



# Assessment and certification /Inspection Criteria for GMP+ Certification/Inspection – additional / specific scopes

GMP+ C 7

Version EN: 4 April 2019



**GMP+ Feed Certification scheme**

## History of the document

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
0.0 / 12-2011	Previous versions can be found in history		01-01-2012
1.0 / 03-2012			01-05-2012
2.0 / 11-2012			01.03.2013
3.0 / 06 -2014	<p>Editorial changes: All editorial changes are listed in a fact-sheet</p> <p>Conditions for GMP+ BCN-DE1 has been added</p> <p>Conditions for GMP+ BCN-CN1 has been added</p> <p>Conditions for GMP+ BCN-Central &amp; Eastern Europe have been added</p> <p>Adjustment of assessment criteria and measures</p> <p>Added audit times additional scopes</p>	<p>Entire document</p> <p>Paragraph 2.4</p> <p>Paragraph 2.5</p> <p>Paragraph 2.6</p> <p>Annex 1</p> <p>Annex 2</p>	01-01-2015
4.0 / 12-2015	Conditions for GMP+ BCN- specific requirements for Italy have been added	Paragraph 2.7 / Annex 1	01.01.2016
5.0 / 09-2016	<p>“company can be replaced by “participant”</p> <p>“should can be replaced by must”</p> <p>“old” application way has been deleted</p> <p>Data of participant on template must be the same as registered by legal business registration.</p>	<p>Entire document</p> <p>Paragraph 2.2</p> <p>Paragraph 2.2 t/m 2.7</p>	01.09.2016
6.0 / 11-2017	<p>Editorial changes and explanation “through the certification body”</p> <p>Implementation of unique certification agreement/certification agreement template</p> <p>After 2 weeks of the audit the checklist must be uploaded to the GMP+ database</p> <p>The certificate template of the relevant chapters of the GMP+ C3/C6/C12 must be used.</p> <p>Text of relevant country note can be combined with FSA/FRA certificates</p>	<p>Entire document &amp; Paragraph 1.4</p> <p>Paragraph 2.1 / 2.7</p> <p>Paragraph 2.2 / 2.7</p> <p>Paragraph 2.2 / 2.7</p> <p>Paragraph 2.2 / 2.7</p>	01.07.2018

Revision no. / Date of approval	Amendment	Concerns	Final implementation date
8.0 / 05-2018	<p>Name of the document has been changed</p> <p>The checklist of BCN-NL1 must be uploaded in the new GMP+ database</p> <p>Certification requirements for GMP+ BCN-VN specific requirement for Vietnam has been added</p> <p>Certification requirements for GMP+ B11 protocol for GMP+ registration for laboratories have been added</p> <p>Assessment criteria and measures for GMP+ BCN-VN specific requirement for Vietnam and GMP+ B11 protocol for GMP+ registration for laboratories has been added</p> <p>Audit times have been added for GMP+ BCN-VN specific requirement for Vietnam and GMP+ B11 protocol for GMP+ registration for laboratories</p>	<p>Entire document</p> <p>Paragraph 2.2</p> <p>Paragraph 2.8</p> <p>Paragraph 2.9</p> <p>Annex 1</p> <p>Annex 2</p>	01-07-2018
9.0 / 03-2018	<p>the auditor/technical/material expert assessing GMP+ B11 Registered Laboratory have to comply with Annex 2 of GMP+ C10.</p> <p>Certification requirements for BCN-IP specific requirements for Iberian Peninsula have been added</p> <p>Assessment criteria and measures for GMP+ BCN-IP specific requirements for Iberian Peninsula have been added</p> <p>Audit times have added/adapted for GMP+ BCN-IP specific requirements for Iberian Peninsula and GMP+ B11 Registered laboratory</p>	<p>2.9</p> <p>2.10</p> <p>Annex 1</p> <p>Annex 2</p>	<p>04.04.2019</p> <p>Publication date of BCN-IP</p> <p>Publication date of BCN-IP</p> <p>Publication date of BCN-IP and for GMP+ B11, 04.04.2019</p>

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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 was published. For this purpose, two modules have been 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 with standards 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 module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA standards, such as requirements for a feed safety management system, for application of HACCP principles, for traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

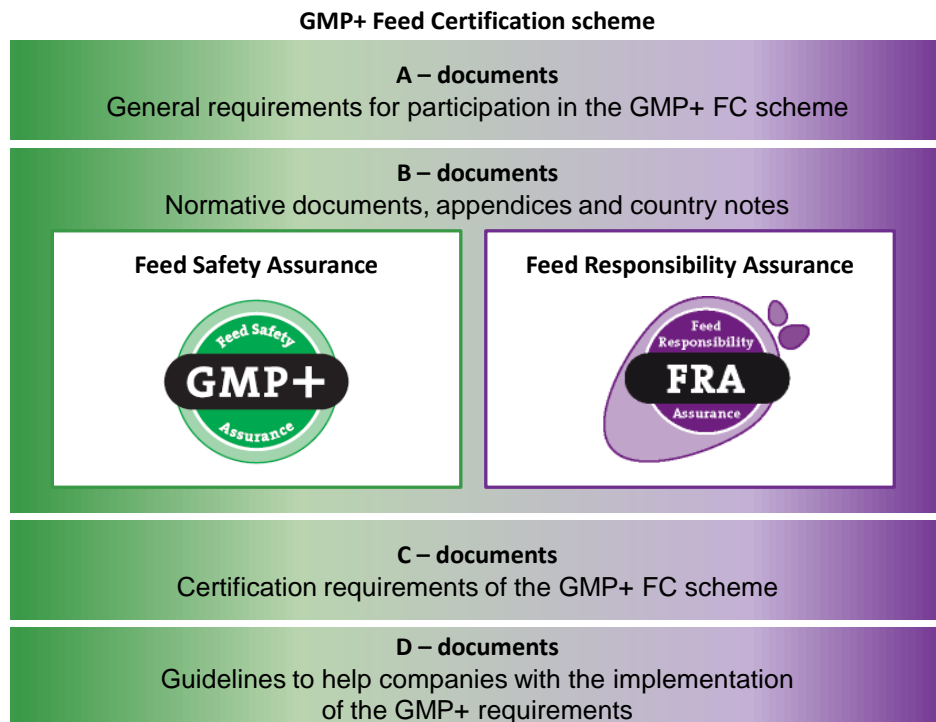
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests from GMP+ participants. The animal feed sector is confronted with requests to operate more responsible. This includes, for example, the sourcing of soy and fishmeal which are produced and 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. GMP+ International facilitates via independent certification the demands from the market.

Together with the GMP+ partners, GMP+ International transparently lays down clear requirements in the Feed Certification scheme. 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 of these documents are available through the website of GMP+ International ([www.gmplus.org](http://www.gmplus.org)) .

This document is referred to as the standard *GMP+ C7 Assessment- and certification criteria with GMP+certification – additional scopes* and is part of the *GMP+ FC scheme*.

### 1.3 Scope

This document contains the assessment and certification/inspection criteria with regard to the implementation of audits/inspections at companies as referred to in *GMP+ A1 General Regulations* of the GMP+ Feed Certification scheme of GMP+ International. These assessment and certification/inspection criteria should be applied through certification bodies in the implementation of audits/inspections of companies for additional scopes of the GMP+ FC scheme as indicated in this document.

Throughout this document the terminology “through the certification body” is used indicating that all activities performed by critical-, non-critical locations and outsourcing party are conducted under the responsibility/liability of the GMP+ accepted certification body.

## 2 Country Notes

### 2.1 General

Certification bodies, accepted by GMP+ International for the GMP+ FC scheme for the proper standard/scope to which the extra scope is linked, may inspect interested companies for one or more of the additional scopes listed below.

### 2.2 GMP+ BCN-NL1 *Antibiotics-free feed*

#### Additional requirements certification bodies and inspectors.

Certification bodies who wish to perform the inspection must send to GMP+ International a completely filled in Annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

For the Certification bodies and inspectors, no additional requirements exist on top of the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*, in respect of this GMP+ BCN-NL1 *Antibiotics-free feed* unless they have been accepted for the scope:

- a. Production compound feed or
- b. Production premixtures or
- c. Production additives or
- d. Production feed materials

#### Scope

The inspection for GMP+ BCN-NL1 *Antibiotics-free feed* shall always be complementary to a GMP+ (or equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a. Production compound feed or
- b. Production premixtures or
- c. Production additives or
- d. Production feed materials

#### Inspection

Based on the inspection, the certification bodies will decide to provide a GMP+ statement, depending on whether or not the assessment criteria in annex 1 have been met. The analysis certificate should must be available for the statement to be issued.

The GMP+ statement, states that, at the time of inspection, the location met the conditions of the GMP+ BCN-NL1 *Antibiotics-free animal feed*. As indicated under “scope an addition to a GMP+ FSA standard with the scope “production animal feed (compound feed, premix, additive or feed)”.

The following inspection must be performed prior to date Y(= X + 14 months) where X is the date of the previous inspection. If date Y comes after the end date of the GMP+ certificate to which it is complementary, the end date of the GMP+ certificate should must be assumes as ‘renewal date Y’.

The LOQ values are listed on the analysis certificate. The standard against which the results should must be tested are included in the GMP+ BA1 *Specific feed safety limits*.

### Duration

The minimum frequency and duration of the implementation of the inspection (incl. document assessment and reporting) have been included in Annex 2 of this document.

If the results of an analysis outcome are positive, through the certification bodies, additional attention and time must be invested, followed by a possible adjustment of the company database. The cost for additional time investment shall be paid by the participant.

### Check list

The inspection checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the inspection.

### Company database

If a statement is issued, the certification body must add an additional scope (antibiotics-free animal feed) to the participant.

In case of exclusion of participation, the company must be given the status withdrawn, does not meet the requirements for the scope antibiotics-free animal feed.

### Statement

The text for a statement will be as follows:

Name of the Certification Body

GMP+ International registration number of the Certification Body

### **BCN-NL1 Antibiotics-free animal feed = scope =**

Name, mailing address, location of participant Y

Visiting address and location of participant Y

GMP+ International registration number of the participant location visited

CI X states that participant location Y was inspected in accordance with the applicable requirements of the Country Note BCN-NL1 Antibiotics-free animal feed and GMP+ C7 Assessment and certification/inspection criteria for GMP+ certification/inspection – additional/specific scopes of GMP+ International B.V. in Rijswijk, The Netherlands.

CI X states, based on reported facts, that the inspected participant location and the sampling regime met the applicable requirements of the Country Note BCN-NL1 Antibiotics-free animal feed and GMP+ C7 Assessment and certification/inspection criteria at the time of inspection, that the participant location inspected and the sampling regime at the time of inspection meet the applicable requirements of the Country Note BCN-NL1 Antibiotics-free animal feed and GMP+ C7 Assessment and certification/inspection criteria for GMP+ certification/inspection – additional/specific scopes of GMP+ International B.V. in Rijswijk, The Netherlands.

Date of inspection

CB Details

Statement start date

Next inspection to be conducted prior to date



**Comments:**

- a. It is not permitted to mention brand names on the statement in any way.
- b. It is required to display the GMP+ logo on the statement.
- c. The start date of the statement is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the statement other than the GMP+ accepted certification body.

Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the inspection time to be invested must be included.

This inspection time must at least meet the minimum inspection time investment as recorded in the Annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of recalculation. If, based on the findings of the inspector, a longer inspection time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

This does not apply to the samples and analytics provided by order of GMP+ International.

Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

### **2.3 GMP+ BCN-NL2 Dioxin-monitoring in laying hens (rearing) feed**

#### Additional requirements certification body and auditors

Certification bodies who want to certify the company must send to GMP+ International a completely filled in Annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies annex 2* , in respect of this GMP+ BCN-NL2 *Dioxin-monitoring in laying hens (rearing) feed*, provided that they have been accepted for the scope:

- a. Production compound feed

#### Scope

The audit for GMP+ BCN- NL2 *Dioxin-monitoring in laying hens (rearing) feed* shall always be complementary to a GMP+ (of equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a. Production of compound feed

#### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in annex 2 of this document.

#### Check list

The audit checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

#### Company database

When a certificate is submitted, the certification body must add an additional scope (Dioxin-monitoring of laying hens (rearing) feed) to the participant.

#### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C3/C6/C12 must be used. The relevant country note must be mentioned on the certificate.

Comments:

- a. It is not permitted to mention brand names on the certificate in any way.
- b. It is required to display the GMP+ logo on the certificate.
- c. The start date of the certificate is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.
- f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.

### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then, through the certification body, it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time investment as recorded in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of re-calculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## 2.4 GMP+ BCN-DE1 – QM-Milch

### Additional requirements certification bodies and auditors

Certification bodies who want to certify the company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*, in respect of this GMP+ BCN-DE1 QM-Milch, provided that they have been accepted for the scope:

- a) Production of compound feed or
- b) Production of feed material or
- c) Production of premixtures or
- d) Production of additives or
- e) Trade in animal feed.

### Scope

The audit for GMP+ BCN- DE1 QM-Milch shall always be complementary to a GMP+ (or equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a) Production compound feed or
- b) Production feed material or
- c) Production pre-mixtures or
- d) Production additives or
- e) Trade in animal feed.

### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in Annex 2 of this document.

### Check list

The audit checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

### Company database

When a certificate is submitted, the Certification Body must add an additional scope (GMP+ BCN- DE1 QM-Milch) to the participant.

### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C3/C6/C12 must be used. The relevant country note must be mentioned on the certificate.

Comments:

- a. It is not permitted to mention brand names on the certificate in any way.
- b. It is required to display the GMP+ logo on the certificate.
- c. The start date of the certificate is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.

- f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.

#### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

#### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time investment as recorded in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of re-calculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

#### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

#### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

#### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## 2.5 GMP+ BCN-CN-1 Supplier Assurance for China

### Additional requirements certification bodies and auditors

Certification bodies who want to certify a company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies* in respect of this GMP+ BCN-CN-1 Supplier Assurance for China, provided that they have been accepted for the scope:

- a) Production of compound feed or
- b) Production of pre-mixtures.

### Scope

The audit for GMP+ BCN-CN-1 Supplier Assurance for China shall always be complementary to a GMP+ (of equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a) Production of compound feed or
- b) Production of pre-mixtures.

### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in Annex 2 of this document.

### Check list

The audit checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

### Company database

When a certificate is submitted, the Certification Body must add an additional scope (GMP+ BCN-CN-1 Supplier Assurance for China) to the participant.

### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C3/C6/C12 must be used. The relevant country note must be mentioned on the certificate.

Comments:

- a. It is not permitted to mention brand names on the certificate in any way.
- b. It is required to display the GMP+ logo on the certificate.
- c. The start date of the certificate is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.
- f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.

### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time investment as recorded in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of re-calculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## 2.6 GMP+ BCN-CEE Additional requirements for Central & Eastern Europe

### Additional requirements certification bodies and auditors

Certification bodies who want to certify a company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*, in respect of this GMP+ BCN-CEE Additional requirements for Central & Eastern Europe, provided that they have been accepted for the scope:

- a) Production of compound feed
- b) Production of pre-mixtures

### Scope

The audit for GMP+ BCN-Central & Eastern Europe shall always be complementary to a GMP+ (of equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a) Production of compound feed
- b) Production of pre-mixtures

### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in Annex 2 of this document.

### Check list

The audit checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

### Company database

When a certificate is submitted, the Certification Body must add an additional scope (GMP+ BCN-CEE Additional requirements for Central & Eastern Europe) to the participant.

### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C3/C6/C12 must be used. The relevant country note must be mentioned on the certificate.

Comments:

- a. It is not permitted to mention brand names on the certificate in any way.
- b. It is required to display the GMP+ logo on the certificate.
- c. The start date of the certificate is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.
- f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.



### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time investment as recorded in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes* is not sufficient.

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It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## 2.7 GMP+ BCN-IT specific requirements for Italy

### Additional requirements certification bodies and auditors

Certification bodies who want to certify a company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*, in respect of this GMP+ BCN-IT specific requirements for Italy, provided that they have been accepted for the scope:

- a) Production of compound feed
- b) Production of pre-mixtures
- c) Production of feed materials
- d) Trade (in compound feed, premixtures, feed materials).
- e) Road transport of animal feed.

### Scope

The audit for GMP+ BCN-specific requirements for Italy shall always be complementary to a GMP+ (of equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a) Production of compound feed
- b) Production of premixtures
- c) Production of feed materials
- d) Trade (in compound feed, premixtures, feed materials).
- e) Road transport of animal feed.

### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in Annex 2 of this document.

### Check list

The audit checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

### Company database

When a certificate is submitted, the Certification Body must add an additional scope (GMP+ BCN-IT specific requirements for Italy) to the participant.

### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C3/C6/C12 must be used. The relevant country note must be mentioned on the certificate.

Comments:

- a. It is not permitted to mention brand names on the certificate in any way.
- b. It is required to display the GMP+ logo on the certificate.
- c. The start date of the certificate is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.

- f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.

#### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

#### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time investment as recorded in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of re-calculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

#### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

#### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

#### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## 2.8 GMP+ BCN-VN specific requirements for Vietnam

### Additional requirements certification bodies and auditors

Certification bodies who want to certify a company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*, in respect of this GMP+ BCN-VN *specific requirements for Vietnam*, provided that they have been accepted for the scope:

- a) Production of compound feed
- b) Production of pre-mixtures
- c) Production of feed materials
- d) Trade (in compound feed, premixtures, feed materials).

### Scope

The audit for GMP+ BCN-VN *specific requirements for Vietnam* shall always be complementary to a GMP+ (of equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a) Production of compound feed
- b) Production of pre-mixtures
- c) Production of feed materials
- d) Trade (in compound feed, pre-mixtures, feed materials).

### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in Annex 2 of this document.

### Check list

The checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

### Company database

When a certificate is submitted, the Certification Body must add an additional scope GMP+ BCN-VN *specific requirements for Vietnam* to the participant.

### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C3/C6/C12 must be used. The relevant country note must be mentioned on the certificate.

Comments:

- a. It is not permitted to mention brand names on the certificate in any way.
- b. It is required to display the GMP+ logo on the certificate.
- c. The start date of the certificate is a date that shall always be after the date of the positive final assessment.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.
- f. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.

### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time as mentioned in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes/specific scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes/specific scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of recalculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## 2.9 GMP+ B11 Protocol for GMP+ registration for laboratories

### **Guidance:**

*Because the assessment of the performance criteria as stated in the GMP+ BA11 are related to specific critical contaminants and not of the assessment of the management system and the assessment is a desk study, it was decided to implement the certification requirements into this document.*

*Although in the GMP+ B11 terminology verification and registration is used, it was decided for certification requirements the following:*

- Verification is equal to audit.
- Registration is equal to certification.

*Instead of a “certificate” a “statement” will be issued.*

Certification bodies who want to certify a company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies* to apply for acceptance for the scope Registered Laboratory by GMP+ International.

No additional requirements will be applicable the certification bodies and auditors if they have a valid acceptance for the scope:

- a) Laboratory testing.

### **Additional requirements certification bodies and auditors:**

When the certification body/auditor is not (yet) accepted for the scope Laboratory Testing, the certification body must ensure that the auditor/technical/material expert complies with the requirements as stated in Annex 2 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*. ~~part of the assessment of the participant by means of a desk study performed by the certification body.~~

### **Audit**

Only if the company complies with the requirements as set out in the GMP+ B11 *Protocol for GMP+ registration for laboratories* and in the GMP+ BA11 *Performance Criteria for GMP+ Registered Laboratories* a statement can be issued by the certification body. Assessment by the certification body have to be performed in accordance with Annex 1 of this document. The auditor and technical/material expert may only perform the desk study of the same participant six consecutive times. Then rotation of the auditor and technical/material expert must take place.

### **Duration**

The mandatory minimum frequency and audit times (incl. preparation and reporting) has been included in Annex 2 of this document. For the initial assessment the audit time for the Initial Certification Audit must be used and for the annual assessment the audit time for the unannounced/announced surveillance audit must be used.

### **Check list**

The checklist report must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

GMP+ company database

When a statement is submitted, the Certification Body must add an additional scope *Registered Laboratory* to the participant in the GMP+ company database.

Statement

The validity of the statement is maximum 14 months. The text for a statement will be as follows:

Name of the Certification Body

GMP+ International registration number of the Certification Body

**GMP+ B11 Protocol for GMP+ registration for laboratories  
Registered Laboratory**

Name, location of the participant

GMP+ International registration number of the participant

The certification body (name of the certification body) states that participant (name participant) was audited in accordance with the applicable requirements of the GMP+ B11 Protocol for GMP+ registration for laboratories and GMP+ C7 Assessment and certification/inspection criteria for GMP+ certification/inspection – additional/specific scopes of GMP+ International B.V. in Rijswijk, The Netherlands.

The certification body (name of the certification body) states, based on desk study, that the performance criteria as mentioned in the GMP+ BA11 Performance criteria for GMP+ Registered Laboratory are met for the following analyses:

No	Operation	Material/matrix		
		Feed material	Feed additives and premixtures	Feed (compound feed and complementary feed)
<b>1. Aflatoxin B1</b>				
1.01	Aflatoxin B1			
<b>2. Dioxins and dioxin-like PCBs</b>				
2.01	Sum of dioxins and dioxin-like PCBs			
2.02	Dioxins			
2.03	Dioxin-like PCBs			
2.04	Non-dioxin-like PCBs			
<b>3. Heavy metals and fluorine</b>				
3.01	Arsenic			
3.02	Lead			
3.03	Cadmium			
3.4	Mercury			
3.5	Fluorine			
<b>4. Pesticides</b>				
4.01	Pesticides			

Date of audit

Certification Body Details Statement start date and end date
---

Comments:

- a. It is not permitted to mention brand names on the statement in any way.
- b. It is mandatory to display the GMP+ logo on the statement.
- c. The start date of the statement is a date that shall always be on or after the date of the positive final assessment/decision of the certification body.
- d. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- e. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the statement other than the GMP+ accepted certification body.

Exclusion

If it is established that a GMP+ participant no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1 of this document.

Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time as mentioned in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes/specific scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes/specific scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of re-calculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).



## **2.10 GMP+ BCN-SP specific requirements for Iberian Peninsula (Andorra, Portugal and Spain)**

### Additional requirements certification bodies and auditors

Certification bodies who want to certify a company must send to GMP+ International a completely filled in annex 1 of the GMP+ C10 *Acceptation requirements and procedure for Certification Bodies, applying for the expansion of the applicable scope(s)*.

No additional requirements exist for the certification bodies and auditors in addition to the requirements stated in GMP+ C10 *Acceptation requirements and procedure for Certification Bodies*, in respect of this GMP+ BCN-IP *specific requirements for Spain*, provided that they are accepted for the scope:

- a) Production of compound feed
- b) Production of pre-mixtures
- c) Production of feed additives
- d) Production of feed materials
- e) Trade (in compound feed, premixtures, feed additives, feed materials)
- f) Transport of feed, road transport.

### Scope

The audit for GMP+ BCN-IP *specific requirements for Iberian Peninsula* shall always be complementary to a GMP+ (of equivalent – see GMP+ BA10 *Minimum purchase conditions*) standard with the scope:

- a) Production of compound feed
- b) Production of pre-mixtures
- c) Production of feed additives
- d) Production of feed materials
- e) Trade (in compound feed, premixtures, feed additives, feed materials)
- f) Transport of feed, road transport.

### Duration

The minimum frequency and duration of the implementation of the audit (incl. document assessment and reporting) has been included in Annex 2 of this document.

### Assessment and checklist

The assessment must take place in accordance with Annex 1 of this document. The checklist must be uploaded to GMP+ International's company database within 2 weeks after the end of the audit.

### Company database

When a certificate is submitted, the Certification Body must add an additional scope GMP+ BCN-IP *specific requirements for Iberian Peninsula* to the participant.

### Certificate

For the certificate, the template as stated in the relevant chapters of the GMP+ C6/C12 must be used. The relevant country note must be mentioned on the certificate.

#### Comments:

- g. It is not permitted to mention brand names on the certificate in any way.
- h. It is required to display the GMP+ logo on the certificate.
- i. The start date of the certificate is a date that shall always be after the date of the positive final assessment.

- j. The data of the participant must exactly be the same as registered in the legal business registration of the participant (for example Chamber of Commerce/registration at competent authority, tax/vat number).
- k. The text of the relevant certificate of a country note can be combined/integrated in the text of other FSA/FRA certificates.
- l. It is not permitted to use the logos of critical location, non-critical location and outsourced party on the certificate other than the GMP+ accepted certification body.

#### Exclusion

If it is established that a GMP+ participant or temporarily accepted company no longer complies with the requirements then through the certification body it is obliged to impose measures and sanctions immediately in accordance with Annex 1.

#### Unique certification agreement/certification agreement template

In the agreements (or quotations that are part of the agreements) through the Certification Body with companies, the audit time to be invested must be included. This audit time must at least meet the minimum audit time as mentioned in the annex 2 of GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes/specific scopes*. Referral to GMP+ C7 *Assessment and certification criteria for GMP+ certification – additional scopes/specific scopes* is not sufficient.

It is not permitted to deviate from the minimum obliged audit times by way of invoicing on the basis of recalculation. If, based on the findings of the auditor, a longer audit time is required, this is possible in consultation with the participant.

It is also laid down in a unique certification agreement/certification agreement template that the GMP+ certified participant is allowed to use the GMP+ logo and that it commits to strictly comply with the conditions defined by GMP+ International in this respect.

#### Exclusion of liability GMP+ International

GMP+ International has no liability whatsoever with regard to the assessment of participants through the certification bodies. The relevant certification bodies shall indemnify GMP+ International in this regard.

#### Tariffs

The certification bodies use their own rates. On behalf of GMP+ International, through the Certification Body relevant rates as listed in GMP+ C4 *Tariffs* are charged.

#### Disputes between certification bodies and participants

Any disputes between certification bodies and participants about the assessment shall first be handled in accordance with the dispute regulations of the Certification Body. If this does not lead to a solution, the dispute can be handled in accordance with the dispute regulations (GMP+ A4 *Dispute Procedure*).

## Annex 1 Assessment criteria and measures

Inspection non-conformities are to be classified based on the general assessment criteria below. In addition, the specific assessment criteria as listed in the check lists remain in full force. The measures mentioned are the minimum measures to be imposed. A Certification Body is allowed to impose stricter measures, but not to deviate from them by less strict measures.

### GMP+ BCN-NL1 Antibiotics-free animal feed

Nonconformity	Measures
<ul style="list-style-type: none"> <li>The company doesn't meet the conditions in the Country Note (such as: antibiotics and attests are found at the company)</li> </ul>	<ul style="list-style-type: none"> <li>1-year exclusion</li> </ul>
<ul style="list-style-type: none"> <li>Antibiotics are found in 1 or more of the samples analyzed in the context of verification</li> </ul>	<ul style="list-style-type: none"> <li>In order to meet the conditions, an additional sample (this may be a contra sample) should be analyzed to verify whether the result of the first sample is correct. If this sample contains antibiotics as well, the company will face a 1-year exclusion.</li> </ul>

Please note: When a non-conformity in these additional standard leads to exclusion, this will have no consequences to the certificate to which this country note is an addition (GMP+ or equivalent – see GMP+ BA10 *Minimum Requirements for purchasing*)

### GMP+ BCN-NL2 Dioxin monitoring in laying hens(rearing) feeds

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

### GMP+ BCN-DE1 QM-Milch

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

### GMP+ BCN-CN-1 Supplier Assurance for China

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

### GMP+ BCN-CEE Additional requirements for Central & Eastern Europe

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

#### **GMP+ BCN-CI Additional requirements for Italy**

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

#### **GMP+ BCN-VN Additional requirements for Vietnam**

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

#### **GMP+ B11 Protocol for GMP+ registration for laboratories**

The assessment criteria and measures are in compliance with the GMP+ ~~C3~~/C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

#### **GMP+ BCN-IP Additional requirements for Iberia Peninsula**

The assessment criteria and measures are in compliance with the GMP+ C6 *Assessment and Certification Criteria for GMP+ certification*; chapter 2.9, GMP+ C12; chapter 2.7 Assessment and reporting.

## Annex 2 Minimum audit / inspection times

	Audit/ Inspection frequency	Minimal time investment in hours		
		Initial Certification or recertification audit/inspection	Unannounced/an- nounced surveil- lance audit/inspec- tion	Comment
GMP+ BCN-CN1 <i>Supplier assurance for China</i>	1x / year	1.5 hour per file	1.5 hour per file	2
GMP+ BCN-CEE <i>Additional requirements for Central &amp; Eastern Europe</i>	1x / year	1.5 hour per file	1.5 hour per file	2
GMP+ BCN-NL1 <i>Antibiotics-free animal feed:</i>				
Scope: Antibiotics-free feed produced at an antibiotics-free production site	1x / year	2	2	
Scope: Antibiotics-free feed produced at an antibiotics-free production line(s)	1x / year	4	4	
GMP+ BCN-NL2 <i>Dioxin monitoring in laying hens (rearing) feeds</i>	1x / year	2	2	3
GMP+ BCN-DE1 <i>QM-Milch</i>	1x / year	2	2	3
GMP+ BCN-IT <i>Specific requirements for Italy</i>	1x / year	1.5 hour per file	1.5 hour per file	3
GMP+ BCN-VN <i>Specific requirements for Vietnam</i>	1x / year	1.5 hour per file	1.5 hour per file	3
GMP+ BCN-IP <i>Specific requirements for Iberian Peninsula</i>	1x / year	1.5 hour per file	1.5 hour per file	3
GMP+ B11 <i>Protocol for GMP+ registration for laboratories outsourcing all analysis</i>	1x / year	4 hours <sup>6</sup>	4 hours <sup>6</sup>	4

	<b>Audit/ Inspection frequency</b>	<b>Minimal time investment in hours</b>		
		<b>Initial Certification or recertification audit/inspection</b>	<b>Unannounced/announced surveillance audit/inspection</b>	<b>Comment</b>
<i>GMP+ B11 Protocol for GMP+ registration for laboratories partly outsourcing analysis</i>	1x / year	8 hours <sup>6</sup>	8 hours <sup>6</sup>	4 & 5
<i>GMP+ B11 Protocol for GMP+ registration for laboratories without outsourcing of any analysis</i>	1x / year	8 hours <sup>6</sup>	8 hours <sup>6</sup>	5

Comment 2 Initially, all files are to be assessed, afterwards they need to be assessed, then based on random samples during the course of the certificate.

Comment 3 Initially, if an supervision audit is conducted simultaneously with a regular supervision audit the audit time of the supervision audit may be reduced with 50%.

Comment 4 The audit times are for the assessment of one analysis. For the assessment of each outsourced additional analysis 0,5 hours must be added.

Comment 5 The audit times are for the assessment of one analysis. For the assessment of each performing additional analysis 2,0 hours must be added.

Comment 6 The audit times for auditing B11 may be reduced up to 50% if the assessment will be performed in combination with de scope Laboratory testing. The audit times auditing B11 may be reduced up to 50% if the company has an accreditation in accordance with ISO17025.

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