The implementation of a quality assurance procedure for the Veterinary Services of France

F. Gerster (1), N. Guerson (2), V. Moreau (3), O. Mulnet (4), S. Provot (3) & C. Salabert (5)

(1) Direction départementale des Services vétérinaires du Puy-de-Dôme, RN 89, B.P . 120, 63370 Lempdes, France
(2) Services vétérinaires, Poste d’inspection frontalier, Hôtel des Services publics de la Madrague, Enceinte portuaire, Port de Marseille, 13002 Marseille, France
(3) Direction départementale des Services vétérinaires de la Côte-d’Or, 4 rue Hoche, B.P . 1533, 21035 Dijon, France
(4) Direction départementale des Services vétérinaires du Maine-et-Loire, Cité Administrative, 26 ter rue Brissac, 49047 Angers Cedex 01, France
(5) Services vétérinaires, Poste d’inspection frontalier, Aéroport, Bâtiment 9, Porte C, Allée Henri-Potez, 31700 Blagnac, France

Summary
Due to the increasing complexity of food production systems and the concerns that these systems raise, there has been increasing demand from the general public for more State control of these processes. In France, it is the official Veterinary Services who are responsible for food safety and who must respond to these demands.

The Veterinary Service is formulating a quality assurance procedure in accordance with standard EN 45004-ISO 17020, which determines the requirements that inspection bodies must follow to be recognised, at national, European and international level, as competent and reliable. As part of this procedure, the Veterinary Service will review requirements in terms of organisation, functions, qualifications and resources.

The progress of inspection service orders, from their conception by the Central Administration, to their implementation by decentralised services, must be carefully managed. It is essential that service orders be implemented effectively and systematically by using recognised methods and issuing adequate inspection reports.

The training and qualifications of inspectors are very important: their skills must remain up-to-date so that there is always a network of qualified staff, that is, staff who have an understanding of production processes and who have recognised competences in terms of initial training, continuous professional development and adequate experience.

The quality systems implemented will only meet expectations if they are continuously monitored by means of regular evaluations. For this reason, both internal and external audits are performed.

These new practices contribute to establishing a basis for the improvement of internal evaluation.

In order to facilitate the implementation of a quality assurance procedure for inspection services, several tools, that are linked with the information system of the government department responsible for food, are, or will be, at the disposal of the decentralised Veterinary Services, i.e. a national database, mail and service order processing software, and inspection procedures.

Keywords
Introduction

The Veterinary Services of France have been involved in the implementation of a quality assurance procedure since 1996. The process was embarked upon in response to concerns raised by the general public and was rapidly given priority status by the Minister of Food and Agriculture. Quality assurance is intended to improve the reliability of the inspection process, a process which is fundamental for the issuing of official guarantees and certification.

The authors discuss the concerns of the general public which prompted the implementation of this procedure. Then, in the light of several years of experience, they describe the processes of inspection and all the arrangements that have been put in place to ensure that they are reliable.

The authors describe the entire quality assurance process, from the moment a service order is issued until the inspection is completed by competent and qualified staff. Practical examples are provided in the attached CD-ROM and there is also a discussion of the importance of impartiality in the work of Veterinary Services.

Finally, the principles of creating a quality system are briefly outlined, as is the evaluation of the procedure, by means of quality indicators, quality audits and management reviews.

In conclusion, the authors describe the experiences that different ministries have had when implementing a quality policy and also outline the practical field applications of this new and original procedure.

A necessity originating from public concern

Food safety is a vital component of public health and the general public is increasingly aware that it should be well controlled. The process of ensuring the safety of the food supply has become increasingly complex, because, in a globalised society, food products now come from all over the world. This is a cause for concern for consumers and they are insisting that the authorities analyse the possible risks and implement effective preventative measures.

In this area, as in others, the general public looks for organisation and sense: ‘organisation’ in terms of rules, procedures and stability, and ‘sense’ in terms of projects, initiatives and change. Thus, while freedom of enterprise, as enshrined in the French constitution, should be maintained in the areas of public health and food, to what extent is this really possible in food production processes, which require strict adherence to set methods and procedures?

As technology in food-processing advances, legislation is being adapted to ensure that free enterprise does not put public health at risk. Recent and current public debates on issues such as bovine spongiform encephalopathy (BSE), genetically modified organisms, and human blood contaminated by the human immunodeficiency virus, demonstrate the growing public concern over food safety.

To be free is not to reject all constraints. ‘To be free is to obey the law that one has prescribed for oneself’ (Jean-Jacques Rousseau).

The rules implemented to satisfy public requirements must be acceptable to both producers and consumers.

Food risks have always existed and will always exist but the State intervenes to reduce the risks.

Furthermore, it is extremely important that the same guarantees apply to all citizens wherever they are in the country. ‘Between the strong and the weak, freedom oppresses and law liberates’ (Père Lacordaire).

Food safety cannot be thought of in terms of high and low standards. Food is either safe (at a level determined by the State) or it is not, and it is the duty of the food safety authorities to guarantee this safety.

Article 15 of the Declaration of Human Rights (1789), states that society has the right to ask any public sector employee to account for their actions (1). During the last two centuries society rarely made use of this right, but it appears that over the past ten years or so it has rightfully decided to make up for lost time. It seems right that the State be reminded of its duties when necessary, all the more so since article 410.1 of the 1994 Penal Code states that maintaining safety (in all its various forms) is of vital importance for the nation (17).

With regard to food, as in all other areas, it is the Government that defines national policies. This is asserted under article 20 of the Constitution of 4 October 1958, which also stipulates that the enforcement of policies relies on the work of the Civil Service (16). Thus the role of the Civil Service is clearly defined.

It is political decision-makers who determine national food policies. The Government sets the level of risk that it is willing to guarantee, while striving to meet public demands. The Civil Service (at both national and decentralised levels) implement the policy.

The responsibility of the State is to reduce public uncertainty with regard to food. The objective is to gain public confidence in the ability of the State to guarantee a safe food supply.

Within this framework, and as part of the work of the Ministry of Agriculture, Food, Fisheries and Rural Affairs, the Veterinary Services of France must ensure that food production is safe and
that no harm or suffering is caused to animals during the process. Details of the mission and fields of activities of the Veterinary Services in each département of France (for administrative purposes France is divided into 96 départements) can be found in the appendix at the end of this paper.

To reach these objectives, the organisation of the State has been reformed so that food safety control policy is as effective as possible in protecting consumers and their health.

Confidence in the State means that the public always trust what the State certifies. Yet at this point, the level of confidence in the inspection of food products remains low. This lack of trust in government assurances is a serious problem and warrants the implementation of new solutions.

What conditions must be met to gain public confidence?

– confidence is earned by being able to establish that projects are always carried out efficiently while conforming exactly to what was promised

– confidence is maintained by agreeing to the evaluation of activities and performance, i.e., by being ‘transparent’.

It was to discover which methods of operation are liable to inspire confidence among the general public, and among countries importing products from France, that in 1996 the ministers of food and agriculture decided to apply the principles of quality assurance to the process of inspection (7).

The inspection process

Inspection can be defined as ‘reviewing a product, the design of a product, a service, a process or a production plant, and its conformity to specific requirements, or on the basis of a professional judgement, to general requirements’ (this definition can be found in standard EN 45004-ISO 17020) (11). The inspection of processes concerns personnel, equipment, technology and methodology. Inspection results can be used to support certification.

Each département has a local unit of the Veterinary Service, which acts as an inspection body, that is, it performs evaluations which ensure that standards are being met. These controls assess to what extent products, equipment, installations, work procedures and services conform with stipulated regulations.

The inspections are performed when the central authority issues service orders to do so (4) (Fig. 1).

Local Veterinary Services offer the full range of veterinary services and have complete budgetary control.
In order to comply with service orders, it is essential to do the following:
– to quantify inspections and to also quantify control operations when needed
– to specify the frequency of inspections
– to define the methodology of inspection controls accurately
– to define other related analyses (quantity, methods, threshold).

The reliability of an inspection process

An inspection process must comply with all the quality policies of the agricultural and food sector and must strive to reinforce the credibility of the government by performing inspections that are beyond reproach in terms of both methods and results.

The responsibilities, organisational procedures and resources of an organisation must be examined in order to prove that it is competent, reliable and impartial. The evaluation of its resources involves the examination of human resources, operation budgets, premises, communication systems, means of transport, analysis facilities (diagnostic laboratories and research laboratories), intervention capacity, regulatory support, monitoring programmes and scientific competence.

The effective management of ISOs is vital in maintaining reliability, because as well as drawing up a regulation, a competent authority must demonstrate not only that all the service orders that it has issued have been processed effectively but also that the orders have been implemented by suitably qualified staff. Only staff who are properly qualified to perform inspections can deliver appropriate and reliable certificates.

Prior to explaining the progress of a service order, from the moment it is issued by the Central Administration through to implementation by the decentralised services, it will be helpful to define some of the concepts described in this chapter.

Definitions

General considerations
A ‘service order’ refers to all directives from an order-giver, such as:
– the competent national authority at central Government level, i.e. the DGAL
– the local authority, i.e. the Prefect of a region or département
– the representative of the competent national authority, i.e. the veterinary inspector in charge of interregional operations
– the judicial powers, i.e. the Public Prosecutor
– the Ministry for Ecology and Sustainable Development
– the Prefect of the defence zone.

If a request relates to inspection, it is considered to be an ISO.

Concepts relating to inspection service orders

Regulatory inspection service orders
These service orders result from legislation or regulations (laws, decrees, orders, etc.).

Infra-regulatory inspection service orders
These are service orders that have been issued by the DGAL (memorandum, circulars, notifications, etc.).

Permanent inspection service orders
Permanent inspection service orders consist of a coherent series of ISOs that are carried out on an ongoing basis.

Long-term elementary ISOs can constitute a permanent ISO.

Elementary inspection service orders
These are long-term ISOs that modify or complement a permanent service order. A series of elementary ISOs constitutes a permanent ISO.

Periodical inspection service orders
These service orders are for inspections which must be completed within a short space of time. Unlike inspections which are performed for more general purposes, the inspections which are performed in response to periodical ISOs have a very clear focus and well-defined parameters.

Local inspection service orders
Local ISOs are determined at a local level (département or region), not issued by the Central Administration (by order of the Prefect, etc.).

Record of an inspection service order
This is a record of all the elementary ISOs which constitute a permanent ISO, plus any details of methodology or planning that the inspection body wishes to include. The authority that has issued the ISO will have made reference to the order in several documents, e.g. regulatory and infra-regulatory texts, the aim of the ISO record is to consolidate all that information in a single document. It is the paper equivalent of a reference programme (or a combination of programmes) in SIGAL, the general data system of the DGAL.
The record of an ISO documents a group of ISOs for a given type of inspection (e.g. central kitchens, bovine slaughterhouses, etc.).

**Service order filing system**

All the tasks undertaken by the DGAL can be classified according to various themes. The filing of service orders follows this thematic organisation.

**Impact study**

The impact study is an analysis of what is needed to implement a service order (personnel, equipment, material, laboratory tests, financial resources, etc.). The survey can also include simulations of the effects that an inspection will have on the body undergoing inspection: once the inspection has been completed the inspected body may well be asked to make changes and undertake improvements; the impact study can provide an indication of what effect this will have. What will be the financial impact? What effect will it have on the public image of the inspected body? What will be the political consequences?

The study will result in recommendations for the local services concerning the implementation of the inspection, the average time of the inspection, the hierarchical organisation and inspection constraints.

**GALATEE**

GALATEE is the national database of legislative, regulatory and infra-regulatory texts. This database makes it possible to edit ISO records.

**SIGAL**

SIGAL is a comprehensive food information system, consisting of software used to process information provided by the services or information that is essential to their operations.

**TOSCA**

TOSCA is the software used throughout the country to process service orders, mail and alerts.

**Data storage system**

The data storage contains all the documents produced by the DGAL (infra-regulatory ISOs, information memorandum, reports, etc.).

**Inspection service order review**

This refers to the review of an ISO carried out by a qualified person (a person who has been delegated by the Director of the *département* for the technical leadership of a team of inspectors); it aims to determine if the requirements of the service order are clearly specified and if they are applicable to the inspection body.

**Inspection service order review sheet**

The review sheet is a record which is completed by the person in charge of reviewing the ISO when one of the following events occurs:

- there are difficulties in interpreting the ISO
- the service order is wholly or partly inapplicable.

It is then forwarded to the central authority.

**Concepts related to inspection**

**Standard report**

There is a different standard report for each sector, e.g. cutting plants or cheese dairy farms. These reports include inspection grids, which are tick-lists of all the items and regulatory requirements that must be checked. There is an electronic equivalent of each specific form included in SIGAL.

**Vade mecum**

The vade mecum is a compilation of know-how providing an inspector with the proper tools with which to give an objective judgement in any given situation. The life-cycle of an ISO proceeds as follows:

- **initiation:** an ISO is initiated by the Central Administration. The inspection is undertaken by the decentralised services once the impact study has been completed, so it is important that the Central Administration provides clear and unambiguous instructions and that the aims of the inspection are achievable
- **implementation:** once the ISO has been reviewed, and as per the hierarchical structure that was described earlier, the decentralised services then implement the service order
- **follow-up:** depending on the results of an inspection an organisation may be required to make improvements. The obligation to meet these requirements may mean that an organisation has to make difficult adjustments; the effect this has on the organisation should be closely monitored and help provided where necessary.

The data resulting from these inspections helps to shape health, animal welfare and food safety policies. This process of analysing inspection results and taking appropriate action in the light of those results is carried out by both decentralised services and the DGAL.

**Inspection service orders that are designed and issued by the Central Administration**

The principal stages in this process are described below.
Impact study
The first stage in the process is to perform an impact study. This study determines what will be needed to implement the service order and assesses the possible outcomes.

Updating the GALATEE database
This database is set up with a filing scheme. For those regulatory ISOs that relate to food and veterinary issues, GALATEE is updated by the national institute for the training of Ministry of Agriculture technicians.

Infra-regulatory ISOs are issued by the Central Administration or their representatives and are included in the data storage system which supplies the GALATEE database. Local ISOs are not recorded on the GALATEE database.

Inspection service order record sheet
Provided that the GALATEE database is updated on a regular basis, a complete record sheet will be issued for a given area of inspection, e.g. central kitchens, cutting plants, etc.

Establishing methods of inspection
Inspection methods are drawn up which can be used for all inspections in general, whether they concern food safety, animal health, animal welfare, imports and exports or the environment. These methods are recommended for use in the inspection of all types of establishments and products.

It would be highly advisable if accreditation was granted to inspection services, at Community level and possibly even at international level, on the basis that they agreed to use these methods (3).

Methods of inspection are contained in the standard report and the vade mecum, which vary according to the type of inspection. These methods may also provide recommendations in terms of sampling, examples of what constitutes non-conformity, and methods of transmitting the report to the establishment that has been inspected. They are linked to the database for compiling and processing inspection data (SIGAL).

The detail contained in inspection reports
The European Union will soon be implementing new hygiene regulations and it is important that inspection methods are drafted in accordance with this new approach.

The inspection report contains basic information about each item that was inspected. It must contain the findings of the inspection but it need not include details of the inspection methods. Therefore, each organisation belonging to the same category of establishment, i.e. a group of establishments which are subject to the same ‘basic’ requirements, will have the same type of standard report.

For each item on an inspection report the vade mecum provides details of all the relevant elementary regulatory requirements.

In the case of food hygiene, the different items on the inspection list correspond to the elementary regulatory requirements of the impending regulations of the European Parliament and the Council on foodstuffs (H1) and foodstuffs of animal origin (H2).

For those establishments that only come under H1, the standard report will be based solely on H1. When both H1 and H2 regulations are applicable to an establishment there are as many inspection report models as categories of establishment.

A similar logic is applied in other fields, particularly animal health.

Items are grouped together according to a set of themes (food safety groupings used in H1/H2) and not according to the type of inspection.

The Central Administration is currently drafting these various standard reports.

The correlation between the report and the vade mecum
The vade mecum describes all the elementary regulatory requirements, item per item. The elementary requirement is re-worded in more explicit terms if necessary, and states exactly which regulation it relates to. Observations that are not related to the regulations may also be included (infra-regulatory or otherwise), but they must be clearly identified as such.

The vade mecum varies according to the category of establishment. Several vade mecum may apply to a single standard inspection report (a standard report for a direct consignment might include several vade mecum for a supermarket, a market stall, etc.).

Defining non-conformity
An inspector will mark each item on an inspection report in one of four ways: conforms, does not conform, not examined, not applicable.

The first stage is quite simple; an item either conforms, or it does not. In a case of non-conformity, an order number is assigned and the precise nature of the non-conformity is recorded objectively on the last page of the report; the specific section of the regulatory requirement to which it relates is also included (text, article, paragraph).

The second stage is to classify a case of non-conformity according to nationally defined specifications. A non-conformity can be classified as a minor non-conformity, a relative non-conformity, or a major non-conformity, depending on the level of risk that it entails. Having definitions of non-
conformity that are used and recognised at national level is an important part of ensuring that establishments that undergo inspection are evaluated according to the same criteria, wherever they are in the country.

The cover letter

After each inspection, the completed inspection report is sent to the inspected establishment. A cover letter, reviewing the main items and highlighting the decision of the Director of the local Veterinary Services is enclosed.

Links with SIGAL

All the different items in an inspection report are entered on to SIGAL. They appear as keywords, chapters and/or entries related to a reference document, on the following basis:

– an inspection corresponds to an operation, and vice versa
– a type of inspection corresponds to a reference document, and vice versa.

In each case, it is recorded whether or not the item formed part of the inspection and if so whether or not it conformed to requirements. The order in which items are entered is thus independent of the order set out in the standard report. These data may be used for statistical analysis.

In order to maintain detailed records, when the statistical study of a particular item shows a rate of non-conformity which is a cause for concern, the Central Administration inserts a description of the non-conformity into the SIGAL database.

The report (the tick-list and statement of non-conformity) must be able to be printed straight away, and if possible it should be saved as a word processing document. At this point, the order of recorded items is in accordance with the order of the standard report.

The idea that SIGAL could automatically produce the cover letters was rejected.

Preparing and setting the parameters for data capture

After designing and formalising inspection methods, the logical next step for animal health, animal welfare and food safety departments, was to set up the SIGAL database so that it became possible to capture data on inspection results. A standard report correlates with an act of reference in the SIGAL database. Hence, an inspector performs an inspection, enters the results on SIGAL, and the report is produced automatically.

To summarise, the process of issuing service orders involves the following steps:

– performing the preliminary impact study which provides useful information for decentralised services in terms of what is needed for the inspection, and gives an indication of the repercussions that the inspection is likely to cause
– maintaining accurate records by updating the GALATEE database and the ISO record sheet
– creating practical inspection tools, i.e. the standard report, which contains nationally recognised inspection methods and which serves as a guide for the inspection, and the vade mecum, which explains the requirements in greater detail
– defining the parameters of the database (SIGAL or specific databases for managing the quality and protection of plants) to enable inspectors to obtain data on the results of their inspections.

These four stages must be well co-ordinated, as they help to harmonise inspections, record their results, and monitor the efficiency of inspections.

Figure 2 shows the existing areas of inspection. It will be adapted as new developments occur, e.g. the emergence of diseases.

The processing and implementation of an inspection service order by decentralised services

Before detailing the life cycle of a service order within the Veterinary Services, it will be useful to look at planning as an organisational tool.

Planning

The reasons for planning

Tasks should be organised hierarchically to ensure that the appropriate level of resources is used for each one. This is not set in stone. Planning can be reviewed and the details can be determined by the different heads of service.

Planning determines the expected level of diligence of local services. Article 121-3 of the New Penal Code, 3rd paragraph, stipulates that: ‘A misdemeanour also exists, where the law so provides, in cases of recklessness, negligence, or failure to observe an obligation of due care or precaution imposed by any statute or regulation, where it is established that the offender has failed to show the expected level of diligence, taking into consideration where appropriate the nature of his role or functions, of his capacities and powers and of the means then available to him’ (17).

The expected level of diligence, in the sense of legal responsibility, also refers to those actions taken after an inspection in which discrepancies were discovered (it is not enough to simply ask an establishment to make improvements, it is vital to check that the improvements are made).

Planning is a standardised requirement. Chapter 11.2 of EN 45004-ISO 17020 states that ‘Whenever the absence of
written instructions would compromise the efficiency of the inspection process, the inspection body must have at its disposal, and make use of, adequate written instructions on inspection planning and the standardised techniques for inspection and sampling. When applicable, this will require sufficient knowledge of statistical techniques to ensure that sampling procedures are statistically correct and the treatment and interpretation of the results are satisfactory (11).

General principles for planning
Planning is dynamic; it changes with every new ISO. It relies on a risk analysis, performed to harmonise the way in which
inspections are carried out, so that the safety expected by consumers can be guaranteed.

When deciding upon appropriate methods and resources for each task, the following factors should be taken into account:

a) external factors:
   - risk analysis criteria
   - the priority of one or several order giver(s)
   - new regulatory requirements
   - the possibility of unforeseen events, e.g. cases of BSE, alerts, dioxin, foot and mouth disease.

b) internal factors:
   - the number of staff available, e.g. unpredictable factors, such as sickness or transfers
   - geography, e.g. district, location (if an inspector has to travel a long way to reach an establishment in a remote area, there may be less time than is necessary for the inspection), relief, etc.
   - the type of département in which the inspected establishments are situated
   - the need to ensure that the establishments who were asked to make improvements have complied within the time allowed.

Planning control
Planning is regularly assessed to check if the schedule is progressing as planned.

Each head of service determines how often the planning will be assessed, according to the local context. Evaluation will be done in one of the following ways:

- at a pre-determined, regular time, e.g. monthly or quarterly
- whenever a meeting is held to monitor how well things are going
- after any major event which has consequences for the future activity of the service.

Planning is, without a doubt, just the dynamic organisational tool that is needed to be able to redirect inspections quantitatively and qualitatively, in accordance with the above-mentioned factors. This follow-up phase is systematically recorded.

Annual programming simplifies the analysis of the impact that ISOs have on the workload of local services. Recommendations may be made to help in adjusting the programming.

Management of service orders
An inspection body is only reliable if it is organised to handle all incoming inspection orders.

Figure 3 shows the management of service orders by local units of the Veterinary Services in the départements. To help the reader understand this diagram, each stage will now be explained in greater detail below.

The different stages in the management of inspection service orders

The inspection body must keep up to date with all current ISOs. For this reason, identifying ISOs from among all other incoming information of various origins is the first vital stage in the organisation of an inspection body; it is the key moment in the inventory and recording of all incoming ISOs. ISOs must be identified from among memorandum and circular letters, mail, official papers, e-mails and faxes.

Once the ISOs have been identified, wherever they come from, they must be recorded. The recording system is the starting point for tracking the management of ISOs. It is imperative that this system be computerised as this allows for greater transparency and administrative simplification.

TOSCA, the national database for the management of ISOs, can be accessed remotely so that anyone can check on the progress of a particular ISO. The fact that TOSCA is connected to GALATEE means that identification and recording are more reliable because the responsibility for logging the service order lies with whoever gave the order. A demonstration CD-ROM of this software has been included with this issue of the Review, as has a user’s guide and an example of the database, complete with fictitious examples.

Once an ISO has been logged, it must be reviewed. This will be done by a director, a head of service, or a staff member charged with this particular task. The ISO is then sent to its final destination, i.e. the person(s) who will be in charge of the order.

Reviewing the ISOs involves examining their requirements and analysing how easy they will be to implement, by taking into account available resources, both human and material.

Usually, the ISOs are carried out immediately upon the completion of this review.

If there is a need for further staff training or additional equipment, etc., and the ISO cannot be implemented immediately after the review, it remains on hold, a review sheet is completed and the director of the inspection body informs the order giver.

This postponement of an ISO is unusual and is rapidly resolved by supplying additional resources or adapting the existing resources of the inspection body.
It is essential to distinguish between periodical ISOs and permanent ISOs:

– periodical ISOs require meeting a target within a limited time. Inspection service orders are completed when the action is concluded, e.g., a request is responded to or information is provided.

– permanent and elementary ISOs are recorded on a record sheet (for a new permanent ISO, a new record sheet will be created) and the order giver forwards the ISO, together with the record sheet, to the inspection body.

If the order giver has issued an initial standard report, he will send the modified standard report to the inspection body.

**Traceability of inspection service orders**
The inspection body must register all the ISOs that it receives and give proof that this has been done. It is necessary to guarantee the traceability of ISOs by keeping records and making copies every time someone deals with the ISO.

The ISOs are dealt with first of all by the director, the head of the service or the staff member in charge of that particular

---

**Fig. 3**
The management of service orders by local inspection bodies
*Source: the quality assurance network (RésAQ) of the General Directorate for Food (Ministry of Animal Husbandry and Animal Industries)*
order. The second and final person to deal with the inspection orders, as identified by the ISO review, is the head of service or inspector.

The need for traceability also has other ramifications. Each user of the TOSCA database, who receives an ISO or a copy, will provide his input by entering information at his level. It is worth noting that this information can be linked by computer so that the complete account of an ISO can be displayed (Fig. 4).

For the sake of the consistency and simplification of administrative duties, the interface between the various tools, GALATEE, SIGAL and TOSCA, must be extremely good.

**Competences and qualifications**

The assessment of the technical and scientific competence of inspectors is one of the most important criteria when evaluating resources (2).

**Definition of the term ‘functions/areas of activity’**

The term ‘functions/areas of activity’ is used when referring to competence: the same function may be performed in various areas of activity, i.e. the same function may be assigned to several different staff members, each in a different area (see the section on function sheets and job descriptions).

**The different levels of qualifications**

**Definitions**

Theoretical training simply means the acquisition of theoretical knowledge.

Tutoring means the acquisition of field experience (supervised by a well-qualified senior staff member).

There are four different levels of staff:
- unqualified staff
- deputies
- senior staff
- tutors.

Senior staff members have both experience and appropriate theoretical knowledge in one of the following combinations:
- experience and ongoing theoretical training
- theoretical knowledge and ongoing tutoring
- on-going theoretical training and ongoing tutoring.

Deputy staff members have experience or the adequate theoretical knowledge, but not both. Both the situations described below enable a staff member to qualify as a deputy:
- completed or ongoing tutoring
- theoretical knowledge acquired.

Tutors have experience, adequate theoretical knowledge and the teaching skills to share that knowledge. It is the director who decides who will pass from senior staff member to tutor.
Assignment of qualification
A tutor recommends qualification but it is the head of service who takes the final decision. The latter may then assign the staff member with new responsibilities in accordance with his qualification.

Additional staff
Additional staff are only contracted in emergencies. When this happens, tools such as emergency sheets, emergency plans, etc., are used.

There are two different types of tools, as follows:
– tools providing complete management of the emergency (simple process)
– tools providing partial management of the emergency (an information compilation sheet, a list of organisations to contact in case of emergencies, etc.), before competent persons take over.

Recording competencies: individual qualification sheets
An individual qualification sheet may contain the following information:
– the initial training of the staff member
– the further training undertaken (after joining the Veterinary Services)
– the professional experience (positions held since joining the Veterinary Services and those held before joining the Service, tutoring, etc.).

Eventually, it will be possible to access this sheet from a personnel management database.

Defining responsibilities: function sheets, job descriptions and the organisational chart
Function sheets, job descriptions and the organisational chart meet the requirements of the standard concerning qualifications and responsibilities. These documents make it possible to define the role of each person within the Veterinary Services in every département.

List of functions
Fourteen standard functions have been identified as being common to all Veterinary Services in every département:
– management
– middle management
– inspection
– quality assurance
– secretarial services
– information technology
– training and development
– accounting
– personnel management
– reception/switchboard
– metrology
– material resources
– certification
– sector management (district, abattoir, etc.).

There is an additional list which regroups these standard functions with other functions that may be found within the Veterinary Services.

Function sheets
Each function identified in the procedures must correlate to a function sheet. These sheets should not contain the names of staff members. The sheets make it possible to determine:
– the hierarchical position of a particular function
– the responsibilities of that function
– the authority that that function has over other staff members
– the relations maintained with functions external to the inspection body and the possible requirements in terms of category, qualifications and continuing training (Fig. 5).

Job descriptions
Every member of staff has a job description listing his functions as a senior staff member or deputy for a given area of activity. The job description lists the tasks that the Director for Veterinary Services in the département has assigned to him. The staff member signs the document to demonstrate that he/she accepts the assigned tasks (Fig. 6).

The section ‘maintaining a basic service’, which is included in the job descriptions, does not imply that staff are not permitted to be absent at the same time as each other under any circumstances, but their absence must be limited according to the urgency of the work they are involved in at any given time.

A confidentiality agreement, details of which are given in another document, is referred to in the job description. It may also be mentioned in the quality handbook that adherence to the confidentiality agreement is an integral part of being a Veterinary Service employee.

The functional and hierarchical organisational chart
The organisational chart makes it possible to see how the various functions relate to one other, by indicating the hierarchical links (vertically) and functional links (horizontally) between them. For each function that appears in the organisational chart there must be a corresponding function sheet.
### Position hiérarchique et fonctionnelle

- Direction générale
  - Organisation interne
    - Détermination de l'organisation générale et d'une politique qualité
    - Validation des documents qualité
    - Gestion du budget
    - Gestion du personnel : recrutement, évaluation, notation des agents
    - Supervision de la gestion des compétences
  - Inspection
    - Présentation des bilans d’activité et des comptes-rendus de missions aux donneurs d’ordres (DGAI, Préfet, CGIR)
    - Gestion du contentieux et des cas difficiles
    - Gestion des crises
  - Représentation et communication extérieures
  - Direction technique
  - Choix des priorités d'action en fonction des ordres de service
  - Coordination des missions et supervision des actions (métodes et bilans)
  - Décisions et actes administratifs par délégation préfectorale
  - Subdélégation et autorisation de signature au sein de l’organisme d’inspection

### Autorité
- Sur l'ensemble du personnel

### Relations externes
- Donneurs d’ordres, directeurs des administrations déconcentrées, élus, organismes et responsables professionnelles, sous-traitants, médias, ...

### Exigences
- Catégorie : A
- Qualification requise : cadre A titulaire ayant exercé au préalable une fonction d’encadrement
- Formation continue : management, communication, mise à jour des connaissances techniques et réglementaires nécessaires à l’inspection

<table>
<thead>
<tr>
<th>Examen par le Responsable Assurance Qualité</th>
<th>Validation par le Directeur départemental des Services Vétérinaires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nom :</td>
<td>Nom :</td>
</tr>
<tr>
<td>Signature :</td>
<td>Signature :</td>
</tr>
<tr>
<td>Date :</td>
<td>Date :</td>
</tr>
</tbody>
</table>

*Cette fiche annule et remplace celle du : …………………*

---

**Fig. 5**

*An example of a function sheet detailing the responsibilities of management*

*Source: the quality assurance network (RésAQ) of the General Directorate for Food (Ministry of Animal Husbandry and Animal Industries)*
Therefore, the inspection body that forms a part of an organisation involved in activities other than sanitary inspection must be identifiable in order to be recognised easily within this organisation. Such a body must always have a legal structure and documents describing the activities undertaken and its field of competence.

In order to maintain credibility, sanitary inspection departments must be clearly separated from the departments in charge of

The organisational chart may or may not contain the names of staff members; if it does not, it will be inserted in the quality handbook, if it does, it will be recorded elsewhere (Fig. 7).

**Impartiality**

The organisation of Veterinary Services must prove to be reliable in terms of structure, independence and confidentiality. Therefore, the inspection body that forms a part of an organisation involved in activities other than sanitary inspection must be identifiable in order to be recognised easily within this organisation. Such a body must always have a legal structure and documents describing the activities undertaken and its field of competence.

In order to maintain credibility, sanitary inspection departments must be clearly separated from the departments in charge of...
production or promotion. Staff of the inspection body must not be subjected to any pressure, commercial, financial or otherwise, that may influence their judgement. Procedures must be set up to ensure that persons or organisations outside the inspection body are in no position to influence the results of the inspections performed.

Impartiality and independence

Consumers and establishments that undergo inspection will only have faith in the inspection body if it is impartial and independent.

The concepts of impartiality and independence are not quite the same. Impartiality (not taking sides) is an absolute criteria, whereas independence is a relative criteria:

– impartiality: the results of an inspection must be completely impartial, it is a non-negotiable requirement. It is impossible to think of a State inspection body not being impartial

– independence: inspections must be carried out independently of outside influences. The notion of independence is essentially relative: one is independent of certain people, bodies, activities or functions. The independence of a body implies that it does not submit to any other body or community: it is the absence of dependence between institutions. The independence of an inspection body is not an absolute quality: it is a prerequisite for the impartiality and integrity of the inspection body and its staff.

The notion of impartiality necessarily contains the notion of independence (not being influenced by others), but the reverse is not true as it is possible to be independent but not impartial. It must be possible to demonstrate that an inspection process has been carried out independently, so that the independence of inspections becomes a reality and not just an ideal.

Impartiality and confidence

Very often requirements of economy and production can cast a doubt on the sincerity of certification and the value of a certificate, so it is vital that the impartiality of an inspection body can be relied upon. The structure of the Veterinary Services, which clearly separates the Service from the
agricultural and food-processing production decision-makers, guarantees impartiality at both international and national levels. This credibility is the main argument for the State financial commitment regarding food safety.

It must be stressed that confidence in this official guarantee only exists if the criteria of impartiality and independence are applied to inspections throughout the whole industry (from plants and live animals to foodstuff). A weak link destroys the credibility of the entire inspection process.

Impartiality must be guaranteed in both the inspection process and the certification process. The decision to grant a sanitary certificate is taken after the inspection, so the two processes can be seen as separate. However, there must be a single structure in charge of these two responsibilities so that the decision to grant a certificate is consistent with the inspection report.

**Confidentiality**

Finally, the Veterinary Services of each département must ensure the confidentiality of the information collected during the course of inspection, otherwise sources of relevant information would rapidly dry up. This particularly applies to information given in statements.

**Quality system**

After analysing the requirements for establishing and maintaining confidence in inspections and sanitary certificates, in terms of resources, responsibilities and organisation, the way in which these requirements can be consistently put into practice (and appropriately evaluated) will now be discussed.

The solutions used in industry are useful when considering this question. Businesses use quality assurance systems to give the client proof that his demands will always be satisfied. This system, devised to give the client confidence, is applied to a whole range of organisational structures in different firms all over the world.

Quality may be defined as the sum of the properties and characteristics of a product or service which enable it to satisfy explicit or implicit needs.

For an inspection body, the quality of inspections will be measured according to the satisfaction of the order giver (the competent authority, i.e. the DGAL or the Prefect). Criteria for satisfaction could include promptness, reliability, confidentiality, impartiality or cost.

The best way to implement quality is to include quality assurance processes in the everyday practices of the organisation, that is, to organise the structure of a service in such a way as to guarantee that its quality objectives will be achieved. Quality assurance is the sum of pre-established and systematic actions that are required to give the appropriate assurance that a product or service will meet demands relating to quality. Quality assurance can thus be defined as all the organisational means a service implements to reach a specific objective, namely, to generate confidence in the quality of its work.

It is necessary therefore to determine the precise degree of confidence that is to be guaranteed and to establish an organisation which enables these objectives to be systematically achieved. There should also be an internal system for monitoring the organisational structure.

For a quality assurance procedure to be effective, an inspection body must implement a quality system (a combination of the organisational structures, responsibilities, procedures, processes and resources required for quality management) which is appropriate for the type, field and volume of work that it does. The establishment and maintenance of a suitable quality system is, without a doubt, the most appropriate solution for demonstrating the reliability and competence of an inspection body. However, whatever the size, type of organisation or field of competence of an inspection body, the principles of quality assessment remain the same; evaluating the work of a sanitary inspection body entails using exactly the same quality assessment processes as evaluating a central authority that issues service orders: the whole Veterinary Service is assessed using the same criteria.

Requirements in terms of organisation, functioning, competencies and resources are known as ‘quality requirements’.

A coherent group of quality requirements constitutes a quality assurance reference system. Such a system makes it possible to guarantee the minimum performance level of an organisation.

There are several standardised reference systems at national, European and international level. These standardised systems make it much easier for different countries to discuss quality assurance matters with each other. Countries can also request official recognition from these systems, for example, the ISO 9000 certificate for food processing plants, or the accreditation for inspection bodies and laboratories issued by the French Accreditation Committee (5).

The best way for an organisation to meet its set objectives is to implement methods and organisation structures on the basis of the reference system that corresponds to its activities. After studying the feasibility of applying quality assurance, a working group selected the EN 45004-ISO 17020 standard as a reference system (15). This European norm determines the ‘general criteria for the functioning of the various types of bodies carrying out an inspection’ and still more precisely, the
general requirements that an inspection body must apply to be acknowledged at a national and European level as being competent and reliable for the inspection of products’.

This standard contains seventeen chapters covering the following subjects:
– field of application
– reference standards
– definitions
– administrative requirements
– independence, impartiality and integrity
– confidentiality
– organisation and management
– quality systems
– staff
– facilities and equipment
– methods and procedures of inspection
– handling samples and items displayed for inspection
– record-keeping
– inspection reports and certificates of seizure
– sub-contractors
– claims and complaints
– co-operation.

ISO 17020, which is based on the experience of European inspection bodies and takes into account the requirements and recommendations of international guidelines (the ISO 9000 standards series, the ISO/CEI 39 guide) (12), is the standard applied to the inspection services of ministries of agriculture.

However, two important items are missing from this standard, which prevent it from being fully applied by the Veterinary Services, namely, the implementation of a quality assurance procedure for official certification activities and for those activities that take place prior to the inspection, which are as follows:
– the activities of the competent authorities in matters of development and regulations
– the provision of human and material resources
– the organisation of an information network.

To this end, an Ad hoc group of the OIE (World organisation for animal health) devised a system of reference suitable for all Veterinary Services, in conformance with Resolution No. XV of the OIE International Committee adopted on 29 May 1997 during the 65th General Session.

This reference system is featured in the appendix in the CD-ROM attached to this issue of the Review.

The OIE International Animal Health Code (the Code) introduced the principles of quality assurance in the chapter on the evaluation of Veterinary Services (15).

Creating a quality system is a simple way of implementing the objectives contained in the quality policies that are written by inspection body managers.

Quality systems rely on documents for both organisation (quality procedures and the quality handbook) and operation (instructions and recording forms). A description of responsibilities (job descriptions, function sheets, an organisational chart) is also essential.

The quality handbook provides details of the general organisational arrangements of the inspection body (3, 8). It is a tool for internal quality management but the handbook is also useful for external bodies who are interested in the performance of the inspection body.

The procedures describe the organisational arrangements in more detail. They list the tasks and responsibilities that are involved in each process.

The instructions demonstrate how operations are carried out (inspection methods, sampling methods, etc.).

Finally, the recording forms make it possible to demonstrate that all processes conform with the organisational decisions described in the above-mentioned documents (Fig. 8).

Evaluation

As reliable as a quality system may be, it inspires confidence only if it is continually controlled, i.e. evaluated regularly. This evaluation must be as relevant as possible if an organisation is to go on improving (2, 5, 9).

The two main tools for evaluation are as follows:
– internal quality audits, a common process for all organisations that implement quality assurance procedures
– quality indicators, especially developed by the Veterinary Service of France, that relate to the structure and the operation of the system.

There also should be an analysis of how staff perceive the changes that are implemented.

Audits

Definitions and different types of audits

Auditing is described under ISO 9000 (version 2000) as ‘a methodical, independent and documented process, enabling
the collection of relevant information or proof of audit and which make it possible to evaluate them in an objective manner so as to determine to what extent the specifications or audit criteria are being met' (12).

Audits may involve inspecting an entire system or focus on a particular process or procedure. These two types of audit are known respectively as global audits and partial audits.

In either case, the audit can be internal or external, as follows:
- internal audits are performed by the inspection body itself and are applied to its own system. The aim is to ascertain how effectively the organisational arrangements described in the documentary system have been implemented, and how efficient they are
- external audits, e.g. accreditation audits carried out by a client (order giver) or by a third party. The aim is to inspire confidence in the organisation of the inspection body, from an external standpoint.

Audits are performed in the following two phases:
- a documentary phase, which is part of the preparations for the audit, where the auditor assesses whether or not the documentary system is appropriate for the reference system that has been chosen
- an on-site phase, where the auditor validates the effective and efficient implementation of the measures detailed in the documentary system.

Preparation of an audit

Schedule
Audits must be scheduled over a reasonable period of time.

For an internal audit, all the chapters of the reference system must be covered over a period of no more than twelve to eighteen months. The quality assurance manager of the audited site will initiate this process.

For external audits performed by a third party, there is a complete audit every three years, and in-between there are occasional inspections every six months or every year (depending on the accrediting body). These audits occur after the internal audits have already validated the organisational structure that has been implemented.

Auditors
It is imperative that auditors be completely independent of the audited system. In the case of external audits, this condition is automatically fulfilled. For internal audits, the quality assurance manager cannot audit his own work; instead, an auditor from another inspection body will be asked to perform the audit of the quality management systems.

Auditors must have an explicit knowledge of the reference system applied within the inspection body, and be trained in auditing practice. Various theoretical and practical courses are available.

The choice of one or more auditors is influenced in the first instance by the type of audit, internal or external.
Transfer of documents
The inspection body must provide the auditor with enough documents to allow him/her to plan the on-site phase of the audit. In most cases this means the quality handbook and corresponding procedures.

According to the scope of the audit (global or partial), other documents (instructions, recording forms) may be included with the above documents.

The transfer must be carried out within a reasonable amount of time prior to the on-site inspection phase, so that the auditor has time to study them.

During this study, the auditor may have to ask for additional information.

Establishing an audit schedule
The auditor gives a detailed programme of the audit to the quality assurance manager of the inspection body so that he may inform people that they will be audited.

Implementation of the audit
Opening meeting
The auditor calls a meeting of the inspection body management, the quality assurance manager, and any other people who will be involved in the audit process. He explains the purpose of the audit as well as what will happen and when.

The on-site audit
The auditor conducts interviews, usually one-to-one, to check that the people involved are applying the principles described in the document that he has studied. He observes to what extent the staff are aware of these documents and whether or not they are adhered to.

An example of an audit questionnaire, based on the requirements of the EN 45004 standard, can be found in the attached CD-ROM.

Preparing for the closing meeting
The auditor (or auditing team) records, on non-conformity forms, the discrepancies in the documentary system and the differences between the documentary system and what happens in practise.

Each non-conformity in the reference system documents (documentary non-conformity) or in terms of their application (application non-conformity) is given a mark from 1 to 3, as follows (Fig. 9):
1 – a non-conformity that calls the reliability of the inspection body in to question
2 – a non-conformity which has consequences for the inspection body but does not seriously affect its reliability
3 – a minor non-conformity that can easily be rectified.

Closing meeting
The auditor informs the inspection body of his observations and the conclusions of his audit. In the case of an external audit by a third party, the outcome is the granting (or not) of accreditation.

Audit follow-up
An audit must not be considered as having reached its completion after the closing meeting.

Audit report
The auditor will dispatch an audit report including:
– basic information about the audit (cover page), such as the date and place of the audit, name(s) of the auditor(s), the type of reference system, which parts of the system were audited, which services were audited, etc.
– the audit schedule
– the list of persons audited
– the list of documents examined (during the preparatory phase and the on-site audit)
– the non-conformity forms (possibly including comments from the client who was audited)
– an evaluation against the prior audit (if applicable)
– a synthesis (an assessment of how well the system conformed to the relevant reference system).

An internal audit report is sent to the inspection body manager. The report includes instructions for improvements and indicates by when these changes must be completed.

Audit follow-up
The auditor must ensure that the requested modifications are achieved within the time allowed.

Closure and filing
All records related to the audit (correspondence, reports, modification requests) must be filed for future reference.

External audits are considered complete when the inspection body has performed all the requested modifications.

Quality indicators and digital dashboards
The efficiency of the quality procedure must be continually monitored by an internal surveillance system. Quality indicators and digital dashboards are ideally suited for this purpose as they are often built from information already available in the services.
**Definitions**

Quality indicator: data selected periodically to monitor progress in attaining quality objectives.

Quality digital dashboard: a display which provides an overview of the entire situation and makes it easy to check on the progress of the various quality indicators.

**Selected items**

**Indicators**

Based on the experiences of the local units of Veterinary Services in the départements since 1996, a national quality assurance document has been created which provides a list of indicators for measuring the components of the quality system that has been implemented to meet the different standard requirements.

This document provides indications on how to create and operate a quality system. The document is designed to be both a guide for creating a quality system and a tool for evaluating systems once they are in place (Fig. 10).

The information is captured in a database to make it easily available.

---

### Fig. 9

**An example of a non-conformity form**

*Source: the quality assurance network (RéSAQ) of the General Directorate for Food (Ministry of Animal Husbandry and Animal Industries)*

---

<table>
<thead>
<tr>
<th><strong>Non-conformity Constatée</strong></th>
<th><strong>Documentaire</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Auteur / Expert</strong></td>
<td><strong>VRAI</strong></td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td><strong>PAR</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Organisme</strong></th>
<th><strong>Responsable de l'audit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VRAI</strong></td>
<td><strong>Date</strong></td>
</tr>
</tbody>
</table>

**Commentaires sur la pertinence de la (des) action(s) décidée(s)**

<table>
<thead>
<tr>
<th><strong>R.A.</strong></th>
<th><strong>VRAI</strong></th>
<th><strong>Date</strong></th>
</tr>
</thead>
</table>

**Vérification de l'efficacité de la (des) action(s)**

- **Vérification documentaire**
  - Par l'auteur / Expert
  - Prise de décision

- **Vérification de la population**
  - .................
  - Prise de décision

**Commentaires essentiels**

- Ct. nouvelle fiche de non-conformité N° ....
Fig. 10
Quality indicators taken from a fictitious site showing a sample of the requirements of the standard to be applied

Quality indicators were developed on Excel® (example in the CD-ROM with the appendix), then on Access® (example mentioned above).

Two spreadsheets, and a user guide, containing quality indicators, can be found in the attached CD-ROM.

The general principles of the indicators for both creating and operating quality systems are as follows:

For those indicators that are used when creating a quality system, the ‘status’ column on the digital dashboard must be completed according to whether or not a quality document, which meets standard requirements, exists. At this point, the way in which the document is used is not under consideration. The column is completed with one of the following entries:

– if the document is created, codified and approved, the entry is XXX;
– if the document is created and codified but not approved, the entry is XXX;
– if the document is created but not codified, the entry is XX;
– if the document is in the process of being drafted, the entry is X;
– if the document does not yet exist, the entry is 0.

For those indicators which are used for evaluating the implementation of a quality system the ‘status’ or ‘rate’ column must be completed according to how often and how effectively the document is used.

Digital dashboards

A digital dashboard regroups all indicators together so that all the important information is in one place and can be used to evaluate the impact of actions or assist in making decisions about quality objectives.

Digital dashboards provide a computerised method of analysing the indicators so that it is possible to have an overview of the process or to examine to what extent a particular objective of the national quality policy declaration is being fulfilled.

The use of digital dashboards allows the Veterinary Service to measure how quality assurance is being implemented in the départements, as follows:

– in a general way, with an overview of the indicators for both the creation and implementation of the quality system (Fig. 11)
## Indicateurs de construction

<table>
<thead>
<tr>
<th>Numéro</th>
<th>Description</th>
<th>État</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>contact RésAQ</td>
<td>réalisé</td>
</tr>
<tr>
<td>C2</td>
<td>pré-analyse</td>
<td>réalisé</td>
</tr>
<tr>
<td>C3</td>
<td>nomination du RAQ</td>
<td>réalisé</td>
</tr>
<tr>
<td>C4</td>
<td>sensibilisation</td>
<td>réalisé</td>
</tr>
<tr>
<td>C5</td>
<td>formation du RAQ</td>
<td>réalisé</td>
</tr>
<tr>
<td>C6</td>
<td>formation du dirigeant</td>
<td>réalisé</td>
</tr>
<tr>
<td>C7</td>
<td>déclaration de politique qualité</td>
<td>mise en œuvre à 75 %</td>
</tr>
<tr>
<td>C8</td>
<td>fiches de fonction</td>
<td>mise en œuvre à 83,3 %</td>
</tr>
<tr>
<td>C9</td>
<td>fiches de poste</td>
<td>mise en œuvre à 75 %</td>
</tr>
<tr>
<td>C10</td>
<td>organigramme</td>
<td>réalisé</td>
</tr>
<tr>
<td>C11</td>
<td>procédures</td>
<td>mise en œuvre à 73,3 %</td>
</tr>
<tr>
<td>C12</td>
<td>intégration des documents qualité nationaux</td>
<td>mise en œuvre à 85,4 %</td>
</tr>
<tr>
<td>C13</td>
<td>rédaction du manuel qualité</td>
<td>mise en œuvre à 87,5 %</td>
</tr>
</tbody>
</table>

## Indicateurs de fonctionnement

<table>
<thead>
<tr>
<th>Numéro</th>
<th>Description</th>
<th>État</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>formation du RAQ à l’audit</td>
<td>non réalisé</td>
</tr>
<tr>
<td>F2</td>
<td>repérage des dysfonctionnements</td>
<td>mise en œuvre à 90 %</td>
</tr>
<tr>
<td>F3</td>
<td>gestion des qualifications</td>
<td>mise en œuvre à 83,8 %</td>
</tr>
<tr>
<td>F4</td>
<td>maîtrise des ordres de service</td>
<td>mise en œuvre à 83,3 %</td>
</tr>
<tr>
<td>F5</td>
<td>mise en place du système qualité</td>
<td>mise en œuvre à 78,6 %</td>
</tr>
<tr>
<td>F6</td>
<td>méthodologie d’inspection</td>
<td>mise en œuvre à 75 %</td>
</tr>
<tr>
<td>F7</td>
<td>programmation des inspections</td>
<td>mise en œuvre à 75 %</td>
</tr>
<tr>
<td>F8</td>
<td>rapport d’inspection</td>
<td>mise en œuvre à 75 %</td>
</tr>
<tr>
<td>F9</td>
<td>supervision de l’inspection</td>
<td>mise en œuvre à 55 %</td>
</tr>
<tr>
<td>F10</td>
<td>audits internes</td>
<td>mise en œuvre à 25 %</td>
</tr>
<tr>
<td>F11</td>
<td>revue de direction</td>
<td>mise en œuvre à 80 %</td>
</tr>
<tr>
<td>F12</td>
<td>traitement des retours d’information</td>
<td>mise en œuvre à 74,6 %</td>
</tr>
<tr>
<td>F13</td>
<td>évaluation - audit global</td>
<td>mise en œuvre à 25 %</td>
</tr>
<tr>
<td>F14</td>
<td>adhésion des personnels</td>
<td>mise en œuvre à 75 %</td>
</tr>
</tbody>
</table>

**Fig. 11**

*Data from the digital dashboard of a fictitious site showing the quality indicators that are used when creating and implementing quality systems. Example of a digital dashboard developed in Access®

*Source: the quality assurance network (RésAQ) of the General Directorate for Food (Ministry of Animal Husbandry and Animal Industries)*

In a very targeted manner, with an examination of the implementation of ISOs by looking at all the indicators that relate to competences (Chapter 9), service order management and relevant technical control (Chapters 7, 8 and 11), and inspection reports (Chapter 14) (Fig. 12).

The digital dashboard displays the results of these detailed examinations as histograms, comparing, for all chapters of the standard, the progress that has been achieved with what was expected in theory (Fig. 13).

Quality indicators and digital dashboards are tools for charting the progress of the creation of quality assurance systems and their implementation in the départements. They can be used as an aid to decision-making and managing the procedure, and as a tool for internal communication. Furthermore, these indicators may be used for management reviews.

**Feedback questionnaire**

In order to ascertain the opinion of all categories of personnel, staff members answer a questionnaire in which they express their level of satisfaction with quality assurance. This questionnaire is based on the Common Assessment Framework (CAF), developed by European Union (EU) Member States as a tool for quality management in the public sector.
A self-evaluation grid based on the CAF grid can be found in the appendix in the attached CD-ROM.

This questionnaire relates to the chapters of the standard and its interpretation relies on the following five themes:

- an understanding of the aims and objectives of the system
- the general organisation
- the technical control
- the acceptance of the procedure among staff
- the satisfaction of the general public.

The questionnaire is sent to around fifteen staff members on each site (a representative sample of the main functions on a site). The questionnaires are completed anonymously.

The completed questionnaires are sent to the management committee. The results give an indication of how the changes are being perceived by staff (Fig. 14).
### Management review

Reviews of quality assurance service orders and organisation systems are scheduled regularly.

In general terms, a review is a critical analysis of a particular stage in a process which ensures that all the requirements of that stage have been met before proceeding onto the next step; in other words, a review ensures that all the set objectives of each phase are accomplished before moving on to the next.

The quality system review is known as the management review. The management review aims to bring to light as quickly as possible any anomalies that are likely to keep the project from running smoothly. The managers concerned can counteract the

---

**Fig. 14**

Excerpt from the feedback questionnaire which is given to staff members to measure their perception of the quality assurance procedure

*Source: the quality assurance network (RéSAQ) of the General Directorate for Food (Ministry of Animal Husbandry and Animal Industries)*

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>partly</th>
<th>no opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Does the system respect your sense of initiative?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Do you feel that quality assurance has made the circulation of information easier?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Is the system easy to understand?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Does your job allow you to use all your skills?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Has the system allowed you to demonstrate the efficiency of your work in certain circumstances?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Has this procedure enabled you to improve your personal organisation and time management skills?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Are your efforts at work appreciated to their full extent?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Have you found your work more in harmony with that of your colleagues or other departments since the implementation of a quality assurance procedure? (methods of inspection, standard reports)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Are your proposals or comments taken into consideration in matters of organisation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Do you think that the procedure has improved the service to the general public?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Do you think that the entities inspected are satisfied with your inspection reports?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Have the function sheets and job descriptions helped to clarify the role of each person?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Are you aware of the quality objectives of the local Veterinary Service?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Have you understood the purpose of implementing a quality assurance system, at both national and local levels?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Do you and your colleagues feel involved with the procedure or does it only concern the person in charge of quality assurance?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Has access to the regulations been improved?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Is the training and tutorial system more efficient?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Do you feel that your training and development is more effectively managed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Do you benefit from a work plan that is based on inspection priorities?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Do you agree with the need to give an account of your work?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Are you satisfied with the evaluation of your work?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Has the procedure contributed to improving the monitoring of service orders? (registering, assignment, results)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Has the procedure contributed to improving the functioning and the transparency of the management team?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Precise corrective actions are decided upon and time-limits are
set for their implementation. All these decisions are recorded
and the quality assurance manager is responsible for ensuring
that these improvements are carried out.

The implementation of the
quality policy of the Ministry of
Agriculture, Food, Fisheries and
Rural Affairs

History

In any country, quality assurance can be implemented
progressively. In France, the progress of quality assurance is
dependent on geographical considerations as well as the
processes concerned. The progress of the Veterinary Services of
France is remarkable however, since it originated in the field.

In 1993, the food processing industry in France started
talking about introducing quality assurance. The Ministry of
Agriculture, Food, Fisheries and Rural Affairs, which is
responsible for hygiene control in food processing, was
involved in this process. The recommendations of the
ISO 9000, which help to create reliable production processes
and promote continuous improvement, were fully integrated
into the hygiene inspection procedures, a decision which was
backed up by European Community directive 93-43, which
promotes the implementation of quality procedures (2, 3, 4,
6, 9).

However, very soon, professionals began to enquire about the
role of quality assurance within local Veterinary Services.

The EN 45004-ISO 17020 reference system was under
consideration at that time. Some local Veterinary Service
managers then formed an informal group to study the
possibility of applying this new standardised text to their own
services. The DGAL at the Ministry of Agriculture, Food,
Fisheries and Rural Affairs then showed interest and this group
quickly issued a report explaining that it was not only possible
but advisable to initiate a procedure within the public
inspection services.

However, standard EN 45004-ISO 17020 had not in any way
been written with public services in mind. It was necessary
therefore to write a guide explaining how this reference system
could be applied to the local Veterinary Services in the
départements.

One of the main problems was establishing the notion of
‘client’. For private firms, the relation between a client and a
supplier is clearly defined by a contract or service order, but in a public organisation, the question of who the client is, is less clear cut. It had to be decided which one of the following groups constituted the ‘client’ of the Veterinary Services:

– the ‘beneficiaries’ of inspection controls, i.e. those organisations that receive the stamp of approval for their animal health conditions and can therefore gain access to the market

– the consumers who use the health guarantee provided by the authorities to buy with confidence

– the part of the public services which has authority over the local services.

It was decided that it was this last group that constituted the ‘client’. The client of local Veterinary Services is the user of the services, and as the service order giver, this means the Central Administration.

Obviously, implementing quality assurance for central and local Veterinary Services is a complex procedure. The central Veterinary Services have the first task, that of translating the political decisions of the Government into practical regulations known as service orders, which are then sent to local organisations (in France this means the Veterinary Services in each département) to be implemented. Consequently, there are two different processes, as follows:

– the drafting of ISOs by the Central Administration

– the implementation of ISOs by the local services.

A country must work with more than one reference system when implementing quality assurance procedures for Veterinary Services. Standard ISO 9001 relates to the drafting of service orders and standard EN 45004-ISO 17020 relates to their implementation.

Establishing the notion of client has not been the only problem. Standard EN 45004-ISO 17020 does not deal with export certification and the process leading to the decision on whether or not to issue a certificate.

The OIE is preparing a more complete reference system, which will be used in France as soon as it is published. In the meantime, the working group has compiled an application guide and proposed that the DGAL trial it in a dozen pilot sites. Initially, this trial is only concerned with inspection activities. The activities of the Central Administration will be included in the second phase of the trial.

The twelve pilot sites form a group that is able to explore all the different elements of the standard, and as they have done this, national explanatory documents have been written to determine the principles of the procedure. An instruction handbook for standard 45004 has been drafted to assist the sites in implementing quality assurance procedures. To date, more than fifty national documents have been written, i.e. compiled by the group, then validated by the Central Administration and distributed to all départements.

These pilot sites are able to ‘spread the word’ and lead the way for other départements.

Implementation methods

The Central Administration nominated a national quality assurance co-ordinator, chosen from among the local directors, to lead the pilot scheme. In particular, he was in charge of verifying the national quality documents (especially ensuring that they conformed to the reference system), explaining the procedure to the various departments, leading working groups, and trialling, in his own département, a number of quality assurance practices.

To consolidate this ambitious experiment, the Minister of Agriculture at the time, drafted a first quality policy declaration, which set out ways of achieving goals and maintaining reliability and high standards in the Veterinary Services.

In 1996, during the BSE crisis, the Minister of Agriculture, Food, Fisheries and Rural Affairs, asserted a strong political willingness to lead a quality procedure: “Far from being ashamed of the actions carried out by our services, we must give proof of the efficiency of our actions”. He added, “Our responsibility does not stop there. I would also like to see you proceed very quickly in implementing quality assurance procedures in your départements. We must of course ensure that control procedures are consistent throughout the country, but more importantly, it would be paradoxical to require manufacturers to submit to constraints that we would not be in a capacity to meet ourselves”.

This then, is how quality assurance procedures came to be implemented in the Veterinary Services of France.

As part of this implementation, an extensive training programme was implemented for managerial staff, i.e., quality assurance managers and local directors.

A year later, the new Minister of Agriculture, Food, Fisheries and Rural Affairs drafted his own quality policy declaration, which was also taken up by the DGAL, and decided to extend this procedure to all sites.

Several new members joined the national co-ordination for quality assurance. One of those new members, the quality assurance network (RésAQ), was in charge of the following:

– ensuring all Veterinary Service staff were aware of quality assurance

– supporting the implementation of procedures on all sites

– harmonising the work of the quality assurance managers.
At the same time, a standard quality handbook was written. Even now, it is this handbook that enables Veterinary Services to implement quality assurance in their organisations, more easily and harmoniously.

The quality assurance procedure for food safety meets the quality requirements of public authorities.

The main aims of the quality assurance procedure are as follows:
– to assure international partners, industry and the general public that inspections are reliable and consistent
– to be in a better position to deal with emergency situations
– to be able to act more quickly in emergency situations
– to maintain the impartiality and credibility of public inspections and State certification.

Quality assurance systems help inspection services demonstrate that they are reliable and effective, which is very important when it comes to international agreements and negotiations.

Creating a quality assurance procedure for the Veterinary Services in France has required a lot of thought and a lot of financial resources.

In order to make progress, the decentralised Veterinary Services have had to adopt new goals, assimilate new concepts and implement new systems, they have had to conceive new ideas, incorporate them into their work and then produce the corresponding documentation, and then, finally, they have had to evaluate the efficiency of these changes (8, 9).

The service of the inter-regional general veterinary inspector has implemented its own quality system under the EN +5004-ISO 17020 reference system.

The central services of the Ministry of Agriculture, Food, Fisheries and Rural Affairs have also set up their own quality assurance procedure. They have supported the progress of the quality assurance implementation and facilitated the nomination of people in the decentralised inspection services to be in charge of quality assurance. They are in charge of formalising inspection services and they have introduced specific ways of doing this.

Staff in pilot sites, who became very familiar with the idea of quality assurance, readily accepted the notion because it requires that management rely on consultations and participation. It brings out their creativity and renews their appreciation of the value of the mission of inspection services. It clarifies, with the utmost transparency, the distribution of responsibilities and powers of decision.

Quality assurance procedures are an effective way of testing all the different functions of an organisation and a useful tool for continuous improvement, but resistance to change often proves an obstacle to implementing these improvements. The balance within a work community can be deeply affected when relationships and responsibilities are clarified. The limitations of each person, some of which may be unknown to other people in the team, and the characteristics that determine how people behave at work and the role they play within a team, are brought to light. It is no longer possible to excuse poor performance on a confusing distribution of roles and responsibilities, the vagueness of reporting lines, or the lack of forward planning.

When quality assurance procedures are implemented the relative capabilities of each link in the chain become apparent to everyone and the weak links feel insecure. If they hold a managerial position, it is highly likely that they will try to delay the procedure, sidestep the implementation and hide its slow progress.

It is for all of these reasons that implementing quality assurance throughout the country is no easy matter. After the enthusiasm of the ‘pioneer’ sites and the eagerness of the many sites who followed in their footsteps, the resistance (for the reasons mentioned above) of the remaining sites has to be addressed, which often entails difficult changes in management.

The Minister of Agriculture, Food, Fisheries and Rural Affairs has decided to designate his service as a public inspection body. The results of such a move concern the general public, public authorities, and their staff.

The general public has confidence in a State that reduces uncertainties by carrying out inspections that are harmonised, independent, impartial and transparent. The public often voice their concerns about food safety and this type of inspection is helpful in allaying their fears. Similarly, public authorities can have confidence in such an inspection process because it ensures that the guarantees that they provide on the basis of these inspections are trustworthy and it helps communication between the authorities, consumers and commercial partners.

People who fully participate in this process benefit from a greater sense of responsibility and inclusion.

The CD-ROM that comes with this issue of the Review includes a presentation describing the policies of the Ministry of Agriculture, Food, Fisheries and Rural Affairs, and the history and implementation of quality assurance.

**Conclusion**

The quality assurance procedure implemented by the DGAL and the local inspection services has been a process of deep and complete reform for the State; deep, in the sense that it
encompasses all the different functions of the organisation, and complete, because it concerns the Central Administration as well as the local services (10, 13).

Much more than a standard quality procedure, it has been an ambitious, and sometimes difficult, total reorganisation, that in the long term is likely to succeed in fully restoring the confidence of the public in the official guarantee of the State in matters of food safety.

Improving the protection of consumer health is one of the major objectives of the State. Ensuring the safety of food is essential if this goal is to be achieved.

Moreover, to restore consumer confidence and to respond to the concerns about some production systems that are over-producing, it is also important to protect animal and plant health and to respect the welfare of animals.

Recent experience has clearly demonstrated that not only is food safety a concern for the consumer but it is also crucial if the market is to function properly. The safety of food is not only a prerequisite for the protection of consumer health, it also serves the interests of producers and those associated with the processing and marketing of foodstuffs and agricultural products.

Appendix

The mission and control activities of local Veterinary Services

Safe food production
Animal health surveillance

Objective
– to perform epidemiological surveillance and detect outbreaks of diseases, whether they result from accidental or deliberate factors.

Expected results
Local services manage both everyday activities and emergency situations by developing the following plans:
– plans for combating specific diseases, e.g. foot and mouth disease
– plans for detecting contaminants
– emergency plans, e.g. in case of an outbreak of food poisoning or accidental pollution
– ministerial plans for preventing contamination and maintaining the food supply.

Methods
– controlling animal movements and the production of animal products
– controlling industries (producers, processors, etc.)
– controlling animal gatherings and fairs
– implementing related national surveillance programmes
– implementing emergency measures where necessary.

Reducing risks throughout the food chain

Types of establishment subject to inspection

All establishments which are involved in the food production process at any stage undergo inspection. That includes establishments which deal with any type of animal, e.g. cattle, sheep, goats, pigs, birds, bees, game, fish or snails, and establishments which are involved in food production, such as breeding farms, abattoirs, processing plants and rendering plants.

Objective
– to protect public health by ensuring that all products, establishments and systems, conform to the regulations.

Expected results
If the goal is being met the result will be that all the relevant products, establishments and systems will be either certified or rejected in one of the following ways:
– product approval
– establishment approval
– zone or territory recognition
– seizure, downgrading (through destruction or other appropriate treatment of a consignment, disqualification), suspension or withdrawal of official approval.

Methods
– registering the different establishments (breeding establishments, professional agricultural organisations, firms, etc.)
– establishing administrative controls
– defining technical veterinary controls/inspections in the regulations
– establishing preventive and curative measures.

Protecting animal and human health

Objective
– to limit the spread of substances that are harmful to public or animal health.
Expected results
The fulfilment of this objective will mean that the local Veterinary Services will achieve the following:
– the implementation of regulatory measures for the control of animal diseases such as equine metritis and rabies.
– the validation and evaluation of the plans of sub-contractors to combat diseases, such as infectious bovine rhinotracheitis and warble infestation.

Methods
– developing disease control plans
– supervising the work of third parties
– disseminating information
– following-up on compensation files.

Regulating the veterinary profession
Objective
– to control the practice of veterinary medicine and surgery
– to give a regulatory framework for the work performed for the State by private veterinarians.

Expected results
These actions will result in the following
– agreement between the State and the veterinarians
– disciplinary action where necessary.

Methods
– evaluating the work of private veterinarians
– disseminating information
– organising information meetings
– participating in professional meetings.

Hazard-free production
Controlling the movement of animals and animal products for import, export and local trade
Items subject to control include the following:
– animals and animal products, including semen, skin, hooves, milk, meat-and-bone meal, manure
– foodstuffs.

Objective
– to verify that products entering the country or the EU or transiting to and from other countries, conform to regulatory requirements
– to verify that products destined for another country conform to the administrative and technical requirements of that country.

Expected Results
This process of verification results in issuing export certificates and import permits for trade into and out of the EU.

Methods
– sampling animals and animal products
– checking the additional certificates within bilateral agreements
– document control
– identity controls
– ensuring that the Washington Convention is being complied with
– carrying out product checks at final destination.

Control of the production, storage and distribution of veterinary drugs (Code of Public Health)
Objective
– to check that producers and distributors (as listed below) comply with regulatory requirements:
  a) production plants
  b) wholesale distributors
  c) medicated food factories
  d) animal breeding establishments
  e) pharmacies and veterinary offices.

Expected results
Whether or not producers and distributors are complying with the regulations will result in either accreditation or sanctions (reports, export certificates).

Methods
– checking documentation and technical processes in operating procedures and/or processing and/or communication (advertising methods for medicines).
– checking the delivery of veterinary drugs (e.g. by pharmacists)
– checking veterinarians and accredited organisations.

Protecting the environment
Objective
– to ensure that the animal production and food processing industries respect regulatory measures for protecting the environment.

Expected results
This involvement in protecting the environment will lead to the following:
– advising the local Hygiene Council
– proposing decrees
– prosecuting when environmental laws are flouted.

**Methods**
– inspecting food processing and animal production establishments
– verifying the rules of installation and operation
– administration and technical control
– disseminating information.

**Production without suffering**

**Animal welfare and protection**
Local services must, as far as they can, ensure that the principals of protection and welfare be respected for all animals, whether they be pets, wild animals, animals used in experiments and food production, or animals used in leisure activities, such as horse racing.

**Objective**
– to ensure that all regulatory requirements relating to the reduction of animal suffering are adhered to.

**Expected results**
– agreements and competency certificates or the introduction of emergency or protective measures and sanctions (reports).

**Methods**
– controlling the animal care staff of animal experimentation teams
– controlling all premises in which animals are kept
– controlling animal production establishments
– controlling animal transportation
– controlling the use of animals
– controlling animal fairs
– controlling slaughter processes.

**References**


