Product Board Animal Feed

Protocol

GMP Equivalence

Suppliers

of

Feed Materials or Feed Additives

for

Animal Feed

Introduction and purpose of this document
Criteria for acceptance and operation
Acceptance procedure for certification bodies

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1 INTRODUCTION

One of the main points of the *1999 Plan of Action Enhancement Quality Assurance in the Animal Feed Sector* of the Product Board Animal Feed[1] is the extension of GMP in the feed materials channel.

Within that framework the Standard GMP Animal Feed[2] requires of certified compound feed manufacturers and traders/suppliers of straight feedings stuffs that they buy feed materials exclusively from suppliers who meet one of the following requirements:

1) The supplier is GMP certified;
2) The supplier has a certified quality assurance system equivalent to GMP;
3) If the supplier is a crop farmer, he participates in the *Quality Project Arable Farming (KPA),* in which case all GMP requirements are met;
4) If the supplier is located abroad, he implements a quality control system (QC-system), that at least meets the requirements from the Standard GMP Animal Feed[3] as specified in the standard Quality Control Suppliers of Feed materials for Animal Feed The QC system need not be certified, but has to be verified periodically as to completeness and performance.

This protocol goes into the option *GMP equivalence* (option 2). It is namely meant for certification bodies that wish to issue statements of GMP equivalence. Chapter 2 provides a further fitting in of the target group of suppliers, who may use GMP-equivalence as the type of quality assurance of animal feed and feed materials. In chapter 3 some notions are defined. In chapter 4 a further completion of the notion GMP equivalence is included.

Certification bodies that meet certain conditions may issue a statement of GMP equivalence. For that purpose this protocol further contains:

- The conditions a certification body has to meet in order to issue a GMP statement of equivalence (chapter 5)
- The procedure a certification body has to go through to be accepted by the Product Board Animal Feed, in order to be allowed to issue GMP statements of equivalence (chapter 5).

Also suppliers that want to qualify for a GMP-equivalence statement can find useful information in this document.

[1] *The Product Board Animal Feed is a regulatory industrial organisation in the Netherlands, established by law. The Product Board Animal Feed is an organisation of regulation and management for the animal feed sector, in order to let this sector function as well as possible. Representatives of trade unions and trade associations this animal feed sector participate in the board. The Product Board Animal Feed introduced the Standard GMP Animal Feed in 1992. In this standard, requirements and demands, aimed at guaranteeing the quality and safety of animal feeds are to be found. Companies that meet these standards, receive a certificate. Participating in the Standard GMP Animal Feed is voluntary.*

[2] *See Standard GMP Animal Feed, appendix II, art. 4.6.1 and appendix IV, article 4.6.1 and appendix X, article 4.6*

[3] *See Standard GMP Animal Feed, appendix V, art. 4.6.1*

2 SCOPE

The option of being recognised as *GMP equivalent* is only important for
- certified[4] suppliers of feed materials to GMP approved companies
- certified suppliers of feed additives[5] to GMP approved companies.

The Product Board Animal Feed wishes, within the framework of the Standard GMP Animal Feed, to harmonise as much as possible with existing certification. *GMP equivalence* involves suppliers who are already certified on the basis of another acceptable quality standard, for example ISO or HACCP. A major target group is the food industry who sells waste flow products in the animal feed sector. These suppliers often have a certified ISO and/or HACCP system within the framework of their food production. A second important group is made up of the producers of feed additives who often have a form of quality assurance which is based and certified on one of the ISO or HACCP standards. The quality assurance of these suppliers can, if certain conditions are met, be recognised as GMP equivalent. This is explained further in the following chapters.

Suppliers of feeds or feed materials domiciled in the Netherlands ought to at least meet the condition of GMP equivalence. Only then may GMP certified animal feed companies and feed material traders[6] purchase their products. This also counts for suppliers of feed additives, who are domiciled abroad. Suppliers of feed materials domiciled abroad [7]may also be approved as GMP equivalent. These companies may, however, also make use of option 4 in chapter 1. For further information on this you are referred to:
- Protocol Verification Audits Foreign Suppliers of Feed Materials
- Standard Quality Control of Feed Materials for Animal Feed – Requirements for a Quality Control System by Foreign Suppliers.

[4] *Zie paragraaf 4.2.*
[5] *Feed additives as defined in appendix I, chapter 3.1 Terms and definitions in the Standard GMP Animal Feed. The definition is also included in Chapter 3 of this protocol.*
[6] *By this both the GMP certified animal feed companies and feed material traders in the Netherlands and abroad are meant. The object is that all GMP certified animal food companies and traders of feed material traders apply to the same conditions when buying feeds and products from producers of feed materials.*
[7] *Abroad should be understood to mean: all countries except the Netherlands*

3 DEFINITIONS AND NOTIONS

Basic Quality: The characteristics of feed additives and veterinary medicines, premixes, feed materials and animal feed that:

a) are laid down in legislation (in the European Unions, and, in addition, nationally) for the benefit of the safety of the animal, the consumer of foodstuffs of animal origin, and/or the environment;
b) as a supplement to a) are formulated on the basis of consensus in the animal feed sector after consultation with the organisations of the livestock sectors concerned, and the related (processing) industries.

Foreign countries/Abroad: All countries except the Netherlands

Committee of Experts Animal Feed Sector:
Committee within the animal feed sector that issues binding advise to the Product Board Animal Feed concerning the certification scheme GMP/HACCP, with members from interested organisations.

Standard GMP Animal Feed:
The Good Manufacturing/Managing Practice standard of the Product Board Animal Feed in The Hague (Netherlands) This standard document specifies the requirements regarding business direction, management, process conditions, processes, procedures, responsibilities and facilities, which must be met to guarantee that the basic quality is realised.

GMP-equivalent quality system:
A quality system with which the basic quality of animal feeds and animal feed materials is guaranteed as required in the Standard GMP Animal Feed, and which as such has been declared equivalent by the Product Board Animal Feed.

HACCP-criteria (for food): Criteria for Assessment of an Operational HACCP system (1998). Compiled by the Dutch National Committee of Experts-HACCP.

ISO-9001-standard The standard ISO-9001 (1994): ' Quality systems. Model for the quality assurance for drafting, manufacturing, installation and after-sales service'. The Product Board Animal Feed takes action to re-write the GMP+ standard according to the arrangement of the standard ISO-9001-2000. This will be carried out in 2002.

Supplier A company that supplies feed materials or feed additives to a GMP-approved company

Feed additives Feed additives as defined in directive 70/524/EC concerning feed additives in the feed sector

4 GMP EQUIVALENCE

4.1 GMP versus ISO/HACCP

4.1.1 GMP and ISO-9001[8]

The Standard GMP Animal Feed has been set up according to the arrangement of *ISO-9001- standard.* This applies namely for the so-called system components. Some requirements, however, have been ' translated' into specific animal feed (production) activities and situations. The contents have thereby not been essentially affected.

4.1.2 GMP and HACCP

The Standard GMP Animal Feed with HACCP is indicated as GMP$^+$ -standard. That means that the Standard GMP Animal Feed, as described above, has been extended with all necessary HACCP elements. In fact the HACCP standard for the food industry[9] is fully integrated in the Standard GMP Animal Feed for the animal feed sector. The HACCP requirements – just as the requirements from the ISO-9001 standard - are focused on specific feed-activities and -situations .

By the full integral entry of HACCP-food requirements in the Standard GMP Animal Feed the contents and range of safety and quality assurance in the animal feed sector is at least equivalent to those in the food industry. This promotes transparency and ambiguity.

4.1.3 GMP goes further

On a number of components, however, the Standard GMP Animal Feed requires more than the ISO-9001 standard, and the HACCP criteria for the food sector. In fact the ISO-9001 standard makes demands on the quality assurance system, and HACCP is a quality assurance system aiming at food safety.
Besides, the Standard GMP Animal Feed lays down conditions on the process and the (end) products. It also makes demands on specific, branch oriented requirements to:

- the application of control actions
- the verification of control actions taken.
- meeting product standards. The latter are included in a separate decree, with standards and limits of action for many specific products.
- the operation of Internal Company Inspections. The requirements for these inspections are also laid down in a separate decree, with minimal frequencies for sampling and analysing. Analytical research ought to be carried out by certified laboratories[10] for those purposes by the Product Board Animal Feed.

Besides, the HACCP in the animal feed sector asks for

- attention for the purchase of products
- a very detailed hazard analysis
- the use of a specific decision tree
- motivation of the judgement

The Standard GMP Animal Feed lays great emphasis on the insight into the control of the critical points in the route of the suppliers of the feed material.

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[8] ISO-9001(1994) 'Quality systems: Model for the quality assurance when designing, producing, installing and after-sales service. The Product Board Animal Feed takes action to re-write the standard GMP Animal Feed according to the arrangement of the standard ISO-9001-2000. This will be effectuated in 2002
[9] Testing criteria HACCP: Criteria for testing of an operational HACCP system (1998).
CCP system (1998)
[10] If a foreign laboratory is used, a recognition by the Product Board Animal Feed is not required. The laboratory must show that at least an equivalent type of quality assurance is applied. See for more details the FAQ-list on the PDV-website.

4.1.4 Summary

The Standard GMP Animal Feed contains all components of the ISO-9001-standard and the HACCP criteria. Besides, the application of specific GMP control actions is required. By the application of requirements from the Standard GMP Animal Feed the safety and quality of the animal feeds and feed materials are assured at a number of levels (system, process and product respectively).

4.2 GMP equivalence for the supplier of animal feed materials

In the Standard GMP Animal Feed, art. 4.6.1 of appendixes II, IV and V and also art. 4.6 of appendix X, it is required:

> *……..*
>
> *2) If the supplier of animal feed materials is not GMP-certified, at least demonstrably equivalent (e.g. ISO 9001/2 and HACCP certified) guarantees have to be granted, in which at least the following matters are realised, and to which the supplier has undertaken by contract towards his purchaser (a GMP-certified company):*
>
> *a) the standards and conditions by virtue of the Standard GMP Animal Feed must be applied, including the specific control actions (as far as applicable) and*
>
> *b) other possible control actions and checks, which are derived from an analysis, based on HACCP.*
>
> *……"*

GMP-equivalent quality assurance is applied by the supplier to those products which may be used in the animal feed sector. For a food company this means that, for example, the waste flows which are sold to animal feed companies should fall within the scope of the quality assurance system. The quality assurance for these waste flows should be GMP equivalent.

The quality assurance of a supplier is equivalent to that which is required in the Standard GMP Animal Feed, if in the quality assurance system:

1. the relevant ISO system elements have been included so that a robust and reliable quality system is created, and
2. the relevant HACCP principles have been included so that a sufficiently in-depth evaluation, assessment and controlling of the risks is guaranteed (focused on the safety of humans, animals and the environment), and

3a in the event of the production of food then also included in the scope of the quality system are the waste flows which are intended for feed materials, and the quality and safety of these waste flows complies with the requirements and conditions formulated in the Standard GMP Animal Feed. By this is meant:

- the use of specific (control) measures formulated in the Standard GMP Animal Feed
- ensuring that there is compliance with the specific standards and requirements in as far as they have been set for feed materials
- the carrying out of inspections in accordance with minimum frequencies in as far as these have been laid down.

3b in the event of the production of feed additives then also included in the scope of the quality system are the feed additives which are intended for feed, and the quality and safety of these feed additives complies with the requirements and conditions formulated in the Standard GMP Animal Feed. By this is meant:

- the use of specific (control) measures formulated in the Standard GMP Animal Feed
- ensuring that there is compliance with the specific standards and requirements in as far as they have been set for feed products
- the carrying out of inspections in accordance with the laid down minimum frequencies in as far as these have been laid down.

In order to be able to implement a GMP equivalent quality assurance, the supplier will have available the relevant regulations and other documents which the Product Board Animal Feed publishes within the framework of the Standard GMP Animal Feed and the associated regulations.

In this way they can guarantee that that new requirements and guidelines in the field of the Standard GMP Animal Feed are known and can be implemented.

Re 1) and 2)

The supplier will have at least one quality system which has been independently verified (preferably certified) whereby the basic quality (as defined in the Standard GMP Animal Feed) of feed materials and/or feed additives is demonstrably guaranteed. This may be shown, for example, via an ISO-9001 or HACCP certificate[11].
There are, however, also food companies for whom the above-mentioned certificate is not (legally) required. These suppliers have no (certified) quality assurance system. A certificate within the framework of a relevant hygiene code or other quality standard may also form a basis whereby a supplier may be declared to have GMP equivalence for the quality assurance of his waste flows. This will be decided by the Product Board Animal Feed.

Appendix 1 indicates which parts are in the Standard GMP Animal Feed but not in the ISO or the HACCP standards[12]. This summary can be used by the supplier to find out with which requirements he still has to comply. The major conclusions from the comparison between the GMP$^+$ standard and the ISO or HACCP standards are:

- Suppliers who have a *certified ISO-9001 quality assurance system* comply to a great extent with the requirements in *appendix I. General* of the Standard GMP Animal Feed. It is important that the scope of the system includes the waste flows (which are often sold as animal feed material).
  In addition there should be compliance with the conditions and requirements of the other relevant appendices to the Standard GMP Animal Feed. For suppliers of animal feed materials it is particularly a matter of the requirements in appendix V. For suppliers of feed additives the requirements of appendix X are important. In addition the relevant requirements in the additional decrees should be demonstrably complied with.

- Suppliers who have a *certified HACCP quality assurance system* comply to a great extent, but not completely, with the requirements in *appendix I. General* of the Standard GMP Animal Feed. Some system requirements may possibly still have to be implemented in the quality system. See the summary for this.
  It is important that the scope of the system includes the waste flows (which are often sold as animal feed material). In addition there should be compliance with the conditions and requirements of the other relevant appendices to the Standard GMP Animal Feed. For suppliers of animal feed materials it is particularly a matter of the requirements in appendix V. For suppliers of feed additives the requirements of appendix X are important. In addition the relevant requirements in the additional decrees should be demonstrably complied with.

Suppliers can make clear, using a reference table based on the enclosed summary table, that the GMP conditions have been met and that there is, in fact, GMP equivalent quality assurance.

The Product Board Animal Feed publishes suppliers who use GMP equivalent quality assurance on a public list. GMP-approved animal feed producers and traders are entitled to purchase feeds from these suppliers
Suppliers will be placed on this list if the certification body approved by the Product Board declares that the requirements set in the Standard GMP Animal Feed and the standards specified in this protocol have been met.

[11] *Certified on the basis of an accredited certification schedule. See also for this, and for the additional criteria for certified bodies, chapter 5.*
[12] *As mentioned, also other standards can be used as a basis for GMP Equivalence. In this protocol (in appendix 1) a comparison is made between the standard GMP Animal Feed and some most used other quality standards, like ISO-9001 and HACCP.*

5 CRITERIA FOR ISSUING A STATEMENT OF GMP EQUIVALENCE BY A CERTIFCATION BODY

5.1 General

The Product Board Animal Feed considers a quality system of a producer of feed materials to be GMP-equivalent, if to the satisfaction of the Product Board Animal Feed the conditions mentioned in this protocol are met.

By doing so the Product Board Animal Feed has the intention to create transparency and clarity as to the contents of the GMP equivalence statement with suppliers. The object behind this is that the purchasers (the GMP certified companies) have confidence in the statement issued by certification bodies, and so also have confidence in the quality assurance system as applied by their supplier.

Certification bodies play an important role determining whether a supplier can be labelled as GMP equivalent for those products which might be sold in the animal feed sector. Preferable, GMP equivalence is determined in an additional audit to the ISO-9001- or HACCP-audit. In this additional audit all the relevant elements from the Standard GMP Animal Feed, which are not covered in the ISO-9001 or HACCP-audit, are checked

The Product Board Animal Feed as yet not requires that this additional GMP-audit is a part of an accredited certification scheme. But it is required that the performance of this additional GMP-audit, the review of the nonconformity's, the sanctions and other elements that are part of a normal certification-scheme, are applied to in the same way as in the accredited ISO-9001 or HACCP certification scheme, and meet the conditions of this protocol. The Product Board Animal Feed may issue certain guidelines on this matter.

If the above is met, the Product Board Animal Feed speaks of a certification scheme that is equivalent to GMP certification. Insight into the equivalence must be provided by means of a reference table or by means of other documentation.

This will be further gone into in the following sections.

5.2 Independence and expertise

Within the framework of this protocol, the certification body is accepted by the Product Board Animal Feed when the following criteria are met:

- independence
- expertise, both with regard to the field (feed[13]) and the manner of inspection ('audit').

The certification body has demonstrated this *independence and expertise* when it has been accredited by the Council for Accreditation or to the satisfaction of the board by a comparable national accreditation body for:

- certification ISO-9001 quality systems according to EN-45012, or
- certification HACCP systems according to EN-45012

and/or

- certification equal[14] systems according to comparable standards.

Further the certification body has to have demonstrable knowledge of the field "feed".

It has the relevant regulations and other documents which the Product Board Animal Feed issues within the framework of the Standard GMP Animal Feed and regulations linked to it. It hereby guarantees that new requirements and directions in the field of the Standard GMP Animal Feed are known.

[13] *By feed we also mean feed materials in this protocol. It is about the field of animal feeds and animal feed materials.*

[14] *This equality is at the discretion of the Product Board Animal Feed. Important is for what type of feed materials a statement of GMP Equivalence has to be made*

5.3 The manner of auditing and assessing

The certification body describes the manner in which the components relevant for GMP can be tested additionally. This description at any rate contains the following components:

- A document (in the form of a table) which brings into vision in an orderly manner which GMP components are already audited within the framework of the ISO/HACCP certification;
- A supplementary *audit protocol* with which the missing GMP-components are audited. In appendix 1 it is indicated which components do occur in GMP+, but not in the ISO, HACCP criteria respectively. This survey may be used for setting up a checklist or something of the sort.
- Assessment criteria, per audit-element (sufficient, minor or major nonconformity's). The auditor classifies the observations on the basis of assessment criteria(sufficient/minor/major) For general guidelines see appendix 4.
- A system for guarding the improvements agreed.

5.4 Auditors

The certification body puts auditors into action who are professional and qualified to be able to carry out audits in the field of feed as well. This means at any rate that the auditor is qualified to audit ISO-9001 and HACCP quality systems respectively. Besides, the auditor has to have demonstrable knowledge of the feed sector. The certification body lays this down in an (internal) document (e.g. a quality matrix).

Requirements demanded of the auditor are:

- He has had relevant training/education
- He has knowledge of systems (quality assurance systems and organisations)
- He has sufficient experience in performing ISO/HACCP-audits
- He has demonstrable material expertise ('feed')

The Product Board Animal Feed attaches great importance to the expertise of the auditor. The certification body has to demonstrate to the satisfaction of the Product Board Animal Feed that an auditor meets the requirements demanded. The Product Board Animal Feed can further make the requirements demanded concrete.

5.5 Reporting

In the report it has to be made explicitly clear that additionally GMP-elements have been audited. This implies at any rate that shortcomings in GMP components are named, including the assessment and the possible arrangements concerning actions for improvement.

5.6 Harmonisation

The Animal Feed Sector Inspection Board (KDD) has a central role in the harmonisation of the supervision carried out on behalf of the Product Board Animal Feed by the approved certification bodies under this GMP equivalence protocol. This harmonisation of the supervision consists of two parts.

5.6.1 Assessment

This means that the general method of auditing and assessing of the certification body is assessed. This is made up, for now, of the following

- a document review;
- yearly attendance at an audit at one or two suppliers where the certification body has issued a statement of GMP equivalence (*joint audit*);
- yearly carrying out a re-check at one or two suppliers where the certification body has issued a statement of GMP equivalence (*audit afterwards*).
- the taking of samples at GMP equivalent suppliers to verify the supplier's own inspections

In this harmonisation the KDD will pay particular attention to the expertise of the auditor (see also 5.4). This expertise must not only be shown in writing but also be demonstrated in practice.
The results will be recorded, discussed with the certification body in question and may be reported to the Product Board Animal Feed. If operations are not in accordance with the guidelines established by the Product Board Animal Feed then Product Board Animal Feed is entitled to establish further conditions for improvement.

5.6.2 Guidance

In addition to a formal assessment of the certification body, a so-called harmonisation meeting ('technical meeting') will be organised between the Product Board Animal Feed and the certification bodies. The agreement between the Product Board Animal Feed and the certification bodies will include the fact that technical questions to be discussed will be raised in this regular harmonisation meeting. Experts (‘auditors’) from the various approved certification bodies will be represented in this meeting. The KDD will also play a central role in this harmonisation meeting
Working agreements will be made and recorded in this meeting. Questions of a more complex nature will be laid before the Committee of Experts for the Animal Feed Sector.

5.6.3 Evaluation

The Animal Feed Sector Inspection Board will evaluate together with the certification bodies the way in which there is an attempt at uniformity. The form and content may be changed depending on developments and experience.

6 PROCEDURE FOR ACCEPTANCE OF A CERTIFCATION BODY

6.1 Registration

The certification body that wishes to issue a statement about GMP equivalence as meant in this protocol, presents itself with a registration form (see appendix 3). The Product Board Animal Feed confirms this registration in writing.

6.2 Documentation

The certification body provides documentation concerning the following points

- A valid accreditation certificate.
- A valid list of activities (an annex to the accreditation certificate) from which it appears that it may issue an ISO or HACCP certificate respectively. It must also appear that the field ('matrix') concerns the feed sector. The certification body can forward additional documents to demonstrate that it meets these conditions, e.g. a description of the standards or something the like.
- A description of the total operation procedure of auditing and assessing, as meant in section 5.3
- Relevant instances of documents that are used for certification, in which the components especially important for GMP are indicated.
- A document in which qualified inspectors are included (CV, experience)
- An example ('model') of a report

6.3 Assessment of documentation forwarded

The KDD assesses the documentation forwarded. Of course confidentiality is observed here. In consultation with the certification body the KDD attends a couple of audits. During these audits the certification body tests the components relevant for GMP with a view to issuing a GMP statement of equivalence.
The KDD reports its findings to the Product Board Animal Feed.

6.4 Acceptance

On the basis of this judgement the Product Board Animal Feed acts as follows:

- it accepts the certification body and concludes an agreement, or
- it postpones the acceptance in a well-founded manner, and asks for additional documentation, or
- it rejects the certification body. A motivation is given here as well.

6.5 Compensations

On acceptance by the Product Board Animal Feed the certification body has to pay a compensation to cover expenses, which the Inspection Service of the Product Board Animal Feed makes within the framework of supervision on supervision. The compensation consists of a fixed sum and an amount per GMP equivalent supplier. These sums ought to be paid annually.
These annual amounts are laid down in the PDV Decree Verification Bodies Contribution 2002 (appendix 5).

6.6 Agreement and entry in the register

The Product Board Animal Feed and the accepted certification body conclude an agreement, in which the rights and duties are laid down. For this see appendix 2.

The following will be declared to the inspection body:

The Product Board Animal Feed hereby declares that the certification body <<Name>> meets the criteria laid down in the Protocol GMP equivalence for Suppliers of Feed materials and Feed Additives for Animal Feed. It may declare to suppliers of feed (animal feed materials) that the quality assurance system meets the demand of GMP equivalence, as referred to in section 4.6.1, 2nd paragraph, sub 2 of appendices II, IV V or X of the Standard GMP Animal Feed, and as specified in appendix 1 of above protocol.

The Product Board Animal Feed puts the accepted certification body on a public list.

In accordance with above statement, the certification body is entitled to provide the following text on a certificate when a supplier has been audited for GMP-equivalence successfully

This is to certify on behalf of the Product Board Animal Feed that the quality assurance of <Supplier name> applied when producing products intended to be used in the animal feed sector, is equivalent with the quality assurance defined in the Standard GMP Animal Feed for suppliers of feed materials for animal feed.
In recognition of this, you are entitled to announce that your quality system meets the requirements for GMP equivalence.

6.7 Other conditions

The acceptance applies for the duration of the accreditation as referred to in 5.2.

Interpretations and realisations of the demands and conditions in this protocol will initially be published by means of the Question and Answer list. Extension GMP in the feed materials channel. This list is to be found on the PDV web site (www.pdv.nl). The interpretations and realisations will be incorporated In the next update of this protocol (schemed in 2002).

7 APPENDIX 1: COMPARISON TABLE GMP+ WITH HACCP AND ISO

1. Introduction

The table on the next pages gives a survey of the requirements from the Standard GMP Animal Feed with the corresponding requirements from the ISO-9001 standard and the HACCP criteria[15] (for the food). It is indicated which requirements correspond, and where the standards differ.

The table departs from the GMP+ standard General and the additional Standard GMP Animal Feeds for the specific types of companies.

Note: Although this table has been made very carefully, perhaps not all the items mentioned might be clear. In case there is doubt about what exactly is the meaning of an item or (abbreviated) requirement, please check the Standard GMP Animal Feed!!

2. General remarks

GMP sets requirements to the following elements:

2.1 The quality system.

To a high degree this is based on the ISO-9001 standard.
These requirements are to be found in the Standard GMP Animal Feed General (appendix 1 of the Standard GMP Animal Feed). There is hardly any difference between the Standard GMP Animal Feed General and the ISO-9001 standard). All the requirements formulated in the ISO-9001 standard for setting up an adequate quality system, are found .in the Standard GMP Animal Feed General.
The general difference is that the system requirements in the Standard GMP Animal Feed aim at meeting the basic quality of animal feeds, while ISO formulates quality systems that are unconnected with a specific industrial or economic sector.

2.2 The safety

The HACCP requirements entered in the Standard GMP Animal Feed are practically in accordance with the HACCP criteria for food.
These requirements are also to be found in the Standard GMP Animal Feed General (appendix1 of the Standard GMP Animal Feed).

2.3 Specific management actions

On a number of specific points GMP requires more than ISO. In that case it is about the operation of specific management actions (whether for specific types of business or not), for instance with a view to towing or hygiene, meeting specific standards, performing (internal business) research in products.
These requirements are to be found in

- The additional standards for specific business types/activities (appendixes II – IX of the Standard GMP Animal Feed). In the survey the following additional standards have been incorporated
  - Appendix V: Trade and production of feeds, destined for certified compound feed manufacturers and suppliers of feeds (GHP/GH)
  - Appendix VII: Storage and transhipment of feeds (OO)
  - Appendix VIII: Transport of feeds, premixes and compound feeds (road transport) (TVw)
  - Appendix IX: Transport of Feeds, premixes and compound feeds (seagoing, inland waterways shipping and rail (TVs)
  - Appendix 10 Trade and production of feed additives (THP/TH)

Other important documents related to the above mentioned, are:

- The Decree PDV Animal Feed Product Norms 1999
- The Decree PDV on internal company inspections and GMP controls in the animal feed sector 1998

[15] *The standards, most commonly used*

- The Decree Product Board Animal Feed Regulations for approval laboratories internal company inspection animal feed sector 1996.

Note: All these documents are in the manual GMP regulations animal feed sector, published by the Product Board Animal Feed

3. Conclusions

Below please find a couple of conclusions. They may also be considered to be general guidelines for the use of the survey below, to be able to demonstrate GMP equivalence.

- Companies with a *certified ISO-9001 quality assurance system* to a large extent meet the requirements, in *appendix 1.General* of the Standard GMP Animal Feed, but not fully, It is important that the scope of the system includes the residual flows (which are mostly sold as animal feed materials.
  Further the conditions and requirements from relevant other appendices from the Standard GMP Animal Feed, as well as relevant requirements from additional decisions, ought to be implemented in the system. Suppliers of animal feed materials namely the requirements from appendix V matter.

- Companies with a *certified HACCP quality assurance system* to a great extent meet the requirements in *appendix 1* General of the Standard GMP Animal Feed, but not fully. Some system requirements will still have to be implemented. For this please see the survey. It is important that the scope of the system includes the by-products (which are mostly sold as feed materials). Further the conditions and requirements from relevant other appendices from the Standard GMP Animal Feed, as well as relevant requirements from additional decrees, ought to be implemented in the system.

By means of a reference table, based on enclosed survey table, companies can make clear that all GMP conditions are met, and that as a result there is a question of GMP equivalence.

4. Final remarks

This survey is no more than an aid to both certified ISO or HACCP companies to check which components still have to be implemented in the system to be considered GMP equivalent.

This survey may also be used by certification bodies to additionally audit on GMP equivalence on the basis thereof. For that purpose this survey may be rewritten into a checklist or something of the kind.

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
0						
1	Scope					
2	Normative references					
3	Definitions					
4	Quality system requirements					
4.1	Management responsibility					
	General					
4.1.1	*Quality policy*					
	determining quality policy	x		x		
	determining policy and objectives regarding safety of feeds	x			x	
	determining scope of the HACCP system	x			x	
	connecting quality policy to chain programmes	x				
4.1.2	*Organisation*					
4.1.2.1	*Responsibility and authority*					
	determining responsibility and competence of person-nel	x		x		
	determining responsibility and competence within the framework of safety of feeds and animal feed materials	x			x	
	determining an organisation scheme	x			x	
4.1.2.2	*Resources*					
	identifying necessary resources and taking care of business accommodations, installations and tools	x		x	x	
	identifying and taking care of skilled personnel	x		x		

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.1.2.3	*Management representative*					
	appointing member of the own management	x		x		
	HACCP-team					
	setting up a HACCP team	x			x	
	determining criteria for team members and the function and required expertise of the team members	x			x	
4.1.3	*Management review*					
	assessment of the quality system as to efficiency	x		x		GMP demands min. 1x/year
4.2	Quality system					
	General					
4.2.1	*General*					
	drawing up a quality manual	x		x	x	
	laying down the manner in which the organisation guarantees safety of animal feeds and animal feed materials	x			x	
	naming points nonconforming the Standard GMP Animal Feed, and also how basic quality is as yet guaranteed	x				
	appointing one responsible person for management of the manual	x				
4.2.2	*Quality system procedures*					
	lay down procedures in writing	x		x	x	
	implementation of the quality system	x		x	x	
	attune procedures at the level of personnel	x		x	x	
	also applies for temporary personnel	x				
4.2.3	*Quality planning*					
	determining the planning of quality control of critical points	x		x	x	HACCP requires monitoring

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation	
4.2.4	*End product specification*						
	determining specifications of animal feeds to be delivered, feed additives and animal medicine, premixes and /or feed materials	x					
	determine product specifications etc. on behalf of HACCP	x			x		
	operating instructions of the product produced	x				also see 4.15	
	Feed additives (T)						
4.2T	*Quality system*						
	Analysis tolerances established (at least legal)		x				*with the n code this 4.3*
4.3	Standards (Contract review)				I	In ISO this is called *Contract assessment. In GPM the standards PVD has laid down in the decision Standards have to be met*	
	General						
4.3.1	*General*						

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	- products and services must demonstrably meet the basic quality. Here it is about: - legal standards - supra-legal standards - possible demands of customer	x		x		Here GPM goes much further than ISO by explicitly setting standards that must at least be met. They are specified in the Standard GMP Animal Feed. It is about • basic quality standards art. 2: various regulations (legal) • additional standards art. 3: aflatoxin art. 4: salmonella art. 4a feeds and compound feeds art. 5: feeds and moist feeds art. 6: cancelled art. 7: storage and transhipment of animal protein art. 8: cancelled art. 9: processing of Cu/Zn in compound feeds Dependent on the feed materials one or more of above standards apply.
4.3.2	*Accepting an order (review)*					
	reviewing the order	x		x		The supplier must check whether the Standard GMP Animal Feeds can be met.
	delivery of product at the location/silo arranged	x				See 4.15 as well
4.3.3	*Records*					This paragraph is comparable with ISO 4.3.4. ISO 4.3.3 is *called Amendment to a contract*. ISO 4.3.3 requires that changes in agreements are communicated in the right manner within the business
	recording of commissions and orders of buyers for tracing	x		x	x	See e.16 as well
	Feed materials (G)					
4.3.1G	*Undesirable substances and products*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
.	Action of mixing of feeds established		x			
4.3.2G	*Working hygienically*					
	Microbiological quality controlled					
	Storage and transhipment (O)					
4.3.1O	*Points of departure*					
	Responsibility: quality of the service Acceptance policy apart from quality/condition of feeds		x			
4.3.2O	*General*					
	Make ST&TR service known to purchasers (including requirements of buyer) - Procedures for acceptance of commissions - Keeping feeds apart - Manner of treatment during ST&TR - Cleaning procedures - Relevant qualities of hygiene established including tolerances (temperature, moisture, smell, colour, vermin etc.		x			
4.3.3O	*Undesirable substances and products*					
	No harmful changes in basic quality		x			
4.3.4O	*Working hygienically*					
	Microbiological quality of service controlled		x			
	Road transport (TVw)					
4.3.1TVw	*Points of departure*					
	Responsibility: transport service GMP certified transport company, or GMP certified animal feed supplier with own transport GMP acknowledgement for transport Except transport of packed products Acceptance policy apart from quality/condition of products		x			
4.3.2TVw	*General*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	Make service clear to purchasers of bulk transport (including demands of purchaser) Procedures for acceptance of commissions Establishing relevant features of product (moisture, temperature, smell, colour, vermin etc.) Establishing actions to be taken and cleaning and disinfection procedures Packed goods: clean and dry loading compartments		x			
4.3.3TVw	*Avoiding risks of towing of feed additives and animal medicine*					
	Record of order of transport to avoid cross-contamination		x			
4.3.4TVw	*Undesirable substances and products*					
	No harmful changes of basic quality		x			
4.3.5TVw	*Working hygienically*					
	Hygienic transport controlled		x			
4.4	Design control					
	not applicable					
4.5	Document and data control					
	General					
4.5.1	*General*					
	management of documents and data concerning GMP	x		x	x	
	taking care that alterations of the law and GMP are implemented in the quality system	x				This paragraph matches ISO-4.3.3
4.5.2	*Document and data approval and issue*					
	setting up procedures for drafting, approving and issuing of documents	x		x	x	
	recording date of latest alteration on each page	x				
4.5.3	*Documents and data changes*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	set up procedure for alteration of contents of the GMP manual	x		x	x	
	Transport seagoing, inland waterways shipping and rail (TVs)					
4.5TVs	Management loading agreements, distribution orders till LCI and the LCI reporting		x			
4.6	Purchasing					
	General					
4.6.1	*General*					
	setting up written procedures for the purchase of products. Taking care that the basic quality is met (4.3)	x		x		
4.6.2	*Evaluation of subcontractors*					
	keeping up an actualised list of suppliers of products and services	x		x		
	Annual evaluation of suppliers of products and services	x		x		
4.6.3	*Purchase data*					
	setting up specifications of products to be received	x		x	x	
	setting up of and release of product specifications to be newly bought	x		x		
	keeping the accounts of an administration of products received	x				This is found in ISO 4.8
4.6.4	*Verification of purchased products*					
	make arrangements with third parties (services) concerning receipt of products	x		x		ISO 4.6.4.2 is not found in GMP
	Feed materials (G)					
4.6.1G	*General*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	Purchase of feed materials from - GMP certified suppliers - GMP equivalent suppliers - KPA farmer		x			
	If supplier from a foreign country does not meet the above, then one has to meet the requirements from the Standard Quality Control of Feed materials for Animal Feed		x			
4.6.2G	*Working hygienically*					
	Microbial quality guaranteed, insight and/or sampling		x			
	Transport, seagoing, inland shipping and rail (TVs0					
4.6.1TVs	*General*					
	Guarantee procedure a) foreknowledge previous load b) pre-selection transport according to law and/or rules c) liquid agri-bulk (tank transport) on the basis of HACCP system d) Acceptation by transport feeds: LCI by (certified) inspection organisation (EN 45000/iso 9000) e) distribution of instruction by LCI to inspection organisation f) Loading after approval of LCI reportage g) Guaranteeing loading control		x			
4.6.2TVs	*Procedure putting out to tender of transport (Feed Safety)*					
4.6.2.1TVs	*Order distribution for loading*					
	Included in transport agreement: a) loading compartment purity clause b) state nature/name of previous loads c) loading compartments inspection clause d) clear description of goods		x			
4.6.2.2TVs	*Recording the loading*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	Include in transport agreement the minimum number of elements to be contained in the record of loading (according to this paragraph)		x			
	Feed Additives (T)					
4.6T	*Purchasing*					
	Purchase of raw materials and auxiliary substances and feed additives from - GPM certified suppliers - GPM equivalent suppliers		x			
	If the foreign suppliers of raw materials and auxiliary substances does not meet the requirements above, then one has to meet the requirements from the Standard Quality Control of Feed Ingredients for Animal Feed.		x			
	Storage of feed additives and raw materials and auxiliary substances: GMP-recognised storage and transhipment or minimal equivalent guarantees		x			
4.7	Control of the customer-supplied product					
	General					
4.7	carrying out checks on reception of goods delivered by the buyer	x		x		
	supervise the processing of registered animal medicine only	x				is a typical GMP addition
4.8	Product identification and traceability					
	General					
4.8	Setting up and carrying out a good tracking & tracing system	x		x	x	Further also see GMP 4.6.3.
	preservation and registration	x		x	x	4.16
	Storage and transhipment (O)					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.8O	*Adequate administration*					
	- feed materials per principal - possible covering documents, certificates - names of customers of the service - linking arriving/outgoing shipments (quick insight Into this)		x			
	Road transport					
4.8TVw	*Transport order received from principal including product categories in accordance with decision*		*x*			
4.8TVw	*Adequate administration*					
	- Amounts, types and category code of product per principal - Possible covering documents, certificates - loading and unloading addresses - Identification and coding of bulk loading compartments - order of transport		x			
	Transport, seagoing inland shipping and rail (TVs)					
4.8.1TVs	*Processing of order for the Inspection of the Load Compartments*					
	Information provided contains the necessary elements and has been confirmed by loading inspector		x			
4.8.2TVs	*Processing of the order for operation by LCI*					
	Procedures (according to this paragraph) by checking organisation to be processed into working instructions for LCI to be incorporated in own quality system (EN 45000)		x			
4.8.3TVs	*Report of the findings during the inspection of the load Compartments*					
	Contents LCI report (in accordance with this paragraph) Keep report for at least 7 years		x			

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.9	Process control					
	General					
4.9.1	*General*					ISO 4.9 is very short. In the Standard GMP Animal Feed this is worked out in numerous paragraphs + additional standards, appendices II – X. All the requirements of 4.9 are practically all pure GMP.
	describing the product process in accordance with the range of the system	x			x	
	controlling the critical points by means of specific control actions	x		x		
4.9.1.1	*Process schemes*					
	describing the production process in process schemes or flow charts	x			x	
	verifying the process schemes after alterations	x			x	
4.9.1.2	*Business organisation*					
	avoid cross- contamination or unintentional mixing	x				se 4.1.2.2. as well
	recording production units, storage rooms and facilities for personnel	x			x	
	store in a hygienic manner	x				
	setting up limitations at the entrance of the storage	x				
4.9.1.3	*Suppression of vermin*					
	take actions to suppress birds, domestic animals and vermin	x				
	recording of suppression programmes applied	x				
4.9.2	*Dangers, risks and control actions*					
4.9.2.1	*Indication of danger*					
	identification and analysis of all potential dangers of all production processes	x			x	

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.9.2.2	*Risk analysis*					
	carrying out risk analysis per identified danger	x			x	
4.9.2.3	*Control actions*					
	recording of control actions for danger and risk analysis	x			x	
4.9.2.4	*Assessment of critical control points*					
	carrying out an assessment of each process step	x			x	
	indicate the aspect upon which assessment is made	x			x	
	indicate whether a danger is a CCP or PoA	x			x	
4.9.3	*Industrial hygiene and documentation*					
	take actions for adequate industrial hygiene	x				
	Setting up of production and storage regulations regarding microbiological quality	x				
	include hygiene protocols in GMP manual	x				
	Feed materials (G)					
4.9.1G	*Storage*					
	Unloading harbours and other places within Europe. GMP-certified or reporting to purchaser equivalent guarantee		x			
4.9.2G	*Production*					
	Ban on use of feed materials Use of too high levels during production Stock-taking of safety; auxiliary substances/cleaners Procedure cleaning of storage rooms and release		x			
	Storage and transport (O)					
4.9.1O	*General*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	No mixing during storage (basic quality) Action in the direction of interested parties Identification transport and storage room Procedure running empty of transhipment route		x			
4.9.2O	*Undesirable substances and products*					
	Procedure of assurance of undesirable substances and products especially if non-feed materials are stored.		x			
4.9.3O	*Working hygienically*					
	Procedure control of industrial hygiene Prevention and correction of rain coming in Control of storage life and quality Cleaning and release after contamination		x			
	Road Transport (TVw)					
4.9.1TVw	*General*					
	No mixing during transport and action in case of nonconformities Identification of loading compartments and traceability Cleaning procedures; inspection before each transport and record of cleaning and disinfecting operations with assessment of the result, and initials by driver in the driving list Logbook office data of driving lists (combine at least once a month) Log (with driving lists) keep for 7 years		x			
4.9.2TVw	*Undesirable substances and products*					
	Procedure prevention of pollution with undesirable substances and products (especially if non- feed materials are also transported)		x			
4.9.3TVw	*Working hygienically*					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	Procedure control of hygiene during transport Procedure avoiding and correcting the rain coming in and splashes in case of dry products Clean and dry cover sail cloth , also in case of empty compartments Outside of transport, including chassis, free of visible components of previous load Procedure control of storage life and quality Procedure of cleaning and release after transport of contaminated shipments		.			
4.9.4TVw	*Order of transport, loading together and disinfection*					
4.9.4.1TVw	*General*					
	Determining the product category of previous and new loads prior to loading Establishing that there were no transports of 'forbidden loads' of category 1 (unless certified according to president's decision PVD) Always disinfect after category 2 Cleaning with water after category 3 Visual inspection whether clean and dry before each transport		x			
4.9.4.2TVw	*Basic principles for cleaning and disinfecting*					
	A) Dry cleaning, vacuum, blowing out or sweeping (brush)		x			
	B) Cleaning with water; procedure a) Remove residue (dry) b) Advance rinsing cold or warm water, possibly by hand with brushes c) High pressure cleaning with water: (flat jet nozzle, > 25 bar; chemicals > 60 degrees C) d) Dry (by ventilation or hot-air blower)					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	C) Cleaning with water and cleanser(after loads rich in protein or fat) procedure: a) Remove residue (dry) b) advance rinsing with warm water (max. 60 C), possibly by hand with brushes c) foam/gel with cleanser (tipper/container) or rinse with CIP cleanser at 80 C (tank cleaning) d) Rinse with warm water of 60 C) e) Dry (by means of ventilation or hot- air blower)		x			
	D) Cleaning with water; cleanser and disinfectant (from microbiological considerations) Distinguish disinfectants: chlorous, quaternary ammonium compounds or peracetic acid Rinsing recommended		x			
4.9.4.3TVw	*Working out basic principles (for cleaning and disinfecting) and validation*					
	Establish detailed cleaning protocol per type of means of transport dependent on the previous load. Specific attention for spots that are difficult to clean tubes, hoses, chinks, pumps, blind spots and the like) in cleaning protocol Include parts to be deactivated in the cleaning protocol Validation (inspection) or cleaning protocol for use		x			
	Feed additives (T)					
4.9.1T	Correct use of raw materials and auxiliary substances		x			
4.9.2T	Installations for: - Uniform distribution - Prevent towing (and towing measured)		x			
	A maintenance control or inspection schedule for in-stallations		x			
4.9.3T	Storage of additives such that:					
	- Easy identification		x			
	- Extreme processing date observed		x			

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	- Separate section for storage of raw materials and auxiliary substances		x			
4.9.4T	Preparation of the additive: - Dose percentages in recipe - Appropriate means of transport		x			
	If use is made of dosage silos: - Proper dosage and locking system - Establishment of transport sequence if use is made of common transport routes And lay down in procedure		x			
4.9.5T	Administering and archiving implemented production sequences		x			
4.9.6T	- Appropriate and clean weighing equipment. - Specification of weighing equipment		x			
4.9.7T	Grounding of transport systems for electrostatically sensitive substances - Cleaning protocol of the transport system - Maintenance schedule for transport systems		x			
4.9.8T	Return flows:					
	- Procedure dealing with substances in powder form originating from filters		x			
	- Procedure for returning internal and external re-turn flows		x			
4.10	Inspection and testing					
	General					
4.10.1	*General*					
	establishing the limiting and target value, which meet the relevant regulations	x			x	
	carry out inspection and checks on critical points in the production process	x		x	x	
	carrying out inspection, checks and measuring with appropriate equipment	x		x	x	this corresponds with ISO 4.2.3

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	recording the manner and frequency of taking samples and analyses to be performed	x			x	See Decree PDV company internal inspections and checks GMP animal feed sector 1998. It is laid down in this decision chapter 2: Towing research chapter 3: Preparing compound feed chapter 4: Aflatoxin chapter 5: Feed materials, among which animal feed materials,. chapter 6: Analyses under L*anced*
4.10.2	*Initial inspection and testing*					
	carrying out initial inspection of goods received	x		x		
4.10.3	*In-process inspection and testing*					
	checking of all components of the production process according to recorded instructions	x		x		
	guarding and checking of products regarding acceptable duration of storage and/or conditions	x				
	blocking of products till the inspection required has been carried out	x		x		ISO requires a form of a re-call procedure, GMP is less explicit
4.10.4	*Hygiene inspection*					
	periodic operation of inspection on various components	x				
4.10.5	*Final inspection and testing*					
	release of products after full conclusion of the inspection and testing	x		x		
4.10.6	*Inspection and test records*					
	recording of results and checks	x		x		
	identifying and keeping samples	x				
	providing data to the product board animal feed	x				
	Road transport (TVw)					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.10TVw	Visual inspection after cleaning (possible sealing of tank lorry Inspection (microscopic) after cleaning of loads containing animal meal Additional inspections to assess effectiveness of cleaning and/or disinfectant methods applied (ATP measuring, agar stamps, HPL/MS)					
	Feed Additives (T)					
4.10	Inspection and testing					
4.10.1T	Register received raw materials and auxiliary sub-stances Check on damages of packing Check label or covering document		x			
4.10.2T	Quality checks on additives: Taking samples per batch regarding traceability		x			
4.11	Control of inspection, measuring and test equipment					
	General					
4.11.1	*General*					
	written procedures for control, calibration and maintenance of means for examining, measuring and testing used to make the basic quality demonstrable	x		x		ISO 4.11.1 mentions more,
	carrying out analyses by a laboratory recognised by the Product Board Animal Feed + recording of laboratories	x				
4.11.2	*Control procedure*					
	record of means of inspection, measuring testing	x		x	x	
	calibration of methods and equipment for checking and measuring according to fixed procedure	x		x	x	
	recording criteria which the means for inspection, measuring and testing to be calibrated have to meet	x		x	x	

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	carry out inspections according to standardised check-lists	x		x	x	
	presence of descriptions of measuring methods to be used for checks	x		x	x	
	at least once a year calibration of all scales used for dosing feeds and ingredients for that purpose	x				
	at least twice a year calibration of weighing equipment used for weighing/dosing of premixes, feed additives and animal medicine	x				
4.12	Inspection and test status					
	General					
4.12	identification of the inspection and test status of prod-ucts			x		
4.13	Control of nonconforming products					
	General					
4.13.1	*General*					
	recording a written procedure for dealing with products and services that do not meet the requirements for basic quality	x		x		
	provide the control in identification, documentation, evaluation, handling of nonconforming products	x		x		
4.13.2	*Review and disposition of nonconforming products*					
	defining of responsibility for the assessment and authority for handling of nonconforming products	x		x		
	reviewing nonconforming products according to fixed procedures	x		x		
	transport of nonconforming products should take place according to the current rules	x				
	Storage and transhipment (O)					

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.13O	Procedure in case of nonconformities from basic quality Record actions in case of nonconformity Report in case of unhealthy trade quality Action when salmonella is established in the operating scheme		x			
	Road transport (TVw)					
4.13TVw	Record actions in case of nonconformities in transports Procedure in case of nonconformity from basic quality Report to purchaser in case of contamination and unhealthy trade quality		x			
4.14	Correcting and preventive action					
	General					
4.14.1	*General*					
	record procedures for implementation of correcting and preventive actions, aimed at meeting the requirements for basic quality	x		x		Logically GMP specialises this on Basic quality
	register and implement modified procedures	x		x		
4.14.2	*Correcting action*					
	effective treatment of complaints and nonconformities	x		x		
	investigation into cause of nonconformities	x		x		
	determining the corrective actions	x		x		
	check on the functioning of the corrective actions	x		x		
4.14.3	*Preventive action*					
	signalling, analysing and removing potential causes of nonconformities	x		x		
	recording of steps necessary for dealing with any problem that requires preventive actions	x		x		
	determining preventive actions	x		x		
	check whether the desired result is achieved	x		x		

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
4.15	Handling, storage, packaging, preservation and delivery of products					
	General					
4.15.1	*General*					
	record procedures for treatment, storage, packing, conservation and delivery of products,	x		x		
	indicate legal mentions on the packing or the covering documents	x				
4.15.2	*Handling*					
	avoiding deterioration or damage of the product by means of treatment	x		x		
4.15.3	*Storage*					
	avoiding deterioration or damage of the product by means of storage	x		x		
	avoid cross-contamination or unintentional mixing	x				ISO is not so specific: no addition as to content, but a clarification
4.15.4	*Packaging*					
	attune packing to control of the standards for basic quality	x		x		
4.15.5	*Preservation*					
	use adequate methods for conservation and separation of products	x		x		
	Delivery					
4.15.6	take actions for the protection of the basic quality	x		x		AGMP demands requirements to transport and previous loads; ISO does not go that far at all
	order of transport known during 7 years	x				

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	inspection of clean loading space (by means of spot checks)	x				
	Feed Additives (T)					
4.15T	Product information/support to clients Meet standard specification agreed Instructions for safe working Mention of relevant stipulations on label		x			
4.16	Control of quality records					
	General					
4.16	recording procedures for control of quality records	x		x	x	
	keeping up quality records	x		x	x	
	register and file the results of inspections and checks	x		x	x	
	make a quarterly survey of analyses performed re-garding check on basic quality	x				
4.17	Internal quality audits					
	General					
4.17	recording of procedures for planning and conducting internal audits	x		x	x	
	Carry out internal quality audits at least once a year	x		x	x	at least once a year
	register results of the audits	x		x	x	
4.18	Training					
	General					
4.18	register knowledge and skill of personnel	x		x	x	ISO requires a procedure
	add to knowledge and awareness regarding safety of animal feeds	x			x	
	bring about that knowledge and skill of personnel re-garding safety of animal feeders is present	x				This is a result or the greater and more concrete emphasis GMP lays on hygieni-cally safe production

	The GMP+-standard versus ISO 9001 and the HACCP-criteria	GMP-standard General	GMP-standards Additional	ISO 9001 (1994)	HACCP-criteria for food	Explanation
	bring about the skill of personnel regarding processing of feed additives or animal medicine is present	x				idem, regarding use and processing of additives and medicines
4.19	After-sales service					
4.20	Statistical techniques					
	General					
4.20.1	*Identification*					
	identification of need for statistical techniques required for establishing, control and verification of basic quality	x		x		
4.20.1	*Procedures*					
	recording procedures for implementation and control of identified statistic techniques	x		x		

8 APPENDIX 2: AGREEMENT WITH REFERENCE TO GMP EQUIVALENCE OF SUPPLIERS OF ANIMAL FEED MATERIALS[16]

The undersigned:

The Product Board Animal Feed, with its registered office in The Hague, represented in this matter by Mr. ing J. den Hartog, secretary, hereinafter referred to as:

PDV

and

the certification body (hereinafter referred to as CL)……., with its registered office……, duly represented in this matter by …….

consider the following:

PDV intends to harmonisation the contents and method of verification of a quality system equivalent to GMP, applied by suppliers of feed materials (animal feed materials) as meant in the *Protocol GMP equivalence for suppliers of animal feed materials.* PDV hereby intends to create transparency and clarity about the performance and contents of audits for the benefit of GMP equivalence. The objective behind this is that the purchasers (the GMP certified companies) have confidence in the statement issued by certification bodies as to the quality system applied, where it is established that the requirements established by PDV from the Standard GMP Animal Feed are met.
One has in mind that hereby suppliers comply with the GMP system, and that the safety of feed materials and auxiliary substances (feeds) in the preceding links of the feed chain is guaranteed.

and have agreed as follows:

Clause 1: Definition of notions

1.1 Supplier: a company that supplies feeds (animal feed materials) to GMP-approved company.
1.2 Certification body: A body accredited by the Council for the Accreditation or, to the assessment of PDV, an equivalent accreditation body outside the Netherlands to be allowed to certify ISO-9001 systems and/or HACCP systems. .
1.3 Scope: the “feed” sector.”.
1.4 GMP-equivalence audit: an audit to establish whether the quality system applied by the supplier meets the requirements in the Standard GMP Animal Feed. This audit is normally additional to an ISO- or HACCP certification audit
1.5 Certification scheme: the whole of procedures, instructions, working method, assessment and reporting that has been set up and is applied when performing a GMP equivalence audit.
1.6 Protocol: Protocol GMP equivalence of suppliers of animal feed materials.
1.7 Standard: The Standard GMP Animal Feed, issued by the Product Board Animal Feed.

Clause 2: obligations PDV

[16] *The definitive agreement can be altered slightly.*

2.1 PDV is responsible for the support of the certification bodies in drafting, modifying and issuing of the conditions, possible interpretations or explanation and guidelines for assessment. The organisation of a periodical meeting to uniform audits and inspections with the certification bodies is part of this. In this consultation technical problems as regard to content are discussed. In this consultation experts ('auditors') of various accepted certification bodies are represented. The KDD plays a central role in these meetings. During this consultation working appointments are made and fixed. Problems of a more complex nature are submitted to the Council of Experts for the Animal Feed Sector.
2.2 PDV gives the certification body information about the possibilities for performing the GMP equivalence audits.
2.3 PDV drafts a standard statement which the body can deliver to the supplier if the quality system is assessed as sufficient.
2.4 PDV places the accepted certification body on a public list.
2.5 PDV places the approved suppliers on a public list.

Clause 3: obligations of certification body

3.1 The certification body ensures that it is accredited by the Council of Accreditation or an equivalent accreditation institution outside the Netherlands according to standard EN 45011/12 for certification of ISO-9001 and HACCP systems respectively.
3.2 The certification body ensures that it has sufficient expertise regarding to 'feed'.
3.3 The certification body is sufficiently informed concerning the relevant PDV publications.
3.4 The certification body performs GMP equivalence audits at the suppliers who have presented themselves to it.
3.5 In case of GMP equivalence audits the certification body follows its certification scheme approved by PDV and passes on modifications as to content in this scheme to PDV.
3.6 The certification body delivers the statement of approval drafted by PDV as meant in the protocol to the suppliers if the quality system applied, where one has to depart from the actual situation and not from actions still to be taken or improvements to be implemented. is satisfactory
3.7 The certification body is obliged to inform PDV immediately on statements issued or retracted.
3.8 The certification body complies with PDV advises and guidelines

Clause 4: Powers PDV

4.1 In the meantime PDV can modify the Standard GMP Animal Feed. The certification body gets a specific term to incorporate these modifications in the certification scheme.
4.2 In the meantime PDV can ask the certification bodies for information, such as the list of approved suppliers or a description of the certification scheme applied.
4.3 PDV can give advises and guidelines to the certification body.

Clause 5: Powers of certification body

5.1 The certification body may propagate being accepted by PVD as meant in the protocol.

5.2 The certification body may carry out GPM equivalent audits with suppliers.

Clause 6: compensations

The certification body annually remits a fixed sum to PVD, and further a sum per approved supplier. These sums are intended to cover expenses made within the framework of

- assessment of certification schemes
- carrying out supervision on supervision, under which among other things the attending of audits and checking afterwards of GMP equivalence certificates
- carrying out sample investigation for the verification of analyses typical of the business
- organising meetings

For 2001 the fixed amount has been established at € 4000,-.The amount to be paid per supplier is fixed at € 100,-.
These sums are consequently tuned with the certification bodies.

Clause 7: responsibility and warranty

PDV cannot be held responsible for damage originating from incorrect application of an accepted certification scheme.

Clause 8: duration and termination of the agreement

8.1 The agreement is entered into for an indefinite period.
8.2 The agreement may at all time be terminated.
8.3 This agreement may be terminated one-sided by parties by registered letter with the observance of a term of notice of six months, should there be well-founded reasons such as::
  - bankruptcy of the certification body
  - suspension of payment of the certification body
  - if after warning in writing by PVD the certification body repeatedly does not observe the provisions in this agreement;
  - dissolution of PVD;
  - if one of the parties demonstrably acts injuriously for the other party.

8.4 The term of notice mentioned in the preceding paragraph does not apply when:
- one of the parties does not observe this agreement, and in this matter, in accordance with the settlement of disputes section 9 of this agreement , can be considered to be the imputable party;
- one of the parties has not met its obligations as described in sections 2 and 3;
- the recognition of the certification body is withdrawn by the accrediting body.

Clause 9: Disputes

9.1 Disputes concerning observance of this agreement are preferably solved by mutual agreement between the certification body and PDV.
9.2 If the application of the previous paragraph has not led to a solution, parties may invoke mediation by the Council for Accreditation. If only one of the parties only desires mediation, the other party offers its co-operation.
9.3 For all disputes between PVD and the certification body, one of the parties or both parties may submit an appeal for settlement to the civil court judge for settlement of the dispute

Clause 10: Final remarks

10.1 This agreement can exclusively be modified if PVD and the certification body have agreed to a modification proposed in writing.
10.2 In cases in which this agreement does not provide the certification body and PDV decide in mutual consultation.
10.3 Dutch law shall govern this agreement.
10.4 This agreement takes effect on ……..

Thus agreed and prepared in duplicate in The Hague on ……

PDV

……..

The certification body

……..

9 APPENDIX 3: APPLICATION FORM[17]

General data

Name of body			
Name of the undersigned			
Location address			
Postcode		Town	
Country			
Postal address			
Postcode		Town	
Telephone number.		Fax nr.	
Country			
E-mail address			

- The undersigned hereby submits an application for acceptance as a body to issue GMP equivalence statements. .
- The undersigned is familiar with the conditions and the acceptance procedures laid down in protocol GMP equivalence, and commits himself to co-operation with the acceptance procedure.

Date: Signature

After receipt and processing of the form the acceptation procedure will be started. You will be receiving notice about that.

[17] *Send to: Product Board Animal Feed, Post-box 29739, 22502 LS The Hague, The Netherlands*

10 APPENDIX 4: GENERAL CRITERIA FOR THE ASSESSMENT

General

A deficiency is evaluated as a Minor Nonconformity when:
- An element is not fully described in the documentation, although this is required. There is negligible risk that this will affect the quality and/or safety of the feed so that it no longer meets GMP conditions;
- An already described element has not been updated, although this is required by revised legislation. There is negligible risk that this will effect the quality and/or safety of the feed so that it no longer meets GMP conditions;
- An element is not effective implemented, but it is decided that this has a negligible negative impact on the quality and/or safety of the feed;
- It is probable that the non conformity concerns a single incident and there is a negligible risk that this will effect the quality and/or safety of the feed so that it no longer meets GMP conditions.

A deficiency is evaluated as a Major Nonconformity when:
- An element is very insufficiently described in the manual, if at all, and the operation of the quality system is at stake. There is a big risk that this will affect the quality and/or safety of the feed so that it will no longer meet GMP conditions;
- An already described element has not been updated, although this is required by revised legislation. There is a big risk that this will affect the quality and/or safety of the feed so that it no longer meets GMP conditions;
- An element is not effective implemented and it is decided on the basis of objective considerations that this is critical to the quality and/or safety of the feed;
- The deficiency is detected for the 2nd time and insufficient improvements have been made.
- A number of Minor non conformities that in total cause an effect on the quality and/or safety of the feed, so that it will no longer meet GMP conditions.

Additional remarks

- On assessing ('weighing') shortcomings the inspector has a certain degree of freedom as regards what has been laid down in this appendix.

- A supplier acquires the status of 'GMP equivalent' if no majors have been found. Besides, not more than 10 minors must have been observed.

- As period of improvement applies:

    - A major NCF: up to 3 months. Critical shortcomings ought to be adapted faster (within 2 weeks), and less critical shortcomings can possibly be remedied in a somewhat longer term. Such at the discretion of the certification body.

    - A minor NCF: at most till the following periodic audit. In practice this means that the shortcoming has to be remedied within 6 months.

11 APPENDIX V: PDV DECREE VERIFICATION BODIES CONTRIBUTION 2002

Product Board Animal Feed

Lett.: AF no. JBA.650

PDV DECREE VERIFICATION BODIES CONTRIBUTION 2002

The Board of the Animal Feed Product Board, taking into account Article 4.6.1 of appendices II, IV and V of Regulation PDV approval regulation GMP animal feed sector 2000, has determined the following on 7 November 2001.

Article 1

1 The certification body as referred to in the "Protocol GMP Equivalence Suppliers of Feed Materials or Feed Additives for Animal Feed" who has been approved by the Product Board Animal Feed for the determination of the status "GMP equivalent" for suppliers of animal feeds, pays an annual charge to the Product Board Animal Feed of € 4,000,- for the approval procedure and supervision of inspection carried out by the Animal Feed Sector Inspection Board.

2. The certification body as referred to in the first section pays an annual charge per approved supplier to the Product Board Animal Feed of € 100,-. The reference date for this is 31 December.

Article 2

The inspection body as referred to in the "Protocol verification audits of foreign suppliers of feed materials" who is approved by the Product Board Animal Feed for the carrying out of verification audits of foreign suppliers of feed materials/materials pays an annual charge per approved supplier of €100,-. The reference date for this is 31 December.

Article 3

The certification body as referred to in the "Regulation for the awarding of the animal feed transport certificate" who are approved by the Product Board Animal Feed for the awarding of a GMP goods carrier transport certificate for animal feeds pays an annual charge per approved supplier of € 125,-. The reference date for this is 31 December.

Article 4

This decree will be published in the Sector Decree Publication and will come into force as of 1 January 2002.

The Hague, 7 November 2001

J.H.M. KIENHUIS
Chairman

J. DEN HARTOG
Secretary

COMMENTARY

As a result of the addition to the GMP code of the requirements for suppliers of animal feed, these suppliers should meet the following requirements:

1) The supplier is GMP certified.
2) The supplier has a certified, GMP equivalent, quality assurance system.
3) A foreign supplier has a quality control system (QC system) which at least meets the requirements of the GMP standard and as further specified in the Standard Quality Control of Feed Materials for Animal Feed.

The Product Board Animal Feed makes use of verification bodies to establish the second and third possibilities. They are required to pay annually the amounts specified in the decree in question to the Product Board Animal Feed.
The amount included for supervision/harmonisation of inspections refers to a check of the certification body which the Product Board Animal Feed asks the Inspection Board for the Animal Feed Sector (KDD) to carry out. The KDD assesses documents, carries out audits together with the certification body and audits companies who have already attained the status "GMP equivalent".

There is a separate appendix in the GMP code for the transport of feed, pre-mixes and compound feeds. This specifies that carriers who are hired externally will be checked by the certification body and that the animal feed supplier's own transport will be checked by the KDD through audits and random samples. The certification body is required to pay annually the amount specified in Article 3 to the Product Board Animal Feed.

The Hague, 7 November 2001

J.H.M. KIENHUIS
Chairman

J. DEN HARTOG
Secretary