

## **GMP<sup>+</sup> Certification Scheme Animal Feed Sector 2006**

### **Approval Requirements and Approval Procedure for Certification Bodies**

#### **C.1**

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## 1. Aim of the document

The establishment of the conditions and procedure for the approval of certification bodies with respect to the carrying out of audits as specified in the Regulation A1 of the GMP<sup>+</sup> Certification Scheme for the Animal Feed Sector 2006 by the Product Board Animal Feed (PDV), referred to hereafter as 'GMP<sup>+</sup>: 2006'. These approval requirements and procedure are based on Article 8 second section of the regulation (A1).

## 2. Scope

These approval requirements are intended for certification bodies which (will) carry out GMP<sup>+</sup> audits at companies in the feed sector on the basis of the GMP<sup>+</sup> standards for the feed sector as specified in GMP<sup>+</sup>:2006

## 3. General

A certification body, which wishes to certify a company in accordance with one or more GMP<sup>+</sup> standards, should demonstrably comply with the requirements. These are laid down in the following sections.

The PDV will, on behalf of the Central College of Experts for the Animal Feed Sector (CCvDD) approve a certification body as a body which can issue a GMP<sup>+</sup> certificate to companies for a particular GMP<sup>+</sup> standard if it complies with that which is determined in Regulation A1, in as far as it is applicable the requirements specified in this document the approval procedure (appendix no. 3). The Product Board Animal Feed determines, on behalf of the CCvDD, within the scope of the approval of the certification body which GMP<sup>+</sup> standards apply.

## 4. Requirements with respect to carrying out GMP<sup>+</sup> feed sector certification

### 1.1 Application for approval and assessment

The certification body applies using an application form (appendix 1) to the CCvDD via the Animal Feed Certification and Control Office (BCD) of the Product Board Animal Feed. The BCD will confirm receipt of this application in writing if this is given the status "complete". This is only possible if all the documents specified in appendix 1 including the CVs of at least 2 auditors are submitted to the BCD.

The application will be handled if the application form has been fully completed and all the requested documents have been sent. The handling of the application will take at least 4 and a maximum of 6 weeks. The application should be accompanied by, depending on the application, a *valid accreditation certificate EN 45011 and/or ISO 17020 + associated actions list*, which shows that it is accredited for the issuing of a GMP<sup>+</sup> certificate. The certification body may send additional documents to show that it meets this requirement.

The assessment will take place as specified in the Regulation (A1).

### 1.2 Contract

If the application for approval is approved then the PDV will offer, on behalf of the CCvDD, the certification body a contract as specified in Regulation (A1). The Product Board Animal Feed will draw up a contract in duplicate and send this to the certification body in question. The certification body will send one signed copy of the contracts to the Product Board Animal Feed. The approval is established on receipt of the signed contract.

The Product Board Animal Feed will put the approved certification body, on behalf of the CCvDD, on a public list with a specification of for which GMP<sup>+</sup> standard the approval applies.

### **1.3 Requirements for certification bodies**

A certification body should be accredited for the GMP<sup>+</sup> standards for which it has applied for approval, in accordance with EN 45011 (ISO Guide 65) and/or ISO 17020 (see appendix 1) not later than one year after the date of approval by the PDV. The certification body should send its field(s) of work to the BCD in writing when applying.

On request the certification body should send to the PDV reports of audits carried out by the Council for Accreditation (or another member of the IAF Multi-Lateral Agreement – MLA) within the framework of the accreditation for the GMP<sup>+</sup> Certification Scheme 2006.

### **1.4 Independence / impartiality**

The certification body and the auditors are not to have conducted any consultancy and/or training activities at the company to be audited over a period of 2 years prior to the audit date. The auditor or the certification body should demonstrably confirm that there is compliance with the requirements with respect to independence in appendix 2. The quality system and the accounting records of the certification body must show this.

### **1.5 Requirements for auditors, coordinators**

The auditors to be used must demonstrably comply with the requirements for the qualification norms specified in appendix 2.

The certification body will appoint one person as coordinator for GMP<sup>+</sup> certification who will act as contact person for the BCD. In addition this coordinator or another authorised person (decision-maker) will assess the reports of the auditors. The coordinator, or the decision maker, must comply with the requirements specified in appendix 2. If the coordinator or the decision maker carries out his own audits then it is not possible for him to assess the reports of these audits himself.

The certification body should when applying hand over to the PDV the CV's of all qualified auditors and the coordinator / decision maker for approval in accordance with appendix 4. This also applies for every new auditor who qualifies and who will be used for GMP<sup>+</sup> audits. The BCD will maintain a register of approved auditors.

## **1.6 Availability of audit data and duty of confidentiality**

The certification body has a duty of confidentiality with respect to the dissemination of information obtained during the audit. The reports will only be issued to the company, the BCD and the accreditation body. Data should be retained for a minimum of 6 years. The certification body should record the mandatory issuing of the reports and certification data to the BCD in the contract with the company. The auditor should report the duty of confidentiality to the company. In the transition of a company from one certification body to another, the certification body is obliged to make available all relevant data to the certification body in question.

## **1.7 Carrying out of the audit**

The certification body describes the way in which it carries out the sections which are relevant for GMP<sup>+</sup> certification (application through to issuing of the certificate) in procedures and other documents. These documents are part of the quality system of the certification body and will be maintained within the framework of the (proposed) accreditation as specified in section 4.3.

In the event of changes in the certification conditions the certification body should begin with auditing these immediately after implementation.

## **1.8 Keeping technical expertise by certification bodies up to date**

The certification body realizes that every auditor and the coordinator / decision-maker attends at least four days (4 x 8 hours) of technical meetings per year in order to keep up to date with developments in quality assurance and legal obligations relating to the animal feed sector. Participation in and the content of the training programme must be demonstrable.

The certification body must ensure that all auditors and the coordinators / decision-makers are obliged to participate in a periodic examination by the CCvDD, to be taken by the BCD of their expertise in the field of animal feed.

The PDV organises two examination periods per calendar year. An auditor may make use of two examination opportunities during the same examination period. If he is not successful then the approval will not be extended or suspended for 6 months and the auditor can not audit companies for the standard in question. The auditor can be approved again by way of an initial examination during the next examination period.

PDV uses two examination periods. An auditor will be approved up to 30 June or 31 December of that year. The approval will be extended following a successful examination. The certification bodies have insight into the approvals of their auditors through the web application. Dates for examinations are notified in the chronological list of GMP examinations.

To keep his knowledge and expertise with respect to GMP<sup>+</sup> :2006 and the animal feed legislation at the proper level, it is necessary for an approved auditor to carry out a minimum number of audits per year at relevant companies (see appendix 2).

This minimum number of audits to be carried out per standard for which the auditor in question is approved has been set at five (5). In addition to the information meeting a policy harmonisation meeting will be organised 4 times per year. There must be at least one person per certification body (preferably the coordinator) present. In the internal technical meeting each certification body is obliged to submit at least one case study per year for discussion at the harmonisation meeting.

## **1.9 Payments**

Under the Regulation (A1) the certification body is due an annual payment to the Product Board Animal Feed plus a payment per certificate issued. Changes to these amounts will be announced annually by

the Product Board Animal Feed to the certification body. Payment of this amount will take place within one month of the reference date of 1 January and will be based on the results of the previous year. PDV will publish the payments each year on the PDV website.

### **1.10 Technical supervision**

In addition to supervision by the Accreditation Council or another accreditation agency, on behalf of the CCvDD, approved by the Product Board Animal Feed which complies with the conditions of NEN-EN-ISO/IEC 17011:2004, BCD supervises the expert, uniform and complete implementation of the GMP<sup>+</sup> audits. Supervision is included in Appendix 3.

The certification body should establish in the contract with the company the obligation for companies to provide cooperation in the carrying out of the witness audits and parallel audits of the CCvDD which are implemented by the BCD.

### **1.11 Disputes and sanctions certification bodies – Product Board Animal Feed**

The General Administrative Law Act applies to disputes between the PDV and the CCvDD on the one hand and the certification bodies on the other hand.

### **1.12 Annual evaluation**

These requirements for approval of certification bodies will be evaluated annually by the Animal Feed Sector College of Experts.

## Appendix 1: Application Form

Application for the approval of a certification body for the carrying out of certification in accordance with the GMP<sup>+</sup> Certification Scheme for the Animal Feed Sector 2006.

### General details

Name of body			
Signatory's name			
Name of coordinator			
Address			
Postal Code		Position	
Country			
Postal address			
Postal Code		Position	
Telephone number		Fax no.	
Country			
E-mail address			

This application relates to the issuing of certificates for the GMP<sup>+</sup> standards specified on this form.

The undersigned hereby applies for approval as a body permitted to carry out GMP<sup>+</sup> inspections and audits in the animal feed industry and to issue GMP<sup>+</sup> certificates.

The undersigned is acquainted with the "Approval Conditions and Procedure for the Approval of Certifying Bodies GMP<sup>+</sup> Animal Feed Sector 2006" of the Product Board Animal Feed and the approval procedure and undertakes to cooperate in the approval procedure.

Date:

Signature:

NB The signatory must be a legal representative of the certification body.

The following must be enclosed:

(NB: without these enclosures the application will not be considered).

No	Description	Remarks
1.	Valid accreditation certificate including a list of actions (EN 45011/ISO 17020 depending on the application)	
2.	Procedure for audit and assessment process	
3.	Other documents used in certification - sample contract - sample certificate - procedure and forms for internal assessment of GMP animal feed audits	
4.	List of qualified auditors including CV (drawn up in accordance with the sample in appendix 5) and list of qualifications and CV for each auditor and coordinator	

	GMP <sup>+</sup> standard *	Accredita- tion	GMP <sup>+</sup> standard
<input type="checkbox"/>	Production and processing of feeds for productive livestock; compound feeds	EN 45011	B1
<input type="checkbox"/>	Production and processing of feeds for productive livestock; premixes	EN 45011	B1
<input type="checkbox"/>	Production and processing of feeds for productive livestock; feed materials	EN 45011	B1
<input type="checkbox"/>	Production and processing of feeds for productive livestock; feed additives	EN 45011	B1
<input type="checkbox"/>	Production of feeds (Quality Control of Feed Materials)	EN 45011	B2
<input type="checkbox"/>	Trading of feeds for productive livestock; compound feeds	EN 45011	B3
<input type="checkbox"/>	Trading of feeds for productive livestock; premixes	EN 45011	B3
<input type="checkbox"/>	Trading of feeds for productive livestock; feed materials	EN 45011	B3
<input type="checkbox"/>	Trading of feeds for productive livestock; feed additives	EN 45011	B3
<input type="checkbox"/>	Trade, Collection and Storage & Transhipment of Feeds; trade	N/A	B3
<input type="checkbox"/>	Trade, Collection and Storage & Transhipment of Feeds; storage & transhipment	N/A	B3
<input type="checkbox"/>	Trade, Collection and Storage & Transhipment of Feeds; transport of own products	N/A	B3
<input type="checkbox"/>	Feed road transport	EN 45011	B4.1
<input type="checkbox"/>	Feed inland waterway transport	EN 45011	B4.2
<input type="checkbox"/>	Inland Waterways Hygiene Code	N/A	B4.3
<input type="checkbox"/>	Feed sea transport	EN 45011	B4.4
<input type="checkbox"/>	Feed rail transport.	EN 45011	B4.5
<input type="checkbox"/>	Storage and transhipment of feeds for productive livestock	EN 45011	B5

	GMP <sup>+</sup> standard *	Accredita- tion	GMP <sup>+</sup> standard
<input type="checkbox"/>	Feed materials cultivation	N/A	B6
<input type="checkbox"/>	Storage, custody and feeding of feeds on poultry farms	ISO 17020	B7.1
<input type="checkbox"/>	Storage, custody and feeding of feeds on pig farms	ISO 17020	B7.2
<input type="checkbox"/>	Storage, custody and feeding of feeds on pig farms	ISO 17020	B7.3
<input type="checkbox"/>	Production of and trade in pet foods	EN45011	B8
<input type="checkbox"/>	Special Regulation for Grass-Fed Chickens	EN 45011	B9.1
<input type="checkbox"/>	Special Regulation for Free-Range Animals	EN45011	B9.2
<input type="checkbox"/>	Laboratory testing	N/A	B10

## Appendix 2: Requirements for auditors, inspectors and coordinators

Personal characteristics	Ethical, open, diplomatic, good powers of observation, alert, versatile, determined, decisive, independent
Independence	The certification body and the auditor may, within a period of two years prior to the audit, not have undertaken any consultancy or training activities for the company to be audited.
Duty of confidentiality	The certification body has a duty of confidentiality with respect to the dissemination of information obtained during the audit. The auditor should report the duty of confidentiality to the company. The duty of confidentiality also applies to the subject specialists who are used.
(Refresher) training, updating and maintaining professional expertise	<p>Each auditor or coordinator to be used should have demonstrably followed the established initial training programme organised by the certification body. The content of the training programme must be demonstrable. After the training programme the auditor must successfully take an initial examination for each GMP+ standard. This examination will be taken by the PDV on behalf of the CCvDD.</p> <p>Each auditor or coordinator will attend at least the mandatory number of hours at the professional meetings organised by the certification body:          Approved for standard B2: 8 hours          Approved for standard B6 or B10: 8 hours          Approved for 1-2 standards with the exception of B2, B6 or B10: 16 hours          Approved for &gt; 2 standards: 32 hours</p> <p>N.B. Approved only for B2 and B4.1: 16 hours          For B1 a distinction is made among the various scopes; 1 scope applies as 1 standard.</p> <p>In order to retain approval each auditor or coordinator should be successful in the periodic examination organised by the BCD (on behalf of the CCvDD). This checks expertise in the field of animal feed.</p> <p>In order to retain approval each auditor or coordinator should carry out at least five audits per year per standard/ scope for which the auditor or coordinator in question has been approved. The audits will take place at the appropriate companies. If the coordinator does not carry out independent GMP audits then attendance at relevant GMP+ audits may be counted.</p> <p>Continuous professional development through supplementary work experience, training, study, meetings, seminars or other activities</p>

Specific

	Training	Required expertise	Audit skills	(Work) Experience	Additional requirements for coordinators
GMPB1	Relevant agricultural or foodstuffs training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum 4 years working experience in the animal feed / foodstuff sector in a relevant function (quality assurance, production)	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor
GMPB2	Relevant agricultural or foodstuffs training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 10 audits) Effective interviews, depth	Minimum 4 years working experience in the animal feed / foodstuff sector in a relevant function (quality assurance, production)	Minimum 1 years experience in the assessment of audit reports or minimum experience of 20 audits (attendances) as auditor
GMPB3	Relevant agricultural or foodstuffs training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum 4 years working experience in the animal feed / foodstuff sector in a relevant function (quality assurance, trade)	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor

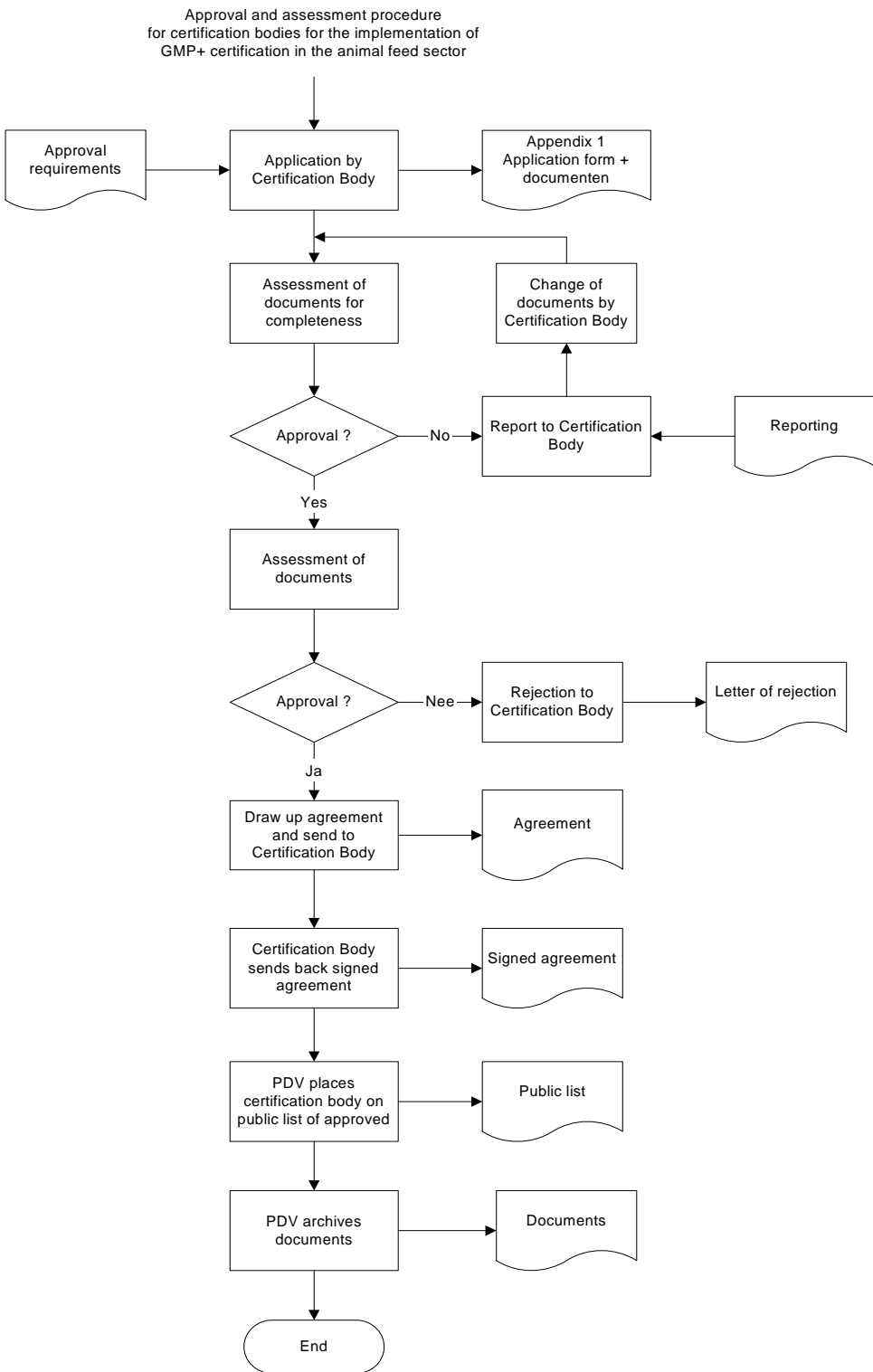
	Training	Required expertise	Audit skills	(Work) Experience	Additional requirements for coordinators
GMPB3 (2007)	Relevant agricultural or foodstuffs training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems Demonstrable expertise in the field of the hygienic transport of feed (practical and administrative check).  GMP+ standard feed HACCP feed, HACCP foodstuff or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum 4 years working experience in the animal feed / foodstuff sector in a relevant function (quality assurance, production)	Minimum 2 years experience in the assessment of audit reports or minimum 40 (attendances at) audits as auditor
GMPB4.1	Relevant training (logistics, transport) at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP+ standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum 4 years working experience in a relevant function (quality assurance, production)	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor
GMPB4.2	Relevant training (logistics, transport) at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP+ standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 10 audits) Effective interviews, depth	Demonstrable knowledge of the affreightment of inland waterways vessels (B4.2). This knowledge to be obtained by demonstrably taking an internal or external course or demonstrable experience in the carrying out of audits or checks at relevant companies	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor

	Training	Required expertise	Audit skills	(Work) Experience	Additional requirements for coordinators
GMPB4.3	Relevant training (logistics, inland waterway transport) to at least HBO level	Knowledge and skills with respect to methods and techniques aimed at practical and administrative auditing Demonstrable expertise in the field of the hygienic transport of raw materials for animal feed. Knowledge of HACCP or ISO 22000. Knowledge of the GMP <sup>+</sup> standard	Performed a minimum of 10 inspections at representative companies in the inland water way sector Effective interviews, depth	Minimum of 3 years' work experience in a relevant position	Minimum 2 years experience in the assessment of inspection reports or carried out a minimum of 20 inspections (attendances).
GMPB4.4	Relevant training (logistics, transport) at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 10 audits) Effective interviews, depth	Demonstrable knowledge of the affreightment of sea vessels (B4.4). This knowledge to be obtained by demonstrably taking an internal or external course or demonstrable experience in the carrying out of audits or checks at relevant companies	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor
GMPB4.5	Relevant training (logistics, transport) at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 10 audits) Effective interviews, depth	Demonstrable knowledge of the affreightment of railway wagons (B4.5). This knowledge to be obtained by demonstrably taking an internal or external course or demonstrable experience in the carrying out of audits or checks at relevant companies	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor

	Training	Required expertise	Audit skills	(Work) Experience	Additional requirements for coordinators
GMPB5	Relevant agricultural or foodstuffs training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum 4 years working experience in the animal feed / foodstuff sector in a relevant function (quality assurance, storage and transshipment)	Minimum 2 years experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor
GMPB6	Relevant agricultural or foodstuffs training to at least MBO level	Knowledge and skills with respect to methods and techniques aimed at the assessment of agricultural production processes Animal feed legislation Demonstrable expertise in the field of the cultivation of feed materials for the animal feed sector and the legal requirements for cultivated crops. Knowledge of B6 Cultivation of Feed Materials	Carried out at least 10 audits independently at representative companies Effective interviews, depth	Minimum of 1 years' work experience in a relevant position (quality assurance)	Minimum 1 years experience in the assessment of inspection reports or minimum experience of 20 audits (attendances) as inspector
GMPB7	Not applicable.				
GMPB8	Relevant agricultural or foodstuffs training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP <sup>+</sup> standard animal feed HACCP animal feed, HACCP food or ISO 22000. Animal feed legislation  Approved for B1 Demonstrable knowledge in the field of the legislation which is applicable to pet foods	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum 4 years working experience in a relevant function (quality assurance, production)	Minimum 1 year experience in the assessment of audit reports or minimum experience of 40 audits (attendances) as auditor
GMPB9	Only in combination with approval for B1				

	Training	Required expertise	Audit skills	(Work) Experience	Additional requirements for coordinators
GMPB10	Relevant laboratory training at least at HBO level or at least an equivalent level of experience	Knowledge and skills with respect to methods and techniques aimed at the assessment of quality assurance systems GMP+ standard B10	Compliance with requirements for auditors EN ISO19011:2002 Lead assessor training Experience as an independent auditor in relevant working areas (minimum 20 audits) Effective interviews, depth	Minimum of 4 years' work experience in laboratories	Minimum 1 year experience in the assessment of audit reports or minimum experience of 20 audits (attendances) as auditor
Subject specialist		The certification body must ensure that there is a satisfactory level of expertise within the audit team. If an auditor does not have a satisfactory level of expertise in a specific matter then the certification body must add an subject specialist to the audit team. This person can also be made available by the company.			

# Appendix 3: Procedure for the approval and assessment of certification bodies



## Appendix 4: Personal details of GMP<sup>+</sup> animal feed auditors and coordinators / decision-makers

Certification body	
Address	
Location	

Name of auditor	
Address	
Location	
E-mail address	
Date of birth	

Education (after secondary school)			
Educational establishment	Year	(Graduation) subjects	Diploma

Relevant courses and training			
Course name and description	Year	Educational establishment	Diploma/Certificate

Working experience (starting with the most recent)			
Name and location of employer	Period	Position	Description of activities

Audit experience (relevant audits in the last three years including number of audits carried out)				
Date	Name of the company	Activities/sector of company	Standard checked	(Lead)Auditor/Observer

Enclosures:  
Relevant diplomas and certificates