Technical Specifications

TS2.2 - Antibiotic-free feed (new)

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GMP+ International

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Index

1. Introduction

Antimicrobial resistance (AMR) – the ability of microbes to gain resistance to the very antibiotics intended to fight them – is amongst the top global health challenges today. Misuse of antimicrobials remains a key driver of AMR. In recent years, in countries all around the world, considerable progress has been made in tackling AMR.

Since long time antibiotics (AB) are also processed in feed (medicated). In the past 2 decades, this use of AB in feed has been (legally) restricted in many countries around the world. The focus of all this legislation is to control AB residues. In the GMP+ scheme, the requirements to control residues of AB are included in the basic standard.

For feed companies that want to go 1 step further, in the GMP+ scheme an additional standard is adopted, focused on assuring that there are no ABs in the production location at all. Subsequently, all the produced feed is free of AB.
The standard is based on a Dutch initiative from around 2010. Certification enables the feed producer to demonstrate that no antibiotics are present in the feed.

This document is referred to as TS2.2 *Antibiotic-free feed* and is part of the GMP+ FSA module.

2. Scope, Application and Certification

2.1. Scope & application

This standard contains requirements for the production and delivery of Antibiotic-free feed.

This standard can be applied as an add-on to the basic GMP+ standard for any company with at least one of the next GMP+ certification scopes:
a. Production of compound feed
b. Production of premixtures
c. Production of feed materials
d. Production of feed additives

This standard cannot be applied stand-alone.

Application of this standard as an add-on to a feed production standard of an equivalent certification scheme is also possible (see TS1.2 *Purchase* for equivalent feed schemes).

Helpful tip:
If the company for production of feed is certified for another standard than those listed in TS1.2 *Purchase*, the company may request GMP+ International to accept this as the basic standard. The company should justify that by applying the standard in question an equivalent management system is operational.

2.2. Certification

Certification takes place for each production facility of the company, similar as to certification for other GMP+ standards.
Certification according to this standard will be registered in the GMP+ company database and will be confirmed with a GMP+ certificate. The scope description will clearly be stated both on the certificate and in the GMP+ Company Database.

Certification for this standard is not mandatory to GMP+ certified companies.

3. Terms and Definitions

Antibiotics: Antibiotic means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases *(Source: Regulation (EU) 2019/6 on veterinary medicinal products)*

Products authorised as feed additive to inhibit or destroy protozoan parasites that cause coccidiosis in poultry and rabbits are excluded from the scope of this standard TS2.2.

Helpful tip:
Above refers to products authorized as feed additives in the scope of Regulation (EC) No 1831/2003. Applications are mentioned in the authorizations. See *EU Register of Feed Additives Database*

Antibiotic-free feed: feed produced at a production facility where no antibiotics are present nor processed.

For further definitions please see F0.2 Definition list.

4. Requirements for Antibiotic-free feed

4.1. General

The GMP+ certified company must demonstrably meet the requirements of this standard using GMP+ the feed safety management system. See R1.0 *Feed Safety Management System requirements*.

If other hazards are identified that can pose a risk to achieve the objective of this standard, these must also be adequately controlled.

Helpful tip:

This standard can only be applied in addition to the GMP+ basic standard R1.0 *Feed Safety Management Systems requirements* (or equivalent; see chapter 2.1). The specific requirements for producing and delivering Antibiotic-free feed should be met using the Feed Safety Management System (FSMS) as required in R1.0 *Feed Safety Management Systems requirements*.

Essential elements of the FSMS that can be used are:

- Duties, responsibilities, and authorities
- Identify and control risks with the Prerequisite Program or HACCP Plan
- Monitoring
- Control of non-conform products and processes
- Internal audit
- Continuous improvement
- Documentation and registration

4.2. Antibiotic-free feed production facility

To assure that on the production facility only AB-free feed is produced the next requirements apply:

The GMP+ certified company is not allowed:

a. to receive,
b. to have in stock (including on consignment),
c. to process and package,
d. to store and/or transport

antibiotics or products containing antibiotics.

The GMP+ certified company must take measures to assure that any incoming feed ingredient and product is free of antibiotics and does not pose any risk for AB contamination of the produced and delivered feed. These measures must be taken based on a HACCP study and monitored accordingly.

Helpful tip:
In case there are more feed production facilities at the same address, there must be a complete physical separation between these feed production facilities, unless all are certified for this standard TS2.2. Labelling must make clear which production facility is certified for TS 2.2.

4.3. Transport and storage

4.3.1. Transport

Bulk transport of AB-free feed must meet the applicable GMP+ requirements. This involves the application of a risk-based approach (HACCP) where at least the IDTF requirements are met.

Despite the results of this HACCP study, the next requirements apply:

- If the loading compartment has been used for the transport of a product, containing antibiotics, the certified company must – to avoid any possible contamination – apply the IDTF cleaning regime C before transporting AB-free feed again.
- Transport of AB-free feed and antibiotic-containing feed/product in separate bulk cells of one bulk trailer/truck is not allowed.

Note: This standard does not prohibit the company from using the loading compartments to transport other feed or other products as well. However, proper cleaning is then required.

The transport of packaged AB-free feed must comply with the applicable GMP+ requirements.

Transport carried out by a third party under the responsibility of the GMP+ certified company
If the certified company makes use of transport which is carried out by a service provider, then the certified company must agree with the service provider that the transport meets the requirements described above.

Transport for which third parties are responsible (Ex Works, EXW, Incoterms® 2020)
If a third party is responsible for road transport, then the GMP+ certified company must take precautionary measures to prevent the feed coming into contact with antibiotics during the transport.
If a customer instructs the certified company to load a batch in a means of transport which is not considered by the certified company to be suitable then the certified company must inform the buyer of this and obtain written confirmation of the instructions from the customer before loading. Copies of the correspondence in question must be kept.

4.3.2. Storage

If the certified company outsources the storage of AB-free feed, the certified company must agree with the service provider that during the storage contamination of AB-free feed with antibiotics is excluded.
As a minimum, the storage service provider must provide a statement that no (feed in bulk containing) antibiotic is stored in the company.

4.4. Labelling

The GMP+ certified company must inform the customer about the status of the feed by specifying the following on the label or another delivery document:

"Antibiotic-free feed"

Note: This labelling requirement is at least applicable if the feed is delivered to customers who request Antibiotics free feed.

4.5. Monitoring

To verify the absence of ABs, feed must periodically be sampled and analyzed for the presence of antibiotics.

4.5.1. Sampling

An independent, qualified person must take samples. The sampling must comply with the relevant requirements of TS1.6 *Sampling*.

Helpful tip:
TS1.6 includes among other requirements for the sampling method, sampling location, material/ equipment to take the samples, the storage and registration of samples.

Helpful tip:
An independent person is someone who has an impartial position regarding production within the company. But it can also be an employee from a service provider like a certification body, an inspection body, or a laboratory.

Number of samples to be analyzed:

Year 1	Year 2	As from year 3
2	1	1 per two years

Notes:
- Year 1: the first full calendar year of certification
- Year 2 (and following): the second and subsequent calendar year of certification

4.5.2. Analyzing

The certified company must investigate which antibiotics could potentially occur in the feed. Appendix 1 gives a list of commonly known and used antibiotics.
The samples must be analyzed by an accepted laboratory (TS1.2 *Purchase)* with the LC-MS/MS method for the presence of these antibiotics.

Helpful tip:

If the company wants to use another analysis method, the company may request GMP+ International to accept this. The company should motivate the equivalence with the LC-MS/MS method, at least on essential performance criteria like reproducibility and measurement uncertainty.

4.5.3. Analysis results

If there is any antibiotic detected in the sample, the products are considered non-conform. In that case the GMP+ certified company must comply with the requirements of the GMP+ FSA module with respect to control of non-conform feed (see R1.0 *Feed Safety Management Systems requirements*, chapter 8.7).

The participant must enter the results of the analysis into the GMP+ Monitoring database and (anonymously) share them with the GMP+ community.

Appendix 1: List of antibiotics

This list is not intended to be a complete, closed list of antibiotics. It lists the known and most used antibiotics. It is intended to support the certified company in defining the antibiotics to be analyzed.

Helpful tip:
GMP+ support documents contain references that can help identify the antibiotics to be analyzed (See S9.34 *Antibiotic-free feed FAQ*).

Antibiotics	
Antibiotics - B lactam	***Antibiotics – Macrolides***
Amoxicillin	*Erythromycin*
Ampicillin	*Spiramycin*
Penicillin G	*Tilmicosin*
Penicillin V	*Tylosin*
Cloxacillin	*Tylvalosin*
Dicloxacillin	*Tulathromycin*
Nafcillin	***Antibiotics - Phenicoles***
Oxacillin	*Thiamphenicol*
Cefalexin	*Florfenicol*
Cefapirin	*Chloramphenicol*
Cefazolin	***Antibiotics – Tetracyclines***
Cefoperazone	*Chlortetracycline*
Cefquinome	*Doxycycline*
Ceftiofur	*Oxytetracycline*
Antibiotics - Quinolones	*Tetracycline*
Danofloxacin	***Antibiotics – Pleuromutilines***
Difloxacin	*Tiamulin*
Ciprofloxacin	*Valnemuline*
Enrofloxacin	***Antibiotics - Lincosamides***
Flumequine	*Lincomycin*
Marbofloxacin	***Antibiotics - Sulfonamides***
Oxolinic acid	*Sulfamonomethoxine*
Sarafloxacin	*Sulfadimethoxine*

Norfloxacin	*Sulfapyrimidine = sulfadiazine*
Cinoxacin	*Sulfamethoxazole*
Antibiotics – Aminoglycosides	*Sulfathiazole*
Apramycin	*Sulfamerazine*
Neomycin	*Sulfamethazine = sulfadimidine*
Paromomycin	*Sulfadoxine*
Spectinomycin	*Sulfamethoxypyridazine*
Dihydrostreptomycin	***Antibiotics – other***
Gentamicin	*Amprolium*
	Colistin
	Trimethoprim
	Gamithromycin

Risk Management tools

That was a lot of information to digest, and one might ask, what is the next step? Luckily, we can offer support for the GMP+ Community when doing this. We provide support by means of various tools and guidances but as each company has a shared responsibility to feed safety, and therefor tailor-made solutions cannot be offered. However, we do help by explaining requirements and provide background information about the requirements.

We have developed various supporting materials for the GMP+ Community. These include various tools, ranging from Frequently Asked Questions (FAQ) lists to webinars and events.

Supporting materials related to this document (Guidelines and FAQ's)
We have made documents available which give guidance to the GMP+ requirements as laid down in the module GMP+ FSA and GMP+ FRA. These documents give examples, answers to frequently asked questions or background information.

GMP+ Monitoring database
The GMP+ Monitoring database contains analysis results from you and other users. It is possible to generate reports based on this data. We have a manual and a frequently asked questions document available.

Where to find more about the GMP+ International Risk Management tools?
Fact sheets
More information: GMP+ Platform
Product list
More information: Product List
Risk Assessments
More information: GMP+ Platform
GMP+ Monitoring database
More information: GMP+ Monitoring database
Support documents
More information: Support documents

We enable every company in the feed chain to take responsibility for safe and sustainable feed.

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