Technical Specifications

TS2.2 - Country Note Antibiotic-free feed

Version EN: 1 March 2021

GMP+ International

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Index

1. Introduction

If a feed manufacturer does not process any antibiotics in feed or use antibiotic-free production lines, the company can apply this Country Note. The certification for this Country Note suffices for the feed manufacturer to demonstrate the company's production facilities are free of antibiotics or uses antibiotic-free production lines and that residue of antibiotics therefore is not present in the feed.

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

2. Scope, Application and Certification

2.1. Scope of this Country Note

This Country Note contains conditions for the production of antibiotic-free animal feed like transport, labelling and monitoring.

2.2. Application

This Country Note can be applied as a supplement to the GMP+ certificate with the scope production of feed. With the scope production of feed is meant:

a. Production of compound feed
b. Production of premixtures
c. Production of feed materials
d. Production of feed additives

Certification for this Country Note is not mandatory to GMP+ certified companies. If a GMP+ certified company manufactures antibiotic-free animal feed, this may be demonstrated by means of supplementary certification against this Country Note. If the GMP+ certified company decides on supplementary certification, the GMP+ certified company must comply with the conditions listed in this Country Note.

Supplementary application of this Country Note in addition to another animal production standard of an equivalent certification scheme is also possible (see TS1.2 *Purchase*).

2.3. Certification for companies

Certification takes place for each site of the company, similar to certification for other GMP+ standards. Certification according to this Country Note will be registered in the GMP+ company database and will be confirmed on a GMP+ certificate. The scope description will clearly state both on the certificate and in the GMP+ Company Database whether the production site is free of antibiotics or that the antibiotic-free feed comes from an antibiotic-free production line.

Two scopes can be distinguished.

<u>Antibiotic-free feed produced at an antibiotic-free production site</u>
A GMP+ certified company who is certified in accordance with this scope produces feed at a location where no antibiotics are processed. No antibiotics are received, processed or traded throughout the whole site.

<u>Antibiotic-free feed produced on antibiotic-free production line(s)</u>
A GMP+ certified company who is certified in accordance with this scope has several production lines but has a strict separation between dedicated production lines on which no antibiotics are processed and production lines where antibiotics are processed.

3. Terms and Definitions

Anti-microbial veterinary drugs (further referred to as antibiotics): Veterinary drugs, not being serums or vaccines containing substances that, after conversion or not, are capable of impeding multiplication of micro-organisms or viruses in an animal in a concentration of 10 micrograms/ml or lower, or that are capable of impeding the growth in a culture of micro-organisms or viruses in a concentration of 5 micrograms/ml or lower;
Source: Regulation of the Minister of Agriculture, Nature and Food Quality of 15 December 2005, Nr. TRCJZ/2005/3760, containing regulations relating to veterinary drugs)
Antibiotics must be allowed and registered. The antibiotics allowed within the Netherlands are registered by the Bureau Diergeneesmiddelen (BD – Veterinary Drugs Agency). The*BD website* shows which antibiotics are allowed within the Netherlands.

Antibiotics, in any case, do not include: the additives allowed by law as listed in the *Regulation EC 1831/2003*. This includes the coccidiostatics and histomonostatics.

For further definitions please see F0.2 *Definition list*.

4. Conditions for antibiotic-free feed

The following table shows the sections in which requirements are included for the various scopes.

Scope	4.1	4.2	4.3	4.4	4.5	4.6
Antibiotic-free feed from a factory where no antibiotics are processed	X	X		X	X	X
Antibiotic-free feed from dedicated production line(s)	X		X	X	X	X

§ 4.2 and § 4.3 contain the generic requirements specifically for this scope. The other paragraphs contain general requirements which apply to both scopes.

4.1. General

The GMP+ certified company must:

a. designate a responsible officer within the organization to ensure compliance with the applicable conditions;
b. include this enforcement in the internal audit;
c. document the total production per year of feed that comply with the requirements in this country note.

Helpful tip:

With the documented year production can be determined how many samples must be taken per year. See § 4.6.

With the Total production per year of feed that comply with the requirements in this country note is meant; the Total volume of feed that is produced on the antibiotics free location of on the antibiotics free production line(s). This is related to the scope linked to the certification.

4.2. Antibiotic-free feed produced at an antibiotic-free production site

Regarding antibiotics or products containing antibiotics, GMP+ certified companies applying this Country Note with the scope 'Antibiotic-free feed produced at an antibiotic-free production site' are not allowed:

a. to receive;
b. to have in stock (including on consignment);
c. to process;
d. or to transport (see § 4.4)
e. antibiotics or products containing antibiotics.

The certified company must demonstrably control the requirements above via the feed safety system (including procedures, instructions etc.). There is no difference between certified

companies that do and certified companies that do not have a license for the production of medicated feed.

Helpful tip:

Manufacturing medicated feed is limited strictly to licensed production. License-holders are companies that were issued a license for preparing, packaging, labeling or trading medicated semi-finished products or medicated animal feedstuffs as referred to in Article 33 of the Veterinary Drugs Act. If a GMP+ certified company to the Country Note Antibiotic-Free Feed is not licensed for production of medicated feed, the certified company must still comply with the requirements in this country note. As antibiotics are not the only medications, it is possible to continue adding other medicines in feed. In that case, the company is licensed for the production of medicated feed.

4.3. Antibiotic-free feed produced on antibiotic-free production line(s)

If the GMP+ certified company processes antibiotics in feed on dedicated production lines (for example where they are intended for export to other countries), then these feed must be strictly separated from the feed produced on a dedicated production line (or lines) where no antibiotics are processed.

Unlike the requirements in *§ 4.2*, there may in this case be antibiotics present at the site which are processed in feed. However, these must be kept strictly separated from the feed produced on a dedicated production line on which no antibiotics are processed. The requirements in this Country Note are related to the feed produced on the production line(s) on which no antibiotics are processed.

The GMP+ certified company must:

a. appoint the production line(s) on which no antibiotics are processed;
b. physically separate the production of feed with antibiotics and feed without antibiotics. Feed with (remains of) antibiotics may not come into contact with feed produced on the production line(s) on which no antibiotics are processed. This means, among other things: separate mixers, presses, internal transport lines and storage of manufactured products, transportation, etc.;
c. prevent raw materials containing antibiotics (used in medicated feed) directly or indirectly coming into contact with (raw materials for) feed which are or were produced on production line(s) on which no antibiotics are processed;
d. determine, based on a HACCP analysis, that using the measures in a) and b) the risk is controlled that feed from a production line where no antibiotics are processed comes into contact with antibiotics;
e. record the measures taken in procedures;
f. demonstrably meet the requirements specified in a) to e).

4.4. Transport

If using a company-owned combined fleet, the GMP+ certified company must:

a. allocate transport vehicles used exclusively for products / feed in which no antibiotics were used (so-called dedicated transport); or
b. the certified company must determine, validate and apply a cleaning regime that demonstrably removes any antibiotics residue from previous loads in the vehicle used before the loading of feed which complies with this Country Note.

Transport carried out by a third party on the orders of the GMP+ certified company
If the certified company makes use of road transport which is carried out by a service provider then the certified company must record in the contract with the service provider that the transport meets the requirements described above.

Transport for which third parties are responsible (ex factory)
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 the certified company is instructed by a customer 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.

4.5. Labelling

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

"the delivered feed meets the requirements of TS2.2 Country Note Antibiotic-free feed".

Or in short;

"complies with TS2.2 CN Antibiotic-free feed"

This statement can only be used for feed which come from a production line where no antibiotics are used. GMP+ certified companies that have a antibiotic free production location, must place the above statement on the label of all products.
It is allowed to use the above statement in some other written form than on the label. This must in all cases be done on delivery at the latest.

Helpful tip:
This labeling requirement is only applicable if the feed is delivered to customers who request antibiotics free feed. This can for example be pig farmers that need to comply with the IKB Varken or IKB Nederland Varkens requirements. In these standards it is explicitly required that farmers purchase the feed from feed producers that comply with the requirements in this standard.

4.6. Monitoring

In order to verify the control measures in this Country Note, a sample must be taken of a compound feed periodically. This sample must be analysed for the presence of residual antibiotics.

4.6.1. Sampling

Sampling is done in accordance with *Regulation (EU) No 691/2013*.

Samples that are required in this country note must be taken by an independent third party sample-taker who meets the requirements in TS1.6 *Sampling*. The GMP+ certified company is not allowed to take these samples himself.

The certified company makes an agreement with the sample-taker that it comes unannounced for sampling at the certified company's location.

Helpful tip:
The GMP+ certified company is responsible that samples are taken at its location.

Samples must be taken from feed from antibiotic-free production lines at the certified company's location.

The number of samples depends on the annual production and the scope for which the certified company is certified. The following tables shows how many samples will must be taken on an annual basis:

Antibiotic-free feed produced at an antibiotic-free production site

Annual production	Number of samples year 1	Number of samples year 2 (and further)
Less than 25,000 tons	2	1 per two years
25,000 to 50,000 tons	3	1 per two years
More than 50,000 tons	4	1 per two years

Antibiotic-free feed produced on antibiotic-free production lines

Annual production	Number of samples year 1	Number of samples year 2 (and further)
Less than 25,000 tons	2	1 per year
25,000 to 50,000 tons	3	1 per year
More than 50,000 tons	4	1 per year

Year 1 will be referred to as the first full calendar year of certification (starting from 1-1-20xx). For example if a company started GMP+ certification in July 2019, year 1 will be the year 2020. After a first positive year of certification (all analysis results comply with *Annex 1* and the

requirements from TS2.2 CN *Antibiotic-free feed* are met), the number of samples is reduced to 1 sample per year/two years.

If a company (for some reason) starts certification again after a period of not being certified, the company starts again in the monitoring regime of year 1.

Helpful tip:
With annual production is meant; the annual production on the antibiotics free location or on the antibiotics free production line(s).

4.6.2. Analyzing

Samples must be analyzed for the presence of residual antibiotics.
The samples must be analyzed with the LC-MSMS method on (at least) all antibiotics mentioned in *Annex 1*.

Analyzes must be performed by a laboratory as described in TS1.2 *Purchase*. The analysis method (including all antibiotics) for the analysis of feed, must be included in the certification / accreditation.

4.6.3. Analysis results

If there is any antibiotic detected in the sample, the products are considered non-compliant. In that case the GMP+ certified company must:

a. Comply with the requirements of the GMP+ FSA module with respect to non-standard products.
b. Inform GMP+ International and the certification body (in accordance with R1.0 *Feed Safety Management Systems Requirements*).
c. Inform the national authorities (if there is a legal obligation).
d. Determine on the basis of a HACCP analysis what raw materials may have caused the increased level of antibiotics and carry out an analysis on these raw materials.

4.6.4. Reporting analysis results

The GMP+ certified company 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

The table below shows the list of antibiotics that must be (as a minimum) analyzed in order to comply with the requirements of this standard.

Antibiotics	
Antibiotics - B lactam	***Antibiotics – Macrolides***
Amoxicilllin	*Erythromycin*
Ampicillin	*Spiramycin*
Penicillin G	*Tilmicosin*
Cloxacillin	*Tylosin*
Dicloxacillin	*Tylvalosin*
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*
Cirprofloxacin	*Valnemuline*
Enrofloxacin	***Antibiotics - Lincosamides***
Flumequine	*Lincomycin*
Marbofloxacin	***Antibiotics - Sulfonamides***
Oxolinic acid	*Sulfadimethoxine*
Sarafloxacin	*Sulfapyrimidine = sulfadiazine*
Norfloxacin	*Sulfamethoxazole*
Cinoxacin	*Sulfathiazole*
	Sulfamerazine
	Sulfamethazine = sulfadimidine
	Sulfadoxine

	Antibiotics – other
	Trimethoprim

Note: This list is not intended to be a complete list of antibiotics, but is a set of most used antibiotics in order to verify (in a risk based approach) that no antibiotics are used.

Risk Management tools

Feed Support Products

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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