa.eu/food/fvo/ir_search_en.cfm. The report included a recommendation to ensure that the testing regimes adopted for animal diseases, in particular bovine brucellosis, comply with the requirements of Annexes A and C of Council Directive 64/432/EEC and that the officially disease-free status of herds is suspended if they are not tested within the intervals prescribed. In their response to the FVO report, the Polish authorities expressed the view that it is not necessary to test bovine herds at least once every two years in order to be considered officially free of the disease.

During the course of 2008, the competent authorities applied to the Commission for official recognition of the whole territory of Poland as a region officially free of both bovine brucellosis and TB.

5 MAIN FINDINGS

5.1 COMPETENT AUTHORITIES

The General Veterinary Inspectorate is the central competent authority (CCA) responsible for the eradication of bovine brucellosis and tuberculosis. Its structure and responsibilities are defined in the Law of 29 January 2004 on Veterinary Inspection and are described in the FVO country profile for Poland, which is available at: http://ec.europa.eu/food/fvo/country_profiles/CP_poland.pdf. In summary, the inspectorate is comprised of the GVI at central level, 16 Voivodship Veterinary Inspectorates (VVIs) in the regions and 304 Powiat Veterinary Inspectorates (PVI), which operate at district level. Private veterinary practitioners may be designated to act as authorised veterinarians (AVs) and perform official duties, including animal tests on farm holdings and *post mortem* checks in slaughterhouses. Representatives from the VVIs and GVI meet on a monthly basis to coordinate their activities and exchange information.

The CCA has established cooperative agreements with the competent authorities responsible for human health controls (the Sanitary Inspectorate) at central, regional and local levels and holds regular meetings with the Agency for Restructuring and Modernisation of Agriculture (*Agencja Restrukturyzacji i Modernizacji Rolnictwa*, ARMA), which is responsible for maintaining the central bovine database (CDB).

The Law of 11 March 2004 on the Protection of Animal Health and Combating Infectious Diseases of Animals (Journal of Laws No. 69, Sec. 625, as amended) provides the CCA with powers to implement Community animal disease control requirements. Ministerial regulations have also been issued covering the eradication of bovine brucellosis and tuberculosis, the declaration of holdings to be officially free of infectious disease as well as the imposition of restrictions on the movement of animals, people and things in the event of a suspected disease outbreak.

Together with a number of implementing regulations, the Act of 2 April 2004 on the System of Identification and Registration of Animals (Journal of Laws No. 91, Sec. 872, as amended) establishes requirements for the identification and registration of bovine animals and the notification of movements to the CDB. It also authorizes veterinary inspectors to apply movement restrictions and other sanctions in cases where keepers are in breach of these requirements.

One of the recommendations made in FVO mission report 8169/2006 from March 2006 on intra-Community trade in live animals was to ensure that sufficient numbers of suitably qualified, trained and experienced staff are employed so that official controls and control duties can be carried out efficiently and effectively. Since then the number of staff posts has been increased at all levels (central, regional and district).

All newly appointed veterinary inspectors must undergo induction training on how to carry out official duties. Subsequently, they are encouraged to undergo specialist training in a work-related discipline. For example, the National Reference Laboratory (NRL) and the Veterinary University are involved in providing training to epizootic disease control specialists. Veterinarians must work for at least five years as official veterinarians

(OVs) before they are considered eligible for promotion to Powiat Veterinary Inspector, responsible for managing the administration at district level. Plans for ongoing training of inspection staff are coordinated centrally. The VVIs are largely responsible for the delivery of this training, with the cooperation and participation of officials from the central level. Training is directed chiefly at Powiat Veterinary Inspectors, who cascade the information to the OVs and AVs working in the districts.

Audit and supervisory systems operate at each level:

- The Controlling Office, which forms part of the GVI, carries out comprehensive audits in the regions. These include visits to VVIs, PVIs and food business operators' (FBOs') premises;
- VVIs perform regular supervisory checks on PVIs in their regions, including checks at FBO premises. A combination of comprehensive audits, which evaluate the organisation and operation of PVIs at general level, and topical checks, which evaluate the implementation of specific programmes, such as disease eradication, are performed;
- PVIs perform regular documentary and on-the-spot controls on AVs working in their districts. These include checks during the performance of on-farm testing and *post mortem* controls in slaughter houses.

Observations:

- Copies of written agreements with the Sanitary Inspectorate were available at central, regional and district levels. The authorities in one region visited held quarterly meetings with the regional Sanitary Inspectorate to exchange information on the occurrence of zoonotic diseases;
- Legal instruments establish the framework for the disease eradication programmes and are supplemented by CVO instructions, which address the technical requirements of the control process.
- Additional posts had been created in all of the regions visited and staff had been appointed in most cases. However the competent authorities experienced difficulties recruiting appropriate staff. For example, in one DVO an animal health specialist post was vacant, which resulted in some scheduled inspections being postponed. In another DVO, agronomists were appointed to fill veterinary posts;
- The staff at central, regional and district levels who participated in meetings with the mission team were well informed about the eradication programme requirements and understood their role in implementing them;
- Audits by the Controlling Office are not targeted at control programmes for TB or bovine brucellosis but do include an evaluation of the implementation of eradication programmes in general;
- Records of audits and supervisory inspections, which recorded the deficiencies identified during controls and specified the corrective actions to be taken, were available in the VVIs, PVIs and the slaughterhouse visited;

- The slaughterhouse visited had recently been inspected by the VVI;
- Some VVIs visited check each PVI annually. In other cases, 30% of PVIs were checked annually, with a follow up inspection being carried out in each during the subsequent year. Financial sanctions were imposed on individual inspectors in cases where corrective actions had not been taken within agreed periods;
- The frequency and scope of the supervisory checks on AVs to be performed by PVIs was not defined nationally or in the regions visited. Written reports submitted by AVs were checked in all of the PVIs visited. However, the extent to which on-the-spot checks on AVs were performed during the course of official activities varied considerably. In one PVI visited, where on-the-spot checks were performed during animal tests, the records indicated whether the testing officer had the necessary equipment (including scissors, calipers and syringes). However, no requirements have been established on how often or by whom the equipment should be maintained. The set of equipment examined by the mission team, which was routinely used by an AV, included a poorly repaired calipers which were likely to give inaccurate test readings;
- The mission team visited a slaughterhouse in which more than 15 000 cattle were slaughtered each year. The slaughterhouse received cattle from districts in which TB had been confirmed but no suspect TB lesions had been detected during routine *post mortem* controls for many years. The mission team noted significant variation in the standard of the *post mortem* controls performed. One inspector accepted bovine heads from which the submandibular lymph nodes had already been removed and examined the retropharyngeal lymph nodes by making a single lateral incision, which was unlikely to reveal lesions that might be present. At the same time, another inspector inspected the mediastinal and bronchial nodes thoroughly by making multiple parallel incisions in each node. The PVI checked the performance of inspectors annually but had not detected any shortcomings in the controls performed. However, immediate corrective actions were taken following the FVO visit.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL

Responsibility for the cattle tracing system is shared between the CCA and the ARMA:

- ARMA maintains the central database, including the registration of new herds and the entry of data on bovine births, deaths and movements;
- PVIs are responsible for carrying out on-the-spot checks on 10% of holdings selected according to risk, in accordance with Regulation (EC) No. 1082/2003.

Officials from both services also carry out *ad hoc* checks on farms to investigate anomalies detected in the course of their work.

PVIs impose movement restrictions and other administrative sanctions in cases where non-compliances cannot be resolved on-the-spot.

A number of important changes have been made to the system over recent years, which

reduce delays in the notification of information to the CDbs:

- Cattle passports may now be printed at district ARMA offices, with non-reusable, serially numbered holograms being used to ensure their security;
- A facility has been developed to enable larger operators (such as slaughterhouses) to make batch movement notifications on line.

From 2009, keepers who fail to comply with identification, registration and notification requirements will face additional sanctions as part of the cross-compliance system governing the payment of EU funds to farmers.

Observations:

- Despite the improvements noted above, PVI's continue to experience difficulties when accessing the CDb. Many PVI's declared that connections are slow and unreliable and that the information was not presented in an easy to use format. The CCA explained that most of these problems relate to basic design flaws in the system, which are difficult and expensive to correct;
- ARMA provided information to the mission team indicating that compliance with notification requirements has improved somewhat since 2004.
- ARMA is responsible for deciding whether separate parcels of land within the same business should be treated as a single holding, in which case cattle movements between them need not be registered or reported to the CDb, or as separate holdings. The CCA is not involved in this decision-making process. However, PVI's are expected to consider the epidemiological links between holdings when investigating disease occurrences;
- The mission team noted a number of anomalies that had not been detected during veterinary supervision visits. For example, the date of arrival of an animal that subsequently reacted positively to a TB test was recorded differently in the holding register and on the database. This anomaly was not investigated or corrected. In another herd, two cows which had been in the herd since it was established were not recorded in the holding register for several years, although an on-the-spot inspection to verify compliance with identification and registration rules was conducted during this period;
- The mission team visited an animal collection centre at which keepers bought and sold cattle. No records of the animals that moved through this centre were being maintained, contrary to the requirements of Article 8 of Commission Regulation (EC) No. 911/2004. Information recorded on the CDb for cattle traded through the centre did not include details of their movements to or from the premises. PVI officials responsible for the supervision of the animal collection centre carried out regular checks to ensure that it complied with biosecurity requirements and that animals were correctly identified and treated in accordance with animal welfare requirements. However, they understood that requirements concerning the registration and notification of movements had been dropped with the introduction of new national licensing conditions for animal collection centres, which were

introduced in early 2008. The market had been subject to a joint inspection by the PVI and VVI in October but the absence of movement records was not identified as an anomaly. At the final meeting, representatives from the Ministry of Agriculture and Rural Development confirmed that such movement records are still required by Community and national rules.

5.3 IMPLEMENTATION OF THE BOVINE BRUCELLOSIS AND TUBERCULOSIS ERADICATION PROGRAMMES

5.3.1 Routine testing

All bovine holdings in Poland are included in the official eradication programmes. The following table summarises the results of routine tests carried out during 2007:

	Brucellosis	Tuberculosis
Number of bovine herds included in the programme	860 215	860 215
Number of herds tested during 2007	223 484	224 747
Number of herds in which disease was confirmed by bacteriological tests	0	86
Number of herds depopulated	0	19

The same approach is taken to the organisation of routine testing for both diseases: Eligible animals in each holding are tested once every three years. Testing campaigns are typically organised geographically, with all holdings within a village being tested together once during each three year testing cycle. Tests should be completed in the first half of each year. Tests are performed by AVs, who receive lists of herds selected for testing, which PVIs prepare using data provided by ARMA. These lists provide information on each holding in the district, including the number of bovines present, and a breakdown of the number of animals present according to age group (this information is used to forecast the number of animals that will be eligible for each test category). Newly created herds should be tested once they are formed and then together with other herds in their village in subsequent test cycles.

For bovine brucellosis, AVs collect blood samples from officially free herds. PVIs supervise the dispatch of samples to approved regional laboratories where they are routinely tested using the rose bengal test (RBT) – pooling of blood samples is not practised. Positive and inconclusive samples undergo confirmatory testing using the serum agglutination test (SAT) and complement fixation test (CFT) methods. A long term research programme involving the NRL and cattle herds in three VVIs is under way to determine whether commercially available ELISA tests could be used to monitor the health status of herds using bulk milk samples as an alternative to blood samples.

The tuberculin skin test methods described in Annex B 2.2 to Council Directive 64/432/EEC are both used in Poland. The single intradermal test (SID) is the routine TB test used for officially free herds. Any animals that give a positive result to that test are retested at least 42 days later using the intradermal comparative test (ICD). Animals that give an inconclusive result to the ICD are retested. Animals which give a second inconclusive result to the ICD are considered to be positive. Although not used officially, the gamma interferon test method has been used on a trial basis, particularly in an area of high disease incidence in Mazowieckie. In future it may be used as an additional official test method for inconclusive animals.

AVs complete test reports and submit them either electronically or in paper form to PVI, which report regularly to RVI. The RVIs prepare twice yearly summary reports for the GVI on the tests performed and the results obtained.

Observations:

- As indicated in section 4 above, the Commission informed the Polish authorities in 2006 that three years exceeds the maximum interval between herd tests specified in Council Directive 64/432/EEC. However, no corrective actions have been taken;
- Although paper-based reporting systems were widely used, an electronic reporting system had been established in one of the regions visited. Separate modules allowed the VVI to exchange information with AVs on the herds that were tested and to receive test reports from the regional laboratory and NRL;
- Tests were generally carried out according to schedule. In one PVI some tests were completed in June and July. This was because they had been tested in later months during previous years and the PVI was in the process of bringing them in line with the prescribed schedule;
- Test reports were available in all PVI visited and were generally complete. In a small number of cases the batch number of the tuberculin used was not recorded;
- ARMA data indicates that the proportion of herds tested nationally each year is less than 30% of the number of registered herds. This shortfall was also noted in the districts visited by the mission team. In the case of tests carried out since 2007, PVI could largely account for this difference by referring to records completed by AVs indicating the number of herds in which no stock was present at the time of the scheduled test. Limited information was available for the previous years, when the CDdb was being established and the register of holdings was still incomplete;
- No arrangements are currently in place to ensure that PVI are informed by keepers or by ARMA when new herds are created or when animals are moved into existing herds that were previously without stock. During the course of its evaluation of the testing records in a village of 17 herds, the mission team noted that two newly formed herds were not tested during their first year of operation. They were included in the next cycle of testing carried out in the village.

5.3.2 Passive Disease Surveillance

The investigation of abortions is the main surveillance tool used in the case of bovine brucellosis. National legislation (Article 42 of the Ministerial Regulation of 11 March 2004 on the Protection of Animal Health and Combating Infectious Diseases of Animals) has been amended in response to a recommendation made in a previous FVO mission report 7177/2004. The revised article emphasizes the obligation placed on keepers, transporters and veterinarians to notify the authorities if they have any suspicion of a contagious animal disease, including abortions.

PVIs should investigate reported abortions by collecting foetal and placental samples for microbiological testing and blood samples from affected cows 12 days following abortion. Herds in which an abortion is reported are subject to movement restrictions pending a negative result.

For TB, routine *post mortem* inspections conducted in slaughterhouses are the main means of passive surveillance. Histological and bacteriological tests are carried out on sample materials collected from carcasses in which TB lesions are detected. Differential culture and molecular analytical techniques are used to identify the strain of TB isolated and to distinguish between infections caused by *Mycobacterium bovis* and *Mycobacterium tuberculosis*. OVIs in slaughterhouses should notify the PVIs responsible for the holding of origin if suspect TB lesions are detected during routine slaughter.

Observations:

- 453 abortions were reported from approximately 860 000 bovine holdings throughout Poland during 2007. In one region visited, in which cattle were kept on more than 100,000 farm holdings, 20 cases of bovine abortion were investigated during 2007. No abortions had ever been reported in several of the PVIs visited by the mission team. However, all PVIs stated that veterinary practitioners and farmers within their districts were regularly reminded of their obligations in this regard and public awareness campaigns have been organised with the Centre for Agricultural Assistance to highlight the importance of notifying abortions;
- Restrictions on the movement of animals and the supply of milk to processing establishments were applied by PVIs promptly following the notification of abortions. These restrictions typically remained in force for several weeks, pending the outcome of laboratory tests. For example, a herd in one of the PVIs visited was placed under restriction on 5 August, following the notification of an abortion. Samples were submitted to the regional laboratory the following day. The laboratory conducted the standard bacteriological test methods and reported a negative result on 6 September, at which time the restrictions on the holding were removed;
- The owners of herds that notify cases of abortion are not entitled to receive compensation for any financial costs incurred as a consequence of the restrictions imposed on their activities;
- The mission team reviewed two cases where bacteriological tests had been conducted on materials collected from aborted cows. No serological tests had been performed on either animal;

- Regarding TB surveillance, no information was available at central level on the number of cases of TB suspicion detected during routine *post mortem* checks. However, the mission team noted several cases in which PVIs were notified promptly following the detection of suspect TB lesions at slaughter. In each case, PVIs imposed movement restrictions immediately pending the results of laboratory tests.

5.3.3 *Suspicion and confirmation of disease*

CVO instructions establish measures to be applied in case of disease suspicion. These include:

- restrictions on the movement of cattle to and from the affected holding;
- a ban on the use of milk from suspect animals (except for feeding calves on the same farm and only if it has been heat treated);
- notification of relevant bodies, including neighbouring PVIs and any establishment receiving milk from the affected herd;
- investigation of the animal health situation in the affected herd by a veterinary inspector specialised in epizootic controls.

As part of the investigation of each suspected or confirmed outbreak the keeper is obliged to provide an up to date inventory of the animals present on the holding, together with details of the quantities of meat, milk, feed and manure held there. All animals are subject to a clinical examination and additional testing, as necessary. An epizootic investigation questionnaire is completed in order to determine the period during which the disease may have been present, its likely origin and further spread.

If animals are deemed to be positive or the outbreak is otherwise confirmed, affected animals are usually killed on the farm and the carcasses are sent for rendering. In some regions, reactor animals are slaughtered. In either case, arrangements should be made for the collection of appropriate *post mortem* samples. Arrangements may be made at PVI level to kill negative animals that have been in contact with infected animals. Vaccination against bovine brucellosis and TB and the treatment of animals for these diseases is prohibited by ministerial regulations. The premises and equipment potentially contaminated by the affected animals are cleaned and disinfected under official supervision. National legislation on the eradication of animal diseases establish conditions for the cleaning and disinfection of holdings, animal collection premises and transport vehicles in the event of disease outbreaks. The Polish Office for the Registration of Medicinal Products (*Urząd Rejestracji Produktów Leczniczych*) maintains a list of registered biocides authorised to be used in such cases. Keepers are entitled to the payment of compensation for the animals killed. The value of the animals destroyed are evaluated by a panel of experts, including the Powiat Veterinary Inspector;

The ministerial regulation of 23rd November 2004 on the Eradication of Bovine Tuberculosis (Journal of Laws No. 258, item 2585) requires all herds from which officially disease free status has been suspended or withdrawn to undergo two clear herd tests of all animals aged more than six weeks, regardless of whether the presence of the disease has been confirmed by bacteriological investigation. The ICD is used for all tests

carried out on these herds. The stricter and more sensitive test interpretation rules described in point 2.2.5.3.5 of Annex B of Council Directive 64/432/EEC as a means to detect the maximum number of infected and diseased animals in a herd or region are applied in herds where TB has already been confirmed.

Observations:

- In most cases, movement restrictions and other control measures were imposed within 1-2 days following the declaration of disease suspicion. Reactor animals were isolated on holdings and were generally removed within 60 days and compensation was subsequently paid within a further 60 days. For example, in the case of one brucellosis outbreak detected during routine testing, positive animals were slaughtered 36 days after the collection of blood samples and the keeper received financial compensation 48 days afterwards;
- Some shortcomings were noted:
 - o Two tests were carried out on a herd from which official brucellosis-free status had been suspended following the detection of serologically positive animals (brucellosis reactors). However, some of the cows present in the herd were not tested twice, contrary to the requirements of Annex A, II, 3B to Council Directive 64/432/EEC. This was because they were at the point of calving at the time when the tests were scheduled and no arrangements had been made to test these animals at a later date. Once the omission had been detected the PVI took prompt corrective actions;
 - o The status of a confirmed TB outbreak herd was restored following depopulation and the completion of a single herd test more than eight months after repopulation began. Council Directive 64/432/EEC requires a minimum of two clear herd tests both in the case of herds from which official TB-free status has been withdrawn (Annex A, I, 3B) and in the case of newly established herds (Annex A, I, 1);
- In some cases, Community requirements were not implemented to the extent necessary to ensure the rapid eradication of these diseases:
 - o In all of the confirmed TB outbreaks reviewed, follow up testing was limited to the affected herd. No epidemiological links were established with other herds, including neighbouring herds and herds in which reactor animals originated. For example, multiple reactors were detected in a herd during 2006 following the detection lesions during the routine *post mortem* examination of a slaughtered animal. The herd had last been tested for TB in 2005, together with the other herds in the village. Although no link could be established between the affected holding and any other outbreak, no follow up testing or other control measures were applied in any of the other holdings in the village. The entire village, including the affected holding, were tested as part of the routine three-year cycle in 2008 and no additional reactors were disclosed. In another case, two recently purchased animals were included in a group of three reactors detected during routine testing. However, no actions were taken to impose

restrictions or to carry out testing on the holding of origin. This is not in accordance with Annex A, I, 3B (d) to Council Directive 64/432/EEC, which requires the tracing and checking of any herd considered to be epidemiologically related;

- o The more strict interpretation rules mentioned above are not routinely applied to the rest of the animals in an officially tuberculosis free herd in which multiple reactors are disclosed. On the other hand, in one TB outbreak the PVI switched to severe test interpretation in a herd in which numerous reactors were disclosed, although this was not required by the CVO instruction. The PVI subsequently agreed with the keeper to depopulate the herd entirely;
- o A higher incidence of confirmed TB has been reported in parts of the Mazowieckie and neighbouring regions over several years. The NRL has organised a pilot test project in the area using the gamma-interferon test method. However, in other respects the normal testing cycle and test interpretation rules continue to be applied in the affected districts and no analysis of the available epizootic information has been carried out to determine the significance and likely causes for the disease hotspot.

5.3.4 Laboratories

All official tests for bovine brucellosis and tuberculosis are performed in the regional laboratories, which are supervised by the Veterinary Inspectorate, or in the NRL in Pulawy, which is an independent institute.

In the case of brucellosis, 27 regional laboratories are authorised to carry out the RBT, SAT and CFT on blood samples collected during routine tests and from cows following abortion. Regional laboratories also perform microbiological investigations on materials collected from aborted animals that have been notified to PVI. The NRL organizes proficiency trials at national level for the test methods employed by regional laboratories. It also performs confirmatory tests on all positive and inconclusive serological and microbiological findings reported by the regional laboratories.

In the case of TB, the NRL performs all phases of analysis on samples submitted from the carcasses of animals suspected of being affected by bovine TB. Prior to July 2008, one regional laboratory also performed these tests.

The NRL is also responsible for preparing or certifying the reagents (such as the tuberculin used in intradermal skin tests) and substrates (such as the broths used to culture *Brucella spp.*) used within the disease eradication programmes.

Observations:

- The NRL was accredited to carry out the RBT, SAT and CFT for brucellosis. The accreditation did not cover brucellosis ELISA test methods, for which commercially produced kits are used. In addition, the NRL was not accredited for bacteriological isolation of *Brucella abortus* nor has it been possible to participate in international proficiency tests for this disease agent. However, the NRL maintains a library of

reference strains which it uses periodically to verify its competence to culture the organism;

- One of the regional laboratories visited carried out serological testing for bovine brucellosis. It was accredited by the Polish Centre for Accreditation to perform the RBT test according to the test method prescribed by CVO instructions. It had plans to be accredited for the SAT and CFT methods during 2009. The laboratory was last audited in March 2008. The laboratory participated in annual proficiency trials organised by the NRL for all of the authorised serological test methods, with favorable results.
- So far no laboratories in Poland have been accredited to perform microbiological investigation methods for *Brucella abortus*. No arrangements have been made to demonstrate the proficiency of regional laboratories in these methods, which is a prerequisite for accreditation. The NRL considered it unsafe and impractical to organise ring trials for Category III organisms.
- On the other hand, records were available at the NRL to show that the regional laboratory that previously conducted bacteriological tests on TB samples had participated in proficiency trials organised by the NRL, using a panel of coded tissue samples inoculated with reference strains of *Mycobacterium bovis*. and that the results of these trials were satisfactory.
- The regional laboratories visited operated according to CVO instructions and maintained clear records of their activities.
- The mission team detected one case in which broth was used to culture isolates from samples of aborted materials beyond its stated expiry date. This anomaly had already been detected during quality checks in the laboratory and appropriate corrective actions and preventive measures had already been taken.
- Although the NRL was generally well-organised, the mission team noted that controls on reagents (such as the purified protein derivatives used in intradermal tests for TB) and substrates (such as the broth used for the isolation of *Brucella abortus*) used in official tests were not specified in the laboratory's quality manual and that records of these activities were not controlled by official procedures.
- The NRL does have procedures in place to notify PVIs in cases where samples from animals suspected of bovine brucellosis or TB are unsuitable for testing. However, neither the VVI nor GVI are informed in such cases, which limits their ability to supervise this part of the control chain.

5.4 FOOD SAFETY CONTROLS

Establishments that process milk collected from primary producers are subject to regular supervision by PVIs. As part of this supervision, regular checks are performed to ensure that lists of herds supplying milk for processing are kept up-to-date.

In the event of an outbreak of bovine brucellosis or TB, the PVI immediately suspends the disease-free of the herd and informs the milk processing establishments that it supplies. A notice is served on the person responsible for the herd prohibiting the use of

milk from suspect animals except for the purpose of feeding animals and providing that it has been heat treated. The milk from other animals in the herd may be dispatched to a milk processing establishment where it must undergo heat treatment, under the supervision of the official veterinarian, before it may be used for human consumption.

Slaughter of reactors is permitted subject to the prior agreement of the official veterinarian responsible for the slaughterhouse in order to ensure that they are slaughtered separately and that appropriate samples are collected.

Observations:

- Almost all of the milk delivered to processing establishments in Poland is routinely subject to pasteurisation on arrival;
- The FBO in the milk processing establishment visited established a procedure to inform the PVI before adding primary producers to the approved supplier list so that the disease-free status of the herd could be verified;
- Measures were in place in all PVIs visited to inform milk processing establishments receiving milk from herds whose officially disease free status had been withdrawn or suspended. This notification was made on the same day that the status was suspended, in all cases reviewed by the mission team;
- The FBO responsible for the milk processing establishment visited took measures beyond those required in Community regulations by excluding all milk from herds that were not officially disease free. The PVIs outlined the contingency measures that they would take to handle milk rejected in this way;
- The official veterinarians in the slaughterhouse visited had arrangements in place to detain carcasses suspected of being affected by TB. The FBO acknowledged these arrangements in their manual of procedures;
- The routine *post mortem* inspection of bovine carcasses in the slaughterhouse visited included the incision of the lymph nodes, the palpation of gastric and mesenteric lymph nodes and visual inspection of the lungs, kidneys and other organs likely to reveal evidence of TB. However, as noted in section 5.1 of this report, the submandibular nodes, which are listed in Annex I, Section IV, Chapter I to Regulation (EC) No. 854/2004, were not examined and the extent to which one inspector examined other lymph nodes was limited.

6 CONCLUSIONS

6.1 COMPETENT AUTHORITIES

Responsibility for different aspects of the disease eradication programmes are clearly designated and systems are in place to coordinate the activities performed at different

levels within the CCA and by other competent authorities. Officials responsible for the implementation of the disease eradication programmes have sufficient legal powers and generally work according to documented procedure. Significant progress has been made to ensure that sufficient numbers of suitably qualified staff are available. Systems are in place to verify that controls and checks are carried out according to plan. However, these systems do not ensure that checks performed on live animals and routine *post mortem* controls at slaughter are performed consistently, which could jeopardise the ability of the competent authorities to detect disease outbreaks at an early stage.

6.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL

Improvements have been made to the system of holding registration, bovine identification and movement control that significantly improve the reliability of the information available to the veterinary competent authorities. However, fundamental design problems with the CDb and limited attention given to the correction of animal identification and registration anomalies during animal health visits mean that the system is not yet being used to its full potential as a disease eradication tool.

The extent to which the requirements set out in Regulation (EC) No. 1760/200 and Regulation (EC) No. 911/2004 concerning the registration of movements through animal collection centres were misunderstood in one region visited causes concern about the implementation of these requirements elsewhere in Poland.

6.3 IMPLEMENTATION OF THE BOVINE BRUCELLOSIS AND TUBERCULOSIS ERADICATION PROGRAMMES

Despite a previous FVO recommendation, the interval between herd tests of officially Brucellosis-free herds exceeds the maximum stipulated in Annex A II 2(a) to Council Directive 64/432/EEC. Otherwise, the routine test schedules comply with Community requirements and testing is generally carried out as planned. However, the procedures in place do not ensure that newly created herds meet the test requirements set out in Annex A I 1 and Annex A II 1 to Council Directive 64/432/EEC, in order to be recognised as officially disease free. The development of electronic reporting systems in some regions provides a means to integrate reports on disease eradication activities from field and laboratory sources. This information can be used to verify that the eradication programmes are being implemented correctly and to highlight instances where tests have been omitted or delayed.

Animal keepers, veterinarians and other members of the public are legally obliged to notify the competent authorities if they suspect bovine brucellosis or TB and systems are in place to respond to such reports. However, the financial and practical hardships that result from the imposition of restrictive measures in herds that report abortions have a dissuasive effect and many cases of bovine abortions are not notified to the competent authorities. The lack of a system to ensure that serological samples are collected in each case where bacteriological samples are analysed significantly reduces the sensitivity of the investigation procedure.

The procedures defining the measures to be taken in suspected and confirmed outbreaks of bovine brucellosis and TB are generally in accordance with the requirements set out in Annex A to Council Directive 64/432/EEC. However, the herd testing schedules defined in Annex A, I, 3B and Annex A, II, 3B to Council Directive 64/432/EEC for the restoration of official disease-free status are not consistently applied. Epidemiological investigations to determine the likely sources of disease in confirmed outbreaks and in the region with a high disease incidence are limited and do not prevent the appearance of new cases. Although national requirements regarding the use of herd depopulation and the application of severe interpretation for the tuberculin skin test are limited, decisions taken by PVIs to deploy these measures accelerate the eradication of disease from affected herds.

Although many of the laboratory test procedures conducted within the framework of the eradication programmes are not accredited, progress is being made to ensure that most methods will be included by the end of 2009. The laboratory network is well-established and provides assurance that analytical methods are performed in accordance with the standards set out in Annexes B and C to Council Directive 64/432/EEC. Laboratories within the network have quality control schemes in place for the diagnostic test that they conduct. However, the exclusion of analytical checks on the reagents and substrates used in eradication programmes from the NRL's quality systems is not in accordance with Article 18 of Regulation (EC) No. 2076/2005 and undermines the validity of the test results reported.

6.4 FOOD SAFETY CONTROLS

Although systems are in place to exclude products originating from animals suspected or known to be affected by bovine brucellosis and TB from the human food chain, the lack of consistency in the implementation of routine *post mortem* checks for TB means that these systems are not fully effective.

6.5 OVERALL CONCLUSION

Measures to control bovine brucellosis and tuberculosis are generally implemented according to Community requirements and national eradication programmes. However, the control system does not ensure that these measures are applied consistently and effectively, which may lead to delays in the detection of new outbreaks and create obstacles to the eradication of these diseases.

7 CLOSING MEETING

The mission team held a closing meeting with the CCA and representatives from ARMA and the NRL on 30 October 2008, at which the main observations and preliminary conclusions of the mission were presented. The CCA provided clarification on a number of the observations, which are reflected above, and proposed to provide additional comments and clarification upon receipt of the draft report.

8 RECOMMENDATIONS

The following recommendations are addressed to the Polish authorities:

No.	Recommendation
1	To consider establishing technical standards at national level as a means to ensure the effectiveness and consistency of the routine post mortem controls required by Annex I, Section IV, Chapter I of Regulation (EC) No. 854/2004 and the tuberculin skin tests performed on live animals in accordance with Annex B of Council Directive 64/432/EEC
2	To ensure that holding registers and cattle passports are checked during epidemiological investigations and that appropriate corrective actions are taken where it is found that keepers have not complied with the requirements of Article 7 of Regulation (EC) No. 1760/2000 and Article 8 of Regulation (EC) No. 911/2004
3	To ensure that the operators of animal collection centres comply with the requirements to record the movement of animals that pass through their centres, as required by Article 7 of Regulation (EC) No. 1760/2000 and Article 8 of Regulation (EC) No. 911/2004
4	To ensure that testing carried out in order to establish and maintain the official disease-free status of herds, and to restore that status following suspension or withdrawal, is conducted according to the schedules established in Annex A to Council Directive 64/432/EEC
5	To review the investigation procedures and measures applied following the notification of bovine abortions and to consider possible incentives for keepers who make notifications, taking account of the application made by Poland to be recognised as a Member State officially free of bovine brucellosis and the requirements set out in Annex A II 7 to Council Directive 64/432/EEC
6	To extend the scope of epidemiological investigations of bovine tuberculosis outbreaks so as to ensure that all herds related by their location or by cattle movements are identified and checked, as required by Annex A I 3B to Council Directive 64/432
7	To ensure that all laboratories designated to carry out official analyses are accredited by 31 December 2009, as required by Commission Regulation (EC) No. 2076/2005
8	To ensure that all reagents and media used in tests for bovine brucellosis and tuberculosis are prepared in accordance with the standards established in Annexes B and C to Council Directive 64/432 and that the analyses performed on them are included in the laboratory's quality control system, as required by Article 18 of Regulation (EC) No. 2076/2005

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_poland_7794_2008.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Directive 64/432/EEC	OJ 121, 29.7.1964, p. 1977–2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Regulation (EC) No 1760/2000	OJ L 204, 11.8.2000, p. 1–10	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
Regulation (EC) No 1082/2003	OJ L 156, 25.6.2003, p. 9–12	Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 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
Regulation (EC) No 911/2004	OJ L 163, 30.4.2004, p. 65–70	Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers
Regulation (EC) No 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Regulation (EC) No 2076/2005	OJ L 338, 22.12.2005, p. 83–88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the

Reference	OJ Ref.	Detail
		Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Decision 2004/840/EC	OJ L 361, 8.12.2004, p. 41–53	2004/840/EC: Commission Decision of 30 November 2004 approving programmes for the eradication and monitoring of certain animal diseases and of checks aimed at the prevention of zoonoses presented by the Member States for the year 2005 and fixing the level of the Community's financial contribution
Decision 2005/873/EC	OJ L 322, 9.12.2005, p. 21–28	2005/873/EC: Commission Decision of 30 November 2005 approving programmes for the eradication and monitoring of animal diseases, of certain TSEs, and for the prevention of zoonoses presented by the Member States for the year 2006
Decision 2006/875/EC	OJ L 337, 5.12.2006, p. 46–56	2006/875/EC: Commission Decision of 30 November 2006 approving programmes for the eradication and monitoring of animal diseases, of certain TSEs, and for the prevention of zoonoses presented by the Member States for the year 2007
Decision 2007/782/EC	OJ L 314, 1.12.2007, p. 29–39	2007/782/EC: Commission Decision of 30 November 2007 approving annual and multi-annual national programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses, presented by the Member States for 2008 and following years