

Guideline

Antibiotics Monitoring Pigs



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Note: The Guideline Antibiotics Monitoring Pigs is written in German and translated into English. In case of discrepancies between the translation and the German version, the German original is valid.

1 Basic principles

With the systematic recording of antibiotics applications and deliveries in a central database, the industry creates a solid inter-company data basis. This gives all those involved the opportunity to recognize the actual situation regarding the use of antibiotics and identify areas where action is needed. A proper evaluation guarantees the necessary transparency for future action – reduction strategies can be derived and implemented.

The monitoring shall contribute to the continuous optimization of the use of antibiotics in livestock farming and to reducing the risk of antibiotics resistance development.

The data from antibiotics monitoring can be used - also together with other data - for evaluations as part of quality assurance, in particular for the purpose of continuous improvement, risk assessment and crisis prevention. These evaluations are used in the QS scheme by QS and by the service providers working in the QS scheme for the purpose of quality assurance.

1.1 Scope of application

This guideline serves as a binding guide for the implementation of the antibiotics monitoring in pigs. All companies in the QS scheme which farm pigs are obliged to participate in the antibiotics monitoring. The antibiotics database can also be used by livestock owners who do not participate in the QS scheme. They must register in the QS scheme via a coordinator and sign a commitment (contractual agreement between livestock owner and coordinator) in order to use the antibiotics database. This guideline is therefore intended for

- Livestock owners of pigs participating in the antibiotics monitoring in the QS scheme,
- coordinators and
- veterinary practices/veterinarians (including veterinarians working for animal health services, producer groups, scientific institutions etc.) who deliver antibiotics to pig farming companies participating in the antibiotics monitoring in the QS scheme.

1.2 Responsibilities

Livestock owners, coordinators and veterinarians must always comply with the requirements in this guideline and prove that compliance at all times. Livestock owners, coordinators and veterinarians must ensure that, in addition to the requirements of this guideline, the applicable legal provisions (comparable foreign legal provisions outside Germany) are fulfilled. Further, the requirements of the QS scheme are to be fulfilled.

Livestock owners

The livestock owners are responsible for a complete and correct report of their master and production data. Any changes must be notified immediately to their coordinator.

The livestock owners may only obtain antibiotics from veterinarians who are registered in the QS scheme and are responsible for checking the complete and correct documentation of antibiotics applications and deliveries on their company in the antibiotics database. If a livestock owner recognizes that his veterinarian has not entered all or any data in the antibiotics database or that the data entered is incorrect, he shall ask his veterinarian to complete or correct the data. If the data is not completed or corrected by the veterinarian, the livestock owner shall inform QS. The documentation of the antibiotics applications and deliveries has to begin with the registration in the QS scheme and is therefore also obligatory for applicants.

In addition, the purchase and use of antibiotics in the QS scheme must comply with the requirements of the Guideline Agriculture Pig Farming, refer to www.g-s.de:

⇒ Guideline Agriculture Pig Farming

The livestock owners are responsible to actively confirm in the antibiotics database if no antibiotics have been applied for their pig farming company during a calendar semester. The livestock owners can transfer the responsibility of the confirmation in the antibiotics database to the coordinator or veterinarian.

Coordinators/sub-coordinators

The coordinators are responsible for a complete and correct report of the master and production data of the companies they take care of in the QS software platform and the antibiotics database. This also includes information on the number of averagely housed animals per location and animal group.

The coordinators inform participating companies at least once a quarter about the therapy index or the trend analysis or actively inform the livestock owners about the recalculation of the therapy index or trend analysis, respectively. The coordinators submit the access data to the QS software platform (username and password) to

the livestock owners. Via the QS software platform, the livestock owners gain access to the antibiotics database.

A coordinator can assign a sub-coordinator to perform certain coordinator tasks. In relation to the monitoring programs, this includes all tasks. However, the coordinator remains responsible for the implementation of the requirements as a contractual partner of QS.

The coordinators may also be supported by marketers or conglomerations. This requires written agreements.

Veterinarians

The veterinarians are responsible for entering the relevant data on antibiotics applications or deliveries into the antibiotics database. For this, the veterinary practices/veterinarians register with QS in the antibiotics database (<http://www.vetproof.de>). The veterinarians must at all times comply with the requirements of the declaration of commitment, which has to be accepted upon registration. Further, the veterinarians must always be able to demonstrate compliance with said declaration of commitment.

2 Antibiotics database

The antibiotics database is the data processing system for a comprehensive registration and evaluation of all antibiotics applications or deliveries in the QS antibiotics monitoring and can be reached on the internet via <https://db.vetproof.de>.

2.1 Maintenance of master data of agricultural companies

The following master data of agricultural companies is automatically transferred into the antibiotics database from the QS software platform and is regularly synchronized with it:

- Address with name, first name, street, house number, post code, town,
- company registration number according to the Livestock movement order (Germany: Viehverkehrsverordnung → VVVO number),
- QS identification number and
- contract date (generally corresponds to the obligatory date for participation in antibiotics monitoring).

Additionally, the following information must be stored by the coordinators in the antibiotics database for each company (VVVO number) and production group:

- Number of averagely housed fattening pigs with a live weight between approx. 30 and 120 kg per quarter
- Number of averagely housed weaners per quarter
- Number of averagely housed sows per quarter (including gilts; data related to suckling piglets are not necessary).

The information on the number of averagely housed animals are binding for a calendar quarter. If no information on the animal places is available, the livestock owner loses the eligibility of delivery to the QS scheme until the information has been updated.

2.2 Registration of veterinarians

Veterinarians who apply or deliver antibiotics on companies participating in the antibiotics monitoring in the QS scheme must be registered in the antibiotics database. For this purpose, the veterinary practice/the veterinarian registers online in the antibiotics database under <http://www.vetproof.de>. In the following, the registration documents (declaration of commitment and data protection declaration) are dispatched by e-mail. If an online registration is not possible, a written registration can be made with QS. The registration documents will then be sent by post or e-mail. After signing and returning the declaration of commitment as well as the data protection declaration, the registration in the antibiotics database is successfully completed.

2.3 Activation of veterinarians

Each livestock owner instructs his coordinator to activate the antibiotics database for the veterinarian(s) who apply or deliver antibiotics on the respective company. A search function (name or address) can be used to check in the antibiotics database whether a veterinary practice/a veterinarian is registered. If there is no veterinarian allocated to a pig farming company, the company loses its eligibility to deliver into the QS scheme until the information has been supplemented.

2.4 Registration of antibiotics applications and deliveries by veterinarians

The recording of antibiotics applications and deliveries in the antibiotics database is carried out either via input masks or via interfaces. The veterinary practice/veterinarian reports each application and delivery of medicinal products containing substances with antibiotic effect and assigns them to the company with the corresponding production group and, if applicable, to the animal group. If the application or delivery of antibiotics is carried out by a veterinary practice, traceability within the veterinary practice to the veterinarian treating the animal(s) must be ensured. When reporting the data, a distinction is made between obligatory and voluntary information.

From the veterinary drug record ("drugs delivery and application document") must and can (voluntarily) be reported:

- Name of responsible veterinarian
- Document number
- Date of delivery (in accordance with drugs delivery and application document)
- VVVO number of the company to which the veterinary drug was supplied
- Production scope of the company (production groups 2001 to 2015)
- Group of the treated animals
- Number of animals to be treated
- Veterinary drug
- Amount applied/delivered
- Duration of treatment with days of effect
- Indication (voluntary)
- Diagnosis details (voluntary)
- Application form (voluntary)
- Dosage per animal per day (voluntary)
- Treatment day (date) (voluntary)
- Waiting time (voluntary)
- Treatment instructions (voluntary)
- Batch number (voluntary)
- Usage duration (voluntary).

Entering the data regarding the antibiotics applications and deliveries has to be finished in a timely manner and by no later than 30 days after application or delivery. If the antibiotic is not consumed completely, a return record (if veterinarian takes back remaining quantity) or a zero amount record (if follow-up prescription of remaining quantity) can be created.

When applying and delivering veterinary medicinal products from abroad, the specific regulations of the German Medicines Act must be observed.

Periods without antibiotic treatment

If no antibiotics are applied for a production group in pig farming company during a calendar semester, this must be actively confirmed in the antibiotics database by the livestock owner, the coordinator or the veterinarian. The responsibility for the completeness of the data lies with the livestock owner.

2.5 Data protection/Data access

The data in the antibiotics database are only available to authorized users. Specific access regulations exist. All users have access to the data only after registration in the antibiotics database. Each authorized user receives a username and password via the database administration.

Livestock owners

The livestock owners have access to all data available in the antibiotics database for their company. This includes master data, data on antibiotics applications and deliveries with all mandatory and voluntary data entered as well as evaluations and statistics.

Coordinators/sub-coordinators

The coordinators have access to master data and evaluations of the companies they manage. With regard to antibiotics applications and deliveries, they only receive information on the delivery date, the identity of the treated animal group, the number of animals treated and whether the antibiotics are critical. If a coordinator has instructed a sub-coordinator to perform certain coordinator tasks, the sub-coordinator receives the access rights of the coordinator. With regard to the monitoring programs, this includes all tasks and therefore all access rights.

The livestock owner can authorize both the coordinator and the sub-coordinator to view all information from the veterinary drug records (= particularly sensitive data) in the antibiotics database. The authorization is given by the livestock owner in the antibiotics database. With this authorization the livestock owner declares that his veterinarian approves the activation of the coordinator and/or sub-coordinator. The veterinarian can recognize in the drug records of the company that the coordinator and/or sub-coordinator is allowed to see the complete veterinary drug records.

Veterinarians

The veterinarians have access to all data available in the antibiotics database of companies for which they are authorized. This includes master data, data on antibiotics applications and deliveries with all entered obligatory and voluntary data as well as evaluations.

Access to data on antibiotics applications and deliveries of other veterinarians, who have been granted access to a company, can only be obtained if the livestock owner authorizes this in the database. Otherwise, the veterinarian only receives information on the delivery date, the identity of the treated group of animals and the indication.

Third parties

Livestock owners may allow other persons/groups of persons (third parties) access to their therapy indices and trend analyses in the antibiotics database. For this, the livestock owner authorizes his coordinator in writing to clear third parties for specified information in the antibiotics database. In order to be able to access the data of a livestock owner, the third party must be registered in the antibiotics database. The registration is carried out via QS.

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As scheme owner, QS has access to all data and evaluation results in the antibiotics database. Access to the data is restricted to individual authorized employees of QS.

QS will provide the operating company of the animal welfare initiative "Initiative Tierwohl" access to information that is defined for the implementation of the Animal Welfare Initiative in this respect.

The data in the antibiotics database can be made available to research establishments (e.g. universities, colleges, and Federal Institute for Risk Assessment (BfR)) for research projects and scientific evaluations in the field of animal welfare/animal health after pseudonymization while ensuring appropriate data protection.

2.6 Evaluation of the use of antibiotics in the QS scheme

The data from the antibiotics monitoring are evaluated both on a company-specific basis and on accumulated inter-company basis. The evaluation of company-specific data enables livestock owners and veterinarians to assess the situation regarding the use of antibiotics on the company and to compare it with other companies (benchmark). The therapy index and the trend analysis serve as measurement variables for this. The evaluation of accumulated inter-company data enables a professional presentation of the actual situation regarding the use of antibiotics as a whole and creates transparency for veterinarians and industry.

Therapy index and trend analysis

Both the therapy index and the trend analysis describe how many treatment units per animal were administered on average over a period of time. For each antibiotics application or delivery, the number of treatment units is calculated by multiplying the number of animals treated by the duration of treatment including days of effect and the number of active substances within the pharmaceutical (see formula). For the therapy index, the treatment units are summarized for all antibiotics applications and deliveries within the previous calendar semester. For the trend analysis, the treatment units are summarized quarterly for all antibiotics applications and deliveries of the previous three calendar quarters. The respective sums of treatments are then divided by the herd size, so that the therapy index can be defined as the number of treatment units per animal place in the previous half year and the trend analysis as the number of treatment units per animal place in the previous three quarters. The herd size is the average number of averagely housed animals per company. The information on the average number of animals per company is stored quarterly. If different data on the animal places are available for an evaluation period in two calendar quarters, the mean value from both data is formed for the calculation of the therapy index.

The therapy index is calculated on February 1 and August 1, the trend analysis on May 1 and November 1.

$$\text{Therapy index} = \frac{\sum(\text{Duration of treatment with days of effect} \cdot \text{active substances} \cdot \text{number of treated animals})}{\text{herd size}}$$

Both measurement variables are calculated separately for each company (VVVO number) and for each production group. In farrowing companies, the therapy index and trend analysis are calculated separately for sows and suckling piglets. In the calculation for suckling piglets, the number of averagely housed sows is used as the herd size.

The therapy index can only be calculated if for a company either veterinary drug records or the information that no antibiotics have been applied are available in the antibiotics database for each calendar semester, separated by production group. If no therapy index has been calculated for a company that has participated in the QS scheme for at least two full calendar quarters, the company loses its eligibility to deliver into the QS scheme until a therapy index can be calculated.

Therapy index for selected classes of antibiotics

The use of antibiotics in veterinary medicine from classes of active substances that are particularly important for human medicine (so-called critical antibiotics or reserve antibiotics) is increasingly viewed critically and should therefore be made transparent for livestock owners and veterinarians. A separate therapy index is therefore calculated for antibiotics containing active substances of cephalosporines of 3rd and 4th generation and fluoroquinolones and is made available to livestock owners and veterinarians.

3 Definitions

3.1 Abbreviations

VVVO Livestock movement order (Viehverkehrsverordnung – ViehVerkV)

3.2 Terms and definitions

- **Antibiotics**

Antibiotics are drugs containing substances with an antibacterial effect.

A list of general terms and definitions can be found in the **guideline "General Requirements"**.

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Criterion/Requirement	Changes	Date of change
1 Basic principles	<p>Restructuring: The Objectives chapter has been integrated into this chapter to standardize the guidelines for the monitoring programs.</p> <p>Clarification: The data collected in antibiotics monitoring can be used for evaluations as part of quality assurance.</p>	01.01.2024
2.5 Data protection/Data access	<p>Clarification: Data access by third parties after authorization by the livestock owner relates to the therapy index and the trend analysis.</p>	01.01.2024

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