



*GMP+ Feed Safety Assurance scheme*

**BCN**

**Antibiotics-free feed**

**NL1**

**Country Note Netherlands 1**

**EN**

**GMP+ BCN-NL1**

Version: January 1<sup>st</sup>, 2012

© GMP+ International B.V.

Alle rechten voorbehouden. De informatie uit deze publicatie mag worden geraadpleegd op het scherm, gedownload en geprint, mits dit gebeurt voor eigen, niet-commercieel gebruik. Voor ieder ander gewenst gebruik dient vooraf schriftelijke toestemming van GMP+ International B.V. te worden verkregen.

Stadhoudersplantsoen 12  
2517 JL The Hague  
The Netherlands

Tel: +31 (0)70 370 86 70  
Fax: +31 (0)70 370 86 71

[info@gmplus.org](mailto:info@gmplus.org)  
[www.gmplus.org](http://www.gmplus.org)

## History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 03-2011	New document		1-7-2011
1.0 / 09-2011	Introduction has been updated	1.1; 1.2	01-01-2012
	New scope: Dedicated antibiotics-free production lines	2.2	01-01-2012
	Extension of the transport requirements	4.4	01-01-2012
	Labelling requirements added	4.5	01-01-2012
	Change of sampling frequency	4.6	01-01-2012

## INDEX

<b>1</b>	<b>INTRODUCTION</b>	<b>4</b>
1.1	GENERAL	4
1.2	STRUCTURE OF THE GMP+ FEED SAFETY ASSURANCE SCHEME	4
<b>2</b>	<b>BACKGROUND, APPLICATION AND CERTIFICATION</b>	<b>6</b>
2.1	BACKGROUND	6
2.2	SCOPE	6
2.3	APPLICATION	7
2.4	CERTIFICATION	7
<b>3</b>	<b>TERM AND DEFINITIONS</b>	<b>8</b>
<b>4</b>	<b>CONDITIONS FOR ANTIBIOTICS-FREE FEED</b>	<b>9</b>
4.1	GENERAL	9
4.2	ANTIBIOTICS-FREE FEED PRODUCED AT AN ANTIBIOTICS-FREE PRODUCTION SITE	9
4.3	ANTIBIOTICS-FREE FEED PRODUCED ON ANTIBIOTICS-FREE PRODUCTION LINE(S)	10
4.4	TRANSPORT	10
4.5	LABELLING	11
4.6	VERIFICATION	11

# 1 Introduction

## 1.1 General

The GMP+ Feed Safety Assurance Scheme (GMP+ FSA 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.

The GMP+ FSA scheme is a complete scheme 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.

The basic principle of the GMP+ FSA scheme is that the feed chain is part of the food production chain. Proper quality assurance of feed safety throughout the feed chain has a high priority. It is important that companies take their responsibilities in this respect by responding in a proper and convincing way to the need for safe feed materials in the food production chain.

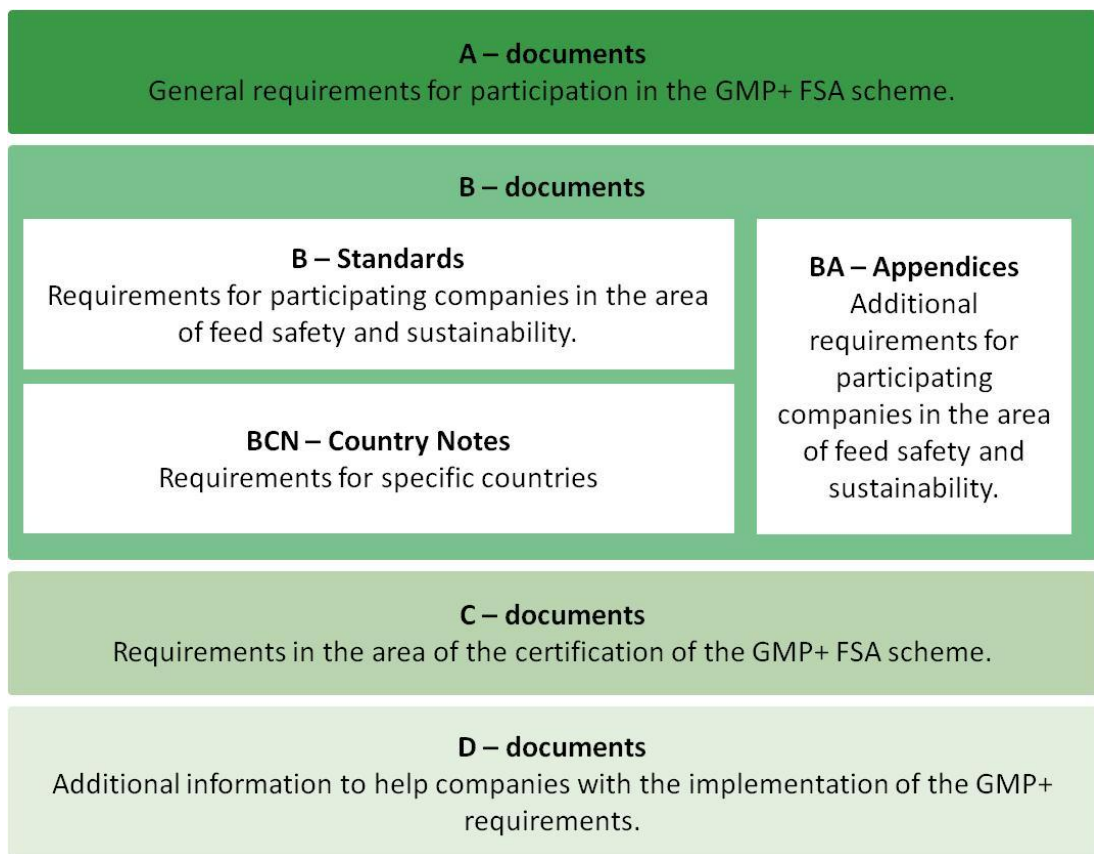
Based on needs in practice, multiple components have been integrated into the GMP+ FSA scheme, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

Together with the GMP+ partners, GMP+ International transparently sets clear requirements so that feed safety is guaranteed and certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of its various databases, newsletters, Q&A lists and seminars.

## 1.2 Structure of the GMP+ Feed Safety Assurance scheme

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



All these documents are available via the website of GMP+ International ([www.gmpplus.org](http://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 new 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. All animal feeds produced on this site must be free of antibiotics. With the scope production of feed is meant:

- Production feed, compound feed
- Production feed, premixtures
- Production feed, feed materials
- Production feed, 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:

- designate a responsible officer within the organisation to ensure compliance with the applicable conditions.
- include this enforcement in the internal audit.
- 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:

- to receive;
- to have in stock (including on consignment);
- to process;
- 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, labelling 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. ~~if it is not possible to use dedicated transport,~~ the participant must determine, validate and apply a cleaning regime that demonstrably removes any antibio-

tics 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”.*

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.

### **4.6 Verification**

In order to verify the control measures in this Country Note 4.1.1 and 4.1.2, an independent sampler, acting on instructions from GMP+ International, will come and take a sample of a compound feed periodically each quarter year. This sample will be analysed for the presence of residual antibiotics by a laboratory on instructions from GMP+ international.

This sample will be taken from feeds from antibiotics-free production lines.

The number of samples which will be taken depends on the annual production. The following table shows how many samples will be taken on an annual basis:

Annual production	Number of samples
Less than 25,000 tons	2
25,000 to 50,000 tons	3
More than 50,000 tons	4

#### Guidance:

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

*The costs relating to sampling and analysis will be charged to the participant directly by GMP+ International.*

*The samples will be analyzed with the LS-MSMS method by an appointed laboratory.*

*Note: As applicable for all other situations where the auditor has doubts, it is also in this case possible to request an extra sample to be taken by GMP+ International. If antibiotics are found in this then the costs of this extra analysis will be charged to the participant.*

The participant will receive the analysis result from the laboratory. If the analysis result shows that antibiotics is found in the sample taken at the participants location, the participant must inform the certification body immediately.

See GMP+ BA1 for the relevant product standards.

**Guidance:**

*In the case of a positive result, the participant can let the sample that is left behind with the participant, be analyzed as well by the laboratory. Please contact GMP+ International for more information.*