



**Gesellschaft für
Versuchstierkunde**

Society for Laboratory Animal
Science

GV SOLAS

Working Group on Nutrition

Guidelines for the Quality-Assured Production of Laboratory Animal Diets

June 2002

The present text has been drawn up by the Committee for the Nutrition of Laboratory Animals and released for publication by the Board of Directors and the Advisory Council of the Society for Laboratory Animal Science.

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Note: The following information is based on a comprehensive data validation and experience with technical applications. It is intended to be continually adapted to the latest state of scientific knowledge.

Preamble

The standardization of laboratory animal nutrition has an important effect on the performance, evaluation and reproducibility of experimental animal research projects as well as on the special requirements in the area of breeding.

In addition to observing legal directives and taking into account animal-protection aspects, this standardization requires a limited selection of raw materials, processing characteristics (e.g. separate production lines), the fulfillment of special nutrient restrictions, the greatest possible elimination of undesirable substances, a complete batch tracing, as well as continuous proof of the product quality.

Since the production of laboratory animal diets significantly differs from that of compound feeds for livestock and pets, e.g. in the limited selection of raw materials, the production has been concentrated in special plants. These are ready and able to fulfill specific restrictions and the special requirements to comply with GMP/GLP.

With the “Guidelines for the Quality-Assured Production of Laboratory Animal Diets”, the nutrition committee of the GV-SOLAS intends to provide a binding guide to manufacturers as well as users. These guidelines replace existing documents, such as e.g. “standard contract”, and are subject to the updating service.

Introduction

The objective of these binding guidelines is to give the manufacturers and users of laboratory animal diets information on standardizing and fulfilling quality requirements from GMP and GLP areas.

Furthermore, these guidelines are to be integrated in existing quality assurance and management systems. As a result, manufacturers and users are equally able to compare the described methods and procedures with those that are present at their own companies and to optimize them if necessary.

These guidelines comprise the following areas

- Quality assurance (1)
- Raw materials (2)
- Recipes (3)
- Specifications (4)
- Production (5)
- Packing, storage, shipment (6)
- Quality control / analysis (7)
- Documentation, monitoring (8)

The Appendix (9) describes the areas of standards and regulations (9.1), labeling (9.2), ingredients and their tolerances (9.3), additives and their tolerances (9.4), undesirable substances and their limit values (9.5) and microbiology (9.6).

These guidelines find application with all usual laboratory animal diets for breeding and maintenance.

1 Quality assurance

1.1 QM systems

Manufacturers of laboratory animal diets have to operate a functioning quality management system (QMS). This must provide for the active participation of management and personnel. In particular, the manufacturing and testing instructions must be checked at regular intervals and adapted to the state of scientific and technical knowledge if necessary. The system must be completely documented.

Systems in accordance with DIN EN ISO 9000ff, PIC-GMP and GLP are particularly recommended. The former is a private-sector system that certifies through accredited certification firms and is monitored at least once a year. Systems are subject to government monitoring according to the PIC-GMP (pharmaceutical inspection convention on a good manufacturing practice for pharmaceutical products) or according to GLP (good laboratory practice); these are anchored in the Medicines Act or in the Chemicals Act.

The above-mentioned systems basically consist of the following elements.

- Responsibility of personnel (incl. management), training courses
- QA system and organization
- Means of production (incl. personnel, premises, equipment)
- Product creation, in particular manufacturing
- Quality control (incl. test equipment)
- Release / faulty products
- Self-inspection and improvement
- Documentation, archiving

1.2 Organization

A company diagram (organization chart) is used to represent the responsibilities, authorizations and interrelationships of employees. The independence of manufacturing and quality control in particular must be observed, and the overlapping of responsibilities must be avoided at the same time.

1.3 Maintenance

The manufacturer must make sure that the QM system is maintained. The written records of procedures (e.g. manual with standard work instructions) serve as aids for maintaining and demonstrating a functioning QM system. This ensures that detailed descriptions exist for each process and the necessary process sequences and quality tests are recorded, evaluated and archived. Quality plans, quality circles and inspections for monitoring and improving the effectiveness of the QM system should be mentioned as well. Reports to management in the form of QM reviews are recommended as a summarizing record.

1.4 Personnel / training

The maintenance of a QM system and the faultless production of quality products considerably depends on the personnel. Qualified personnel should therefore be available in sufficient numbers. The management has to provide for the training of all people – especially for personnel in key positions. In addition to the basic theoretical and practical instruction, the personnel must also be appropriately trained for the respective tasks that they are assigned. This also holds true for personal hygiene. Measures are determined and corresponding activities are documented as part of a training plan.

1.5 Deviations in quality / market recalls / alarm plan

A system should be present for recording deviations in quality and introduced measures, as well as for evaluating their effectiveness. If a deviation in quality is present, the corresponding products must be sorted out and labeled. It must be impossible to access blocked goods accidentally. If a market recall should be necessary, it must be ensured that the appropriate people are quickly informed (e.g. via an alarm plan) and the affected batch can be traced (e.g. through batch management).

2 Raw materials

Raw materials should only be obtained from authorized suppliers who guarantee that the corresponding specification is observed. It is recommended to evaluate suppliers regularly.

2.1 Purchasing

The purchasing of raw materials is an important process, which should involve qualified personnel. The purchasing is based on specific procurement documents that contain clear names and specifications of the products to be procured and other quality-relevant information. Special attention must be paid here to consistent nutrient levels, hygiene, and the status of contamination with undesirable substances.

2.2 Incoming inspection

An incoming inspection is performed according to the procurement documents (cf. Chapter 7.1). In particular, sensory and/or chemical analyses are to be performed to ensure conformance with the specifications. Only released raw materials may be processed.

2.3 Raw material storage

Raw materials should be separated from finished products. The principles of controlled storekeeping are valid here (cf. Chapter 6.2). Packed raw materials are to be stored in their original packing or in correspondingly labeled containers.

3 Recipes

Developing and manufacturing laboratory animal diets requires knowledge of animal nutrition (e.g. physiology, requirement standards, acceptance), veterinary medicine (e.g. health maintenance, prevention, therapy), animal feed science (e.g. raw materials, ingredients, additives, processing, technological characteristics, hygiene), laws governing animal feed and medicine (e.g. manufacture, storage, sales) and laboratory animal science (e.g. testing methods, standardization, repeatability, biometry). This knowledge must be kept at the latest state of science and technology.

3.1 Development

The development and verification of products generally consists of planning, specifications, results, testing, verification and validation. When designing recipes, national and international scientific recommendations from the field of laboratory animal science must be taken into account.

3.2 Manufacturing and testing instructions

Manufacturing instructions and testing instructions must be defined as part of product development. The definition of the raw materials to be used, the processing steps and the testing specifications ensures a consistent product quality.

3.3 Recipe, optimized / fixed

In addition to their levels of minerals and additives, laboratory animal diets are generally based on raw materials of vegetable and animal origin or on their treated and processed products. The components of defined recipes should not be changed without the customers being correspondingly informed. In the above-mentioned initial products, the ingredients are subject to native variations, but they must be kept as constant as possible in the end products. Therefore, it is necessary and possible to optimize the proportion of ingredients to a limited extent.

Purified diets (“experimental diets”) are based on highly refined and particularly specified components (e.g. casein, starch, cellulose, soy oil). These raw materials only show very low variations in their ingredients. This makes it possible to use “fixed recipes” without changing the proportions.

3.4 Purpose

Laboratory animal diets can be divided into the following groups:

- Complete diets for breeding and/or maintenance: Laboratory animal diets that are intended to cover the nutritional needs of the animals by themselves.
- Testing diets: Mixed feeds to which test substances (generally chemicals or medicines) have been added; these are used for special research areas and tests.
- Diets for special nutritional purposes: e.g. deficiency/surplus nutrition or to cover the special nutritional needs of animals in which specific digestion, resorption or metabolic disorders are present, are to be expected, or are to be produced.

4 Specification

4.1 Raw materials

Only legally allowed single feeds and additives may be used. In addition, the specific quality requirements for the laboratory animal field regarding a consistent nutrient level, hygiene and contamination with undesirable substances must be observed.

4.2 Ingredients / additives

The specifications for a particular laboratory animal diet must be defined according to the current care recommendations for laboratory animals. A corresponding data sheet should contain information on the ingredients (e.g. crude protein, crude fat, crude fiber, crude ash, calcium, phosphorus, sodium, amino acids), additives (vitamins and trace elements) and other relevant restrictions, in addition to the article name and instructions for use.

4.3 Undesirable substances / contamination

For special research areas and experiments with defined GLP requirements, the proof that undesirable substances do not exceed the limit values defined in 9.5 is very important. It is recommended to have the listed substances analyzed according to standardized and validated methods by accredited test institutes. The listed limit values are binding here.

5 Production

Premises and equipment are to be arranged, designed and maintained so that they are suitable for the intended work routines, a thorough cleaning and maintenance is possible, and the risk of faults is reduced to a minimum. This is to prevent contamination, collection of dust or dirt, and all effects that impair the quality of the product. This also holds true for storage areas.

Production processes are planned, controlled and checked to ensure consistent quality for recurring orders. This is based on a strict, understandable and approved process description, the use of trained personnel and suitable means of production, the monitoring and control of process parameters and product features, as well as the verification of the process.

5.1 Premises / machines

The production always takes place on suitable premises and with corresponding machines. To prevent contamination, storage and production should be separate and the operational processes or cleaning steps should be validated.

5.2 In-process controls

It is recommended to record critical points during the process in the manufacturing and test instructions, check them, and document the test results. The used raw

material batches, the weights, the process parameters and the people responsible for the process should also be documented.

5.3 Hygiene regime

The observance of hygienic rules preventatively ensures that products are stored and delivered in a hygienically faultless way. It is recommended to include personnel, sanitary facilities, buildings, machines and equipment in the regular measures and checks as well. In particular, the type, extent and frequency of pest control measures must also be determined. The implemented measures must be documented.

5.4 Cleaning, maintenance

The design of the machines and equipment should allow good cleaning. The machines and equipment are to be serviced, inspected and repaired in regular intervals and as needed. Protocols must be created for this purpose. It is recommended to rule out the use of contaminated machines by placing a label on the machine (in use / cleaned).

6 Packing, storage, shipment

6.1 Packing / labeling

The goods are to be packed according to set packing instructions with quality-maintaining materials in order to protect them from e.g. contamination and damage and to prevent confusion. Industrial safety and environmental protection regulations should be observed. The packaged goods are to be labeled according to legal specifications. At the same time, measures for traceability are implemented. The use of transport safeguards is advisable.

6.2 Storage

The storage areas are to be designed in such a way that the risk of faults is minimal and a thorough cleaning and maintenance is possible (cf. Chap. 5). The warehouse spaces should be clearly arranged; storage on marked warehouse spaces and admission/removal according to the "FiFo principle" (first in, first out) is recommended. Furthermore, separate areas should be available for raw materials, finished products, quarantine stocks and blocked goods. A regular monitoring of the stock ensures that damage to goods is minimized and expired products (expiration of the "best before" date) are sorted out.

6.2.1 Shipping

The hygiene status of the transport vehicles should be checked before they are loaded. During transport in closed freight compartments, care must be taken that the hygiene status is maintained and the contamination risk is reduced to a minimum.

6.3 Field warehouses

Field warehouses (or intermediate warehouses) are the responsibility of the manufacturer and must always be included in the manufacturer's hygiene regime. A regular monitoring and inspection of the premises for contamination and hygiene risks as well as for the faultless condition of the stock (cf. Chap. 5.3) and the compliance with determined stockkeeping methods (Chap. 6.2) should be documented.

7 Quality control / analysis

Quality control concerns sampling, specifications and tests, among other things. It ensures that the necessary tests are carried out. The quality control is to be performed by trained personnel with suitable equipment. This should be independent of the function area, the products of which it tests. The test methods, the test result, the test decision and the testing person should be listed in the test records. The records are to be archived.

7.1 Goods inspection

Raw materials as well as finished goods are subject to inspection. Samples are taken, and their agreement with determined specifications for physical, chemical and microbiological characteristics is verified on the basis of inspection plans, and corresponding inspection and test records are documented. The tolerances are set in the Feedstuffs Act (Futtermittelgesetz). Limiting regulations are listed in 9.3, 9.4 and 9.5. Inspected and released goods are to be identified as such; non-conforming goods are to be blocked and unauthorized access to them prevented.

7.2 Sampling

The regulations of the official "Sampling and Analysis Decree for Animal Feed" are valid for this area. The samples are to be stored separately and evaluated at regular intervals. After the expiration of the "best before" date plus a defined period of time, the replacement patterns should be re-examined during disposal; deviations are to be documented.

7.3 Analysis methods

The analysis should only be carried out according to standardized and validated methods in accredited laboratories. A (re)validation of the method and/or the test laboratory should be carried out if necessary. It is recommended to list the methods and the analysis tolerances in the test reports.

7.4 Test result / release

If the test results are within the set tolerances (see Appendix), the goods are to be released; only these may be processed or put on the market. If the test results do not meet the specifications, the goods are to be blocked. They must then be retested, processed again with a new test or sorted out if necessary. If test results are lacking,

the goods are to be identified accordingly (e.g. "goods being tested") The test result is to be documented. It is recommended to perform statistic evaluations in order to determine trends.

8 Documentation and monitoring

8.1 Documentation

A good documentation is an important part of the quality assurance. Clear documents prevent errors and allow batches to be traced. All quality-relevant documents, data and records are to be controlled and archived according to the procedures, responsibilities and deadlines set in the QM system. This is especially true for specifications, manufacturing and testing instructions as well as related records (protocols).

8.2 Monitoring

Self-inspections/audits are to be performed by trained personnel at regular intervals. The protocols to be created should contain all of the relevant observations and any suggestions for improvement made during the inspection. The effectiveness of the corrections and improvement measures should also be recorded. These results should be included in summary reports (QM reviews).

Independently of this, regular external inspections / audits should be performed by the responsible agency or the accredited certification firm.

9 Appendix

9.1 Standards and regulations (always up to date)

- DIN EN ISO 9000 ff
- Feedstuffs Act and Feedstuffs Decree (Futtermittelgesetz, Futtermittelverordnung)
- Analysis margins for feedstuff tests
- Decree on sampling procedures and analysis methods for official animal feedstuffs monitoring
- Medicines Act
- Operating regulations for pharmaceutical firms
- Pharmaceutical Inspection Convention – PIC – Guideline of a good manufacturing practice for pharmaceutical products
- Law on the protection from dangerous substances (ChemG), in particular good laboratory practice
- Revised GLP Consensus document no. 5 "Compliance of laboratory suppliers with GLP principles"
- Characterization and manufacturing methods of laboratory animal diets, GV-SOLAS

9.2 Identification of laboratory animal diets (declaration)

Following the German Feedstuffs Act and the Feedstuffs Decree (Futtermittelgesetz, Futtermittelverordnung), the following information must be given for laboratory animal diets:

- Name: The name must indicate whether the laboratory animal diet is intended to be a complete diet or a supplementary diet and for which animal species or animal category it is to be used
- Ingredient levels: Crude protein, crude fat, crude fiber, crude ash
- The net weight
- The “best before” date: This must be indicated as follows
“best before ... (month and year)”
- The reference number of the lot (batch number)
- The purpose and information on proper use
- Name and address of the party putting it on the market
- The recognition number (if issued)

9.3 Ingredients and their tolerances

Tolerances are always only given for the levels of ingredients indicated by the manufacturer. When determining the tolerances, it must be taken into account that the (total) tolerance includes the procedural error margins of the chemical analysis, the previous sampling, the sample preparation, as well as the manufacturing process (raw material fluctuations, technological work accuracy, demixing).

The tolerances for laboratory animal diets were set on the basis of the Feedstuffs Decree (Futtermittelverordnung § 15). The special demands for a laboratory animal diet were taken into account here by limiting the legally allowed tolerances, in particular on the side of the “larger limitation”.

Information on the levels of ingredients in laboratory animal diets is still correct if the determined levels do not deviate from the given levels by more than the values that are listed in the following table. The values include the procedural error margins during the sampling and analysis.

Levels of ingredients in laboratory animal diets:

Ingredients	Given level in %	Permissible deviation	
		Falling short by %	Exceeding by %
Crude protein	below 10	1.0 a	1.5 a
	10 - 20	10 r	15 r
	over 20	2.0 a	3 a
Crude fat	below 8	0.8 a	1.2 a
	8 - 15	10 r	15 r
	over 15	1.5 a	2.3 a
Crude fiber	below 6	1.4 a	0,9 a
	6 - 10	22.5 r	15 r
	over 10	2.7 a	1.8 a
Crude ash	below 5	1.5 a	0.5 a
	5 - 10	30 r	10 r
	over 10	3 a	1 a
Water	below 5		0.5 a
	5 - 10		10 r
	over 10		1 a
Ca, P	below 1	0.15 a	0.3 a
	1 - 6	15 r	22.5 r
	over 6	0.9 a	1.4 a
K, Mg, Na	below 0.7	0.1 a	0.15 a
	0.7 - 5	15 r	22.5 r
Met, Lys, Thr		15 r	
Cys, Try		20 r	

"a": absolute deviation in % of the given level

"r": relative deviation in % of the given level.

9.4 Additives and their tolerances / analysis margins

Due to the very low mixing proportions of additives, the tolerance regulation according to § 19 Feedstuffs Decree gives the manufacturer a margin between the determined and the declared levels of additives for labeling. The analysis margin must also be taken into account when testing for compliance with the manufacturer's level data.

Information on the levels of additives in laboratory animal diets is still considered correct when a determined level deviates from the given one by a maximum of:

1. up to 0.5 units (mg, 1,000 µg, 1,000 IE) by 40 %
1. over 0.5 to 1.0 units by 0.2 units
2. over 1.0 to 50 units by 20 %
3. over 50 to 100 units by 10 units
4. over 100 to 500 units by 10 %

5. over 500 to 1,000 units by 50 units
6. over 1,000 units by 5 %.

Examples of analysis margins for additives:

Determination	Determined level	Analysis margin
Trace elements Cu, Co, Fe, Mn, Zn	below 5 mg/kg 5 to 10 mg/kg 10 to 30 mg/kg 30 to 50 mg/kg over 50 mg/kg	$\pm 50\%$ r ± 2.5 E $\pm 25\%$ r ± 7.5 E $\pm 15\%$ r
J	-	$\pm 25\%$ r
Se	0.05 to 0.5 mg/kg more than 0.5 to 1 mg/kg	$\pm 50\%$ r ± 0.25 E
Vitamin A	2,000 to 4,000 IE/kg more than 4,000 to 100,000 IE/kg	$\pm 1,000$ E $\pm 25\%$ r
Vitamin D	1,000 to 3,000 IE/kg more than 3,000 to 6,000 IE/kg	± 50 r $\pm 1,500$ E
Vitamin E	less than 25 mg/kg over 25 to 50 mg/kg over 50 to 150 mg/kg over 150 to 200 mg/kg over 200 to 500 mg/kg more than 500 mg/kg	$\pm 40\%$ r ± 10 E $\pm 20\%$ r ± 30 E $\pm 15\%$ r ± 75 E

"E": absolute units

"r": relative deviation in % of the determined level.

9.5 Undesirable substances and their limit values

Undesirable substances according to the Feedstuffs Act are unplanned and uncontrolled contaminations of the feed. Maximum levels that are binding for all EU countries have been set for these substances.

Limit values for undesirable substances:

Chlorinated hydrocarbons	mg/kg	Phosphoric acid esters	mg/kg
HCB	0.01	Malathion	1.0
α , β , δ -HCH	0.02	Fenitrothion	1.0
γ -HCH (Lindane)	0.10	Pirimiphos (-methyl)	1.0
Heptachlor and heptachlor epoxy	0.01	Chlorpyrifos (-methyl)	1.0
α , γ -chlordan	0.02	Other phosphoric acid esters	0.5
Aldrin and dieldrin	0.01		
Endrin	0.01		
DDE + DDD+ DDT	0.05		
α , β -endosulfan and -sulfate	0.10	Polychlorinated biphenyls (PCB's)	mg/kg 0.05
Heavy metals	mg/kg	Mycotoxins	mg/kg
Arsenic	1.0	Aflatoxin B 1	0.010
Lead	1.5*	Aflatoxin B 2	0.005
Cadmium	0.4	Aflatoxin G 1	0.005
Mercury	0.1	Aflatoxin G 2	0.005
Fluorine	150**		
Nitrosamines		Fusarium toxins ***	mg/kg
Nitrosodiethylamine (NDEA)	0.01	Deoxynivalenol	0.500
Nitrosodimethylamine (NDMA)	0.01	Ochratoxin	0.100
		Zearalenone	0.100

The above levels of undesirable substances refer to feedstuffs with 88 % dry matter.

- * With a protein level of over 20 % in the feed or with a crude fiber level of over 12 %, values of up to 2.5 mg/kg feed are possible.
- ** Fluorine is an undesirable substance and is listed under heavy metals in this case, even though it is not one.
- *** The given limit values are valid for complete feed for monogasters. Limit values for further fusarium toxins must be determined specifically according to the experiment and in relation to the order, according to the state of scientific knowledge; this is also true for other undesirable substances such as e.g. lipopolysaccharides (LPS).

The Nutrition Committee of the GV-SOLAS has added a few undesirable substances to those listed in the Feedstuffs Decree, in order to take into account laboratory animal diets, and they have adapted the maximum levels to the requirements of laboratory animal care. That means that the given maximum levels were developed in the sense of an acceptance level, taking into account known values in literature on acute toxicity, the "minimum effect level" or "no effect level" and a sufficiently large safety factor.

When checking the determined maximum levels, the analysis margins (in relation to the confirmed value) must be taken into account.

Examples of analysis margins for undesirable substances:

Determination	Determined level	Analysis margin
Arsenic	less than 1.0 mg/kg 1.0 to 2.5 mg/kg	50% r 0.5 E
Lead	1.0 to 3.0 mg/kg more than 3.0 to 5.0 mg/kg	50% r 1.5 E
Cadmium	0.1 to 0.2 mg/kg more than 0.2 to 0.4 mg/kg more than 0.4 to 1.0 mg/kg	50% r 0.1 E 25% r
Fluorine	less than 12 mg/kg more than 12 to 15 mg/kg more than 15 to 30 mg/kg more than 30 to 60 mg/kg more than 60 to 500 mg/kg	50% r 6 E 40% r 12 E 20% r
Mercury	0.04 to 0.06 mg/kg more than 0.06 to 0.10 mg/kg more than 0.10 to 0.20 mg/kg	50% r 0.03 E 30% r
Aflatoxin B 1	1 to 4 µg/kg more than 4 to 10 µg/kg more than 10 µg/kg	50% r 2 E 20% r
Chlorinated hydrocarbons*	** 5 to 100 µg/kg more than 100 to 200 µg/kg more than 200 µg/kg	50% r 50 E 25% r

“E” – absolute units

“r” - relative deviation in % of the determined level.

* Since lawgivers have set maximum levels for the sum of several chlorinated hydrocarbons in Appendix 5 of the Feedstuffs Decree, the data in the column “Determined level” refers to the sum (e.g. DDT + DDE + DDD, calculated as DDT).

** Only valid for HCH isomers and HCB

For undesirable substances not mentioned in the table, the following analysis margins must be taken into account:

Amount of the analysis value	Analysis margin
0.005 – 0.100 mg/kg feed	50 % relative
0.100 - 0.200 mg/kg feed	0.050 mg/kg absolute
over 0.200 mg/kg feed	25 % relative

Antibiotic activity

Antibiotics may not be added to laboratory animal diets.

The antibiotic activity in a diet is determined for test purposes. Since antibiotics are detected here with very different sensitivities, it is not possible to determine a valid limit value for an antibiotic activity for all antibiotics.

In order to differentiate naturally occurring, antibiotically active substances, the applied method must also identify the antibiotic as well as determine the antibiotic activity if necessary.

9.6 Microbiology

(This chapter was developed in cooperation with the Hygiene Committee of the GV-Solas).

9.6.1 Objective

The objective of the recommendations for microbiological testing and evaluation of feedstuffs is to ensure a systematic testing of feed samples for defined microorganisms using validated methods.

Recommendations on limit values for special microorganisms are still given.

These recommendations only take into account the routine testing for pathogens or pathogen groups that is necessary to evaluate the hygienic quality of laboratory animal diets. In concrete cases as well as when the given limit values are exceeded, it can become necessary to perform further tests.

9.6.2 Taking, storage and transport of feedstuff samples

The number of batch-related samples for microbiological testing is to be determined according to the specifications of the legally defined sampling and analysis decree for animal feed.

The sample-taking must be done under hygienically faultless conditions.

The length and type of the sample storage until transport to the testing laboratory are to be documented by the feedstuff manufacturer.

The sample packaging should be selected so that the feed samples are appropriately protected during transport.

The transport times to the testing laboratory should be kept as short as possible.

9.6.3 Testing methods

The preparation of the feed samples sent to be tested and the subsequent analysis may only be carried out in accredited (e.g. acc. to DIN EN ISO/IEC 17025) institutions and only according to current, official and validated methods (e.g. plate-casting or surface methods).

9.6.4 Recommendation of maximum permissible limit values for microorganisms in mixed diets for laboratory animals:

Bacteria	Mixed diets for laboratory animals	
	Crude fiber level < 7 %	Crude fiber level > 7 %
Aerobic germs (TTC ^{**})	< 1 x 10 ⁵ CFU*/g	< 5 x 10 ⁵ CFU/g
Escherichia coli	< 10 ¹ CFU/g	< 10 ¹ CFU/g
Yeasts/molds	< 1 x 10 ³ CFU/g	< 5 x 10 ³ CFU/g
Salmonellae	not detectable	not detectable

* CFU – colony forming units

** TTC – total colony count