Quality assurance of Veterinary Services at the international level: a proposed approach

D. Nannini (1), A. Giovannini (1), G.L. Fiore (2), R. Marabelli (2) & V. Caporale (1)

(1) Istituto Zooprofilattico Sperimentale dell’Abruzzo e del Molise ‘G. Caporale’, 64100 Teramo, Italy
(2) Dipartimento alimenti e nutrizione e sanità pubblica veterinaria – Ministero della Sanità, Piazza G. Marconi 25, Palazzo Italia, 00144 EUR – Rome, Italy

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Summary
A proposal for the harmonisation of quality assurance of Veterinary Services at the international level is made. This proposal is based on the hypothesis of accreditation of Veterinary Services according to the 9000 series of the International Standards Organisation (ISO) standards. An example of a way in which ISO 9000 standards can be used within the context of management of Veterinary Services is given, together with an explanation of the possible role of the Office International des Epizooties in ensuring fairness of evaluations of Veterinary Services at the international level.

Keywords

Introduction
The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) concerns sanitary measures in the international trade of animals and animal products. The Agreement came into force with the establishment of the World Trade Organization (WTO) on 1 January 1995. According to the Agreement, when Member States define measures to protect human, animal and plant health against risks which may arise from the importation of animals and animal products, standards, guidelines and recommendations developed by the relevant international organisations must be applied. Protective measures must be based on an appropriate risk analysis, implemented using techniques developed by the Office International des Epizooties (OIE). The OIE is recognised by the SPS Agreement as the reference international organisation for animal health.

According to the OIE International Animal Health Code: The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the risk associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products, and pathological material. The analysis should be transparent in order that the exporting country may be provided with a clear and documented decision on the conditions imposed for importation, or refusal of importation. Import risk analysis is preferable to a zero-risk approach because it provides a more objective decision, and enables Veterinary Administrations to discuss any differences in conclusion which may arise concerning potential risks (7).

The Code defines risk analysis as a multiphase process including hazard identification, risk evaluation, risk management, evaluation of Veterinary Services and, if necessary, zoning and regionalisation.

The existence of epidemiological surveillance systems is a prerequisite of risk analysis in countries involved in international trade. The SPS Agreement recognises that the measurement and management of risks is impossible if documented and reliable quantitative information on the sanitary status of animal populations and animal products is lacking.
As mentioned above, the evaluation of Veterinary Services is one of the components of risk analysis and management at the international level. This is the tool used by countries to evaluate both the ability of surveillance systems to identify, quantify and manage risks connected with international trade and the trustworthiness of international certificates.

The evaluation of risks in general, and of Veterinary Services in particular, should be performed in a transparent manner and, as reported by the OIE Code, should ‘be conducted by Member Countries on a bilateral basis. The two countries concerned should consult mutually on the evaluation criteria, the information required and on the outcome of the evaluation’ (7).

**The risks of evaluation models for Veterinary Services**

Many criteria and methods exist for the evaluation of an organisation and the performance thereof. These depend on the functions and the structure of the organisation, and on the objectives of the evaluation process. A method to evaluate Veterinary Services at the international level is difficult to define. The difficulty is mainly caused by the following obstacles:

- **a)** marked differences in the organisation of Veterinary Services in different countries

- **b)** the number of tasks that Veterinary Services must undertake world-wide.

Furthermore, tasks assigned to Veterinary Services, may vary according to the country and many are either directly or indirectly linked to international trade. The model used in Italy is provided as an example (Table 1). Given the variety of models that could be used, the risk of generating biased evaluation models which are either too specific or too general, is very real.

Organisation models that are either abstract or, worse still, those which refer to a given country or to a group of countries, considered ‘the best’, often condition evaluation models with high degrees of specificity. Given the specificity of the model, it is often difficult to adapt the model to the realities of the Service under evaluation. Thus, it is practically impossible to build a truly bilateral evaluation model as envisaged by both the OIE Code (7) and the SPS Agreement. In fact, the true danger is that the evaluation method is chosen by the country which is economically and politically stronger and is based on the organisation model of that country. Therefore, the bilateral recognition of the validity of the method is purely formal and does not have any real substance.

On the contrary, the use of models based on very general elements creates difficulties in the evaluation of results. Most questions are open and therefore answers are not homogeneous. Consequently, a comparison is difficult to make.

In both cases, the evaluation will *de facto*, always be subjective, strongly conditioned by the entity performing the evaluation, by the organisation models referred to and by a subjective evaluation of the exporting country. As is often the case, if one tries to render the evaluation objective, assigning arbitrary points to qualitative data, as though they were quantitative data, the situation worsens. In fact this leads to the following situation:

- a loss of the true meaning of the evaluation process, which becomes a function of the specific objectives of the entity which has created the evaluation scale

- the temptation of applying an evaluation scale, created for certain specific objectives, in circumstances which may differ vastly

- the occurrence of numeric objectiveness in the case of an evaluation which is essentially subjective.

Documented evaluation attempts have used check-lists with markedly different contents (1, 6). Differences reflect the varying objectives pursued by the evaluation process that has inevitably generated different evaluation criteria. In the check-list of the OIE guide, qualitative questions with open answers are prevalent. Understandably, this is because the check-list was designed to be used in as many countries as possible. However, an objective analysis of results and a real comparison between countries becomes very difficult for the reasons mentioned above. Reciprocal trust between Veterinary Services world-wide is practically impossible unless fair and transparent evaluation methods are used. Obstacles to the harmonious development of trade in animals and animal products will continue to exist and, furthermore, the fairness and equal opportunity required by the OIE, will be a mere verbal expression, which will not have a concrete chance of being implemented.

**A possible solution to problems of evaluation**

The solution to the problem of risk evaluation in international trade in animals and animal products might be to transform risk analysis and management into discrete activities, as suggested by the OIE Code. However, it is essential that all countries accept the validity of the evaluation standards. Whatever the circumstances, a risk analysis which is based entirely on rigorous quantitative data is the only analysis which can be recognised as valid.
Examples of local Veterinary Service processes in Italy

<table>
<thead>
<tr>
<th>Animal health</th>
<th>Hygiene of food of animal origin production</th>
<th>Hygiene of animal production</th>
</tr>
</thead>
<tbody>
<tr>
<td>First line of activity</td>
<td>Slaughterhouses, meat cutting and meat preparation factories</td>
<td>Inspection and control of animal well-being, of experiments on animals and of animal reproduction</td>
</tr>
<tr>
<td>National eradications scheme, mass prophylaxis, sanitary herd controls, management of outbreaks of infectious diseases</td>
<td>Planning of inspection and control activities in the territory of competence in relation to the objectives assigned for this group of activity</td>
<td>Planning of inspection and control activities in the territory of competence in relation to the objectives assigned for this group of activity</td>
</tr>
<tr>
<td>Planning of control activities in the territory of competence in relation to the objectives assigned for this group of activity</td>
<td>Implementation of planned activities in the territory of competence</td>
<td>Implementation of planned activities in the territory of competence</td>
</tr>
<tr>
<td>Implementation of planned activities in the territory of competence</td>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
</tr>
<tr>
<td>Evaluation of results</td>
<td>Re-planning</td>
<td>Re-planning</td>
</tr>
</tbody>
</table>

Second line of activity

<table>
<thead>
<tr>
<th>Inspection and control, import and export of animals, collection of samples</th>
<th>Inspection and control of fish products</th>
<th>Inspection and control of animal feeding, pharmaceutical treatment, production and distribution of animal feed (veterinary practices and clinics, pharmacies, veterinary drug wholesalers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning of activities in the territory of competence in relation to the objectives assigned for this group of activity</td>
<td>Planning of activities in the territory of competence in relation to the objectives assigned for this group of activity</td>
<td>Planning of activities in the territory of competence in relation to the objectives assigned for this group of activity</td>
</tr>
<tr>
<td>Implementation of planned activities in the territory of competence (including collection of data provided by the first sub-supplier)</td>
<td>Implementation of planned activities in the territory of competence</td>
<td>Implementation of planned activities in the territory of competence</td>
</tr>
<tr>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
</tr>
<tr>
<td>Re-planning</td>
<td>Re-planning</td>
<td>Re-planning</td>
</tr>
</tbody>
</table>

Third line of activity

| Inspection and control of food of animal origin at the production factory, transport, wholesale and retail levels, etc. | |

Other activities

General and support activities

Line A

<table>
<thead>
<tr>
<th>Management of information system (data collection, data validation, management of archives, documentation, data transfer, interfacing with other information systems)</th>
<th>Management of information system (data collection, data validation, management of archives, documentation, data transfer, interfacing with other information systems)</th>
<th>Management of information system (data collection, data validation, management of archives, documentation, data transfer, interfacing with other information systems)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning of activities in relation to information needs of first, second and third lines of activity</td>
<td>Planning of activities in relation to information needs of first, second and third lines of activity</td>
<td>Planning of activities in relation to information needs of first, second and third lines of activity</td>
</tr>
<tr>
<td>Implementation of planned activities</td>
<td>Implementation of planned activities</td>
<td>Implementation of planned activities</td>
</tr>
<tr>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
</tr>
<tr>
<td>Re-planning</td>
<td>Re-planning</td>
<td>Re-planning</td>
</tr>
</tbody>
</table>

Line B

<table>
<thead>
<tr>
<th>Verification and control of internal activities and qualification of suppliers</th>
<th>Verification and control of internal activities and qualification of suppliers</th>
<th>Verification and control of internal activities and qualification of suppliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning of activities in relation to operation needs of all lines of activity</td>
<td>Planning of activities in relation to operation needs of all lines of activity</td>
<td>Planning of activities in relation to operation needs of all lines of activity</td>
</tr>
<tr>
<td>Implementation of planned activities</td>
<td>Implementation of planned activities</td>
<td>Implementation of planned activities</td>
</tr>
<tr>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
<td>Evaluation of results</td>
</tr>
<tr>
<td>Re-planning</td>
<td>Re-planning</td>
<td>Re-planning</td>
</tr>
</tbody>
</table>

Veterinary Services evaluation is the basic instrument of measuring trustworthiness and reliability. Consequently, it is essential that the data and elements on which risk analysis is based are validated. The objective of Veterinary Services evaluation in the context of risk analysis can be interpreted as a measurement of the quality of those Services in relation to international veterinary certification. According to a definition agreed upon at the international level by the International Standards Organisation (ISO), which is given in ISO standard 8402, quality is defined as 'the totality of characteristics of an entity that bears its ability to satisfy stated and implied needs'.

Internationally accepted standards for quality assessment of processes, products and services already exist. These are the standards of the ISO 9000 and ISO 25 series. The application
of these standards could solve the problem of the evaluation of Veterinary Services and laboratories at the international level.

Initially, the 'processes' leading to the 'product' (international veterinary certificate) should be identified and analysed and then quality evaluation models should be adopted, based upon the ISO 9000 series standards for the Veterinary Services, and on the ISO 25 for laboratories. Furthermore, such a choice ensures the coherence of the service evaluation model with those adopted by the industry for process quality control. This coherence is essential. International veterinary certificates are basic documents which ensure the quality of both food of animal origin production processes and products. The quality of food of animal origin becomes inexistent if Veterinary Services do not guarantee health security to consumers.

The use of internationally approved standards is the most transparent way in which quality standards of management can be accredited. Veterinary Services which are accredited according to these standards, therefore, will fulfil the following criteria:

a) meet the requirements of national and international markets

b) generate the trust of their 'clients' both at national and international levels

c) provide assurance of the equivalence of the quality of their operations independently of differences in culture, production methods, organisation and legislation.

Besides facilitating transparency, the use of internationally recognised standards on quality assurance, already adopted within production processes world-wide, clarifies the intention of the Services towards both the final and the intermediate clients (consumers of food of animal origin and other Veterinary Services and industry, respectively).

Quality assurance and management standards

A Technical Committee of the ISO developed the 9000 series to make available a unique standard for the functions of quality assurance and management (3). In the 1990s, the ISO 9000 family was extended further and has been revised to better satisfy the needs of users. The ISO standards that can be used to build a quality system for Veterinary Services (Appendix I), are as follows:

- ISO standard 8402
- all ISO standards from 9000 to 9004 (inclusive)
- all ISO standards from ISO 10001 to ISO 10020 (inclusive).

These standards describe the items which should be included in quality systems, but do not describe how an organisation should make use of them. The objective of the standards is not to impose the homogeneity of quality by imposing a specific model on organisations and processes. On the contrary, assuming that different organisations have different needs, these standards recognise that the planning and implementation of a quality system must necessarily be influenced by the specific objectives, products, processes and practices of the individual organisation (UNI/EN ISO 9000-1:1994). The standards indicate the objectives and the basic responsibilities for quality which an organisation should declare. Degrees of freedom are permitted in the planning of the quality system and encouragement is given to each organisation to structure its own system in relation to specific needs, within a cultural and operational context.

An approach to quality systems

The ISO 9000-1 standard specifies the principal concepts which relate to quality, including specifications and inter-relations. A guideline is also provided for choosing and using the ISO 9000 standards in the management of quality and of quality assurance (Appendix II).

Assuming that the structure of a Veterinary Service organisation includes central, intermediate (regional) and local levels, an attempt could be made to clarify, on the one hand, how to use quality as a decision-making and management tool and, on the other hand, how to decide which ISO standards should be applied. The examples given allow for a global quality system to be built, involving the entire Service, and also for quality systems applied to specific objectives only, involving parts of the Service (i.e. those involved in international certification of animals and animal products).

Objectives, identification of stakeholders and of expectations

The main objective of an organisation which adopts the ISO 9000 standard is customer satisfaction. In terms of the ISO 9000-1, an organisation working in accordance with quality criteria should attain the following objectives:

a) continuously achieve, maintain and seek to improve the quality of products in relation to quality requirements

b) improve the quality of operation, thereby being able to continually meet all stated and implied needs of customers and other stakeholders

c) provide confidence to internal management and employees by ensuring that the quality requirements are being fulfilled and maintained and that quality improvement is taking place

d) provide confidence to customers and other stakeholders by ensuring that the requirements for quality are being, or will be, achieved in the products delivered.
e) provide confidence that quality system requirements are fulfilled.

In accordance with ISO 9000-1, five principal groups of stakeholders are recognised for each organisation which delivers products and services, as follows:
- clients
- employees
- owners
- sub-suppliers
- society (at large).

All stakeholders must be taken into account by the supplier (Table II).

Table II
The stakeholders of suppliers: expectations and needs

<table>
<thead>
<tr>
<th>Stakeholders of suppliers</th>
<th>Typical expectations or needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
<td>Product quality</td>
</tr>
<tr>
<td>Employees</td>
<td>Work/career satisfaction</td>
</tr>
<tr>
<td>Owners</td>
<td>Investment performance</td>
</tr>
<tr>
<td>Sub-contractors</td>
<td>Continuing business opportunity</td>
</tr>
<tr>
<td>Society</td>
<td>Responsible stewardship</td>
</tr>
</tbody>
</table>

Table III details the possible stakeholders interested in the supply of veterinary services, at central, intermediate (regional) and local levels.

Table III
Stakeholders interested in the supply of veterinary services at central, intermediate (regional) and local levels

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Examples for the central level</th>
<th>Examples for the intermediate level (regional)</th>
<th>Examples for the local level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
<td>- Veterinary Services of other countries (also as mediators of interests of national industry and consumers) - National animal industry - National consumers</td>
<td>- Central Veterinary Service - Veterinary Services of other regions (also as mediators of interests of regional industry and consumers) - Regional animal industry - Regional consumers</td>
<td>- Veterinary Service of the intermediate level - Other local Veterinary Services (also as mediators of interests of local industry and consumers) - Local animal industry - Consumers of territorial unit</td>
</tr>
<tr>
<td>Employees</td>
<td>Employees of the Central Veterinary Service</td>
<td>Employees of the regional Veterinary Service</td>
<td>Employees of the local Veterinary Service</td>
</tr>
<tr>
<td>Owners</td>
<td>National community and/or political representatives</td>
<td>Regional community and/or political representatives</td>
<td>Local community of territorial unit and/or political representatives</td>
</tr>
<tr>
<td>Sub-contractors (sub-suppliers)</td>
<td>- Veterinary Services of the intermediate level and/or local level - Field veterinarians - Central and/or peripheral laboratories and/or international reference laboratories - Inspection services operating in slaughterhouses, food industries, etc. - Other suppliers of goods and services</td>
<td>- Local Veterinary Services - Field veterinarians - Central and/or peripheral laboratories (of the region or of other regions) - Inspection services operating in slaughterhouses, food industries, etc. - Other suppliers of goods and services</td>
<td>- Field veterinarians - Central and/or peripheral laboratories (of the region or of other regions) - Inspection services operating in slaughterhouses, food industries, etc. - Other suppliers of goods and services</td>
</tr>
<tr>
<td>Other stakeholders</td>
<td>International community and national community (either in their entirety or a part thereof); the former have to be assumed as owners and the latter as customers</td>
<td>National (and international) community</td>
<td>National (and international) community</td>
</tr>
</tbody>
</table>

To ensure that the producer achieves customer satisfaction, each activity of Veterinary Services can be represented according to the diagram given in Figure 1 (ISO 9000-1).

Fig. 1
Diagram showing how all work is accomplished by a process (International Standards Organisation standard 9000-1)

The production of an international veterinary certificate is used as an example, as follows:

a) the supplier is the Central Veterinary Service of the exporting country and is responsible for ensuring that the product conforms with the expectations of the customer
b) the product/service is the international certificate
c) the sub-suppliers are local Veterinary Services and the diagnostic laboratories of the exporting country
d) the customer is the Veterinary Service of the importing country
e) customer expectation is the conformity of imported animals to a series of requirements established by international agreements (bilateral or multilateral).

The various sub-processes and services involved in this process are illustrated in Figure 2.

Macro representation can be developed further, according to the true organisation of individual Services. It is necessary to recognise and accept that the customer of each sub-process must be in a position in which a relationship of confidence exists with the supplier, who is able to provide assurance of the quality required. Each link in the chain influences the quality of the entire process.

The required quality is given for each process, as follows:
- for the laboratory: by the reliability of the test result, determined not only by the use of standard recognised methods, but also by a diagnostic process which is controlled and documented
- for the local Veterinary Service: by the reliability of the certificate; this is a consequence of a diagnostic process based on surveillance systems; the adequacy of the latter must be demonstrated by the documented ability to collect and analyse objective quantitative data on the health status of animal populations (animals traded, herd of origin, animal population in the area of origin) and on the relationship with the environment (trade relationship with other populations, environment of origin, etc.).

- for the Central Veterinary Service: by the reliability of the international certificate which depends on the reliability of management and on the reliability of sub-suppliers; the entire process which leads to the international certificate conforms with quality criteria which can be demonstrated.

Each sub-process must be able to prove and document to the customer that all requirements have been satisfied. This is possible only if the process/sub-process is controlled and documented.

A specific case in point is that of the quality of laboratory testing required for certification. To be able to demonstrate objectively to clients that all requirements have been fulfilled, testing laboratories, which function as sub-contractors of Veterinary Services, must be accredited according to systems that assure the quality of test results (2). In the European Union, for example, since 11 November 1998, laboratories are no longer able to conduct tests for the official control of food products, unless the criteria set by the European standards UNI/EN 45000 (Directive 93/99/EC) are met (3). The UNI/EN 45000 standards are equivalent to the ISO 25 standard.

A quality system is more than a simple addition of sub-processes. The efficiency of such a system does not depend solely on the control of individual sub-processes, but also on the coherence of those sub-processes. The quality of processes depends on the compatibility and co-ordination of the sub-processes which constitute the quality system and on the adequacy of the definition of the responsibilities, authorities and activities (interfaces).
An example of a model quality system for a group of activities of the Veterinary Services

Method

The principal activities of Veterinary Services involved in the international certification process are associated with the ISO 9000 standard in such a way that service operations are linked to criteria of quality management.

The main lines of activity of one of the sub-suppliers – the local Veterinary Service – are identified in Table I. One of the lines of activity identified is associated with the ISO 9001 standard to build and maintain a quality system, with the objective of securing from the customer, the Central Veterinary Service, adequate trust in the sub-supplier. Lines of activity, already associated with the ISO 9001, must then be associated with the guides ISO 9000-1, ISO 9004-1 and 9000-4, to provide all indications which will be useful in creating a coherent system (Table IV).

The model proposed could be adapted to all other sub-suppliers and to the customer (the Central Veterinary Service) which has the function of supplying international certificates.

The model takes the following into account:

a) in the ISO 9000 family, the only standards are the ISO 9001, 9002 and 9003, while the others are guidelines
b) the framework of the standards in the ISO family are based on two basic principles, as follows:

- the ability to control conditions, irrespective of whether or not these are processes or services, activities or part of an activity, the ability to correct and/or to prevent the occurrence of problems must be anticipated
- the ability to objectively demonstrate and document the conditions listed in the preceding sub-paragraph.

Phases

The first line of action which must be undertaken to organise the Veterinary Service, or a part thereof, according to quality management, is to prepare and disseminate a document in which the undertaking to implement a policy for quality, and the strategic objectives of this policy, are clearly stated. The document must be prepared in accordance with the reference standards and originate from the Chief Veterinary Officer (CVO). The latter must formally define and attribute the responsibilities of those co-ordinating and maintaining the quality system. The quality system must also be reviewed periodically by the CVO to ensure that the objectives are redefined if necessary.

A basic preliminary activity is the preparation of the quality manual of the Veterinary Service. This manual is the reference tool for the implementation and the updating of the quality system. The general criteria adopted by the Veterinary Services to manage and maintain the quality system must be described in the manual.

The procedures adopted for the implementation of the general criteria and for the maintenance of the quality system must also be described and documented in detail. These are called quality system procedures and can either be included in the manual or can be kept separate. In the latter case, the manual must be cross-referenced to the quality system procedure documents. Examples of quality system procedures can be those for the management of projects and plans, for the documentation and filing of the progress of programmes, for document transmission and the communication of standards, for the management and control of data input and output, for the control of service delivery, etc.

Those responsible for individual areas of activity must provide documented evidence of the implementation and delivery of services, in accordance with the criteria established in the quality manual and quality system procedures. They must also adopt and document technical methods used. In relation to these technical methods, standards established by the OIE, in particular the Code (7) and Manual of standards for diagnostic tests and vaccines (9), and by the Food and Agriculture Organization Codex Alimentarius Commission (4), must be taken into account. Technical methods can be included in the quality manual or can be kept separate. If the methods are kept separate, the manual must be cross-referenced to the technical methods documents.

Training for the quality system

Quality assurance programmes must include training for quality and for the implementation of the quality system. Training is a key strategic element for the success of the entire programme. In general, veterinarians, who are familiar with solving technical problems using scientific methods (i.e. risk analysis, tuning of an analytical method, etc.), should not have insurmountable difficulties. It is fundamental to understand that a quality system is, in practice, the application of the scientific method to the management of organisations and of daily activities. Figure 3 explains this concept.

Each phase, particularly in regard to operations, can in turn be sub-divided according to the same cycle (Fig 4).

Organisations in general, and Veterinary Services in particular, should not underestimate the difficulty of understanding and of accepting quality systems. This is particularly true in cultural environments in which the daily working routine does not include the use of standard operational procedures and operation manuals.
Table IV
The organisation of a quality system using reference guidelines

|---|---|---|---|
| **Processes activities of the second sub-supplier**<br>Regional Veterinary Service<br>First group of activities<br>State-wide disease control programmes, health control of herds, management of infectious disease outbreaks, other diseases control programmes<br>Planning of control of field activities in relation to the objectives of this group of activities<br>Implementation of planned field activities<br>Evaluation and re-planning<br>Second group of activities<br>Inspection and control, import and export of animals, collection of samples<br>Planning of control of field activities in relation to the objectives of this group of activities<br>Implementation of planned field activities (including data acquisition from the first sub-supplier) | 4.4. Planning control<br>4.5. Control of documents and data<br>4.6. Supplies (materials and services)<br>4.20. Statistical techniques<br>4.6. Supplies<br>4.9. Process control<br>4.5. Control of documents and data<br>4.20. Statistical techniques<br>4.4. Control of planning<br>4.5. Control of documents and data<br>4.6. Supplies<br>4.20. Statistical techniques<br>4.9. Process control<br>4.5. Control of documents and data<br>4.20. Statistical techniques | 8. Quality of requirements and planning<br>5.3. Documentation of quality system<br>11.5. Documentation<br>9. Quality of supplies<br>20. Use of statistical methods<br>10. Quality of processes<br>11. Control of processes<br>5.3. Documentation of quality system<br>11.5. Documentation<br>20. Use of statistical methods<br>8. Quality of requirements and planning<br>5.3. Documentation of quality system<br>11.5. Documentation<br>9. Quality of supplies<br>20. Use of statistical methods<br>10. Quality of processes<br>11. Control of processes<br>5.4.3. Documentation and recording of quality system<br>6.2.4.3. Quality of supplies<br>6.4.3. Statistical methods<br>6.2.4.3. Quality of supplies<br>6.2. Planning<br>6.3. Implementation<br>6.2.5. Requirements of quality control<br>6.3.6. Control of measurements system<br>6.2.4.3. Quality of supplies<br>6.3.6. Control of measurements system<br>6.2.4.3. Quality of supplies<br>6.4.3. Statistical methods<br>6.2.4.3. Quality of supplies<br>6.2. Planning<br>6.3. Implementation<br>6.2.5. Requirements of quality control<br>6.3.6. Control of measurements system<br>6.4.3. Statistical methods<br>6.2.4.3. Quality of supplies<br>6.2. Planning<br>6.3. Implementation<br>6.2.5. Requirements of quality control<br>6.3.6. Control of measurements system | 6. Operation elements of quality system<br>5.4.3. Documentation and recording of quality system<br>6.2.4.3. Quality of supplies<br>6.4.3. Statistical methods<br>6.2.4.3. Quality of supplies<br>6.2. Planning<br>6.3. Implementation<br>6.2.5. Requirements of quality control<br>6.3.6. Control of measurements system<br>6.2.4.3. Quality of supplies<br>6.3.6. Control of measurements system<br>6.2.4.3. Quality of supplies<br>6.4.3. Statistical methods<br>6.2.4.3. Quality of supplies<br>6.2. Planning<br>6.3. Implementation<br>6.2.5. Requirements of quality control<br>6.3.6. Control of measurements system
<table>
<thead>
<tr>
<th>Certification process for a Central Veterinary Service and sub-suppliers</th>
<th>ISO 9001 Quality systems – Model for quality assurance in design, development, production, installation and servicing</th>
<th>ISO 9004-1 Guideline Quality management and quality system elements – Guidelines</th>
<th>ISO 9004-2 Guideline Quality management and quality system elements – Guidelines for services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process activities of the second sub-supplier</strong>&lt;br&gt;Local Veterinary Services</td>
<td><strong>Third group of activities</strong>&lt;br&gt;Management of information system (data collection and validation, management of archives, documentation, data transfer, interfacing with other information systems)&lt;br&gt;<strong>Fourth group of activities</strong>&lt;br&gt;Verification and control of internal performances and qualification of suppliers</td>
<td>Verification and control of performance of each element of the service (personnel, methods, equipment, materials) and of sub-suppliers</td>
<td><strong>4.7. Control of product provided by the client</strong>&lt;br&gt;(feedback information)&lt;br&gt;<strong>4.8. Identification and traceability of product</strong>&lt;br&gt;<strong>4.10. Tests, controls, final inspection</strong>&lt;br&gt;<strong>4.11. Control of test and measurement equipment</strong>&lt;br&gt;(thermometers, microchip readers, skin thickness callipers, etc.)&lt;br&gt;<strong>4.12. State of tests, control and final inspection</strong>&lt;br&gt;<strong>4.1. Corrective and preventive actions</strong>&lt;br&gt;<strong>4.16. Control of quality records</strong>&lt;br&gt;<strong>4.17. Internal audits</strong>&lt;br&gt;<strong>4.20. Statistical techniques</strong></td>
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Auditing
Two basic objectives govern the implementation, maintenance and improvement of a quality system for Veterinary Services, namely: the improvement of the efficiency of the Veterinary Service management and operations, thereby assuring the CVO, customers and other stakeholders that quality requirements are or will be met and are constantly maintained. Consequently, the measurement and documentation of the quality of management and operations are compulsory. This implies the planning and implementation of auditing.

Auditing must be both internal and external. Internal auditing must be performed in accordance with pre-defined criteria, using specific check-lists, as recommended by ISO 10011-1, ISO 10011-2 and ISO 10011-3. Check-lists must be designed in such a way to ensure the implementation of all requirements for quality specified in the quality manual, procedures and technical methods.

The performance of Veterinary Services which are self-controlled is enhanced by improvements in organisational and operational processes. Furthermore, self-evaluation is an internal instrument designed to prevent and analyse organisational and technical risks. As such, trust is encouraged because it demonstrates that the Service measures its ability to identify, quantify and manage health risks in general and those linked to trade in particular.

It is also indispensable to have external audits conducted by a third and independent party, thereby guaranteeing to the international community that the management and operation of the Veterinary Services comply with both international veterinary requirements and quality requirements.

The role of the Office International des Epizooties
The OIE has played a fundamental role in defining international veterinary standards to overcome obstacles to the free trade of animals and animal products (2). Recent examples of this activity are the resolutions on risk assessment of the International Committee of the OIE (8), the harmonisation of veterinary certifications by the OIE Regional Commission for Europe (10) and the guidelines for the evaluation of Veterinary Services (1) and laboratory proficiency testing (11). The activity of the OIE has been and continues to be essential in defining international veterinary standards and requirements of a technical nature. However, international veterinary standards must take into account the existence of relevant international standards defined by other international organisations. In particular, standards on quality assurance defined by the ISO should be taken into account to avoid duplication and/or confusion. Unfortunately, this has not always been the case, as illustrated by the OIE guidelines.
for the evaluation of laboratory competence. The latter appear to be a duplication of the ISO 25 standard, but, at the same time, are not consistent with the ISO standard.

The possibility for a country to trade animals and animal products can depend on the method used to evaluate Veterinary Services and on the results of this evaluation. It is extremely important, therefore, that the OIE play a role of super partes organisation providing not only standards for Veterinary Service evaluation but also for the interpretation of the auditing of results. However, this might not be sufficient. Auditing is a very delicate issue and the need to recognise that an international guarantor complies with the internationally agreed criteria for the auditing of Veterinary Services is obvious. It is also perfectly clear that only qualified independent auditors can perform competent and fair audits at the international level. Besides fulfilling the obvious role of the international guarantor, the OIE should also promote the institution of an international roster of quality system evaluators with specific competence in the veterinary field.

The adoption of internationally recognised standards for audits (ISO 10011-1), and for the qualification of auditors (ISO 10011-2 and ISO 10011-3) in the veterinary field as well, would foster a climate of reciprocal trust between countries. Relationships between Veterinary Services and other certification bodies which operate in the field of interest of Veterinary Services, in particular in the sector of food of animal origin, could be clarified and regulated homogeneously at the international level (2).

Conclusions

Numerous advantages could be derived from recourse to the criteria of quality by Veterinary Services in the organisation of management and activities. The advantages are both internal and external.

Internally, the ability to control all activities, from the technical and the managerial points of view – as required by the standards for quality assurance – increases the efficiency of the Veterinary Service. In particular, the constant documentation of activities and the existence of internal control systems make available factual data which are both clear and well organised. These are useful not only for the planning and verification of activities which lead to the production of a veterinary quality certificate, but also to the reliable control of the production chain of animals and animal products. This not only makes available detailed, reliable and transparent information on the environment in which Veterinary Services operate but also guarantees the quality of the entire production chain, thereby generating a climate of trust both within a country and at the international level.

The adoption of international standards for the evaluation of Veterinary Services is strategic to promote the much needed development of a climate of trust which is required for facilitating international trade in animals and animal products. The entire national Veterinary Services could be ‘certified’ at the international level or only that department which is involved in international certification (i.e. for certain animals or categories of animal products, certain defined geographical areas, etc.). ‘Certified Veterinary Services’ should be mutually recognised at the international level and, consequently, should not be evaluated before each bilateral agreement. This would not only increase fairness, but also the standardisation of evaluation criteria which would be in the interests of both the exporting and importing countries.

Furthermore, in this context, the check-list for the evaluation of Veterinary Services proposed by the OIE could be used with ease (1). If considered independently from the context of the ISO 9000 series, this check-list presents the serious risk of generating subjective evaluations. However, were it to include the ISO 9000 series, it would be widely applicable for audits performed in accordance with ISO 10011.

Finally, as a ‘by-product’, the application of management criteria for quality provides precise instruments for evaluating the ability of surveillance systems to identify, quantify and manage risks linked to international trade. Activities inherent to quality systems, the purpose of which is to keep current activities under control, give added value to all information. They provide, therefore, the basis for objective evaluation, supported by documented evidence of risks linked to international trade and of the ability to manage the risks identified. This could be a great asset in solving many of the technical problems presently linked to the application of risk evaluation methods in the international trade of animals and animal products.
Proposition d’une méthode pour l’assurance qualité des Services vétérinaires au niveau international

D. Nannini, A. Giovannini, G.L. Fiore, R. Marabelli & V. Caporale

Résumé
Les auteurs proposent une procédure d’harmonisation de l’assurance qualité des Services vétérinaires au niveau international. Cette proposition se fonde sur l’hypothèse de l’agrément des Services vétérinaires conformément à la norme ISO 9000 de l’Organisation internationale de normalisation. Ils donnent un exemple d’application possible de cette norme à la gestion des Services vétérinaires et expliquent comment l’Office international des épizooties pourrait s’assurer que l’évaluation de ces Services soit équitable au niveau international.

Mots-clés

Propuesta de sistema internacional de garantía de calidad de los Servicios Veterinarios

D. Nannini, A. Giovannini, G.L. Fiore, R. Marabelli & V. Caporale

Resumen
Los autores proponen un procedimiento para armonizar a escala internacional la garantía de calidad de los Servicios Veterinarios. El sistema propuesto se basa en la acreditación de cada Servicio Veterinario de acuerdo con los criterios de la Serie 9000 de la Organización Internacional de Normalización (ISO). Tras ofrecer un ejemplo del uso de las normas ISO 9000 en el contexto de la gestión de los Servicios Veterinarios, los autores describen la posible función de la Oficina Internacional de Epizootias para garantizar, a escala internacional, la imparcialidad en la evaluación de esos Servicios.

Palabras clave
Appendix I

Guidelines of the International Standards Organisation relative to quality management and quality assurance

ISO 9000-1:1994  Quality management and quality assurance standards – Guidelines for selection and use
ISO 9000-3:1991  Quality management and quality assurance standards – Generic guidelines for the application of ISO 9001 for development, delivery and servicing of software
ISO 9000-4:1993  Quality management and quality assurance standards – Guidelines for management of trustworthiness
ISO 9001:1994   Quality systems – Model for quality assurance in design, development, production, installation and servicing
ISO 9002:1994   Quality systems – Model for quality assurance in production, installation and servicing
ISO 9003:1994   Quality systems – Model for quality assurance in final inspection and test
ISO 9004-1:1994  Quality management and quality system elements – Guidelines
ISO 9004-2:1991  Quality management and quality system elements – Guidelines for services
ISO 9004-3:1993  Quality management and quality system elements – Guidelines for continuous processes
ISO 9004-4:1993  Quality management and quality system elements – Guidelines for quality improvement
ISO 10011-1:1990 Guidelines for auditing quality systems – Auditing
ISO 10012-1:1992 Quality assurance requirements for measuring equipment – Metrological confirmation system for measuring equipment
ISO 10013-1) Guidelines for developing quality manuals
ISO/TR 13425-1) Guidelines for the choice of statistical methods in training and in requirements

Appendix II

Quality management and quality assurance – Glossary
(ISO 8402:1995)

- quality: totality of characteristics of an entity (activity, process, product, organisation or any combination) that bear on its stated ability and implied needs
- quality system: organisational structure, procedures, processes, and resources needed to implement quality management
- requirements for quality: expression of the needs or their translation into a set of quantitatively or qualitatively stated requirements for the characteristics of an entity to enable its realisation and examination
- quality management: all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system
- quality control: operational techniques and activities that are used to fulfil requirements for quality
- quality assurance: all the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality
- quality improvement: actions taken throughout the organisation to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organisation and its customers
- entity: that which can be individually described and considered

Note: an entity can be:
- an activity, a process
- a product
- an organisation, a system, a person
- any combination of the above

- service: result generated by activities at the interface between the supplier and the customer and by supplier of internal activities to meet customer needs

- customer: recipient of a product provided by the supplier (within or without an organisation)

- supplier: organisation that provides a product to the customer

- sub-supplier: an organisation that provides a product to the supplier

- process: set of inter-related resources and activities which transform inputs into outputs

- product: result of activities or processes (can be a service, hardware, processed materials, software or a combination thereof).

References


