



# GMP+ Certification Guidance for Oqualim certified companies

GMP+ D5 1

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**GMP+ Feed Certification scheme**



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# 1. Introduction

## 1.1. Scope

The content of this document is created by GMP+ International and Oqualim. It gives guidance for a company to implement a feed safety management system for compliance with the standards from both the GMP+ FSA scheme and the Oqualim scheme. Further, this document gives guidance to a certification body to apply the certification rules from both schemes during one audit and certification procedure.

GMP+ International and Oqualim have published this document, each in the usual format of their scheme documents.

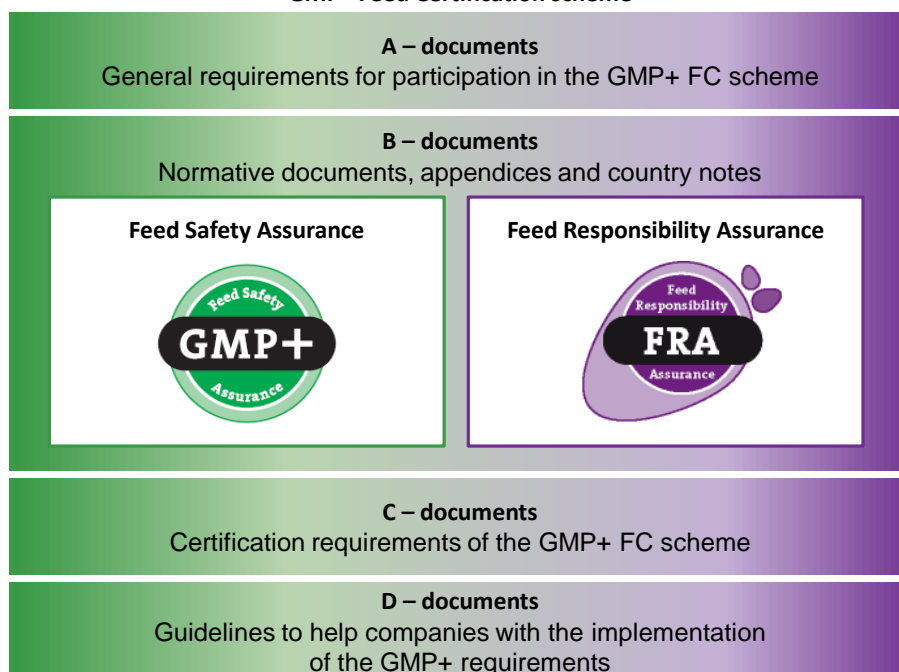
This document is referred to as GMP+ D5.1 *Guidance for combined GMP+ FSA and Oqualim certification*, and is part of the GMP+ FSA module.

## 1.2. Introduction GMP+ Feed Safety Assurance

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 Certification scheme



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.

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.

### 1.3. Introduction Oqualim Certification standard Animal Nutrition

The OQUALIM certification scheme was initiated and developed in 2008 by the French industry.

OQUALIM is an association which supports, structures and coordinates joint initiatives in the animal feed sector in order to ensure feed safety.

OQUALIM has both given tangible form to and made visible more than ten years of work conducted within the profession to control and continually improve the quality and safety of livestock feed. The tools offered by OQUALIM are adapted to the needs of the sector and its constituent industries. They also are a response to the expectations from food chain.

The Feed Certification Standard by OQUALIM integrate multiple components, such as requirements for a feed safety management system, for application of HACCP principles, for traceability, prerequisites programmes, for controlling the processes impacting on feed safety, specificities and technicalities of feed manufacturer's know-how, for respecting the clients expectations and a monitoring plan mutualized to insure the sanitary follow-up of feed materials and finished products.

Certification bodies are able to carry out OQUALIM certification independently. The rules of certification are clearly established.

More information about OQUALIM and the Feed Certification Standard by OQUALIM can be found on this website: <http://www.oqualim.fr/>.

## 2. Certification Guidance

### 2.1. Introduction for companies

This document describes which requirements from the GMP+ Feed Certification scheme need to be implemented in addition to the Oqualim standard (*'Certification Standard Animal Nutrition V2.0'*) in order to obtain full GMP+ FSA certification (GMP+ B1 *'Production, Trade and Services'* for the scopes: *Production of Compound Feed* and *Production of premixtures*). It also describes what conditions a GMP+ certified company must additionally assure to obtain a full Oqualim certificate.

Because many of the requirements for both GMP+ FSA and Oqualim certification are similar, this document guides the companies towards the specific elements that need to be implemented on top of the existing (feed) safety certification.

### 2.2. Introduction for certification bodies / auditors

Also certification bodies / auditors can find guidance in this document how a combined audit and certification procedure can be carried out. As a basic condition, the auditor and the certification procedure must comply with the conditions from both schemes. This guidance provides more detailed information.

### 2.3. Disclaimer

This document doesn't replace the relevant documents from both schemes, but is a tool to identify the relevant additional requirements in one scheme to obtain certification for the other scheme, and vice versa.

It is the responsibility of the individual company and the certification body to assure that there is compliance with all the relevant requirements from both schemes. In no way can GMP+ International nor Oqualim be held liable for the use of the information provided in this document.

## 3. Guidance for the company

### 3.1. General

A company wishing to be certified under both certification schemes must demonstrably comply with the requirements laid down in both the Oqualim scheme and the GMP+ Feed Certification scheme.

The company must be able to demonstrate that there is compliance with the conditions of each individual standard.



Regarding the conditions, there are some differences between both schemes. This chapter highlights the most important differences

### 3.2. Oqualim certification as a base for GMP+ certification

This chapter describes the additional GMP+ requirements which an Oqualim-certified company must implement to obtain GMP+ certification.



#### 3.2.1. Feed Safety Limits

Feed safety limits are used in the HACCP analysis and define if a product is safe to use as feed.

	<p>The Oqualim Certification Standard Animal Nutrition requires compliance to applicable legislation. This means that in France (where this standard is used), all feed safety limits from EU legislation apply.</p>
	<p>The GMP+ B1 standard also requires compliance to applicable legislation. All EU feed safety limits are included in GMP+ BA1 <i>Specific feed safety limits</i>. Also some additional GMP+ feed safety limits are included. These feed safety limits do not originate from legislation, but are agreed upon by the market. These feed safety limits can be recognized by the reference 'GMP+' in the column 'source' of the GMP+ BA1 document.</p>
<p><b>Additional GMP+ requirement:</b> GMP+ participants must comply with GMP+ BA1 <i>Specific feed safety limits</i>. As Oqualim companies are already obliged to comply with EU legislation, most of the limits are already implemented. Only the GMP+ feed safety limits apply additionally.</p> <p>The following additional GMP+ Feed Safety limits are applicable:</p> <p><b>1. GMP+ feed safety limits for wet mixes.</b> GMP+ BA1 <i>Specific feed safety limits</i> contains specific GMP+ feed safety limits for Chloride, Potassium, Sodium, Sulphate, Plastics and Polyethylene in wet mixes. Wet mixes are feeds that contain more than 20% moist, are industrially produced, need conservation to protect the feed against molds and bacteria growth and are delivered directly to the livestock farmer. If the GMP+ participant doesn't produce wet mixes, these feed safety limits are not applicable.</p> <p><b>2. GMP+ feed safety limits for Salmonella and Mycotoxins</b> GMP+ BA1 <i>Specific feed safety limits</i> contains specific GMP+ feed safety limits for Salmonella, Deoxynivalenol, Ochratoxin A, Zearalenon, Fumonisin B1 + B2, sum of T-2 and HT-2 toxin.</p>	



### 3.2.2. Negative list

Negative list refers to a list of products that are not allowed to be used as feed.

	<p>The Oqualim Certification Standard Animal Nutrition requires compliance to applicable legislation. This means that in France (where this standard is used), the EU legislation regarding products that are not allowed to be used as feed is applicable.</p>
	<p>The GMP+ B1 standard also requires compliance to applicable legislation. All products that are not allowed to be used as feed according to EU legislation are included in GMP+ BA3 <i>Negative list</i>. Also some additional products are included on the negative list. These forbidden products do not originate from legislation, but are agreed upon by the market.</p>
<p><b>Additional GMP+ requirement:</b> GMP+ participants must comply with GMP+ BA3 <i>Negative list</i>. As Oqualim companies are already obliged to comply with negative list from EU legislation, most of the requirements are already implemented. Only the GMP+ forbidden products apply additionally.</p> <p>The additional requirements are included in paragraphs 4.2 and 4.3 from GMP+ BA3 <i>Negative list</i>.</p>	



### 3.2.3. FSP product list

The FSP product list is used in GMP+ FSA certification as a 'positive list of feed materials'. Only feed materials that are included in this list may be produced, traded or used within the GMP+ feed chain.

	<p>The Oqualim Certification Standard Animal Nutrition requires compliance to applicable legislation. This means that all used feed materials must be allowed by law.</p>
	<p>The GMP+ B1 <i>Production, Trade and Services</i> standard requires, on top of compliance with legislation, inclusion of a generic risk assessment of any used feed material in the product list of the Feed Support Products (FSP). This generic risk assessment is, before inclusion in the FSP product list, assessed by a team of experts and approved once considered safe to be used in feed. The FSP product list is in cases more detailed than legislation.</p>
<p><b>Additional GMP+ requirement:</b> Oqualim certified companies that want to be GMP+ certified must comply with the requirement that of all feed materials purchased or received, there must be a generic risk assessment included in the FSP product list. When a product is missing in the FSP product list, inclusion can be requested via the website of GMP+ International.</p> <p><i>As there are many feed materials already included in the FSP product list, most feed materials that Oqualim companies are using are probably already included.</i></p>	


### 3.2.4. Purchasing requirements

Both certification schemes include purchasing requirements to ensure a good selection of suppliers of products and services.


	<p>The Oqualim Certification Standard Animal Nutrition requires to take into account the physical, chemical and biological hazards to formalize the quality requirement in the specification for suppliers.</p> <p>The requirements on selecting, monitoring and evaluating suppliers described in Appendix 1, which may be covered by the certification of suppliers of certain (groups of) products and services. A growth model is implemented to increase the percentage of certified suppliers during the years of certification of the Oqualim certified company. This appendix is under construction and will fully apply only when finished. This means that, for the time being, the purchasing options within the GMP+ certification scheme are accepted by Oqualim.</p>
	<p>The GMP+ certification scheme has a very strong chain approach and requires GMP+ (or equivalent) certification of suppliers of products and services for which a scope is included in the GMP+ certification scheme. In some cases gatekeeper protocols are allowed. All these requirements are laid down in the GMP+ B1 <i>Production, Trade and Services</i> standard with reference to GMP+ BA10 <i>Minimum requirements purchase</i>.</p>
<p><b>Additional GMP+ requirement:</b></p> <p>Oqualim certified companies that want to be GMP+ certified must comply with the GMP+ purchasing requirements from GMP+ BA10 <i>Minimum requirements purchase</i> for the purchase of:</p> <ul style="list-style-type: none"> <li>- feed materials</li> <li>- feed additives</li> <li>- storage</li> <li>- laboratories</li> </ul> <p>GMP+ BA10 can be used for the purchase of compound feed, premixtures and transport as well. Oqualim purchase requirements for these feed products and services are considered equivalent to the GMP+ purchase requirements.</p>	

### 3.2.5. Monitoring



Monitoring is part of HACCP and is important to check if control measures are sufficient and effective to ensure safe feed.

	<p>The Oqualim Certification Standard Animal Nutrition requires monitoring based on HACCP and provides a collective monitoring program for it.</p>
	<p>The GMP+ B1 <i>Production, Trade and Services</i> standard also requires monitoring based on HACCP, but has minimum monitoring protocols for the analysis on specific undesirable substances in compound feed.</p>





	
<p><b>Additional GMP+ requirement:</b>                  Oqualim certified companies that want to be GMP+ certified must comply with the monitoring requirements as stated in GMP+ BA4 <i>Minimum requirements for sampling and analysis</i>.</p> <p>Special attention is asked for the monitoring protocols for:</p> <ul style="list-style-type: none"> <li>- Salmonella (Protocols P1 &amp; P2, chapter 3 from GMP+ BA4)</li> <li>- Animal protein (Protocol P7, chapter 4 from GMP+ BA4)</li> </ul> <p>Both are specific monitoring protocols for compound feed with minimum monitoring requirements. The details can be found in the applicable protocols.</p>	

### 3.2.6. Positive declaration

	<p>The Oqualim Certification Standard Animal Nutrition requires no specific labelling, besides what is required by legislation. All feed produced in an OQUALIM certified plant has to comply with OQUALIM requirements. Companies are allowed to use the Oqualim logo to show that a feed is produced in a plant compliant with certification requirements.</p>
	<p>The GMP+ B1 <i>Production, Trade and Services</i> standard also requires legal compliance, but additionally requires a positive declaration on GMP+ products and services. This is to confirm to the client that the product (or service) is covered within their GMP+ certification.</p>
<p><b>Additional GMP+ requirement:</b>                  Oqualim certified companies that want to be GMP+ certified must comply with the labelling requirements as stated in GMP+ BA6 <i>Minimum Requirements Labelling &amp; Delivery</i>.</p>	



### 3.2.7. EWS procedure

	<p>The Oqualim Certification Standard Animal Nutrition requires a copy of the report to the public authorities on the CSNA guidelines "reporting nonconformities manual". The Oqualim Certification Standard Animal Nutrition is also linked with pooled monitoring plan in which each non conformity generate an alert for the participants.</p>
	<p>The GMP+ B1 <i>Production, Trade and Services</i> standard also requires reporting to both the national authorities and GMP+ International. GMP+ specifies when and what should be reported. An internal procedure is in place to handle the reports and use the information to send out anonymous information to other GMP+ participants as a precaution. The requirements regarding the EWS procedure are included in GMP+ BA5 <i>Minimum requirements EWS</i>.</p>
<p><b>Additional requirement:</b>                  Companies certified for both certification schemes, must comply with both EWS procedures. This means that both the CSNA guidelines and the GMP+ BA5 <i>Minimum requirements EWS</i> are applicable.</p>	



### 3.3. GMP+ certification as a base for Oqualim certification

This chapter describes the additional Oqualim requirements which an GMP+ -certified company must implement to obtain Oqualim certification.



#### 3.3.1. Homogenization

	<p>The GMP+ B1 <i>Production, Trade and Services</i> standard requires in chapter 6.7.1.3 Mixing the insurance by the participant that feed materials and feed additives and veterinary medical products are mixed uniformly. GMP+ International is working on more specific requirements (for example including testing) regarding homogenization, but this is not yet included in the standard.</p>
	<p>The Oqualim Certification Standard Animal Nutrition also requires to control the capability of homogenization, but has defined minimum values of the validation tests of homogenization and test frequencies.</p>
<p><b>Additional Oqualim requirement:</b> GMP+ certified companies that want to be OQUALIM certified must comply with the appendix 2 of Oqualim certification standard (RCNA) <i>Homogenization</i>.</p>	



#### 3.3.2. Residue control

	<p>In the GMP+ B1 <i>Production, Trade and Services</i> standard, based on a risk assessment, the participant must implement procedures to control the cross-contamination in order to meet the quality and safety standards. Knowledge of the carry-over is necessary as part of Good Manufacturing Practices, and also to establish adequate procedures for controlling cross-contamination. Accepted methods to measure the carry-over are laid down in GMP+ BA2 Control of residues.</p>
	<p>For the Oqualim Certification Standard Animal Nutrition also each manufacturing site shall establish its rules establishing production schedules, taking into account the HACCP study, inter-batch transfers tests, the characteristics of incoming goods and species for which they are authorized. In France only the method for residue control of Tecaliman is allowed to be used.</p>
<p><b>Additional Oqualim requirement:</b> GMP+ certified companies that want to be OQUALIM certified must comply with the appendix 3 of Oqualim certification standard <i>Inter-batch transfer</i>.</p>	

### 3.3.3. Heat treatment

	<p>In the GMP+ B1 <i>Production, Trade and Services</i> standard, if the participant produces poultry feed, in which Salmonella-critical feed materials have been processed, a Salmonella kill step must be applied. Results must be validated by additional requirements for sampling and analysis.</p>
	<p>For the Oqualim Certification Standard Animal Nutrition the participant must first control salmonella risk in feed by process qualification, According to French legislation (AM of 23 April 2007), the qualification of the process must validate the expected microbiological reduction factor of 3 log and a contamination end of cooler below 1000 enterobacteriace/g.</p>
<p><b>Additional Oqualim requirement:</b>                  Even though GMP+ B1 requires compliance with the applicable legislation, national legislation (such as above mentioned) is not included specifically in the GMP+ requirements. Therefore it will be expected that companies working on additional Oqualim certification already complies with the French legislation. Nonetheless it is good to mention that this national legislation is included in the Oqualim standard.                  GMP+ certified companies that want to be OQUALIM certified must comply with the requirements 5.7 of <i>Heat treatment</i>.</p>	

### 3.3.4. Pelletising and crumbling

	<p>In the GMP+ B1 <i>Production, Trade and Services</i> standard, chapter 6.7.1.4 for pelletising the conditions must be attuned to the stability of the processed feed additives and veterinary medical products, in accordance with the processing advice as provided by the supplier.</p>
	<p>In the Oqualim Certification Standard Animal Nutrition, beyond feed safety requirements there is quality requirements. For pelletising, a quality requirement is the achievement of durability tests. The performance of durability tests is checked.                  In case of crumbling, the conformity of particle size of the "product" with respect to the defined specifications is checked during the audit.</p>
<p><b>Additional Oqualim requirement:</b>                  GMP+ FSA certification focusses on requirements relevant for feed safety. The Oqualim requirements for pelletizing and crumbling refers to feed quality (not feed safety), but is agreed upon to be covered in Oqualim certification. Therefore this is an additional requirement for GMP+ certified companies that want to be Oqualim certified. The Oqualim requirements regarding pelletizing and crumbling can be found in paragraph 5.9 and 5.11 of the Oqualim standard (RCNA).</p>	

## 4. Guidance for Certification bodies / auditors

### 4.1. General

A certification body wishing to certify a company under both certification schemes must demonstrably comply with the requirements laid down in both the Oqualim scheme and the GMP+ Feed Certification scheme.

Regarding the certification requirements, there are some differences between both schemes. These differences are:

- Rotation of auditors,
- Review of audit reports,
- Assessment criteria and measures and classification of nonconformities:

Before issuing an Oqualim and/or a GMP+ certificate the certification body must be able to demonstrate that the certification requirements of each individual scheme are met. Where requirements are similar, they can be combined.

The possibility to conduct a Oqualim/GMP+ combination audit will be secured in the newest version of the GMP+ C6/GMP+ C12. The objective to finalize this is the second quarter of 2017.

Audit times:

- The minimum obliged audit time is 4 hours on site in addition to the audit time of the initial feed certification (either Oqualim or GMP+), excluding time for preparation, reporting, review, etc. This applies both when the additional Oqualim requirements and/or the additional GMP + requirements are audited.

Audit report:

- The audit report must comply with the applicable requirements of the Oqualim- and GMP+ FC scheme. The certification body is allowed to share information about the audit (report, plan, etc.) after written approval by the certified participant (GMP+ and/or Oqualim).

Certificates:

- After a positive assessment the GMP+ accepted certification body issues a GMP+ certificate. It is possible to streamline the end dates of the validity of the Oqualim- and GMP+ certificate into one end date. The maximum validity period may never exceed the applicable requirements of the Oqualim-/ and GMP+ FC scheme.



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