



FAQ GMP+ Country Note Italy

GMP+ D 3.16

Version EN: 1 January 2016

GMP+ Feed Certification scheme



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1 GENERAL, APPLICATION & CERTIFICATION

1.1 The country note does not address specific options for sourcing of feed additives. Why not?

In the basic GMP+ FC scheme, already for a long number of years, a general gate-keeper protocol for buying feed additives from non-assured sources is published, to be used as a regular option for all companies. See for this GMP+ BA10, Annex 3. There is no need to create specific option for this in the Country Note 'Italy'.

1.2 I am an Italian compound feed company. I have bought a feed material from a trader, which is declared as 'GMP+ FSA –assured-IT'. How should I be certified?

Any feed product, which is produced or trade by applying the Country Note 'Italy', must be labelled with 'IT'. The status is clear and can not be changed. Processing of such a feed material can only be done under the scope of the country note. So you, as a compound feed company, must also apply the country note and make sure that any compound feed you produce with such a feed material, is also clearly labelled as 'GMP+ FSA –assured-IT'. Summarizing: once a product is 'IT', it must stay 'IT'. Also, as a consequence, a compound feed, in which this product is processed, has the status 'IT'.

1.3 I am an Italian compound feed company. I only apply the Country Note 'Italy' for sourcing one feed material which I process in poultry feed. Pig feed complies with the regular GMP+ conditions. How should I proceed?

Any feed, produced or traded with just application of the regular GMP+ standards, must be labelled as such (GMP+ BA6). In this situation, this counts for the pig feed. These pig feed can be sold to anyone, also outside Italy. The poultry feed must be labelled with the addition 'IT', as stated in chapter 7 of the country note. For this feed, the limited delivery options, as given in the country note, apply.

This is exactly the reason why the country note is applicable additional to the regular GMP+ standards, and why you, as a compound feed company are certified for 2 scopes:

- Production of compound feed: this scope covers the pig feed production
- Production of compound feed –IT: this scope covers the poultry feed production

1.4 In the country note sometimes 'participant' is used, but also sometimes 'feed company'. This is confusing

The expression 'participant' is quite abstract and is indicating a feed company which has a GMP+ certificate. It is the formal expression, also defined and used in the GMP+ A1 'General regulations'.

To make the country note more readable and more understandable sometimes 'feed company' (or 'gatekeeper') is used. These expressions indicate the same: the feed company which is GMP+ certified and applies this country note. This is also explained in chapter 3 Definitions.

1.5 Can you explain whether the current changes in ISO 9001:2015 will have an impact on the GMP FSA standards or not?

The structure and some contents of our standards (in particular the B1) are indeed based on elements of ISO9001: 2008. With the publication of the new ISO standard (ISO9001:2015) we have also started an internal discussion if we should integrate these changes in our the GMP+ standards. Opinions vary and therefore we are extending these discussions to other stakeholders. Some companies in Northern Europe claim adaptation to ISO standards is not imperative anymore while other regions are still very focussed on ISO. We shall communicate about the outcome of this discussion shortly.

The opinion of Italian companies can contribute to make a balanced final decision.

1.6 I am a trader in grains. In the framework of the regular GMP+ standards, I can apply a gatekeeper protocol (GMP+ BA10, annex 5) for buying unprocessed products (grains, seeds) from collectors in Eastern Europe, and sell these products throughout Europe to feed companies. But if I apply the GMP+ BCN-IT I can only sell in Italy, is this correct?

This is maybe a little bit complicated but we will try to explain.

The gatekeeper protocol, as laid down in Annex 5 of GMP+ BA10, can not be applied for buying unprocessed products (grains and seeds) from Italian collectors. This means that these collectors need to be certified (as they must comply with the regular GMP+ requirements). This is an obstacle for starting with GMP+ feed safety assurance in the Italian feed chain.

The country note makes it possible (article 4.1) that also grains and seeds can be bought (under certain gatekeeper conditions) from non-certified Italian collectors. So this is actually an extension of the gatekeeper option. This extension is in line with the purpose of this country note.

The limitation, however, is that this grain and the seeds can only be sold to Italian companies for processing in the feed. This is in line with the purpose of the GMP+ BCN 'Italy': more options, so Italian companies can start with feed safety assurance.

The purpose of the GMP+ BCN 'Italy' is not to create extra options for trading unprocessed grains or seeds to all other countries in Europe. If that would be the purpose, the country 'Italy' should have been deleted from the list of so-called A-countries in Annex 5 of GMP+ BA10.

Any unprocessed grain or seeds from Eastern European countries can still be traded (as 'GMP+ assured') under the conditions of the Annex 5 protocol.

1.7 Should outsourced activities also be certified or can you perform a gatekeeper protocol for this?

Yes outsourced activities do have to be certified under GMP+ FSA. You cannot apply a gatekeeper protocol for outsourced activities, unless an option is given in this country note. For example: for transport a gatekeeper option is given. But not for outsourcing of production activities. If you for example make use of another company for drying of a feed, this activity needs to be covered under the certificate of that company.

1.8 We are a GMP+ certified oilseed crusher. We purchase whole oil seeds from farmers and do not know if they are all certified. We also source from food companies. We would like an exemption because our end product is sold to Food companies. How does this work under GMP+ conditions?

Under GMP+ conditions it is important to determine where the chain begins. Your company is considered as the beginning of the feed chain. When sourcing from farmer or food companies these suppliers do not have to be certified. Soon a new guidance (D-document) will be published with some examples of when this chain begins/ends.

1.9 What are next actions after the publication of this Country Note?

The Italian Country note will be published in December 2015, and certifiable by 01 January 2016.

It is not the end of a process but the beginning. We will continue to work together with certification bodies and Italian companies to tackle also in the next years practical problems. After a year we will evaluate the GMP+ BCN-IT and make some small adjustments, if necessary. Therefore we encourage you to send us your comments as soon as you start working with the GMP+ BCN-IT. There is Italian speaking staff in our office to assist where necessary.

1.10 How should I proceed when I already have a certificate and I will extend it with the BCN-IT?

You should contact your certification body for advice.

1.11 How long will the BCN-IT be valid?

The BCN-IT will be valid for a maximum of 4 years till end 2019. By that time we expect the GMP+ BCN-IT is not necessary anymore

1.12 We are certified under B3 (scope: trade) as a part of a multi site certificate. Our head office (HQ) is a Dutch company and that is the location of the centralized purchasing department. When we apply the GMP+ BCN-IT, will this only affect our Italian sub location or does it have consequences for our Dutch HQ, too?

Yes, this will have impact on the Dutch HQ. First, in terms of adding the necessary procedures and controls to the central feed safety management system. Further, the current multi site requirements prescribe that the Dutch HQ must also be come certified for the same scope as the sub location.

Pleas: production can not be certified under a multi site construction. .

1.13 Can I only buy feed materials under this country note from non-certified companies that are located in Italy?

No, a company that applies this country note, can purchase feed materials from non-certified suppliers, located anywhere in the world. Delivery is only allowed to Italian companies. So: global sourcing and local delivery.

2 GATEKEEPER, PRODUCTION, TRANSPORT & LABELING

2.1 Why is this CN only applicable for Italian companies? Why is application not possible for a trader, located outside Italy, but delivering to an Italian feed company?

This country note is meant to make it possible for Italian companies to start with GMP+ feed safety assurance. It is a first step towards full compliance with the regular GMP+ standards. It should contribute in a movement towards a high level of feed safety assurance in Italy.

It is certainly not meant to be used by foreign feed companies, delivering on the Italian feed market.

2.2 What about the minimum monitoring as required in chapter 4.3?

The formula, which is mentioned in this chapter, gives a clear minimum for the frequency. This formula has been added because the Italian companies has requested it as such. They consider it useful and necessary to establish a monitoring plan and to avoid discussion with auditors.

Note that this formula does not define risks as such. This is still the responsibility of the company. However, once a hazard has been identified as a risk, the frequency which is calculated with the formula, applies

2.3 Is it possible to combine feed production line under GMP+ B1 conditions (GMP+ assured) with a production line of non-GMP+ assured feed in the same facility?

Yes this is possible under the conditions for the BCN-IT. A part of your production process can be excluded from certification.

This is a typical situation for which the country note has been developed - to overcome some specific obstacles in the regular GMP+ standards.

2.4 Is there a cleaning protocol for transport equipment under the B4 standard?

Yes. The main GMP+ principle for transportation is to carefully clean before transporting any feed. A GMP+ company has to comply with the IDTF-regulation. Depending on the nature and characteristics of a certain product, there are four cleaning methods: a (dry cleaning), b (cleaning with water), c (cleaning with water and a cleansing agent) and d (cleaning and disinfection). Some products may be forbidden.

Although these methods have been validated, you as a transport company should ensure /check that these methods are effective, the drivers are properly instructed and trained, etc. This should be confirmed in a written procedure.

The Q and A list for transport is currently being revised and will be published shortly.

2.5 We currently have an exemption related to the production of compound feed. If we source a premix product under the GMP+ BCN-IT conditions and we use it for the production of our GMP+ assured end products, will the status 'GMP+ assured -IT' change to 'GMP-assured'?

Ingredients sourced under GMP+ BCN-IT will have to be labeled as such and will always keep this status. Also products, in which these ingredients are processed, will have the status 'GMP+ assured-IT'.

2.6 How can you combine the delivery of GMP+ assured products with products assured under the GMP+ BCN-IT?

By applying clear labelling - mentioning on the label that the products are GMP+ assured (regular GMP+, or 'GMP+ assured-IT' (GMP+ BCN-IT)

2.7 In Italy we are aware of the mycotoxins issue in maize and wheat. This is very much linked to the minimum monitoring requirements for aflatoxin. What is GMP+ International's vision on this matter?

Following serious incidents in 2012, GMP+ International recently developed the Aflatoxin B1 protocol. The protocol is meant to reflect a risk-based approach, and will be evaluated from time to time. Monitoring is an important part of this protocol, the sampling requirements are based on Regulation (EU) no. 691/2013. Currently our technical committee's discuss adjustments of the current protocol to address these practical issues.

We hope to be able to publish more on this topics in a few months' time.

2.8 We are exporting to Japan in containers. Is there a cleaning protocol for containers? Should I apply the BCN-IT?

It is the responsibility of the participant to verify if the container is clean before loading the container. Risk assessments must consider any potential hazards and ensure that controls effectively preclude any serious risk of contamination. During shipping the container is sealed so the contents are protected from contamination. This requirements are described in GMP+ B1, B2 and B3 standard. You do not need to apply the BCN-IT

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