

## Q&A list GMP+ BA4 Minimum requirements for inspection and analysis

In this document you will find a number of frequently asked questions about GMP+ BA4 *Minimum requirements for inspection and analysis*. If you have a question that does not occur in this list, you may submit it by sending an E-mail to [info@gmpplus.org](mailto:info@gmpplus.org).

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### **1.1 Which requirements are imposed on the laboratory where the analyses must be performed?**

In the GMP+ B- documents the requirement is imposed that an analysis must be performed by a GMP+ B10 certified laboratory or by another laboratory which has been approved as equivalent. See GMP+ BA10 *Minimum requirements for purchase*. ISO17025 accredited laboratories, among others, have been declared to be equivalent.

In addition to GMP+B10 certification or ISO 17025 accreditation, the laboratory must also have been certified / accredited specifically for the feed analysis concerned. A laboratory which has been accredited under ISO 17025 for dioxin analysis in polluted soil, can not therefore be used just like that for the analysis of feed. It is therefore not sufficient to merely check whether the laboratory has been certified or accredited.

For performing the compulsory analyses within the frequency of GMP+ BA4 *Minimum requirements for inspection and analysis* you can only use a laboratory which has been ISO17025 accredited for those analyses. For supplementary analyses (for example for parameters which have not been included as compulsory in GMP+ BA4), use can be made, obviously, of a GMP+ B10 certified laboratory.

### **1.2 Must I analyse all feed materials myself?**

Every GMP+ certified company is responsible itself for compliance with the monitoring obligation. It must be in possession of the relevant analysis results to demonstrate this.

It is possible to use the analysis results of the supplier or customer for your own monitoring obligation. Obviously the analyses of the supplier/customer must comply with the same requirements as your own analyses. A convention about the use of analyses of suppliers/customers must be recorded, for example in a contract. Incidentally, suppliers or customers are not obliged to make analysis results available.

However, conditions have been imposed on the use of analysis results of third parties. It is important that the analysis result is representative for the batch supplied. This means that the batch comes from the same origin but, for example, also from the same location.

Note: the above does not apply to analyses for microbiologically undesirable substances where recontamination may occur. These analyses will therefore have to be conducted (once more) by the participant himself. See also the answer to question 1.12.

### **1.3 Is it allowed with moisture-rich feed materials to convert the volume to dry substance?**

With moisture-rich feed materials it is allowed to convert the volume to the dry substance content. Next this calculated volume can be used for calculating the monitoring frequency. There is no reason to include the water content in the determination of the analysis frequency.

**1.4 Is it possible in the event of small amounts of certain feed materials to merge the total amount with other feed materials? For example the merging of a small amount of spelt with wheat.**

No it is not possible to merge volumes of (similar) feed materials. Even if you purchase only a small amount of a certain feed material, monitoring still has to take place. This often means that you have to have analysed only one sample on an annual basis.

It is allowed, however, to merge by-products of the same primary product (with the same risk profile with regard to the chance of occurrence of the same undesirable substances). Merging wheat feed meal and wheat grits is an example of this.

We can give you another tip. If you purchase only small quantities of certain feed materials, it may be advantageous to participate in a sector monitoring programme. A group of companies may submit a joint proposal to GMP+ International in which the volumes of the individual companies can be merged.

**1.5 If I am a participant in an approved collective monitoring programme, do I meet all conditions then?**

In principle you do. You should verify however that the collective programme covers all conditions which your individual company must meet. If necessary, perform additional analyses yourself, for example on specific products which are not included in the monitoring programme.

Furthermore it is important to realise that meeting the monitoring conditions is not a goal in itself. You should therefore always verify whether the analysis results generated collectively which you have at your disposal, constitute a reason to take corrective measures.

**1.6 Drying maize is a seasonal activity. Is the company allowed to spread the total number of samples over the year or must it take samples only in the season in which the activity is carried out?**

The starting point is the total volume which is produced on an annual basis, regardless of whether this volume is produced in a short period of time or spread over the entire year. In this case the company will therefore have to take and analyse all samples in the 'season'. However, the company must take these samples in a representative way, meaning not all samples from the first new crop.

**1.7 If I analyse my products in accordance with GMP+ BA4, do I then completely fulfil my monitoring obligation?**

The purpose of GMP+ BA4 is to impose minimum conditions on monitoring. However, this does not alter the fact that each GMP+ participant must also assume its own responsibility to assure the safety of feed and to verify the control measures taken. The participant must determine on the basis of its own HACCP analysis whether additional monitoring is necessary.

**1.8 I purchase my grain in accordance with the Gatekeeper Protocol from GMP+ BA10 *Minimum requirements for purchasing*. These too include**

**requirements for the monitoring of these grains. Must I start from the monitoring mentioned in GMP+ BA10 or GMP+ BA4?**

The Gatekeeper Protocol from GMP+ BA10 includes specific conditions for the purchase of grains of uncertified origin. One of these requirements is the monitoring for some undesirable substances. You must comply with these monitoring requirements if you purchase grains under this protocol. It goes without saying that you do not have to include this volume in the calculation from 2.2.1 of GMP+ BA4.

(Incidentally, we intend to harmonise and streamline the monitoring requirements of the above-mentioned GMP+ documents on the occasion of the next changes in the GMP+ FSA scheme).

**1.9 I find it difficult to estimate in advance what my annual volume will be. How must I calculate the analysis frequency?**

It goes for many feed materials that the volume which you produce/trade on an annual basis is not known yet at the beginning of the year. However, you do need this volume to calculate the analysis frequency (see paragraph 2.2.1). In that case you must make an estimation with all the accuracy possible of the volume which you expect to produce/trade (for example on the basis of the volume of the previous year) and determine the analysis frequency on that basis. Should you notice in the course of the year that the total volume will be higher or lower than your estimation, then you may adjust the number of samples at that moment. It is not permitted to carry out the monitoring programme as a whole at the end of the year because you cannot make the calculation until then.

**1.10 As a trader without storage, must I also comply with GMP+ BA4?**

Also as a trader without storage it is your responsibility that the feed which you sell complies with the GMP+ requirements. Even if the feed does not pass physically through your hands, you must make sure that the product which you sell is of a good quality. You will also have to demonstrate this by means of a monitoring programme.

It is possible, by the way, to make use of analysis results from your supplier or customer to comply with our own monitoring obligation (with the exception of microbiologically undesirable substances where recontamination is possible; however, see also question 1.12). Obviously, you may also decide to carry out the monitoring programme yourself. In that case you will have to take samples or have samples taken of the feed. This can be done at the moment of unloading at your customer or at the moment of lading onto the transport means at your supplier.

**1.11 As a compound feed producer, must I also comply with GMP+ BA4?**

Compound feed companies also 'process' feed materials and must therefore comply with the minimum monitoring of GMP+ BA4. It is possible, however, to make use of the analysis results of the supplier in order to meet the monitoring obligation in this way.

**1.12 All non-microbiological analysis results are allowed to be shared with the supplier/customer. In which cases am I allowed to use microbiological results from my supplier/customer as well?**

It is possible of course that you purchase and sell a lot without this lot of feed changing location (for example while it is stored in a storage silo or is purchased and sold during transport). In that case there is no risk of recontamination and you are allowed to use the analysis result of your supplier/customer.

**1.13 If I know that my customer performs a process step whereby all micro-organisms in my feed material are killed, must I still analyse my feed material for micro-organisms then?**

If your customer performs as a control measure a process step whereby all micro-organisms are killed, it is not necessary to analyse the feed material for those micro-organisms. In that case you will have to make a (written) arrangement with your customer that he indeed takes an effective control measure that kills the micro-organisms (should these be present).

**1.14 How must I use the formula in paragraph 2.2.1?**

The formula from paragraph 2.2.1 is as follows:

$$\text{Frequency} = \frac{\sqrt{\text{Volume}}}{100} * \text{chance} * \text{seriousness}$$

Assuming that you have purchased and sold, on an annual basis, 3,000 tons of a certain feed material, you then calculate the analysis frequency as follows:

$$\sqrt{3.000} = 54.77$$

Next you divide this number by 100, therefore  $54.77 / 100$  is 0.5477.

You multiply this value by the chance (the standard chance is 1 but is allowed to be lowered to 0.5 or 0.25) and after that by the seriousness (is 5 for almost all cases, but cannot be lowered).

On the basis of the standard values for chance and seriousness, the analysis frequency is therefore  $0.5477 * 1 * 5 = 2,7$  in this case  
Rounded, this means 3 samples.

Appendix 1 to this enclosure contains a table in which the associated analysis frequency has been calculated for a number of volumes.

## Appendix 1 Analysis frequency

In the table below it has been calculated which analysis frequency belongs to which volume.

Note: the volumes are stated in tons. You will have to determine yourself which seriousness and which probability apply to your situation.

seriousness	3	3	3	5	5	5
chance	1	0.5	0.25	1	0.5	0.25
500	1	1	1	2	1	1
1000	1	1	1	2	1	1
2000	2	1	1	3	2	1
3000	2	1	1	3	2	1
4000	2	1	1	4	2	1
5000	3	2	1	4	2	1
6000	3	2	1	4	2	1
7000	3	2	1	5	3	2
8000	3	2	1	5	3	2
9000	3	2	1	5	3	2
10000	3	2	1	5	3	2
12000	4	2	1	6	3	2
14000	4	2	1	6	3	2
16000	4	2	1	7	4	2
18000	5	3	2	7	4	2
20000	5	3	2	8	4	2
25000	5	3	2	8	4	2
30000	6	3	2	9	5	3
35000	6	3	2	10	5	3
40000	6	3	2	10	5	3
45000	7	4	2	11	6	3
50000	7	4	2	12	6	3
60000	8	4	2	13	7	4
70000	8	4	2	14	7	4
80000	9	5	3	15	8	4
90000	9	5	3	15	8	4
100000	10	5	3	16	8	4
120000	11	6	3	18	9	5
140000	12	6	3	19	10	5
160000	12	6	3	20	10	5
180000	13	7	4	22	11	6
200000	14	7	4	23	12	6
250000	15	8	4	25	13	7
300000	17	9	5	28	14	7
350000	18	9	5	30	15	8
400000	19	10	5	32	16	8