GMP+ International

Antibiotics-free feed

GMP+ BCN NL1

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GMP+ Feed Certification scheme

Feed Safety Worldwide

gmpplus.org

History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 03-2011	Previous versions can be found in History		1-7-2011
1.0 / 09-2011			01-01-2012
1.1 / 11-2012			01-03-2013
1.2 / 04-2013			01-01-2013
1.3 / 12-2014	Monitoring is no longer performed by GMP+ International, but must (under conditions) be arranged by the participant. Change in sampling regime for antibiotics free production location Report results to the GMP+ Monitoring database	4.6 4.6.1 4.6.4	01-01-2015 01-01-2015 01-01-2015
1.4 / 11-2015	Product standards are removed from Annex 1. This means that as from this change, no residues of antibiotics can be found in the analysed samples.	4.6.2 4.6.3 Annex 1	01-04-2016

Editorial note:
All changes in this version of the document are made visible. This is how you can recognize:
- New text
- ~~Old text~~
The changes must be implemented by the participant latest at the final implementation date.

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1 Introduction

1.1 General

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

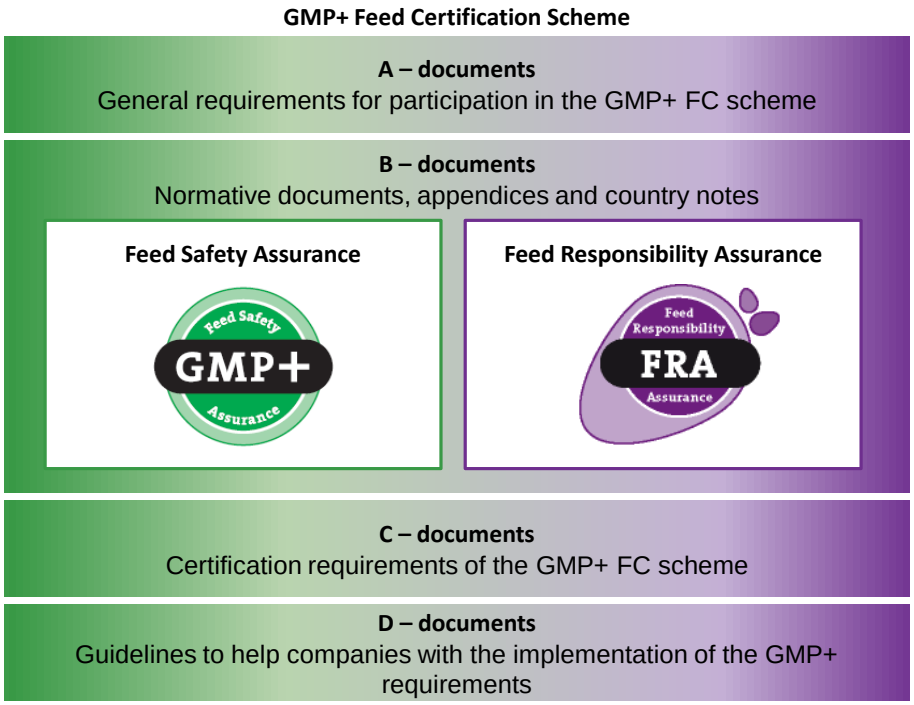
GMP+ Feed Safety Assurance is a complete module for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA scheme can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA scheme, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance.
Together with the GMP+ partners, GMP+ International transparently sets clear requirements to guarantee feed safety & responsibility. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

1.2 Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:



All these documents are available via the website of GMP+ International (www.gmpplus.org).

This document is referred to as GMP+ BCN-NL1 *Antibiotics-free feed* and is part of the GMP+ FSA scheme.

2 Background, application and certification

2.1 Background

Antibiotics are used in livestock farms in order to prevent or combat infection in farm animals. Livestock farmers – in consultation with their vet – have various options for administering antibiotics. One of these options is dosing the animal feed as so-called medicated animal feed.

During the production process of medicated animal feed, a small amount of residue (including the antibiotics) in the production line is inevitable. Due to carry-over to other animal feedstuffs produced subsequently on the same production line, farm animals are unintentionally exposed to antibiotics residue. Animal feedstuffs are subject to legal residue levels for antibiotics that may not be exceeded. The GMP+ FSA scheme includes strict rules in order to control these legally required residue limits.

The general public is increasingly interested in the use of antibiotics in livestock farms and the consequent antibiotics resistance. On 18 November 2010, the Bureau Risicobeoordeling en Onderzoeksprogrammering (*Risk Assessment and Research Programming*) of the Dutch VWA (*Food and Consumer Product Safety Authority*) issued an advice to the Minister of Economy, Agriculture and Innovation and the Minister of Public Health, Wellbeing and Sports relating to increased resistance as a result of very low concentrations of antibiotics due to carry-over. One of the conclusions is that with a carry-over percentage of 2.5% or less, the resistance development of the E.Coli bacteria is very limited (based on tests with 3 different antibiotics). The advice reports that without any supplementary tests, it is not possible to establish whether or not a carry-over percentage of 2.5% or less causes resistance development in other combinations of bacteria and antibiotics.

As antibiotics may be administered to animals in a different manner, another option is to decide on a full stop of processing antibiotics in animal feed. The Dutch animal feed industry and livestock farms wish to increase their quality image and preventatively chose to stop processing any antibiotics in animal feedstuffs.

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

2.2 Scope

This Country Note contains conditions for the production of antibiotics-free animal feed. Two scopes can be distinguished.

Antibiotics-free feed produced at an antibiotics-free production site
A participant 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.

Antibiotics-free feed produced on antibiotics-free production lines
A participant 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.

2.3 Application

This Country Note may also 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+ participants. If a GMP+ participant manufactures antibiotics-free animal feed, this may be demonstrated by means of supplementary certification with this Country Note. If the GMP+ participant decides on supplementary certification, the GMP+ participant 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 GMP+ BA10).

2.4 Certification

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 company database of GMP+ International and will be confirmed on a GMP+ certificate. The scope description will clearly state both on the declaration and in the companies database whether the production site is free of antibiotics or that the antibiotics-free feed comes from an antibiotics-free production line.

The applicable certification requirements can be found in GMP+ C7 *Assessment- and certification/inspection criteria for GMP+ certification/inspection – additional scopes*.

3 Term 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 refer to: GMP+ A2 Definitions and abbreviations.

4 Conditions for antibiotics-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
Antibiotics-free feed from a factory where no antibiotics are processed	X	X		X	X	X
Antibiotics-free feed from dedicated production line(s)	X		X	X	X	X

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

4.1 General

The participant should:
a. designate a responsible officer within the organisation to ensure compliance with the applicable conditions.
b. include this enforcement in the internal audit.
c. Document the total production per year of feeds that comply with the requirements in this country note.

Guidance:
With the documented year production can be determined how many samples should be taken per year. See paragraph 4.6.

With the Total production per year of feeds that comply with the requirements in this country note is meant; the Total volume of feeds 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 Antibiotics-free feed produced at an antibiotics-free production site

Regarding antibiotics or products containing antibiotics, GMP+ participants applying this Country Note with the scope 'Antibiotics-free feed produced at an antibiotics-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 Section 4.4)

The participant, in that case, must demonstrably control the requirements above via the feed safety system (including procedures, instructions etc.). There is no difference between participants that do and participants that don't have a license for the production of medicated feed.

Guidance:
Manufacturing medicated animal feedstuffs 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 participant to the Country Note Antibiotics-Free Animal Feedstuffs is not licensed for production of medicated animal feedstuffs, the participant 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 animal feedstuffs. In that case, the company is licensed for the production of medicated animal feedstuffs.

4.3 Antibiotics-free feed produced on antibiotics-free production line(s)

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

Unlike the requirements in Section 4.2, there may in this case be antibiotics present at the site which are processed in feeds. However, these should be kept strictly separated from the feeds 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 participant should:
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 feeds 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) feeds 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 participant should:

a. allocate transport vehicles used exclusively for products / animal feedstuffs in which no antibiotics were used (so-called dedicated transport);

or

b. the participant 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 participant

If the participant makes use of road transport which is carried out by a service provider then the participant should 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 participant must take precautionary measures to prevent the feed coming into contact with antibiotics during the transport.

If the participant is instructed by a customer to load a batch in a means of transport which is not considered by the participant to be suitable then the participant 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 participant must inform the customer about the status of the feed by specifying the following on the label:

"the delivered feed meets the requirements of GMP+ BCN-NL1 Antibiotics-free feed".

Or in short;

"complies with GMP+ BCN-NL1"

This statement may only be used for feeds which come from a production line where no antibiotics are used. Participants that have a antibioticsfree 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 should in all cases be done on delivery at the latest.

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 chapter 3 of GMP+ BA13 *Minimum Requirements for Sampling*. The participant is not allowed to take these samples himself.

The participant makes an agreement with the sample-taker that he comes unannounced for sampling at the participant's location.

Guidance:
The participant is responsible that samples are taken at his location.

Samples must be taken from feeds from antibiotics-free production lines at the participant's location.

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

Antibiotics-free feed produced at an antibiotics-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

Antibiotics-free feed produced on antibiotics-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 2012, year 1 will be the year 2013. After a first positive year of certification (all analysis results comply with Annex 1 and the requirements from GMP+ BCN-NL1 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.

Guidance:
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 analysed 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. ~~The detection limit must be suitable for determining whether the product standards (see Annex 1) are met.~~

Analyzes must be performed by a laboratory, which is GMP+ B10 Laboratory testing certified or ISO17025 accredited. The analysis method (including all antibiotics) for the analysis of feed, must be included in the certification / accreditation.

4.6.3 Analysis results

~~In case a sample exceeds the antibiotic product standards~~ If there is any antibiotic detected in the sample, the products are considered non-compliant. In that case the participant must:

a. Comply with the requirements of the GMP+ FSA module with respect to non-standard products (see section 7.8 in GMP+ B1 *Production, Trade and Services*).
b. Inform GMP+ International and the certification body (in accordance with GMP+ BA5 *Minimum Requirements EWS*).
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 participant must enter the results of the analysis into the GMP+ Monitoring database and (anonymously) share them with the GMP+ community.

ANNEX 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.

~~The table below shows the product standards that are applicable for the Country Note GMP+ BCN-NL1 Antibiotics-free feed.~~

Antibiotics	
Antibiotics - B lactam	***Antibiotics – Macrolides***
AmoxiciIllin	*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.

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