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([1]) Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 429/2008

of 25 April 2008

on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 7(4) and (5) thereof,

After consulting the European Food Safety Authority in accordance with Article 7(4) and (5) of Regulation (EC) No 1831/2003,

Whereas:

(1) It is necessary to establish implementing rules concerning the procedure for the authorisation of feed additives under Regulation (EC) No 1831/2003, including rules for the preparation and the presentation of the applications and for the assessment and the authorisation of such additives. These rules are intended to replace the provisions laid down in the Annex to Council Directive 87/153/EEC [2] fixing guidelines for the assessment of additives in animal nutrition.

(2) Those rules should provide for the requirements to be satisfied by the dossier accompanying the application. They should, in particular, set out the scientific data to be submitted for the identification and the characterisation of the additive concerned and the studies to be submitted to demonstrate its efficacy and its safety for humans, animals and the environment in view of the verification and assessment of the applications for authorisation by the European Food Safety Authority (the Authority).

(3) Depending on the nature of the additive or its requested conditions of use, the extent of the studies necessary to evaluate its properties or its effects may vary. Operators should, therefore, be granted some flexibility with respect to the kind of studies and material to be submitted to demonstrate the safety and the efficacy of the additive concerned. Operators making use of that flexibility should have to justify their choice in the dossier.

(4) The Authority should have the possibility to request supplementary information, where appropriate, in order to determine whether the additive complies with the conditions for authorisation referred to in Article 5 of Regulation (EC) No 1831/2003.

(5) It is indispensable to apply appropriate quality standards when developing dossiers for additives intended for use in feed or water to ensure that the results of laboratory tests are not disputed.

(6) Where necessary, specific requirements should be established for each category of additives referred to in Article 6(1) of Regulation (EC) No 1831/2003.

(7) To stimulate efforts to obtain authorisations for minor species while keeping the necessary level of safety, specific

[1] OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 68).

[2] OJ L 64, 7.3.1987, p. 19. Repealed by Regulation (EC) No 1831/2003.

conditions should be provided for taking into account the possibility of extrapolating the results of the studies carried out on major species to minor species.

(8) Implementing rules concerning applications for authorisation should take into account different requirements for food-producing animals and other animals, for which aspects regarding the safety evaluation for the human consumer are not relevant.

(9) Recourse to procedures involving the use of laboratory animals for experimental or other scientific purposes and animal testing according to Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of the animals used for experimental and other scientific purposes [1] should be kept to a minimum.

(10) To avoid repeating studies unnecessarily, simplified procedures should be provided for the authorisation of additives already authorised for use in food.

(11) As regards additives already authorised without a time limit under Council Directive 70/524/EEC [2], where appropriate, the possibility should be provided for the applicant to demonstrate efficacy, where studies are not available, by any other material which is available to demonstrate efficacy, in particular material concerning the long history of use of the additive concerned.

(12) Rules should be provided for applications for modifications of authorisations in accordance with Article 13(3) of Regulation (EC) No 1831/2003.

(13) Rules should also be provided for applications for the renewal of authorisation under Article 14 of Regulation (EC) No 1831/2003.

(14) With respect to the provisions concerning the safety and efficacy studies to be carried out in support of the application, it is necessary to provide for a transitional period during which the present rules continue to apply. Applications submitted before the entry into force of this Regulation should continue to be treated in accordance with the Annex to Directive 87/153/EEC. With respect to applications submitted during a certain period after entry into force, taking into account the long period of time required for some studies, applicants should have a choice between the rules provided for in this Regulation and the Annex to Directive 87/153/EEC. The implementing rules have been drawn up on the basis of present scientific and technical knowledge and they should be adapted if necessary to any new developments.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

The following definitions shall apply for the purpose of this Regulation:

1. 'pets and other non-food producing animals' means animals belonging to species normally nourished, bred or kept, but not consumed by humans, except horses;

2. 'minor species' means food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat animals), pigs, chickens (including laying hens), turkeys and fish belonging to the *Salmonidae*.

Article 2

Application

1. An application for the authorisation of a feed additive, as provided for in Article 7 of Regulation (EC) No 1831/2003, shall be submitted using the form set out in Annex I.

It shall be accompanied by a dossier as provided for in Article 3 (hereinafter 'the dossier'), containing the particulars and documents referred to in Article 7(3) of Regulation (EC) No 1831/2003.

2. Where, in accordance with Article 18 of Regulation (EC) No 1831/2003, the applicant requests certain parts of the dossier referred to in paragraph 1 to be kept confidential, he shall provide verifiable justification for each document or each part of a document that disclosure of this information might significantly harm its competitive position. Confidential parts shall be submitted separately from the rest of the dossier and shall not be included in the summary referred to in Article 7(3)(h) of Regulation (EC) No 1831/2003. The applicant shall send to the Commission a copy of the parts of the dossier requested to be treated as confidential and of the accompanying justification.

Article 3

Dossier

1. The dossier shall adequately and sufficiently demonstrate that the feed additive satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003.

[1] OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of European Parliament and the Council (OJ L 230, 16.9.2003, p. 32).

[2] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

2. The general requirements for the preparation and presentation of the dossier shall be as set out in Annex II.

The specific requirements to be satisfied by the dossier, in the case concerned, shall be as set out in Annex III.

The minimum duration of long term studies shall be as set out in Annex IV.

3. By way of derogation from paragraph 2, the applicant may submit a dossier not satisfying the requirements provided for in paragraph 2, provided that he submits a justification for each element not complying with those requirements.

Article 4

Transitional measures

1. To applications for authorisation submitted before the date of entry into force of this Regulation the Annex to Directive 87/153/EEC shall continue to apply.

2. For applications for authorisation submitted before 11 June 2009 applicants may choose the continued application of Sections III and IV of Parts I and II of the Annex to Directive 87/153/EEC instead of points 1.3, 1.4, 2.1.3, 2.1.4, 2.2.3, 2.2.4, 3.3, 3.4, 4.1.3, 4.1.4, 4.2.3, 4.2.4, 5.3, 5.4, 6.3, 6.4, 7.3, 7.4, 8.3 and 8.4 of Annex III and instead of the provisions laid down in the column 'Minimum duration of long term efficacy studies' of the tables of Annex IV.

Article 5

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 April 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX I

APPLICATION FORM REFERRED TO IN ARTICLE 2(1) AND ADMINISTRATIVE DATA

1. **APPLICATION FORM**

EUROPEAN COMMISSION

HEALTH AND CONSUMER PROTECTION

DIRECTORATE-GENERAL

(Address)

Date: .....

Subject: Application for authorisation of a feed additive in accordance with Regulation (EC) No 1831/2003.

- ☐ Authorisation of a feed additive or a new use of a feed additive (Article 4(1) of Regulation (EC) No 1831/2003)
- ☐ Authorisation of an existing product (Article 10(2) or 10(7) of Regulation (EC) No 1831/2003)
- ☐ Modification of an existing authorisation (Article 13(3) of Regulation (EC) No 1831/2003)
- ☐ Renewal of a feed additive authorisation (Article 14 of Regulation (EC) No 1831/2003)
- ☐ Urgent authorisation (Article 15 of Regulation (EC) No 1831/2003)

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the Community (Article 4(3) of Regulation (EC) No 1831/2003), under the conditions required in Article 7(3)(a) of Regulation (EC) No 1831/2003 (name, address….)

.....

.....

submit(s) the present application in order to obtain an authorisation for the following product as a feed additive:

1.1. **Identification and characterisation of additive**

Additive name (characterisation of the active substance(s) or agent(s) as defined in the subsections 2.2.1.1 and 2.2.1.2 of Annex II):

.....

.....

Trade name (if appropriate for the authorisations linked to the holder):

.....

.....

under the category/ies and functional group/s of additives ([1]) (list):

.....

.....

target species:

.....

.....

.....

Name of the authorisation holder: (Article 9(6) of Regulation (EC) No 1831/2003)

.....

.....

This additive is already authorised in feed legislation by Directive …/…/(E)EC or Regulation (EC) No …/… under number … as (additive category)

.....

This additive is already authorised in food legislation by Directive …/…/(E)EC or Regulation (EC) No …/… under number … as

.....

for use in

.....

If the product consists of, contains or is produced from a Genetically Modified Organism (GMO), please provide the following information:

- ☐ unique identifier (Commission Regulation (EC) No 65/2004 ([2]) (where appropriate):

  .....

- ☐ either the details of any authorisation granted in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([3]):

  .....

- ☐ or the details of any pending application for authorisation under Regulation (EC) No 1829/2003:

  .....

1.2. **Conditions of use**

1.2.1. *Use in complete feedingstuffs*

Animal species or category:

.....

.....

([1]) For the functional group 'other zootechnical additives' under the category of zootechnical additives, it shall be necessary to define clearly which function is sought for the additive.

([2]) OJ L 10, 16.1.2004, p. 5.

([3]) OJ L 268, 18.10.2003, p. 1. Regulation as last amended by Regulation (EC) No 298/2008 (OJ L 97, 9.4.2008, p. 64).

Maximum age or weight:

.....

.....

Minimum dose (if appropriate): mg or Units of activity ([4]) or colony forming units (CFU) or ml/kg of complete feedingstuffs with a moisture content of 12 %

.....

.....

Maximum dose (if appropriate): mg or Units of activity or CFU or ml/kg of complete feedingstuffs with moisture content of 12 %

.....

.....

For liquid feeds the minimum and maximum doses can be expressed per litre.

1.2.2. *Use in water*

Minimum dose (if appropriate): mg or Units of activity or CFU or ml/l of water

.....

.....

Maximum dose (if appropriate): mg or Units of activity or CFU or ml/l of water

.....

.....

1.2.3. *Special conditions of use (if appropriate)*

Animal species or category:

.....

.....

Maximum age:

.....

.....

Minimum dose (if appropriate): mg or Units of activity or CFU/kg of complementary feedingstuffs with moisture content of 12 %

.....

.....

([4]) Definition of 'Unit' shall be provided by the applicant.

Maximum dose (if appropriate): mg or Units of activity or CFU/kg of complementary feedingstuffs with moisture content of 12 %

……

……

For liquid feeds the minimum and maximum doses can be expressed per litre.

Conditions or restrictions for use (if appropriate):

……

……

……

Specific conditions or restrictions for handling (if appropriate):

……

……

……

……

Maximum residue limit (if appropriate):

animal species or category:

……

……

marker residue:

……

……

target tissues or products:

……

……

……

Maximum residue in tissues or products (μg/kg):

……

……

……

Withdrawal period:

.....

1.3. **Reference samples**

Community Reference Laboratory (CRL) sample number (if applicable):

.....

Lot number/batch code:

.....

Manufacturing date:

.....

Expiry date:

.....

Concentration:

.....

Weight:

.....

Physical description:

.....

Container description:

.....

Storage requirements:

.....

1.4. **Modification requested (where appropriate)**

.....

.....

.....

.....

Copy of this application has been sent directly to the Authority with the dossier and to the CRL with the reference samples.

Signature .....

1.5. **Enclosures:**

- ☐ complete dossier (only to the Authority);
- ☐ public summary of the dossier;
- ☐ detailed summary of the dossier;
- ☐ list of the parts of the dossier requested to be treated as confidential and a copy of the respective concerned parts of the dossier (only to Commission and Authority);
- ☐ copy of administrative data of applicant(s);
- ☐ three samples of the feed additive to the CRL following Article 7(3)(f) of Regulation (EC) No 1831/2003 (only to the CRL);
- ☐ material safety data sheet (only to the CRL);
- ☐ certificate of identification and analysis (only to the CRL); and
- ☐ confirmation that the fee to the CRL has been paid (Article 4 of Regulation (EC) No 378/2005 ([5]).

Complete the parts of the form where appropriate, and delete those parts that are not relevant. The original application form (with other enclosures requested) shall be sent directly to the European Commission.

2. **ADMINISTRATIVE DATA OF APPLICANT(S)**

Contact details for submitting an application for the authorisation of a feed additive under Regulation (EC) No 1831/2003

(1) Applicant company or person

(a) Name of the applicant or company

(b) Address (street, number, post code, city, country)

(c) Telephone

(d) Fax

(e) E-mail (if available)

(2) Contact person (for all correspondence with Commission, Authority and CRL)

(a) Name of contact person

(b) Position

(c) Address (street, number, post code, city, and country)

(d) Telephone

(e) Fax

(f) E-mail (if available)

([5]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8). Regulation as amended by Regulation (EC) No 850/2007 (OJ L 188, 20.7.2007, p. 3).

ANNEX II

GENERAL REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3

GENERAL ASPECTS

This Annex sets out the requirements for establishing the list and the characteristics of studies and information on substances, micro-organisms and preparations to be submitted with dossiers under Article 7 of Regulation (EC) No 1831/2003 for:

— an authorisation as a new feed additive,

— an authorisation of a new use of a feed additive,

— a modification of an existing authorisation of a feed additive, or

— a renewal of the authorisation of a feed additive.

The dossiers must enable an assessment to be made of additives based on the current state of knowledge and permit verification of the compliance of these additives with the fundamental principles for authorisation, which are laid down in Article 5 of Regulation (EC) No 1831/2003.

The studies to be submitted and the extent of them will depend on the additive nature, the category and functional group, the type of authorisation (non-holder specific vs. holder specific), the substance itself, the target animals and the conditions of use. The applicant shall refer to this Annex and to Annex III in order to evaluate which studies and information shall be submitted with the application.

The applicant shall clearly provide the reasons for the omission or deviation from the dossier of any data prescribed in this Annex, Annex III and Annex IV.

The dossier shall include detailed reports of all the studies performed, presented in accordance with the numbering system proposed in this Annex. The dossier shall include references and copies of all published scientific data mentioned and the copies of any other relevant opinions which have already been produced by any recognised scientific body. Where these studies have already been evaluated by a European scientific body following the legislation in force in the Community, a reference to the result of the evaluation shall be sufficient. Data from studies that have been conducted and published previously or coming from peer review shall clearly refer to the same additive as the one subject to the application for authorisation.

Studies, including those that have been conducted and published previously or coming from peer review, shall be performed and documented according to appropriate quality standards (e.g. Good Laboratory Practice (GLP)) in accordance with Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances ([1]) or International Organisation for Standardisation (ISO).

Where *in vivo* or *in vitro* studies are carried out outside the Community, the applicant shall demonstrate that the facilities concerned comply with the Organisation for Economic Cooperation and Development (OECD) principles of Good Laboratory Practice or ISO standards.

The determination of physico-chemical, toxicological and eco-toxicological properties must be performed in accordance with the methods established by Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([2]), as last amended by Commission Directive 2004/73/EC ([3]), or with updated methods recognised by international scientific bodies. The use of methods other than these must be justified.

The use of *in vitro* methods or of methods refining or replacing the usual tests using laboratory animals or reducing the number of animals used in these test shall be encouraged. Such methods shall be of the same quality and provide the same level of assurance as the method they aim to replace.

([1]) OJ L 50, 20.2.2004, p. 44.

([2]) OJ L 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121 of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 852; corrected by OJ L 136 29.5.2007, p. 281).

([3]) OJ L 152, 30.4.2004, p. 1; corrected by OJ L 216, 16.6.2004, p. 3.

The description of the methods of analysis in feed or water shall be in conformity with the rules of GLP as laid down in Directive 2004/10/EC and/or EN ISO/IEC 17025. These methods shall comply with the requirements laid down in Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([4]).

Each dossier shall contain a public summary and a scientific detailed summary in order to enable the additive concerned to be identified and characterised.

Each dossier shall contain a post-market monitoring proposal where required by Article 7(3)(g) of Regulation (EC) No 1831/2003 and a labelling proposal as referred to in Article 7(3)(e) of Regulation (EC) No 1831/2003.

Safety assessment

This is based on studies intended to demonstrate the safety of the use of the additive in relation to:

(a) the target species at the highest proposed levels of incorporation in the feed or water and at a multiple of that level to establish a margin of safety;

(b) consumers who ingest food products obtained from animals that have received the additive, its residues or its metabolites. In this case, safety will be ensured by the setting of maximum residue limits (MRLs) and withdrawal periods based on an Acceptable Daily Intake (ADI) or an Tolerable Upper Intake Level (UL);

(c) persons likely to be exposed to the additive by respiratory, mucosal, eye or cutaneous contact while handling the additive or incorporating it into premixtures or complete feed or water or using feed or water containing the additive concerned;

(d) animals and humans with respect to the selection and spread of antimicrobial resistance genes; and

(e) the environment, as a result of the additive itself or products derived from the additive, either directly and/or as excreted by animals.

Where an additive has multiple components, each one may be separately assessed for consumer safety and then consideration given to the cumulative effect (where it can be shown that there are no interactions between the components). Alternatively, the complete mixture shall be assessed.

Efficacy assessment

This is based on studies that are intended to demonstrate the efficacy of an additive in terms of the aims of its intended use as defined in Article 6 (1) and Annex I of Regulation (EC) No 1831/2003.

1. **SECTION I: SUMMARY OF THE DOSSIER**

1.1. **Public summary according to Article 7(3)(h) of Regulation (EC) No 1831/2003**

The applicant shall submit a summary indicating the main features of the additive concerned. The summary shall not contain any confidential information and shall be structured as follows:

1.1.1. *Contents*

(a) name of the applicant(s);

(b) identification of the additive;

(c) method of production and method of analysis;

(d) studies on safety and efficacy of the additive;

(e) proposed conditions for use; and

(f) proposal for post-market monitoring.

([4]) OJ L 165, 30.4.2004; corrected by OJ L 191, 28.5.2004, p. 1.

1.1.2. *Description*

(a) name and address of the applicant(s)

This information shall be provided in all cases, independent of the type of feed additive authorisation (holder-specific or non-holder specific). When a dossier is submitted by a group of applicants, the name of each of them shall be indicated.

(b) identification of the additive

The identification of the additive shall contain a summary of the information required according to Annex II or III, depending on the type of the feed additive authorisation. In particular: name of the additive, proposed classification by category and functional group, target species/animal categories and doses.

(c) method of production and method of analysis

The manufacturing process shall be described.

The general procedures of the analytical methods to be used for the analysis for the official controls of the additive as such, in premixtures, and in feedingstuffs, as required in this Annex and Annex III shall be described. If appropriate, on the basis of the information submitted in this Annex and Annex III, the procedure of the method(s) to be used for the analysis for the official controls of the additives or its metabolites in food of animal origin shall be included.

(d) studies on safety and efficacy of the additive

The conclusion regarding the safety and efficacy of the additive based on the different studies performed shall be given. The results of the studies may be included in a tabular form to support the conclusion of the applicant(s). Only studies required according to Annex III shall be indicated in the summary.

(e) proposed conditions for use

The proposal for conditions of use shall be provided by the applicant(s). In particular the applicant shall describe the level of use in water or feed, together with the detailed conditions of use in complementary feedingstuffs. Information is also required where other methods of administration or incorporation in feed or water are used. Any specific conditions for use (e.g. incompatibilities), specific labelling requirements and animal species for which the additive is intended shall be described.

(f) proposal for post-market monitoring

This part shall only relates to additives, which according to point (g) of Article 7(3) of Regulation (EC) No 1831/2003, do not belong to categories shown as (a) or (b) in Article 6(1) of the same Regulation and to additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs.

1.2. **Scientific summary of the dossier**

A scientific summary including details of each part of the documents submitted to support the application, according to this Annex and Annex III shall be submitted. This summary shall include the conclusions made by the applicant(s).

The summary must follow the order of this Annex and address all the different parts with reference to the relevant pages of the dossier.

1.3. **List of documents and other particulars**

The applicant must identify the number and titles of volumes of documentation submitted in support of the application. A detailed index with reference to volumes and pages shall be added.

1.4. **List of parts of the dossier requested to be treated as confidential, where necessary**

The list shall make reference to the relevant volumes and pages of the dossier.

2. **SECTION II: IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS**

The additive has to be fully identified and characterised.

2.1. **Identity of the additive**

2.1.1. *Name of the additive*

If appropriate, a proposal for the trade name shall be made for additives linked to a holder of authorisation.

2.1.2. *Proposal for classification*

A proposal for the classification of an additive for one or more categories and functional groups according to its main functions under Article 6 and Annex I of Regulation (EC) No 1831/2003 shall be made.

Any data from other known uses of the identical active substances or agents (e.g. use in food, human or veterinary medicine, agriculture and industry) must be provided. Any other authorisation as feed or food additive, veterinary drugs or other kind of authorisations of the active substance has to be specified.

2.1.3. *Qualitative and quantitative composition (active substance/agent, other components, impurities, batch to batch variation)*

The active substance(s)/agent(s) and all other components of the additive shall be listed, giving the proportion by weight in the final product. The qualitative and quantitative batch to batch variation of the active substance (s)/agent(s) shall be determined.

For micro-organisms: the number of viable cells or spores expressed as CFU per gram shall be determined.

For enzymes: each declared (main) activity shall be described and the number of units of each activity in the final product given. Relevant side activities shall be also mentioned. The units of activity shall be defined and preferably as μmoles of product released per minute from the substrate, also indicating the pH and the temperature.

If the active component of the additive is a mixture of active substances or agents, each of which is clearly definable (qualitatively and quantitatively), the active substance(s)/agent(s) components must be described separately and the proportions in the mixture given.

Other mixtures in which the constituents cannot be described by a single chemical formula and/or where not all can be identified shall be characterised by constituent(s) contributing to its activity and/or typical major constituent(s).

Without prejudice to any request of supplementary information made by the Authority according to Article 8(2) of Regulation (EC) No 1831/2003, the applicant may omit the description of other components with no safety concerns other than active substances or agents for additives not within the categories of zootechnical additives, coccidiostats and histomonostats, and not in the scope of Regulation (EC) No 1829/2003. In any case, all studies reported in the dossier must be based on the actual additive requested for the authorisation and may provide information on the other possible different preparations that could be made. An in-house identifier may be allowed, embedded in third-party documents, and a statement is required to list the identifiers and to confirm that the identifier(s) refers to the formulation(s) for which the request is made.

2.1.4. *Purity*

The applicant shall identify and quantify chemical and microbial impurities, substances with toxic or other undesirable properties that are not intentionally added and do not contribute to the activity of additive. In addition, for fermentation products, the applicant shall confirm the absence of production organisms in the additive. The protocol used for the routine screening of production batches for contaminants and impurities shall be described.

All the data provided have to support the proposal for a specification of the additive.

Specific requirements depending on the production process, complying with existing Community legislation, are listed below.

2.1.4.1. Additives whose authorisation is linked to a holder of authorisation

For additives whose authorisation is linked to a holder of authorisation, the relevant information related to the specific process used by the manufacturer, based on existing standards used for other related purposes, shall be provided. Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications or specifications from European Community food additive authorisations can be used.

2.1.4.2. Additives whose authorisation is not linked to a holder of authorisation

For feed additives whose authorisation is not linked to a holder of authorisation, existing standards used for other related purposes, or that have specifications for food additives as authorised in the European Community or from JECFA can be used. When such standards are not available, or where relevant to the manufacturing process, at least the following particulars shall be described and their concentrations determined:

— for micro-organisms: microbiological contamination, mycotoxins, heavy metals;

— for fermentation products (not containing micro-organisms as active agents): they shall follow the same requirements as for micro-organism products (see above). The extent to which spent growth medium is incorporated into the final product shall also be indicated.

— for plant derived substances: microbiological and botanical contamination (e.g. castor oil plant, weed seeds, rye ergot in particular), mycotoxins, pesticide contamination, maximum values for solvents and, where appropriate, substances of toxicological concern known to occur in the original plant;

— for animal derived substances: microbiological contamination, heavy metals and maximum values for solvents, where appropriate;

— for mineral substances: heavy metals, dioxins and PCBs;

— for products produced by chemical synthesis and processes: all chemicals used in the synthetic processes and any intermediate products remaining in the final product shall be identified and their concentrations given.

The selection of mycotoxins for analysis shall be made according to the different matrices, where appropriate.

2.1.5. *Physical state of each form of the product*

For solid preparations data on particle size distribution, particle shape, density, bulk density, dusting potential and the use of processes which affect physical properties shall be provided. For liquid preparations, data for viscosity and surface tension shall be given. Where additive is intended to be used in water, the solubility or extent of dispersion shall be demonstrated.

2.2. **Characterisation of the active substance(s)/agent(s)**

2.2.1. *Description*

A qualitative description of the active substance or agent shall be given. This shall include purity and origin of the substance or agent, plus any other relevant characteristics.

2.2.1.1. Chemical substances

Chemically well-defined substances shall be described by generic name, chemical name according to IUPAC (International Union of Pure and Applied Chemistry) nomenclature, other generic international names and abbreviations and/or Chemical Abstract Service Number (CAS). The structural and molecular formula and molecular weight must be included.

For chemically defined compound used as flavourings, the FLAVIS number in connection with relevant chemical group shall be included. For plant extracts the phytochemical markers must be included.

Mixtures in which the constituents cannot be described by a single chemical formula and/or not all of them can be identified shall be characterised by constituent(s) contributing to its activity and/or typical major constituent(s). Marker compound shall be identified to allow stability to be assessed and to provide a means of traceability.

For enzyme and enzyme preparations, the number and systematic name proposed by the International Union of Biochemistry (IUB) in the most recent edition of 'Enzyme Nomenclature' shall be given for each declared activity. For activities not yet included, a systematic name consistent with the IUB rules of nomenclature shall be used. Trivial names are acceptable provided that they are unambiguous and used consistently throughout the dossier, and they can be clearly related to the systematic name and IUB number at their first mention. The biological origin of each enzyme activity must be given.

The microbial origin of chemical substances produced by fermentation shall also be described (see 2.2.1.2 Micro-organisms).

2.2.1.2. Micro-organisms

For all micro-organisms, whether used as product or as production strain, the origin shall be provided.

For micro-organisms used as a product or as production strain, any history of modification shall be indicated. The name and taxonomic classification of each micro-organism shall be provided, according to the latest published information in the International Codes of Nomenclature (ICN). Microbial strains shall be deposited in an internationally recognised culture collection (preferably in the European Union) and maintained by the culture collection for the authorised life of the additive. A certificate of deposition from the collection, which shall specify the accession number under which the strain is held, must be provided. In addition, all relevant morphological, physiological and molecular characteristics necessary to provide the unique identification of the strain and the means to confirm its genetic stability shall be described. For GMOs the description of the genetic modifications shall be given. The unique identifier for each GMO, as referred in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, shall be included.

2.2.2. *Relevant properties*

2.2.2.1. Chemical substances

Description of physical and chemical properties shall be given. Dissociation constant, pKa, electrostatic properties, melting point, boiling point, density, vapour pressure, solubility in water and in organic solvents, K_{ow} and K_d/K_{oc}, mass spectrometry and absorption spectra, NMR data, possible isomers and any other appropriate physical properties shall be provided, where appropriate.

Substance produced *via* fermentation shall be free of antimicrobial activities relevant to the use of antibiotics in humans or animals.

2.2.2.2. Micro-organisms

— Toxins and virulence factors

Toxins or virulence factors shall be demonstrated to be absent or of no concern. Strains of bacteria belonging to a taxonomic group that includes members known to be capable of producing toxins or other virulence factors shall be subject to appropriate tests to demonstrate at a molecular and, if necessary, cellular level the absence of any cause for concern.

For strains of micro-organisms for which there is no history of an apparent safe use and whose biology remains poorly understood, a full package of toxicological studies shall be necessary.

— Antibiotic production and antibiotic resistance

Micro-organisms used as additives or as production strain, shall be free of antibiotic activity or shall not be capable of producing antibiotic substances that are relevant as antibiotics in humans and animals.

Strains of micro-organisms intended for use as additives shall not contribute further to the reservoir of antibiotic resistance genes already present in the gut flora of animals and the environment. Consequently, all strains of bacteria shall be tested for resistance to antibiotics in use in human and veterinary medicine. Where resistance is detected, the genetic basis of the resistance and the likelihood of transfer of resistance to other gut-inhabiting organisms shall be established.

Strains of micro-organisms carrying an acquired resistance to antimicrobial(s) shall not be used as feed additives, unless it can be demonstrated that resistance is a result of chromosomal mutation(s) and it is not transferable.

2.3. **Manufacturing process, including any specific processing procedures**

To define the critical points of the process that may have an influence on the purity of the active substance/agent(s) or additive a description of the manufacturing process shall be given. A material safety data sheet of chemicals used in the production process shall be provided.

2.3.1. *Active substance(s)/agent(s)*

A description of the production process (e.g. chemical synthesis, fermentation, cultivation, extraction from organic material or distillation) used in the preparation of the active substance(s)/agent(s) of the additive shall be submitted, if appropriate by way of a flowchart. The composition of the fermentation/cultivation media shall be provided. Purification methods shall be thoroughly described.

For Genetically Modified Micro-organisms (GMMs), used as source of additives and grown under contained conditions, Council Directive 90/219/EC ([5]) applies. A description of fermentation processes (culture medium, fermentation condition and downstream processing of the fermentation products) shall be included.

2.3.2. Additive

A detailed description of the manufacturing process of the additive shall be submitted. The key stages in the preparation of the additive including the point(s) of introduction of the active substance(s)/agent(s) and other components, and any subsequent processing steps affecting the additive preparation should be provided, if appropriate by means of a flowchart.

2.4. **Physico-chemical and technological properties of the additive**

2.4.1. *Stability*

Stability is generally measured by the analytical follow-up of the active substance(s)/agent(s) or its activity/viability. For enzymes, stability may be defined in terms of loss of catalytic activity; for micro-organisms in terms of loss of viability; for flavouring substances in terms of loss of flavour. For other chemical mixtures/extracts stability may be assessed by monitoring the concentration of one or more appropriate marker substances.

Stability of the additive

The stability of each formulation of the additive, on exposure to different environmental conditions (light, temperature, pH, moisture, oxygen and packing material) shall be studied. Expected shelf-life of the additive as marketed should be based on at least two model situations covering the likely range of use conditions (e.g., 25 °C, 60 % relative air humidity (HR) and 40 °C, 75 % HR).

([5]) OJ L 117, 8.5.1990, p. 1. Directive as last amended by Commission Decision 2005/174/EC (OJ L 59, 5.3.2005, p. 20).

Stability of the additive used in premixtures and feedingstuffs

For additives used in premixtures and in feedingstuffs, with the exception of flavouring compounds, the stability of each formulation of the additive shall be studied under common manufacturing and storage conditions of premixtures and of feedingstuffs. Stability studies in premixtures shall be of least six months' duration. Stability shall be tested preferably with premixtures containing trace elements; otherwise the additive should be labelled as 'not to be mixed with trace elements'.

Stability studies in feedingstuffs normally shall extend at least for three months. Generally stability shall be checked in mash and pelleted (including the influence of pelleting or other forms of treatment) feed for the main animal species of the claim.

For additives intended to be used in water, the stability of each formulation of the additive has to be studied in water under condition simulating practical use.

Where there is a loss of stability, and where appropriate, potential degradation or decomposition products shall be characterised.

Data shall be provided from analyses that include at least one observation at the beginning and one at the end of the storage period.

Where necessary, studies shall contain the detailed quantitative and qualitative composition of the premixtures or of the feedingstuffs used for the trials.

2.4.2. *Homogeneity*

The capacity for homogeneous distribution of the feed additive (other than flavouring compounds) in premixtures, feedingstuffs or water must be demonstrated.

2.4.3. *Other characteristics*

Other characteristics, such as dusting potential, electrostatic properties or dispersability in liquids must be described.

2.4.4. *Physico-chemical incompatibilities or interactions*

Physico-chemical incompatibilities or interactions that could be expected with feed, carriers, other approved additives, or medicinal products must be shown.

2.5. **Conditions of use of the additive**

2.5.1. *Proposed mode of use in animal nutrition*

The animal species or categories, age group or production stage of animals shall be indicated in accordance with the categories listed in Annex IV of this Regulation. Possible contra-indications shall be mentioned. The proposed use, in feed or water shall be defined.

Details of the proposed method of administration and level of inclusion must be provided for premixtures, feedingstuffs or water for drinking. In addition, the proposed dose in the complete feed and the proposed duration of administration and proposed withdrawal period must be provided where appropriate. A justification is required where a particular use of an additive in complementary feedingstuffs is proposed.

2.5.2. *Information related to users/workers safety*

2.5.2.1. Chemical substances

A material safety data sheet formatted in accordance with the requirements of Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC ([6]) must be provided. If necessary, measures for the prevention of occupational risks and means of protection during manufacture, handling, use and disposal shall be proposed.

([6]) OJ L 76, 22.3.1991, p. 35. Directive as last amended by Directive 2001/58/EC (OJ L 212, 7.8.2001, p. 24).

2.5.2.2. Micro-organisms

A classification according to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) ([7]) shall be submitted. For micro-organisms not classified in group 1 in this Directive, information shall be provided to customers to allow them to take the relevant protection measures for their workers, as defined in Article 3 (2) of the said Directive.

2.5.2.3. Labelling requirements

Without prejudice to the labelling and packaging provisions laid down in Article 16 of Regulation (EC) No 1831/2003, any specific labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities and contraindications) and instructions for proper use shall be indicated.

2.6. **Methods of analysis and reference samples**

The methods of analysis shall be submitted in the standard layout as recommended by ISO (i.e. ISO 78-2).

According to Regulation (EC) No 1831/2003 and Regulation (EC) No 378/2005, methods of analysis included in this section shall be evaluated by the CRL. The CRL shall submit to the Authority an evaluation report indicating whether these methods are suitable to be used for official controls of the feed additive that is the object of the application. The CRL evaluation shall focus on the methods specified in sections 2.6.1 and 2.6.2.

If an MRL has been established for the substance object of the application by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ([8]), section 2.6.2 will not be subject to evaluation by the CRL. The applicant shall compile section 2.6.2 providing the same method, information and particulars (including relevant updates) for submission to European Medicines Agency (EMEA) in accordance with Annex V of Regulation (EEC) No 2377/90 and in accordance with 'Notice to Applicants and Guidelines', Volume 8 of the series 'Rules governing medicinal products in the European Union'.

Analytical methods described under 2.6.3 may also be included in the evaluation, if considered necessary by the CRL, the Authority or the Commission.

In accordance with Regulation (EC) No 378/2005, the applicant shall provide reference samples directly to the CRL prior to the evaluation of the technical dossier, and replacement samples before the expiration date.

Applicants shall refer to the detailed guidance provided by the CRL in accordance with Article 12 of Regulation (EC) No 378/2005.

2.6.1. *Methods of analysis for the active substance*

Detailed characterisation of the qualitative and, where applicable, quantitative analytical method(s) for determining compliance with maximum or minimum proposed levels of the active substance(s)/agent(s) in the additive, premixtures, feedingstuffs and, when appropriate, water, shall be provided.

2.6.1.1. These methods shall meet the same requirements as those for methods of analysis used for official control purpose laid down in Article 11 of Regulation (EC) No 882/2004 In particular they shall meet at least one of the following requirements:

— comply with relevant Community rules (e.g. Community methods of analysis) where they exist;

— comply with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted, or those agreed in national legislation (e.g. CEN Standard methods);

([7]) OJ L 262, 17.10.2000, p. 21.

([8]) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No203/2008 (OJ L 60, 5.3.2008, p. 18).

— are fit for the intended purpose, developed in accordance with scientific protocols and validated in a ring test in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725 or IUPAC); or

— are validated in-house according to international harmonised guidelines for the in-house validation of methods of analysis ([9]) with respect to the characterising parameters mentioned in 2.6.1.2.

2.6.1.2. The detailed characterisation of the method(s) shall include the appropriate characteristics set out in Annex III of Regulation (EC) No 882/2004.

2.6.1.3. Performance characteristics of in-house validated methods shall be verified by testing the method in a second, accredited and independent laboratory. Results of such tests shall be provided together with any other information supporting the transferability of the method to an official control laboratory. For reasons of independence and involvement in the evaluation of the documentation provided by the applicant, where the second laboratory is a laboratory participating in the consortium of National Reference Laboratories (NRLs) assisting the CRL, as laid down in Regulation (EC) No 378/2005, the laboratory shall send a declaration of interests to the CRL, as soon as the application is received by the CRL, describing the work of the laboratory in the application and shall not participate in the evaluation of the application.

2.6.1.4. The CRL may select appropriate characteristics as mentioned under Annex III of Regulation (EC) No 882/2004 in its evaluation report to the Authority.

2.6.1.5. Performance criteria for methods for specific groups of substances (e.g. enzymes) may be established in the detailed guidance provided by the CRL in accordance with Article 12 of Regulation (EC) No 378/2005.

2.6.2. *Methods of analysis for the determination of the residues of the additive or of its metabolites in food*

Detailed characterisation of the qualitative and quantitative analytical method(s) for determining the marker residues and/or metabolites of the additive in target tissues and animal products shall be provided.

2.6.2.1. These methods shall meet the same requirements as those for methods of analysis used for official control purposes as laid down in Article 11 of Regulation (EC) No 882/2004. In particular, the methods shall meet at least one of the requirements mentioned in 2.6.1.1.

2.6.2.2. The detailed characterisation of the method(s) shall include the appropriate characteristics as set out in Annex III of Regulation (EC) No 882/2004 and shall take into account the requirements set out in Commission Decision 2002/657/EC ([10]). The same performance criteria laid down in Commission Decisions laying down analytical methods to be used for detecting certain substances and residues thereof in live animal products according to Council Directive 96/23/EC shall be considered where appropriate.

The limit of quantification (LOQ) for each method must not exceed half of the corresponding MRL and must be validated across a range at least from one-half to two times the MRL.

2.6.2.3. Performance characteristics of in-house validated methods shall be verified by testing the method in a second, accredited and independent laboratory. Results of such tests shall be provided. For reasons of independence and involvement in the evaluation of the documentation provided by the applicant, where the second laboratory is a laboratory participating in the consortium of National Reference Laboratories (NRLs) assisting the CRL, as laid down in Regulation (EC) No 378/2005, the laboratory shall send a declaration of interests to the CRL, as soon as the application is received by the CRL, describing the work of the laboratory in the application and shall not participate in the evaluation of the application.

2.6.2.4. The CRL may select appropriate characteristics from the ones mentioned under point 2.6.2.2 in its evaluation report to the Authority.

([9]) M. Thompson et al.: Harmonized Guidelines For Single Laboratory Validation Of Methods Of Analysis (IUPAC Technical Report) Pure Appl. Chem., Vol. 74, No. 5, pp. 835-855, 2002.

([10]) OJ L 221, 17.8.2002, p. 8. Decision as last amended by Decision 2004/25/EC (OJ L 6, 10.1.2004, p. 38).

2.6.2.5. Performance criteria for methods for specific groups of substances (e.g. enzymes) may be established in the detailed guidance provided by the CRL in accordance with Article 12 of Regulation (EC) No 378/2005.

2.6.3. *Methods of the analysis relating to the identity and characterisation of the additive*

A description of the methods used for the determination of the characteristics listed under points 2.1.3, 2.1.4, 2.1.5, 2.2.2, 2.4.1, 2.4.2, 2.4.3, and 2.4.4 shall be provided by the applicant.

In accordance with Annex II of Regulation (EC) No 1831/2003 as amended by Regulation (EC) No 378/2005, the methods submitted under this section may also be evaluated if considered relevant by the, the Authority or the Commission for the assessment of the application.

It is recommended that the methods described under this section are internationally recognised. For those methods that are not internationally recognised, the methods have to be fully described. In those cases, studies shall be performed by accredited and independent laboratories and shall be documented according to appropriate quality standards (e.g. GLP in accordance with Directive 2004/10/EC or ISO standards).

Methods for the identification and characterisation of the additive shall meet the same requirements as those for methods of analysis used for official control purposes as laid down in Article 11 of Regulation (EC) No 882/2004, particularly where legal requirements are established (e.g. impurities, undesirable substances).

3. SECTION III: STUDIES CONCERNING SAFETY OF THE ADDITIVE

The studies included in this section and in the specific Annexes are intended to permit assessment of:

— the safety of use of the additive in the target species;

— any risk associated with the selection and/or transfer of resistance to antimicrobials and increased persistence and shedding of enteropathogens;

— the risks to the consumer of food derived from animals given feedingstuffs containing or treated with the additive or which could result from the consumption of food containing residues of the additive or its metabolites;

— the risks from respiratory, other mucosal tissue, eye or cutaneous contact for persons likely to handle the additive as such or as incorporated into premixtures or feedingstuffs; and

— the risks of adverse effects on the environment, from the additive itself, or from products derived from the additive, either directly and/or excreted by animals.

3.1. Studies concerning the safety of use of the additive for the target animals

The studies included in this section are intended to assess:

— the safety of use of the additive in the target species per se; and

— any risk associated with the selection and/or transfer of resistance to antimicrobials and increased persistence and shedding of enteropathogens.

3.1.1. *Tolerance studies for the target species*

The aim of the tolerance test is to provide a limited evaluation of short-term toxicity of the additive to the target animals. It is also used to establish a margin of safety, if the additive is consumed at higher doses than recommended. Such tolerance tests must be conducted to provide evidence for safety for each of the target species/animal categories for which a claim is made. In some cases it is acceptable to include some elements of the tolerance test in one of the efficacy trials provided that the requirements given below for these tests are met. All studies reported in this section must be based on the additive described in Section II.

3.1.1.1. The design of a tolerance test includes a minimum of three groups:

— an unsupplemented group;

— a group with the highest recommended dose; and

— an experimental group with the multi-fold level of the highest recommended dose.

In the experimental group the additive shall generally be given at ten times the highest recommended dose. Test animals shall be routinely monitored for visual evidence of clinical effects, performance characteristics, product quality where relevant, haematology and routine blood chemistry and for other parameters likely to be related to the biological properties of the additive. Critical end-points known from the toxicological studies in laboratory animals shall be considered. Any adverse effect detected during efficacy trials shall also be reported in this section. Unexplained deaths in the tolerance test shall be investigated by necropsy and, if appropriate, histology.

If a 100 times the maximum recommended dose can be shown to be tolerated, no haematology or routine blood chemistry would be required. If the product is tolerated only at lower level than ten times of the highest recommended dose, the study shall be designed in such a way that a margin of safety for the additive can be calculated and additional end-points (by necropsy, histology if relevant, and other appropriate criteria) shall be provided.

For some additives depending on their toxicology and metabolism or use, it may not be necessary to carry out tolerance tests.

The experimental design used must include consideration of adequate statistical power.

3.1.1.2. Duration of tolerance trials

Table 1

Duration of tolerance trials: Pigs

Target animals	Duration of the studies	Characteristic of the target animals
Suckling piglets	14 days	Preferably from 14 days to weaning
Weaned piglets	42 days	For 42 days after weaning
Pigs for fattening	42 days	Body weight at start of the study ≤ 35 kg
Sows for reproduction	1 cycle	From insemination to the end of the weaning period

If suckling and weaned piglets are applied for, a combined study (14 days suckling piglets and 28 days weaned piglets) would be considered sufficient. If the tolerance for weaned piglets has been shown, no separate study for pigs for fattening is required.

Table 2

Duration of tolerance trials: Poultry

Target animals	Duration of the studies	Characteristic of the target animals
Chickens for fattening/ reared for laying	35 days	From hatching
Laying hens	56 days	Preferably during the first third of the laying period
Turkeys for fattening	42 days	From hatching

Tolerance data from chickens for fattening or turkeys for fattening can be used to demonstrate tolerance for chickens or turkeys reared for laying/breeding respectively.

Table 3

Duration of tolerance trials: Bovines

Target animals	Duration of the studies	Characteristic of the target animals
Calves for fattening	28 days	Initial bodyweight ≤ 70kg
Calves for rearing; cattle for fattening or reproduction	42 days	
Dairy cows	56 days	

If calves for rearing and cattle for fattening were applied for, a combined study (28 days for each period) would be considered sufficient.

Table 4

Duration of tolerance trials: Sheep

Target animals	Duration of the studies	Characteristic of the target animals
Lambs for rearing and for fattening	28 days	

Table 5

Duration of tolerance trials: Salmonidae and other fish

Target animals	Duration of the studies	Characteristic of the target animals
Salmon and trout	90 days	

As an alternative to a 90-day duration, a study could be performed where the fish increase their initial body weight at the start of the trial by least a factor of two.

If the additive is intended to be used for brood stock only, the tolerance tests shall be carried out as close to the spawning period as possible. The tolerance tests shall last for 90 days and attention shall be paid to the egg quality and survival of the eggs.

Table 6

Duration of tolerance trials: Pets and other non food-producing animals

Target animals	Duration of the studies	Characteristic of the target animals
Dogs and cats	28 days	

Table 7

Duration of tolerance trials: Rabbits

Target animals	Duration of the studies	Characteristic of the target animals
Rabbits for fattening	28 days	
Breeding does	1 cycle	From insemination to the end of the weaning period

If rabbits suckling and weaned are applied for, a period of 49 days (beginning one week after birth) would be considered sufficient and must include the does until weaning.

If an additive is applied for a specific and shorter period than given by the animal category definition, it shall be administered according to the proposed conditions of use. However, the observation period shall not be shorter than 28 days and shall involve the relevant end-point (e.g. for sows for reproduction the number of piglets born alive when considering the gestation period, or the number and weight of weaned piglets when considering the lactation period).

3.1.1.3. Experimental conditions

The studies shall be reported individually, giving details of all experimental groups. The trial protocol shall be carefully drawn up with regard to general descriptive data. In particular, the following shall be recorded:

(1) herd or flock: location and size; feeding and rearing conditions, method of feeding; for aquatic species, size and number of tanks or pens at the farm, light conditions and water quality including water temperature and salinity;

(2) animals: species (for aquatic species intended for human consumption identification shall be made by their colloquial name followed in parenthesis by the Latin binomial), breed, age (size for aquatic species), sex, identification procedure, physiological stage and general health;

(3) date and exact duration of testing: date and nature of the examinations performed;

(4) diets: description of manufacture and quantitative composition of the diet(s) in terms of ingredients used, relevant nutrients (analysed values) and energy. Feed intake records;

(5) concentration of the active substance(s) or agent(s) (and, where that is the case, substances used for comparative purposes) in the feedingstuffs shall be established by a control analysis, using the appropriate recognised methods: reference number(s) of the batches;

(6) number of test and control groups, number of animals in each group: the number of animals involved in the trials must permit statistical analysis. The methods of statistical evaluation used should be stated. The report shall include all animals and/or experimental units involved in the trials. Cases which cannot be assessed due to a lack or loss of data shall be reported, and their distribution within the groups of animals classified;

(7) the timing and prevalence of any undesirable consequences of treatment in individuals or groups must be reported (give details of the observation programme used in the study); and

(8) therapeutic/preventive treatments, if necessary, shall not interact with the proposed mode of action of the additive and shall be recorded individually.

3.1.2. *Microbial studies*

Studies shall be provided to determine the ability of the additive to induce cross-resistance to antibiotics used in human or veterinary medicine, to select resistant bacterial strains under field conditions in target species, to give rise to effects on opportunistic pathogens present in the digestive tract, to cause shedding or to excrete zoonotic micro-organisms.

If the active substance(s) possesses antimicrobial activity at the feed concentration level, the minimum inhibitory concentration (MIC) for relevant bacterial species shall be determined, according to standardised procedures. Where relevant antimicrobial activity is demonstrated, the ability of the additive to select resistant bacterial strains *in vitro* and in the target species, and to induce cross-resistance to relevant antibiotics shall be established ([11]).

Tests at the recommended use level shall be provided for all microbial additives, and for those other additives in which an effect on the gut micro-flora can be anticipated. These studies shall demonstrate that use of the additive does not create conditions conducive to an overgrowth and shedding of potentially pathogenic micro-organisms.

The choice of micro-organisms to be monitored will depend on the target species, but shall include relevant zoonotic species, regardless of whether or not they produce symptoms in target animals.

3.2. **Studies concerning the safety of use of the additive for consumers**

The aim is to evaluate the safety of the additive for the consumer and to establish potential residues of the additive or its metabolites in food derived from animals given feed or water containing or treated with the additive.

([11]) A non-exhaustive list is available in: www.efsa.europa.eu/en/science/feedap/feedap_opinion/993.html

3.2.1. *Metabolic and residue studies*

The establishment of the metabolic fate of the additive in the target species is a determinant step in the identification and quantification of the residues in the edible tissues or products derived from the animals given the feed or water containing the additive. Studies must be submitted concerning the absorption, distribution, metabolism and excretion of the substance (and its metabolites).

Studies must be carried out using internationally validated test methods and shall be performed in accordance with European legislation in force or OECD Guidelines for methodological details and according to the principles of GLP. The study shall respect the rules on animal welfare laid down by European Community legislation, and they shall not be repeated if not necessary.

Metabolic and residue studies on the target animal(s) shall be performed with the active substance incorporated in the feed (not given by gavage unless it is properly justified).

Structural identification of metabolites representing more than 10 % of the total residues in the edible tissues and products and more than 20 % of the total residues in the excreta shall be established. If the metabolic pathway of the active substance raises any toxicological concerns, metabolites below the above limits shall be identified.

Kinetic studies of the residues will form the basis for the calculation of consumer exposure and the establishment of a withdrawal period and MRLs, if necessary. A proposal for a marker residue shall be provided.

For some additives, depending on their nature or use, it may not always be necessary to carry out metabolic and residues studies.

3.2.1.1. Metabolic studies

The purpose of metabolic studies is to evaluate the absorption, distribution, biotransformation and excretion of the additive in the target species.

The studies required are:

(1) metabolic balance following a single dose administration of the active substance at the doses proposed for use (total amount corresponding to the daily intake) and possibly a multiple dose (if justified) to assess an approximate rate and extent of the absorption, distribution (plasma/blood) and excretion (urine, bile, faeces, milk or eggs, expired air, excretion via gills) in male and female animals, where appropriate; and

(2) metabolic profiling, identification of the metabolite(s) in excreta and tissues and distribution in tissues and products shall be established following repeated dose administration of the labelled compound to animals to the steady state (metabolic equilibrium) identified by plasma levels. The dose applied shall correspond to the highest dose proposed for use, and shall be incorporated into the feed.

3.2.1.2. Residue studies

Consideration shall be given to the amount and the nature of non-extractable residues in edible tissues or products.

Residue studies are required for all substances for which metabolic studies are needed.

If the substance is a natural constituent of body fluids or tissues or is naturally present in significant amounts in food or feedingstuffs, the requirement for residue studies is limited to the comparison of the tissue/product levels in an untreated group and in the group supplemented with the highest dose claimed.

For major species, studies shall simultaneously evaluate the total residues of toxicological significance and identify the marker residue of the active substance in edible tissue (liver, kidney, muscle, skin, skin + fat) and products (milk, eggs and honey). The marker residue is the residue selected for assay whose concentration has a known relationship to the total residue of toxicological concern in the tissues. Studies shall also show the permanence of the residues in the tissues or products to establish an appropriate withdrawal period.

For the determination of a withdrawal period, the suggested minimum number of animals sampled and/or products at each time point are the following:

— edible tissues:

  — bovines, sheep, pigs and minor species 4;

  — poultry 6;

  — salmonids and other fish 10.

— products:

  — milk 8 samples per time point;

  — eggs 10 eggs per time point;

  — honey 8 samples per time point.

Appropriate sex distribution shall be considered.

The residues shall be measured at zero withdrawal time (steady state) and at least three other time sampling points.

A proposal for a marker residue shall be provided.

Studies on the absorption, distribution and excretion, including the identification of main metabolites must be performed in the laboratory animal species in which the lowest NOAEL was obtained, or by default in the rat (both sexes). Additional studies on particular metabolites may be necessary if these metabolites are produced by target species and are not formed to a significant extent in the laboratory species.

3.2.1.3. Metabolic and disposition studies

A metabolism study including the metabolic balance, metabolic profile and identification of the main metabolites in the urine and faeces shall be performed. If another laboratory species shows a marked difference in the sensitivity from the rat, additional information will be required.

3.2.1.4. Bioavailability of residues

The assessment of the risks for the consumers related to bound residues in animal products may take into account an additional safety factor on the determination of their bioavailability using appropriate laboratory animals and recognised methods.

3.2.2. *Toxicological studies*

The safety of the additive is assessed on the basis of the toxicological studies performed *in vitro* and *in vivo* on laboratory animals. They generally include measurements of:

(1) acute toxicity;

(2) genotoxicity (mutagenicity, clastogenicity);

(3) sub-chronic oral toxicity;

(4) chronic oral toxicity/carcinogenicity;

(5) reproduction toxicity including teratogenicity; and

(6) other studies.

Further studies providing additional information necessary for the assessment of the safety of the active substance and its residues shall be conducted if there is any reason for concern.

On the basis of the results of these studies a toxicological NOAEL must be established.

Additional studies on particular metabolites may be necessary if these metabolites are produced by target species and are not formed to a significant extent in the laboratory test species. If metabolic studies are available in humans, data shall be taken into consideration in deciding the nature of eventual additional studies.

Toxicological studies must be carried out with the active substance. If the active substance is present in a fermentation product, the fermentation product shall be tested. The fermentation product tested must be identical to that to be used in the commercial product.

Studies must be carried out using internationally validated test methods and shall be performed in accordance with European legislation in force or OECD Guidelines for methodological details and according to the principles of GLP. The studies involving laboratory animals shall respect the rules on animal welfare laid down by European legislation and they shall not be repeated if not necessary.

3.2.2.1. Acute toxicity

Acute toxicity studies are required to classify and to provide limited characterisation of the toxicity of the compound.

Acute toxicity studies shall be carried out in at least two mammalian species. One laboratory species may be replaced by a target species, if appropriate.

It will be not necessary to determine a precise LD_{50}; an approximate determination of the minimum lethal dose is considered sufficient. The maximum dosage shall not exceed 2 000 mg/kg body weight.

In order to reduce the number and the suffering of the animals involved, new protocols for acute dose toxicity testing are continually being developed. Studies carried out by these new procedures will be accepted, when properly validated.

OECD Guidelines 402 (acute dermal toxicity), 420 (Fixed Dose Method), 423 (Acute Toxic Class Method) and 425 (Up-and-Down Procedure) should be followed.

3.2.2.2. Genotoxicity studies including mutagenicity

To identify active substances and, if appropriate, their metabolites and degradation products with mutagenic and genotoxic properties, a selected combination of different genotoxicity tests must be carried out. If appropriate the tests shall be performed without and with mammalian metabolic activation and the compatibility of the test material with the test system shall be taken into account.

The core set comprises the following tests:

(1) induction of gene mutations in bacteria and/or in mammalian cells (preferably the mouse lymphoma tk assay);

(2) induction of chromosomal aberrations in mammalian cells; and

(3) *in vivo* test in mammalian species.

Additional tests may be needed depending on the outcome of the above mentioned tests and taking into consideration the whole toxicity profile of the substance, as well as its intended use.

Protocols should be in line with OECD Guideline 471 (*Salmonella typhimurium* Reverse Mutation Test), 472 (*Escherichia coli* Reverse Mutation Test), 473 (*in vitro* Mammalian Chromosomal Aberration Test), 474 (Mammalian Erythrocyte Micronucleus Test), 475 (Mammalian Bone Marrow Chromosomal Aberration Test), 476 (*in vitro* Mammalian Cell Gene Mutation Test) or 482 (Unscheduled DNA Synthesis in Mammalian Cells *in vitro*), as well as other relevant OECD Guidelines for *in vitro* and *in vivo* assays.

3.2.2.3. Sub-chronic repeated dose oral toxicity studies

To investigate the sub-chronic toxic potential of the active substance, at least one study on a rodent species must be submitted with duration of at least 90 days. If deemed necessary, a second study must be performed with a non-rodent species. The test item must be administered orally with at least three levels in addition to a control group to obtain a dose response. The maximum dose used should normally be expected to reveal evidence of adverse effects. The lowest dose level should not be expected to produce any evidence of toxicity.

Protocols for these studies should be in line with the OECD Guidelines 408 (rodents) or 409 (non-rodents).

3.2.2.4. Chronic oral toxicity studies (including carcinogenicity studies)

To investigate the chronic toxic potential and carcinogenic potential, a chronic oral toxicity study must be carried out in at least one species, and shall be of at least 12 months' duration. The species chosen shall be the most appropriate on the basis of all available scientific data, including the results of the 90-day studies. The default species is the rat. If a second study is requested, a rodent or a non-rodent mammalian species shall be used. The test item must be administered orally with at least three levels in addition to a control group to obtain a dose response.

If the chronic toxicity study is combined with an examination of carcinogenicity, then the duration shall be extended to 18 months for mice and hamsters, and to 24 months for rats.

Carcinogenicity studies may not be necessary if the active substance and its metabolites:

(1) give consistently negative results in the genotoxicity tests;

(2) are not structurally related to known carcinogens; and

(3) give no effects indicative of potential (pre)neoplasia in chronic toxicity assays.

Protocols should be in line with OECD Guideline 452 (chronic toxicity study) or 453 (combined chronic toxicity/carcinogenicity study).

3.2.2.5. Reproduction toxicity studies (including prenatal developmental toxicity)

To identify possible impairment of male or female reproductive function or harmful effects on progeny resulting from the administration of the active substance, studies of reproductive function must be carried out by:

(1) two generation reproduction toxicity study; and

(2) prenatal developmental toxicity study (teratogenicity study).

For new trials validated alternative methods reducing the use of animals can be used.

3.2.2.5.1. Two generation reproduction toxicity study

Studies of reproductive function must be carried out and extend over at least two filial generations (F1, F2) in at least one species, usually a rodent, and may be combined with a teratogenicity study. The substance under investigation shall be administered orally to males and females at an appropriate time prior to mating. Administration shall continue until the weaning of the F2 generation.

All relevant fertility, gestation, parturition, maternal behaviour, suckling, growth and development of the F1 offspring from fertilisation to maturity and the development of the F2 offspring to weaning must be carefully observed and reported. Protocols for the reproduction toxicity study should be in line with OECD Guideline 416.

3.2.2.5.2. Prenatal developmental toxicity study (teratogenicity study)

The objective is to detect any adverse effects on the pregnant female and the development of the embryo and foetus as a result of exposure from implantation through the entire gestation period. Such effects include enhanced toxicity in the pregnant females, embryo-foetal death, altered foetal growth and structural abnormalities and anomalies in the foetus.

The rat is usually the species of choice for the first study. If a negative or an equivocal result for teratogenicity is observed, another developmental toxicity study shall be conducted in a second species, preferably the rabbit. If the rat study is positive for teratogenicity, a study in a second species is not necessary except where a review of all the core studies indicates that the ADI would be based on the rat teratogenicity. In this case a study in a second species would be required to determine the most sensitive species for this endpoint. Protocols should be in line with OECD Guideline 414.

3.2.2.6. Other specific toxicological and pharmacological studies

Further studies providing additional information useful for the assessment of the safety of the active substance and its residues shall be conducted if there are reasons for concern. Such studies may include examination of pharmacological effects, effects in juvenile (prepubertal) animals, immunotoxicity or neurotoxicity.

3.2.2.7. Determination of No Observed Adverse Effect Levels (NOAEL)

The NOAEL is generally based on toxicological effects, but pharmacological effects might occasionally be more appropriate.

The lowest NOAEL shall be selected. All findings from previous sections together with all other relevant published data (including any relevant information on the effects of the active substance on human) and information, where appropriate, on chemicals having a closely related chemical structure shall be taken into consideration in identifying the lowest NOAEL, expressed as mg per kg body weight per day.

3.2.3. *Assessment of consumer safety*

Consumer safety is assessed by a comparison of the established ADI (Acceptable Daily Intake) and calculated theoretical intake of the additive or its metabolites from food. In the case of vitamins and trace elements, UL (Tolerable Upper Intake Level) can be used in place of ADI.

3.2.3.1. Proposal of the acceptable daily intake (ADI) for the active substance(s)

The acceptable daily intake (ADI) (expressed as mg of additive or additive related material per person per day) is derived by dividing the lowest NOAEL (mg per kg body weight) by an appropriate safety factor and multiplying by the average human body weight of 60 kg.

An ADI shall, where appropriate, be proposed. An ADI can also be 'not specified' because of low toxicity in animal tests. An ADI shall not be proposed if the substance shows genotoxic or carcinogenic properties relevant to humans.

The setting of an ADI normally requires the similarity of metabolic fate of the active substance in the target animals and laboratory animals (see 3.2.1.4 Bioavailability of residues) which ensures that consumers are exposed to the same residues as the laboratory animals used in toxicological studies. If not, additional studies in a second laboratory animal species or with the metabolites specific to the target species may still allow an ADI to be set.

The safety factor used to determine the ADI for a particular additive will take into consideration the nature of the biological effects and the quality of the data used to identify the NOAEL, the relevance of these effects to man and their reversibility and any knowledge of the direct effect(s) of the residues in human.

A safety factor of at least 100 in calculating the ADI (if a full toxicological package has been provided) shall be employed. Where data on the active substance are available for human, a lower safety factor may be acceptable. Higher safety factors might be applied to account for additional sources of uncertainty in data or where the NOAEL is set on the basis of a particular critical endpoint, such as teratogenicity.

3.2.3.2. Tolerable upper intake level (UL)

For some additives it may be more appropriate to base the safety assessment on the UL, which is the maximum level of total chronic daily intake of a nutrient (from all sources) judged (by national or international scientific bodies) to be unlikely to pose a risk of adverse health effects to consumers or to specific groups of consumers.

The dossier shall contain data to demonstrate that use of the additive would not lead to a situation in which the UL could be exceeded considering all possible sources of the nutrient.

If the resulting residue levels of the nutritional additive or its metabolite(s) in products of animal origin are higher than what is considered normal or expected for these products, this shall be clearly indicated.

3.2.3.3. Consumer exposure

The total intake of the additive and/or its metabolites from all sources by the consumer shall be below the ADI or UL.

Calculation of the theoretical intake from food of animal origin shall be performed considering the concentration (total residues as the arithmetic mean and the highest single value) measured in tissues and products at the termination of use of the additive. In addition, if necessary, at the different withdrawal times, the human daily food consumption values shall be determined following a worst case scenario.

For additives intended for multi-species, the exposure from tissues shall be independently calculated for mammals, birds and fish and the highest value taken. Where appropriate, exposure from milk and eggs shall be added to this figure. For example, where an additive is applied for lactating mammals and laying birds, the respective highest edible tissue values are added to those for milk and egg consumption. Where the additive is applied for fish and laying birds and lactating mammals, the respective highest edible tissue values are added to those for egg and milk consumption. Other combinations shall be envisaged in the same way.

In certain situations (e.g. some nutritional and sensory additives or additives intended for minor species) it may be appropriate to subsequently refine the human exposure assessment using more realistic consumption figures, but still keeping the most conservative approach. Where this is possible this shall be based on Community data.

Table 1

Theoretical daily human consumption figures (g tissues or products)

	Mammals	Birds	Fish	Other
Muscle	300	300	300 (*)	
Liver	100	100	—	
Kidney	50	10	—	
Fat	50 (**)	90 (***)	—	
+ Milk	1 500	—	—	
+ Eggs	—	100	—	
+ Honey				20

(*) Muscle and skin in natural proportion.
(**) For pig 50 g of fat and skin in natural proportion.
(***) fat and skin in natural proportion.

3.2.3.4. Proposal for maximum residue limits (MRLs)

Maximum residue limit means the maximum concentration of residues (expressed as µg marker residue per kg of edible wet tissue or product) which may be accepted by the Community to be legally permitted or recognised as acceptable in food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the ADI. An MRL cannot be set in the absence of an ADI.

When establishing MRLs for feed additives, consideration is also given to residues that come from other sources (e.g., food of plant origin). Furthermore, the MRL may be reduced to be consistent with the conditions of use of feed additives and to the extent that practical analytical methods are available.

Where appropriate, individual MRLs (expressed as mg marker residue per kg of edible natural tissue or product) shall be set for different tissues or products of the target animal species. The individual MRLs in different tissues or products shall reflect the depletion kinetics and the variability of the residue levels within those tissues/products in the animal species intended for use. Variability shall normally be reflected by using the 95 % confidence limit of the mean. If the confidence limit cannot be calculated due to a low number of samples, variability is expressed by taking the highest individual value instead.

Studies concerning the Maximum Residue Limits of coccidiostats and histomonostats must be carried out following the appropriate rules in force for veterinary medicinal products (Volume 8 'The rules governing medicinal products in European Union — Notice to applicants and guidelines. Veterinary medicinal products. Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs of animal origin'. October 2005).

The studies to establish maximum residue limits for additive categories other than coccidiostats and histomonostats, where necessary, shall be provided according to this Annex.

To determine the consumer exposure to the total residues (as calculated under 3.2.3.3.), the proposed MRLs for the different tissues or products shall take into account the ratio of marker residue to total residue (Table 2).

Table 2

Definitions used in deriving an MRL

$_{i\text{-}j}$	Individual tissues/products (liver, kidney, muscle, skin + fat, milk, eggs, honey) at different times
$MRL_{i\text{-}j}$	Maximum residue limit in tissues/products (mg marker substance kg^{-1})
$Qt_{i\text{-}j}$	Daily human consumption of individual tissues/products (kg) set by Table 1 or its refinement
$TRC_{i\text{-}j}$	Total residue concentration in individual tissues/products (mg kg^{-1})
$MRC_{i\text{-}j}$	Marker residue concentration in individual tissues/products (mg kg^{-1})
$RMTR_{i\text{-}j}$	Ratio $MRC_{i\text{-}j}$ to $TRC_{i\text{-}j}$ for individual tissues/products
$DITR_{i\text{-}j}$	Dietary intake for individual tissues/products calculated from total residues (mg) $DITR_{i\text{-}j} = Qt_{i\text{-}j} \times TRC_{i\text{-}j}$
$DITR_{MRLi\text{-}j}$	Dietary intake calculated from MRLs (mg) of individual tissues/products $DITR_{MRLi\text{-}j} = Qt_{i\text{-}j} \times MRL_{i\text{-}j} \times RMTR_{i\text{-}j}^{-1}$

The measured values for TRC and MRC shall be inserted as appropriate in the template shown in Table 3, and the other values calculated. Where a full data set is not available because values fall below the limit of detection (LOD), an extrapolation of RMTR may be acceptable.

Deriving an MRL can only be performed if the sum of the individual DITRs is below the ADI. If the ADI is exceeded, an alternative would be to use data from a longer withdrawal time or lower dosages. A first proposal for an MRL can be obtained using the MRC value as a guide and taking into consideration the LOQ of the analytical method. The sum of the $DITR_{MRL}$ obtained from the proposed MRLs must be below the ADI and close to the sum of the individual DITRs. If the ADI is exceeded, then a lower MRL shall be proposed and the comparison repeated.

For certain additives, residues could arise below the MRL values in milk, eggs or meat which could nonetheless interfere with food quality in particular food processing procedures. For such additives, it may be appropriate to consider a 'maximum (food product) processing compatible residue' (MPCR) in addition to establishing MRL values.

Table 3

Template for deriving a MRL proposal

	Liver	Kidney	Muscle	Skin + fat	Milk	Eggs	Honey	Sum
TRC ([1]) (mg kg^{-1})								——
MRC ([2]) (mg kg^{-1})								——
RMTR ([2])								——
DITR ([3]) (mg)								
MRL proposed (mg kg^{-1})								——
$DITR_{MRL}$(mg)								

([1]) Considering the proposed withdrawal time.
([2]) Ideally established at the same time as TRC.
([3]) Calculated from TRC values.

3.2.3.5. Proposal for a withdrawal period

The withdrawal time comprises the period after cessation of the administration of the additive which is necessary to enable the residue levels to fall below the MRLs.

3.3. **Studies concerning the safety of use of the additive for users/workers**

Workers can be exposed mainly by inhalation or topical exposure while manufacturing or handling or using the additive. For example, farm workers are potentially exposed when handling or mixing the additive. Additional information on how the substances are handled shall be provided.

An assessment of risk to workers shall be included. Where available, experience in the manufacturing plant is often an important source of information in evaluating the risks to workers from exposure to the additive itself by both airborne and topical routes. Of particular concern are additives/additive-treated feeds and/or animal excreta, which are in, or may give rise to, a dry powdery form, and feed additives which may have allergenic potential.

3.3.1. *Toxicological risk assessment for user/worker safety*

Risks to workers shall be assessed in a series of studies using the additive in the form for which the application has been submitted. Acute inhalation toxicity studies shall be performed unless the product is unlikely to form a respirable dust or mist. Studies on skin irritancy must be performed, and if these give negative results, mucous membrane (e.g. eye) irritancy shall be assessed. Allergenic potential/skin sensitisation potential shall also be assessed. The toxicity data generated to meet consumer safety (see 3.2.2) shall be used to assess the potential systemic toxicity of the additive. All these shall be assessed, if necessary, by direct measurement and specific studies.

3.3.1.1. Effects on the respiratory system

Evidence shall be provided that airborne levels of dust or mist of the additive will not constitute a hazard to the health of users/workers. This evidence shall include, where necessary:

— inhalation tests in laboratory animals;

— published epidemiological data and/or the applicants own data on its work plant and/or irritancy; and

— respiratory system sensitisation tests.

Acute inhalation toxicity studies shall be performed if particles or droplets with a diameter of less than 50 μm constitute more than 1 % on a weight basis of the product.

Protocols for acute inhalation toxicity studies should be in line with OECD Guideline 403. If sub-chronic toxicity studies are considered necessary, they should follow OECD Guidelines 412 (Repeated Dose Inhalation Toxicity: 28-day or 14-day study) or 413 (Sub-chronic Inhalation Toxicity: 90-day study).

3.3.1.2. Effects on the eyes and skin

Where available, direct evidence of absence of irritancy and/or sensitisation shall be provided from known human situations. This shall be supplemented by findings from validated animal tests for skin and eye irritation, and for sensitisation potential using the appropriate additive. Allergic potential — skin sensitisation potential shall also be assessed. Protocols for these studies should be in line with OECD Guidelines 404 (Dermal Irritation/Corrosion), 405 (Eye Irritation/Corrosion), 406 (Skin Sensitisation), 429 (Skin Sensitisation — local lymph-node assay).

If corrosive properties are known, either from published data or specific *in vi*tro tests, then further *in vivo* tests shall not be performed.

Dermal toxicity must be considered, if the additive is toxic by inhalation. Studies must be in line with OECD Guideline 402 (Acute Dermal Toxicity).

3.3.1.3. Systemic toxicity

The toxicity data generated to meet consumer safety and other requirements (including repeated dose toxicity, mutagenicity, carcinogenicity and reproductive testing and metabolic fate) shall be used to assess systemic toxicity.

3.3.1.4. Exposure assessment

Information shall be provided on how the use of the additive is likely to give rise to exposure by all routes (inhalation, through the skin or by ingestion). This information shall include a quantitative assessment, where available, such as typical airborne concentration, dermal contamination or ingestion. Where quantitative information is not available, sufficient information shall be given to enable an adequate assessment of exposure to be made.

3.3.2. *Measures to control exposure*

Using the information from the toxicology and exposure assessment, a conclusion shall be drawn about the risks to health of the users/workers (inhalation, irritancy, sensitisation and systemic toxicity). Precautionary measures may be proposed to reduce or eliminate exposure. However, use of personal protective devices shall only be regarded as a measure of last resort to protect against any residual risk once control measures are in place. It is preferable, for example, to consider reformulation of the product.

3.4. **Studies concerning the safety of use of the additive for the environment**

Consideration of the environmental impact of additives is important since administration of additives typically occurs over long periods, often involves large groups of animals and the active substance(s) may be excreted to a considerable extent either as the parent compound or its metabolites.

To determine the environmental impact of additives, a stepwise approach shall be followed. All additives have to be assessed through Phase I to identify those additives which do not need further testing. For the other additives a second phase (Phase II) assessment is needed to provide additional information, based upon which further studies may be considered necessary. These studies shall be conducted according to Directive 67/548/EEC.

3.4.1. *Phase I assessment*

The purpose of Phase I assessment is to determine if a significant environmental effect of the additive or its metabolites is likely and whether a Phase II assessment is necessary (see decision tree).

Exemption from Phase II assessment may be made on one of two criteria, unless there is scientifically-based evidence for concern:

(a) the chemical nature and the biological effect of the additive and its conditions of use indicate that impact will be negligible, i.e. where the additive is:

— a physiological or natural substance that will not result in a substantial increase of the concentration in the environment; or

— intended for non-food producing animals;

(b) the worst case Predicted Environmental Concentration (PEC) is too low to be of concern. The PEC shall be evaluated for each compartment of concern (see below), assuming that 100 % of the dose ingested is excreted as the parent compound.

If the applicant cannot demonstrate that the additive falls into one of these exemption categories, a Phase II assessment will be required.

3.4.1.1. Additives for terrestrial animals

When excreta from livestock are applied on land, the use of feed additives can lead to contamination of soil, ground water, and surface water (*via* drainage and run-off).

The worst case PEC for soil (PEC_{soil}) would arise considering all excreted compounds being spread on land. If the PEC_{soil} (default: 5 cm depth) is less than 10 μg/kg, no further assessment is required.

If the PEC for contamination of groundwater (PEC_{gw}) is less than 0,1 μg/l, no Phase II assessment of the environmental impact of the additive on groundwater is necessary.

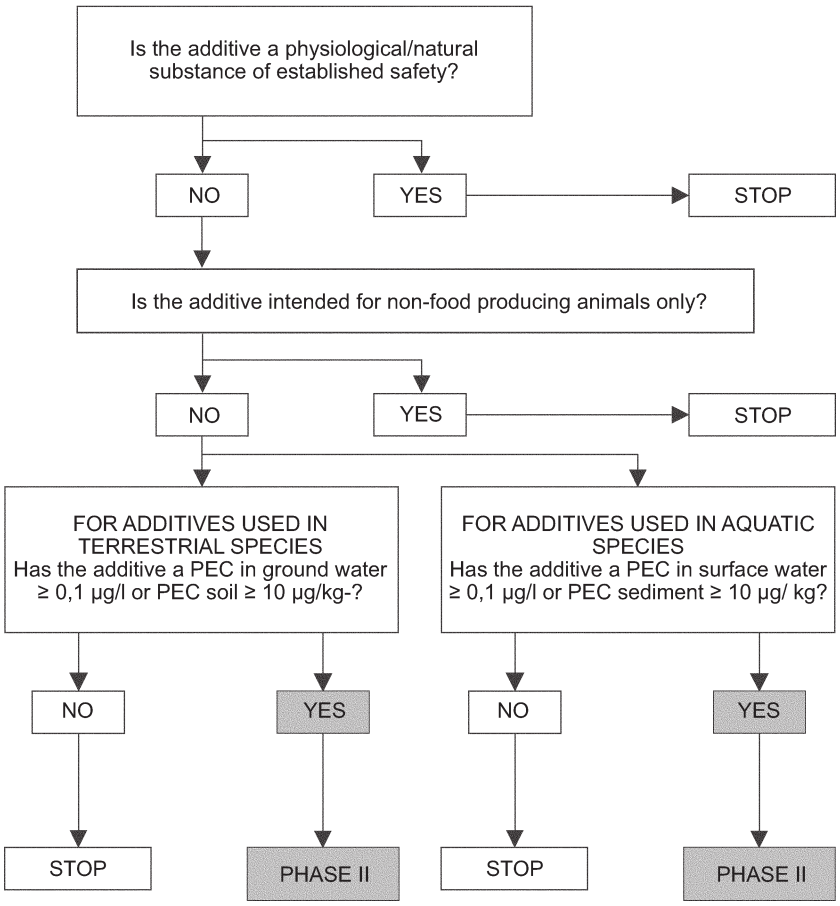
3.4.1.2. Additives for aquatic animals

Feed additives used in aquaculture can result in contamination of sediment and water. The compartment of concern for the environmental risk assessment for fish farmed in cages is assumed to be the sediment. For fish farmed in land-based systems the effluent flowing to surface water is considered to pose the major environmental risk.

The worst case PEC for sediment ($PEC_{sediment}$) would arise considering all excreted compounds being deposited in the sediment. If the $PEC_{sediment}$ (default: 20 cm depth) is less than 10 μg/kg wet weight, then no further assessment is required.

If the PEC in the surface water (PEC_{sw}) is less than 0,1 μg/l, no further assessment is required.

Phase I — Decision tree



3.4.2. *Phase II assessment*

The aim of Phase II is to assess the potential for additives to affect non-target species in the environment, including both aquatic and terrestrial species or to reach groundwater at unacceptable levels. It is not practical to evaluate the effects of additives on every species in the environment that may be exposed to the additive following its administration to the target species. The taxonomic levels tested are intended to serve as surrogates or indicators for the range of species present in the environment.

The Phase II assessment is based on a risk quotient approach, where the calculated PEC and Predicted No Effect Concentration (PNEC) values for each compartment shall be compared. The PNEC is determined from experimentally determined endpoints divided by an appropriate assessment factor. The PNEC value shall be calculated for each compartment.

The Phase II assessment starts with a refinement of the PEC if possible, and uses a two-tiered approach to the environmental risk assessment.

The first tier, Phase IIA, makes use of a limited number of fate and effect studies to produce a conservative assessment of risk based on exposure and effects in the environmental compartment of concern. If the ratio of the PEC to the PNEC is lower than one (1), no further assessment is required, unless bioaccumulation is expected.

If the PEC/PNEC ratio predicts an unacceptable risk (ratio > 1), the applicant shall progress to Phase IIB to refine the environmental risk assessment.

3.4.2.1. Phase II A

In addition to the compartments considered in Phase I, the PEC for surface water has to be calculated considering runoff and drainage.

Based on data not considered in Phase I, a more refined PEC can be calculated for each environmental compartment of concern. In ascertaining the refined PEC, account shall be taken of:

(a) the concentration of active substance(s)/metabolites of concern in manure/fish faeces following administration of the additive to animals at the proposed dose level. This calculation shall include consideration of dosage rates and amount of excreta produced;

(b) the potential degradation of the excreted active substance(s)/metabolites of concern during normal manure processing practice and storage prior to its application to land;

(c) the adsorption/desorption of the active substance(s)/metabolites of concern onto soil or sediment for aquaculture, preferentially determined by studies in soil/sediment (OECD 106);

(d) degradation in soil and water/sediment systems (OECD 307 and 308, respectively); and

(e) other factors such as hydrolysis, photolysis, evaporation, dilution through ploughing.

The highest value for the PEC obtained from these calculations for each environmental compartment of concern shall be adopted for Phase II risk assessment purposes.

If a high persistence in soil/sediment is anticipated (time to degradation of 90 % of original concentration of the compound: DT_{90} > 1 year), the potential for accumulation shall be considered.

The concentrations of additives (or metabolites) producing serious adverse effects for various trophic levels in the environmental compartments of concern shall be determined. These tests are mostly acute tests and should follow OECD or similar well-established guidelines. Studies for the terrestrial environment shall include: toxicity to earthworms; three terrestrial plants; and soil micro-organisms (*e.g.* effects on nitrogen fixation). Studies for the fresh water environment shall include: toxicity to fish; *Daphnia magna*; algae; and a sediment dwelling organism. In case of sea cages, three species of different *taxa* of sediment dwelling organisms shall be studied.

Calculation of the PNEC value shall be carried out for each compartment of concern. The PNEC is normally derived from the lowest toxicity value observed in the above tests and dividing by a safety factor of at least 100 depending on the endpoint and number of test species used.

The potential for bioaccumulation can be estimated from the value of the n-octanol/water partition coefficient, Log K_{ow}. Values ≥ 3 indicate that the substance may bioaccumulated. In order to assess the risk for secondary poisoning it shall be considered whether to carry out a bioconcentration factor (BCF) study at Phase IIB.

3.4.2.2. Phase IIB (more detailed ecotoxicological studies)

For those additives where, following Phase IIA assessment, an environmental risk cannot be excluded, more information is required on the effects on biological species in the environmental compartment(s) in which Phase IIA studies indicate possible concern. In this situation, further tests are needed to determine the chronic and more specific effects on appropriate microbial, plant, and animal species. This additional information will allow the application a lower safety factor.

Suitable additional ecotoxicity tests are described in a number of publications, *e.g.* in OECD Guidelines. Careful choice of such tests is necessary to ensure that they are appropriate to the situation in which the additive and/or its metabolites may be released and dispersed in the environment. The refinement of the effect assessment for soil ($PNEC_{soil}$) could be based on studies on the chronic effects on earthworms, additional studies on soil microflora and a number of relevant plant species, studies on grassland invertebrates (including insects) and feral birds.

The refinement of the effect assessment for water/sediment could be based on chronic toxicity tests on the most sensitive aquatic/benthic organisms identified in Phase IIA assessment.

Bioaccumulation studies, if necessary, should be performed according to OECD Guideline 305.

4. SECTION IV: STUDIES CONCERNING THE EFFICACY OF THE ADDITIVE

Studies shall demonstrate the efficacy for each proposed use and satisfy at least one of the characteristics set out in Article 5(3) of Regulation (EC) No 1831/2003, according to the categories and functional groups of feed additives as provided by Article 6 and Annex I of the said Regulation. Moreover such studies must permit the evaluation of the efficacy of the additive according to common farming practices in the EU.

The experimental design used must be justified according to the additive use, animal species and category. When using animals, the trials shall be conducted such that their health and husbandry conditions do not adversely affect the interpretation of the results. The positive and negative effects, both technological and biological, shall be described for each experiment. Absence of effects that impair the distinctive features of animal products shall also be demonstrated. Trials shall ideally be compliant with the criteria established by a recognised, externally-audited, quality assurance scheme. In the absence of such a scheme, evidence shall be provided to show that the work was done by qualified personnel using appropriate facilities and equipment and responsible to a named study director.

The trial protocol shall be carefully drawn up by the study director with regard to general descriptive data, for example methods, apparatus and materials used, details of the species, breed or strain of the animals, their number and the conditions under which they were housed and fed. For all studies involving animals, the experimental conditions shall be described according to 3.1.1.3. Final reports, raw data, study plans and well characterised and identified test substances shall be archived for future reference.

Studies shall be designed to demonstrate the efficacy of the lowest recommended dose of additive by targeting sensitive parameters in comparison to a negative and, optionally, a positive control group. Such studies shall also include the maximum recommended dose, where this is proposed. No single design is recommended, flexibility being provided to allow for scientific discretion in the design and conduct of the studies.

Attention shall also be paid to known or potential biological or chemical interactions between the additive, other additives and/or veterinary medicines and/or components of the diet, where this is relevant to the efficacy of the additive concerned (e.g. compatibility of microbial additive with coccidiostats and histomonostats or organic acid).

4.1. ***In vitro* studies**

For all technological and some sensory additives affecting the characteristics of feed, efficacy shall be demonstrated using a laboratory-based study. The study shall be designed to cover a representative range of materials to which the additive will be applied. Results shall be evaluated preferably by parameter-free tests, and shall demonstrate expected changes with a probability of $P \leq 0,05$.

In vitro studies, particularly those which simulate aspects of the gastrointestinal tract, may be used for other types of additives in order to support the efficacy. These studies should be capable of statistical evaluation.

4.2. **Short term efficacy studies with animals**

Bioavailability studies may be used to demonstrate the extent to which a novel form or source of a nutrient or colorant can substitute for an equivalent additive already approved or established.

Digestion/balance studies may be used in support of animal performance studies to provide evidence of mode of action. In some cases, particularly in relation to environmental benefits, efficacy may be better demonstrated by balance studies and may be used in preference to long term efficacy studies. Such experiments shall use numbers and species/categories of animals appropriate to the conditions of use proposed.

Other short term efficacy studies with animals may be proposed as appropriate, and these may substitute for long term efficacy studies with animals, provided that this is fully justified.

4.3. **Long term efficacy studies with animals**

The studies should be carried out at least at two different locations.

The experimental design used must include consideration of adequate statistical power and Type 1 and 2 risks. The protocol must be sufficiently sensitive to detect any effects from the additive at the lowest recommended dose (Type 1 α risk, $P \leq 0,05$ in general and $P \leq 0,1$ for ruminants, minor species, pets and non-food producing animals) and of sufficient statistical power to guarantee that the experimental protocol meets the study objective. The Type 2 β risk shall be lower than or equal to 20 % in general, and 25 % for experiments with ruminants, minor species, pets and non-food producing animals, hence a power (1-β) greater than or equal to 80 % (75 % for ruminants, minor species, pets and non food producing animals).

It is recognised that the nature of some additives make it difficult to define experimental conditions under which optimal results may be achieved. Consequently, the possibility of using meta-analysis shall be considered when the number of trials available is greater than three. For this reason, similar protocol designs shall be used for all trials so that data can eventually be tested for homogeneity and pooled (if tests so indicate) for statistical evaluation at a level of $P \leq 0,05$.

4.4. **Duration of long term efficacy studies with target animals**

Generally, the duration of efficacy trials shall correspond to the application period claimed.

Efficacy trials shall be carried out according to farming practices in European Union and be of the minimum duration as stated by Annex IV.

If an additive is applied for a specific and shorter period than given by the animal category definition, it shall be administered according to the proposed conditions of use. However, the observation period shall not be shorter than 28 days and shall involve the relevant end-points (e.g., for sows for reproduction number of piglets born alive when considering the gestation period, or the number and weight of weaned piglets when considering the lactation period).

For other species or animal categories for which a minimum duration period of studies was not established in Annex IV, a period of administration shall be taken in to account, according to the proposed conditions of use.

4.5. **Efficacy requirements for additive categories and functional groups**

For all additives intended to have an effect on animals, *in vivo* studies are requested.

For the categories of zootechnical additives and coccidiostats and histomonostats, efficacy shall be demonstrated by at least three long term efficacy studies. However, for some zootechnical additives and the other additive categories having an effect on animals, short term efficacy studies may be accepted if efficacy can be unequivocally demonstrated.

For other additive categories without a direct effect on animals at least one *in vitro* efficacy study shall be provided.

4.6. **Studies on the quality of animal products where this is not the effect claimed**

In order to demonstrate that the additive does not have a negative effect or other effect not requested on the organoleptic and nutritional (hygienic and technological if appropriate) characteristics of food deriving from animals fed with the additive (when this is not the effect desired), appropriate samples shall be taken during one of the efficacy trials. Two groups shall be observed: an unsupplemented group; and a group with the highest dosage proposed for the additive. The data shall allow statistical evaluation. Omission of these studies shall be adequately justified.

5. **SECTION V: POST-MARKET MONITORING PLAN**

According to Article 7(3)(g) of Regulation (EC) No 1831/2003, a proposal for post-market monitoring shall be submitted for certain categories of additives in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects resulting from the use of the additive on human or animal health or the environment, in accordance with the characteristics of the products concerned.

The design of the monitoring plan shall be detailed on a case-by-case basis and identify who (e.g. applicant, users) will carry out the various tasks that the monitoring plan requires, who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the competent control authorities. The Commission and the Authority will be informed of any observed adverse effects, without prejudice to the provisions on supervision laid down in Article 12 of Regulation (EC) No 1831/2003.

In cases where the active substance is also a recognised antibiotic and its use has been shown to select resistant bacterial strains at its feed use level, field studies to monitor for bacterial resistance to the additive shall be undertaken as part of post-market monitoring.

For coccidiostats and histomonostats, field monitoring of *Eimeria* spp. and *Histomonas meleagridis* resistance, respectively, shall be undertaken, preferably during the latter part of the period of authorisation.

ANNEX III

SPECIFIC REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3 WITH RESPECT TO CERTAIN CATEGORIES OF ADDITIVES OR CERTAIN PART ICULAR SITUATIONS, AS PROVIDED FOR IN ARTICLE 7(5) OF REGULATION (EC) No 1831/2003

Regulation (EC) No 1831/2003 foresees additional assistance for the preparation of dossiers, where necessary, for each category of additives or for other particular aims according to Article 7(5) of Regulation (EC) No 1831/2003.

List of the specific requirements for establishing dossiers for:

(1) Technological additives

(2) Sensory additives

(3) Nutritional additives

(4) Zootechnical additives

(5) Coccidiostats and histomonostats

(6) Extrapolation from major to minor species

(7) Pets and other non food-producing animals

(8) Additives already authorised for use in food

(9) Modification of authorisations

(10) Renewal of authorisations

(11) Re-evaluation of certain additives already authorised under Directive 70/524/EEC.

Any applications may be submitted following more than one of the specific requirements listed above.

General conditions

Reasons shall be given for the omission from the dossier of any data prescribed in these sections.

1. TECHNOLOGICAL ADDITIVES

1.1. Section I: summary of the dossier

The whole of the Section I of Annex II applies.

1.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives not subject to a specific holder of the authorisation the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply;

— for other additives subject to a specific holder of the authorisation, the whole of Section II applies.

1.3. **Section III: studies concerning the safety of the additive**

Subsections 3.1, 3.2 and 3.4 of Annex II do not apply to silage additives where it can be demonstrated that:

— no detectable amounts of the active substance(s) or relevant metabolites or the active agent(s) survive in the final feed; or

— the active substance(s) and agent(s) occur as normal constituents of silage and use of the additive does not substantially increase their concentration compared to silage prepared without use of the additive (i.e. where there is no substantial change in exposure).

In the other cases the whole of Section 3 of Annex II applies.

1.3.1. *Studies concerning the safety of use of the additive to the target animals*

For xenobiotic [1] substances: the full subsection 3.1 of Annex II applies.

1.3.1.1. Tolerance studies for the target species

For silage additives:

— the product shall be added to a basal diet and results compared to a negative control with the same diet. The basal diet may contain a single source of silage prepared without the use of an additive.

— the dose selected for the tolerance studies shall be a multiple of the concentration present in the ensiled material at the time of normal use where this can be conclusively established. Particular consideration shall be given to product containing viable micro-organisms and their capacity for survival and multiplication during ensiling.

Tolerance studies can usually be limited to a ruminant species, normally the dairy cows. Studies involving other species are required only when the nature of the ensiled material makes it more appropriate for use with non-ruminants.

Other substances:

for the other substances requesting authorisation as technological additives not already authorised for feed use the absence of harm to animals at the highest proposed level shall be demonstrated. This demonstration may be limited to one experiment in one of the most sensitive target species or in one laboratory animal species.

1.3.1.2. Microbial studies

The whole of subsection 3.1.2 of Annex II applies.

1.3.2. *Studies concerning the safety of use of the additive for consumers*

1.3.2.1. Metabolic and residue studies

Metabolic and residue studies are not required if:

(1) the substance or its metabolites are not present in the feedingstuff at time of feeding; or

(2) the substance excreted unchanged, or its metabolites can be demonstrated to be essentially not absorbed; or

[1] A xenobiotic is a chemical substance which is not a natural component of the organism exposed to it. It can also cover substances which are present in much higher concentrations than are usual.

(3) the substance is absorbed in the form of physiological compounds; or

(4) the active component(s) of the additive consists only of micro-organisms or enzymes).

Metabolic studies also are not required if the substance is naturally present in significant amounts in food or feedingstuffs or the substance is a normal constituent of body fluids or tissues. However, in these cases, there is a requirement for residue studies which can be limited to the comparison of the tissues/products levels in an untreated group and in the group supplemented with the highest recommended dose.

1.3.2.2. Toxicological studies

Toxicological studies are not required if:

(1) the substance or its metabolites are not present in the feedingstuff at time of feeding; or

(2) the substance is absorbed in the form of physiological compound(s); or

(3) the product consists of micro-organisms commonly encountered in ensiled materials or those already used in food; or

(4) the product consists of enzymes with a high degree of purity arising from micro-organisms with a history of documented safe use.

For micro-organisms and enzymes not excluded above, genotoxicity studies (including mutagenicity) and a subchronic oral toxicity study are required. Genotoxicity studies shall not be made in the presence of living cells.

For xenobiotic substances, not exempted above, the whole of subsection 3.2.2 Annex II applies.

For other substances a case by case approach shall be taken, taking into account the level and means of exposure.

1.3.2.3. Assessment of consumer safety

The whole of subsection 3.2.3 of Annex II applies for additives requested for food producing animals.

1.3.3. *Studies concerning the safety of use of the additive for users/workers*

The whole of subsection 3.3 of Annex II applies. Additives containing enzymes and micro-organisms are assumed to be respiratory sensitisers unless convincing evidence to the contrary is provided.

1.3.4. *Studies concerning the safety of use of the additive for the environment*

The whole of subsection 3.4 of Annex II applies. For silage additives, the effects of the additive on the production of effluent from clamp or silo during ensiling shall be considered.

1.4. **Section IV: studies concerning the efficacy of the additive**

Technological additives are intended to improve or stabilise the characteristics of feed but have generally no direct biological effect on animal production. Evidence of the efficacy of the additive must be provided by means of appropriate criteria as reflected in recognised acceptable methods, under the intended practical conditions of use in comparison with appropriate control feed.

Efficacy will be assessed by *in vitro* studies, with the exception of substances for control of radionuclide contamination. The appropriate end-points are indicated in the following table for the various functional groups.

End-points for different technological additives

Functional group	End-points for demonstration of efficacy
(a) Preservatives	Inhibition of microbial growth, particularly that of biotic and spoilage organisms. The period for which a preserving effect is claimed shall be demonstrated.
(b) Antioxidants	Protection against oxidative damage of key nutrients/components during feedingstuff processing and/or storage. The period for which a protecting effect is claimed shall be demonstrated.
(c) Emulsifiers	Formation/maintenance of stable emulsions of otherwise immiscible or poorly miscible feed ingredients.
(d) Stabilisers	Maintenance of the physico-chemical state of feedingstuffs.
(e) Thickeners	Viscosity of the feed materials or feedingstuffs.
(f) Gelling agents	Formation of a gel resulting in a change in the texture of the feedingstuff.
(g) Binders	Pellet durability or performance of pellet formation.
(h) Substances for control of radionuclides	Evidence of reduced contamination of food of animal origin.
(i) Anti-caking agents	Flow ability. The period for which an anti-caking effect is claimed shall be demonstrated.
(j) Acidity regulators	pH and/or buffering capacity in feedingstuffs.
(k) Silage additives	— Improved production of silage; — Inhibition of undesirable micro-organisms; — Reduction of effluents; — Improved aerobic stability.
(l) Denaturants	Indelible identification of feed materials.

Silage additives

Separate tests shall be made to demonstrate the effect requested on ensiling process ([2]). The trials shall be performed with one example of each of the following categories (where all or unspecified forages are involved):

— easy to ensile forage: > 3 % soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp),

— moderately difficult to ensile forage: 1,5—3,0 % soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa);

— difficult to ensile forage: < 1,5 % soluble carbohydrates in the fresh material (e.g., orchard grass or leguminous plants).

Where requests are restricted to sub-categories of forage described in terms of dry matter (DM), the dry matter range shall be explicitly stated. Three tests shall then be made with material representative of the range, where possible using examples of different botanical origin.

Specific tests are required for the particular feedingstuffs.

([2]) For purpose of this Regulation, 'ensiling process' means process by which natural deterioration of organic matter is controlled by acidification in anaerobic condition resulting from natural fermentation or/and addition of silage additives.

The duration of the study normally shall be 90 days or longer at a constant temperature (recommended range 15—25 °C). Use of a shorter duration must be justified.

As a rule measurements of the following parameters shall be provided in comparison to the negative control:

— dry matter and calculated dry matter losses (corrected for volatiles),

— pH- decrease,

— concentration of volatile fatty acids (e.g. acetic, butyric and propionic acids) and lactic acid,

— concentration of alcohols (ethanol),

— concentration of ammonia (g/kg of total nitrogen), and

— content of hydro-soluble carbohydrates.

In addition, other microbiological and chemical parameters shall be included as appropriate to substantiate the specific claim made (e.g. numbers of lactate assimilating yeasts, numbers of Clostridia, numbers of Listeria and biogenic amines).

An effect sought for effluent reduction will be judged against the total volume of effluent produced over the entire experimental period, taking into account the likely effect on the environment (e.g. ecotoxicity of the effluent or biological oxygen demand). Reduction of effluent production shall be demonstrated directly. The capacity of the silo shall be sufficient to allow effluent to be released with the application of pressure. The duration of the study shall normally be 50 days. If a different period is used, this shall be justified.

Improved aerobic stability shall be demonstrated in comparison with a negative control. Stability studies shall be of at least seven days duration after exposure to air and additive shall provide evidence of stability for at least two days longer than that shown by untreated control. It is recommended that the experiment is made at an ambient temperature of 20 °C and a rise in temperature of 3 °C or more above background taken as indicative of instability. Temperature measures may be replaced by measurement of CO_2 production.

1.5. **Section V: post-market monitoring plan**

This section shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003. That is, a post-market monitoring plan is required only for additives that are GMOs or are produced from GMOs.

2. **SENSORY ADDITIVES**

2.1. **Colourants**

2.1.1. *Section I: summary of the dossier*

The whole of Section I of Annex II applies.

2.1.2. *Section II: identity, characterisation and conditions of use of the additive; methods of analysis*

The Section II of Annex II applies as following:

— for additives not subject to a specific holder of the authorisation the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply;

— for other additives subject to a specific holder of the authorisation, the whole of Section II applies.

2.1.3. *Section III: studies concerning the safety of the use of the additive*

Subsection 3.3 of Annex II applies fully for every additive.

(1) For substances which, when fed to animals, add colours to food of animal origin Section III subsections 3.1, 3.2 and 3.4 of Annex II apply in full.

(2) For substances that add or restore colour in feedingstuffs, studies concerning Section III subsection 3.1 shall be performed on animals receiving the additive at the recommended dose. Evidence can also be provided by reference to existing scientific literature. Section III subsections 3.2 and 3.4 of Annex II apply.

(3) For substances which favourably affect the colour of ornamental fish or birds, studies concerning Section III subsection 3.1 of Annex II are required and shall be performed on animals receiving the additive at the recommended dose. Evidence can also be provided by reference to existing scientific literature. However, subsections 3.2 and 3.4 are not required.

2.1.4. *Section IV: studies concerning the efficacy of the additive*

The whole of Section IV of Annex II applies.

(a) For substances which, when fed to animals, add colour to food of animal origin:

changes of the colour of products obtained from animals receiving the additive at the recommended conditions of use shall be measured using the appropriate methodology. It shall be demonstrated that the use of the additive does not adversely affect product stability or organoleptic and nutritional qualities of the food. In principle, if effects of a particular substance on the composition/characteristics of animal products are well documented, then other studies (e.g. bioavailability studies) may provide adequate evidence of efficacy.

(b) For substances that add or restore colour in feedingstuffs:

evidence of efficacy shall be provided by adequate laboratory studies reflecting the intended conditions of use in comparison with control feedingstuffs.

(c) For substances which favourably affect the colour of ornamental fish and birds:

studies demonstrating the effect(s) shall be performed on animals receiving the additive at the recommended levels of use. Colour changes shall be measured using the appropriate methodology. Evidence of efficacy may also be provided by other experimental studies (e.g. bioavailability) or by reference to scientific literature.

2.1.5. *Section V: post-market monitoring plan*

This section shall apply under the provision of Article 7(3)(g) of Regulation (EC) No 1831/2003. That is, a post-market monitoring plan is required only for additives that are GMOs or are produced from GMOs.

2.2. **Flavouring compounds**

2.2.1. *Section I: summary of the dossier*

The whole of Section I of Annex II applies.

2.2.2. *Section II: identity, characterisation and conditions of use of the additive; methods of analysis*

In general, in the case of the group 'natural products', whole plants, animals and other organisms and parts of these or products thereof resulting from very limited processing such as crushing, grinding or drying (e.g. many herbs and spices), shall not be considered as falling under this functional group flavourings of the category sensory additives.

For the purposes of the evaluation of applications of these products, flavourings are classified as follows:

1. Natural products:

   1.1. Natural products — botanically defined.

   1.2. Natural products — non-plant origin.

2. Natural or corresponding synthetic chemically defined flavourings

3. Artificial substances.

The relevant group, to which the product object of the application belongs, shall be indicated. In case the product does not fit into any of the above groups, this shall be mentioned and justified.

2.2.2.1. Characterisation of active substance(s)/agent(s)

The whole of the subsection 2.2 of Annex II applies.

In addition:

For all groups of flavourings, the relevant identification number(s) (such as FLAVIS ([3]), Council of Europe ([4]), JECFA, CAS ([5]) or any other internationally accepted numbering system) used specifically for the identification of flavouring products in feed and food shall always be provided when available.

(1) Natural products — botanically defined

The characterisation of the natural botanically defined products shall include the scientific name of the plant of origin, its botanical classification (family, genus, species, if appropriate subspecies and variety) and the common names and synonyms in as many European languages as possible or other language(s) (such as the one(s) of the place(s) of cultivation or origin) where available. The parts of the plant used (leaves, flowers, seeds, fruits, tubers, etc) and for lesser known plants the place of cultivation, identification criteria, and other relevant aspects of these plants shall be indicated. The major components of the extract shall be identified and quantified and its range or variability provided. Special attention shall be given to impurities as mentioned in subsection 2.1.4 of Annex II. The concentrations of substances of toxicological concern ([6]) for humans or animals which may occur in the plant from which the extract is produced shall also be reported.

The pharmacological or related properties of the plant of origin, its parts or of derived products thereof shall be fully investigated and reported.

(2) Natural products — non plant origin

An equivalent approach to the above may be used.

(3) Natural or corresponding synthetic chemically defined flavourings

Besides the general requirements of subsection 2.2.1.1 of Annex II, the origin of the flavouring shall be specified.

([3]) Identification number for chemically defined flavouring substances used in FLAVIS, the EU Flavour Information System, the database used within the Commission Regulation (EC) No 1565/2000 of 18 July 2000 (OJ L 180, 19.7.2000 p. 8) laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council (OJ L 299, 23.11.1996, p. 1).

([4]) CoE no.: Council of Europe number used for botanically defined flavouring products in the Council of Europe's Report no. 1 on 'Natural sources of flavourings', Volume I, Strasbourg, 2000 and its subsequent volumes.

([5]) CAS Number (CAS No) Chemical Abstracts Service Registry Number, unique identifier for chemical substances widely used in chemical inventory listings.

([6]) For the purpose of this section of this Regulation, 'substance of toxicological concern' means a substance with a tolerable daily or weekly intake (TDI or TWI), an ADI, or with a restriction in its use, or an active principle as defined in Council Directive 88/388/EEC relating to flavourings for use in foodstuffs and to source materials for their production, or an undesirable substance.

2.2.2.2. Method of production and manufacture

The whole of the subsection 2.3 of Annex II applies.

In the case of non chemically well defined natural products, usually complex mixtures of many compounds obtained by an extraction process, a detailed description of the extraction process shall be provided. It is recommended to use in the description the relevant terminology such as essential oil, absolute, tincture, extract and related terms ([7]) widely used for botanically defined flavouring products to describe the extraction process. The extraction solvents used shall be specified, the precautions taken to avoid residues of the solvents, and the levels of residues where these are of toxicological concern if their presence would be unavoidable. The terms used to characterise the extract may include a reference to the method of extraction.

2.2.2.3. Methods of analysis

(1) For natural products (either botanically defined or non-plant origin) which do not contain substances of toxicological concern for humans or animals, the standard requirement for methods of analysis of subsection 2.6 of Annex II may be replaced by a simpler qualitative method of analysis fit for the purpose for major or characteristic components of the product.

(2) For natural or corresponding synthetic chemically defined flavourings which are not substances of toxicological concern for humans or animals the standard requirement for methods of analysis of subsection 2.6. of Annex II may be replaced by a simpler qualitative method of analysis fit for the purpose.

The whole of subsection 2.6 of Annex II applies for all other flavourings, such as those natural extracts which contain substances of toxicological concern, natural or corresponding synthetic chemically defined flavourings which are substances of toxicological concern themselves and artificial flavourings.

2.2.3. *Section III: studies concerning the safety of the additive*

For all flavourings, animal exposure and intake calculations both from natural exposure and following addition of the flavouring to feedingstuffs shall be provided.

For flavouring belonging to the group artificial substances, the whole of Section III of Annex II applies.

2.2.3.1. Studies concerning the safety of use of the additive for target animals

(1) Natural products (either botanically defined or non–plant origin)

The safety of these products may be assessed on the basis of its major and characteristic components and also considering known substances of toxicological concern. If the major or characteristic components are not already authorised as chemically defined flavourings or as feed additives, then it has to be verified whether they are substances of toxicological concern for humans or animals, and its toxicological properties have to be provided in accordance with subsection 3.1 of Annex II.

(2) Natural or corresponding synthetic chemically defined flavourings

If these substances are authorised flavourings for humans, the safety for target species may be assessed taking into account the comparison between the level of intake by the target species from feed proposed by the applicant with that by humans from food. Metabolism and toxicological data on which the assessment for human used was made shall be submitted.

In all other cases different from the case where both levels of intake are similar, such as where the level of intake by the target animal proposed be the applicant is substantially higher than that by human from food or where the substance is not authorised in food, the safety for the target animals may be assessed by taking into account the following data: the principle of threshold of toxicological concern ([8]), available toxicological and metabolism data for related compounds, and chemical structural alert consideration (following by analogy of the Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation program in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council) ([9]).

Tolerance studies are needed only where threshold values are exceeded or cannot be determined.

([7]) Defined in Appendix 4 of the Council of Europe's Report no. 1 on 'Natural sources of flavourings', Volume I, Strasbourg, 2000.

([8]) JECFA (FAO/WHO, 1996, Food additive series 35, IPCS, WHO Geneva) corresponding threshold for target animal should be adjusted to take into account of animal weight and feed intake.

([9]) OJ L 180, 19.7.2000, p. 8.

2.2.3.2. Studies concerning the safety of use of the additive for consumers

Evidence that the metabolites of the flavouring do not result in an accumulation in the animal of products of toxicological concern for humans shall be provided. In the case that the use of the requested flavouring product as a consequence of its addition to feedingstuffs results in residues in food of animal origin, detailed calculation of consumer exposure shall be provided.

(a) Metabolic and residue studies

(1) Natural products (either botanically defined or non–plant origin)

The safety of these products for humans when used as flavourings in feed, as regards its metabolism, may be based on the metabolism (in the target animal) and residues studies of their major and characteristic components and the absence of substances of toxicological concern in the extract.

If the major or characteristic components are not already authorised as chemically defined flavourings or if the level of intake by the target animals from feed is substantially higher than that by humans from food, the whole of subsection 3.2.1 of Annex II is required.

(2) Natural or corresponding synthetic chemically defined flavourings

If these products are not authorised as flavourings for humans or if the level of intake by the target animal from feed as proposed be the applicant is substantially higher than that by human from food, available data on metabolic fate shall be provided and used to assess the potential accumulation in edible tissues and products according to subsection 3.2.1 of Annex II.

(b) Toxicological studies

(1) Natural products (either botanically defined or non–plant origin)

The safety of these products for humans when used as flavouring in feed may be based on the toxicological data of their major or characteristic components and the absence of substances of toxicological concern in the extract.

A toxicological package is required when the metabolic studies of the major or characteristic compounds show that there is accumulation in animal tissues or products and the threshold of toxicological concern for the target animal is exceeded. This toxicological package shall comprise genotoxicity studies, including mutagenicity and a subchronic oral toxicity study, according to subsection 3.2.2 of Annex II.

(2) Natural or corresponding synthetic chemically defined flavourings

A toxicological package comprising genotoxicity studies, including mutagenicity and a subchronic oral toxicity study, according to subsection 3.2.2 of Annex II, is required when the metabolic studies of these products show that there is accumulation in animal tissues or products and the threshold of toxicological concern for the target animal is exceeded.

2.2.3.3. Studies concerning the safety of use of the additive for users/workers

The whole of subsection 3.3 of Annex II applies.

2.2.3.4. Studies concerning the safety of use of the additive for the environment

The whole of subsection 3.4 of Annex II applies.

2.2.4. *Section IV: studies concerning the efficacy of the additive*

Evidence of the flavouring properties, usually on the basis of the published literature, shall be provided. This may also be demonstrated by experience of practical use, where available, otherwise animal studies may be required.

It has to be fully investigated and reported if the product object of the application exerts other functions in the feed, animal or food of animal origin besides the one in the definition of flavouring compounds in Annex I of Regulation (EC) No 1831/2003.

2.2.5. *Section V: post-market monitoring plan*

This section shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003. That is, a post-market monitoring plan is required only for additives that are GMOs or are produced from GMOs.

3. NUTRITIONAL ADDITIVES

3.1. Section I: summary of the dossier

The whole of Section I of Annex II applies.

3.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives not subject to a specific holder of the authorisation the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply;

— for other additives subject to a specific holder of the authorisation, the whole of Section II applies.

3.3. Section III: studies concerning the safety of the additives

3.3.1. *Studies concerning the safety of use of the additive for the target species*

3.3.1.1. Tolerance of the target species

1. No studies are required for urea, and amino acids, their salts and analogues authorised by Directive 82/471/EEC and compounds of trace elements and vitamins, pro-vitamins and chemically well-defined substances having similar effect which do not have a potential to accumulate already authorised as feed additives under Directive 70/524/EEC.

2. For those additives that fall within the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' and having a potential to accumulate, tolerance will only be required to be demonstrated for compounds for which potency is expected or has been demonstrated to be different from that of the well established vitamin(s). In certain cases elements of the tolerance test (design or criteria) could be combined with one of the efficacy trials.

3. Tolerance will be demonstrated for urea derivatives amino acid analogues and compounds of trace elements not previously authorised. The fermentation products will be requested by tolerance demonstration, unless the active substance is separated from the crude fermentation product and highly purified, or the production organism has a history of apparent safe use and well known about its biology to exclude a potential for the production of toxic metabolites.

4. Where the application is for all animal species/categories, one tolerance study on the most sensitive species (or even an appropriate laboratory animal) under the most recent knowledge is sufficient.

3.3.1.2. Microbial studies

The whole of subsection 3.1.2 of Annex II applies.

3.3.2. *Studies concerning the safety of use of the additive for consumers*

3.3.2.1. Metabolic and residue studies

Metabolic studies normally are not required. For urea derivatives, ruminal metabolism shall be studied in the efficacy trials.

Residue or deposition studies are only required for those additives that fall within the functional group 'vitamins, pro-vitamins and chemically well-defined substances, having similar effect' that have a potential for accumulation in the body and for the functional group of compounds of trace elements where bioavailability has been enhanced. In that case, the procedure described in subsection 3.2.1 of Annex II does not apply. The requirement is limited to the comparison of the levels in the tissues or products between the group supplemented with the highest dose of the substance claimed and a positive control (reference compound).

3.3.2.2. Toxicological studies

These are required for fermentation products and additives not already authorised. For fermentation products, genotoxicity and subchronic toxicity studies must be provided unless:

1. the active substance is separated from the crude fermentation product and is highly purified; or

2. the production organism has a history of apparent safe use and there is sufficient knowledge of its biology to exclude a potential for the production of toxic metabolites.

Where the production organism belongs to a group in which some strains are known to produce toxins, their presence shall be specifically excluded.

3.3.2.3. Assessment of consumer safety

The whole of subsection 3.2.3 of Annex II applies.

3.3.3. *Studies concerning the safety of use of the additive for users/workers*

The whole of subsection 3.3 of Annex II applies

3.3.4. *Studies concerning the safety of use of the additive for the environment*

The whole of subsection 3.4 of Annex II applies for new active substances belong to the compound of trace elements.

3.4. **Section IV: studies concerning the efficacy of the additive**

Efficacy studies are not required for urea, amino acids, amino acid salts and analogues already authorised as feed additives, compounds of trace elements already authorised as feed additives and vitamins, pro-vitamins and chemically well-defined substances having similar effect already authorised as feed additives.

A short term study is required to support efficacy for urea derivatives, amino acid salts and analogues not already authorised as feed additives, compounds of trace elements not already authorised as feed additives and for vitamins, pro-vitamins and chemically well-defined substances having similar effect not already authorised as feed additives.

For other substances for which a nutritional effect is requested at least one long term efficacy study under provisions of Section 4 of Annex II is requested.

Where required, studies shall demonstrate that the additive can provide the animals' nutritional requirements. Tests shall include a test group with a diet that contains the nutrient at concentrations below the animals' requirements. However, trials using a severely deficient control group shall be avoided. Generally, it will be sufficient to demonstrate efficacy in a single animal species or category including laboratory animals.

3.5. **Section V: post-market monitoring plan**

This section shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.

4. **ZOOTECHNICAL ADDITIVES**

4.1. **Zootechnical additives other than enzymes and micro-organisms**

4.1.1. *Section I: summary of the dossier.*

The whole of Section I of Annex II applies.

4.1.2. *Section II: identity, characterisation and conditions of use of the additive; methods of analysis*

The whole of Section II of Annex II applies.

4.1.3. *Section III: studies concerning the safety of the additives*

4.1.3.1. Studies concerning the safety of use of the additive for target animals

The whole of subsection 3.1 of Annex II applies.

4.1.3.2. Studies concerning the safety of use of the additive for consumer

(1) Metabolic and residue studies

These studies are not required if:

— the substance or its metabolites can be demonstrated to be excreted unchanged and essentially to be not absorbed; or

— the substance is absorbed in physiological form and physiological level of compound(s).

No metabolic studies are needed if the substance is naturally present in significant amounts in food or feedingstuffs or if the substance is a normal constituent of body fluids or tissues. However, in these cases, there is a requirement for residue studies which can be limited to a comparison of the levels in the tissues or products in an untreated group to the levels found in the group supplemented with the highest recommended dose.

In all other cases the whole of subsection 3.2.1 of Annex II applies.

(2) Toxicological studies

Toxicological studies are not required if the substance is absorbed in the form of physiological compound(s).

For xenobiotic substances the whole of subsection 3.2.2 of Annex II applies.

For other substances, a case by case approach shall be used, taking into account the level and means of exposure, and any omission of data prescribed in this section must be fully justified.

(3) Assessment of consumer safety

The whole of subsection 3.2.3 of Annex II applies for food producing animals.

4.1.3.3. Studies concerning the safety of the additive for users/workers

The whole of subsection 3.3 of Annex II applies.

4.1.3.4. Studies concerning the safety of the additive for the environment

The whole of subsection 3.4 of Annex II applies

4.1.4. *Section IV: studies concerning the efficacy of the additive*

The whole of Section IV of Annex II applies.

(1) Additives favourably affecting animal production, performance or welfare and for the functional group 'other zootechnical additives'.

The effects can only be demonstrated in relation to each target animal species or category. Depending on the properties of the additive, outcome measures may be based either on performance characteristics (e.g. feed efficiency, average daily gain, increasing of animal products), carcass composition, herd performance, reproduction parameters or animal welfare. Evidence of the mode of action can be provided by short term efficacy studies or laboratory studies measuring relevant end-point.

(2) Additives favourably affecting the environmental consequences of animal production

For these additives which favourably affect the environment (e.g. reduced nitrogen or phosphorus excretion or reduced methane production, off-flavours), evidence of efficacy for the target species can be given by three short term efficacy studies with animals showing significant beneficial effects. The studies shall take into consideration the possibility of an adaptive response to the additive.

4.1.5. *Section V: post-market monitoring plan*

This section shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.

4.2. **Zootechnical additives: enzymes and micro-organisms**

4.2.1. *Section I: summary of the dossier*

The whole of Section I of Annex II applies.

4.2.2. *Section II: identity, characterisation and conditions of use of the additive; methods of analysis*

The whole of Section II of Annex II applies.

4.2.3. *Section III: studies concerning the safety of the additives*

4.2.3.1. Studies concerning the safety of use of the additive for the target animals

The whole of subsection 3.1.1 of Annex II applies.

Applicants are encouraged to use, wherever possible, at least a 100-fold overdose in the experimental group and consequently reduce the number of end-points required. A concentrated form of the additive can be used for this purpose. Concentration shall be adjusted by reducing the amount of carrier present but the ratio of active agent (s)/substance(s) to the other fermentation products must remain the same as in the final product. For enzymes, the diet shall provide the appropriate substrate(s).

The whole of subsection 3.1.2 of Annex II applies for all micro-organisms and for those enzymes with a direct catalytic effect on elements of the microbiota or which otherwise are claimed to affect the gut microbiota.

Where there is novel exposure or a substantial increase in the extent of exposure to micro-organisms, additional studies may be necessary to demonstrate the absence of adverse effects on the commensal microbiota of the digestive tract. For ruminants, direct counts of the microbiota will be necessary only if indicted by evidence of an adverse change to rumen function (measured in vitro as a change in volatile fatty acid concentrations, reduction in propionate concentration or reduced cellulolysis).

4.2.3.2. Studies concerning the safety of the additive use for consumer

(1) Metabolic and residue studies are not required.

(2) Toxicological studies, according to subsection 3.2.2 of Annex II.

Enzymes and micro-organisms form only a part of the whole additive which, in most cases, can include other components originated from the fermentation process. Consequently, it is necessary to test the additive to ensure it does not contain mutagenic or otherwise materials that can harm human consumers of food derived from animals feed with feedingstuffs or water treated with these additives.

However, most viable bacteria intended for direct or indirect ingestion by mammals (including humans) are selected from groups of organisms with a history of apparent safe use or from groups where the toxic hazards are well defined. Similarly, the hazards associated with micro-organisms currently used for the production of enzymes generally are well recognised and substantially reduced by modern production methods. Therefore, for enzymes from microbial sources and for micro-organisms with a history of apparent safe use and where the components of fermentation process are well defined and know, toxicity tests (e.g. oral toxicity or genotoxicity testing) are not considered necessary. However, for both live organisms and those used for the production of enzymes, the specific concerns in section 2.2.2.2 of Annex II shall always be addressed.

When the organism or its application is novel and insufficient is known about the biology of the (production) organism to exclude a potential for the production of toxic metabolites, genotoxicity and oral toxicity studies made with additives containing viable micro-organisms or enzymes shall be introduced. In this case, they shall take the form of genotoxicity studies including mutagenicity and a subchronic oral toxicity study. It is recommended that such studies are performed with the cell-free fermentation broth or in the case of a solid state fermentation, an appropriate extract.

4.2.3.3. Studies concerning the safety of the additive for users/workers

The whole of subsection 3.3 of Annex II applies except:

— enzymes and micro-organisms, as proteinaceous substances, are assumed to be respiratory sensitisers unless convincing evidence to the contrary is provided. Therefore, no direct testing is required.

— the formulation of the product (e.g. micro-encapsulation) may obviate the need for some or all tests. In such cases, appropriate justification shall be provided.

4.2.3.4. Studies concerning the safety of the additive for the environment

The whole of subsection 3.4 of Annex II fully applies for micro-organisms which are not of gut origin or are not ubiquitous in the environment.

4.2.4. *Section IV: studies concerning the efficacy of the additives*

The whole of Section IV of Annex II applies.

(1) Additives favourably affecting animal production, performance or welfare and for the functional group 'other zootechnical additives'.

The effects can only be demonstrated in relation to each target animal species or category. Depending on the properties of the additive, outcome measures may be based either on performance characteristics (e.g. feed efficiency, average daily gain, increasing of animal products), carcass composition, herd performance, reproduction parameters or animal welfare. Evidence of the mode of action can be provided by short term efficacy studies or laboratory studies measuring relevant end-point.

(2) Additives favourably affecting the environmental consequences of animal production.

For these additives which favourably affect the environment (e.g. reduced nitrogen or phosphorus excretion or reduced methane production, off-flavours), evidence of efficacy for the target species can be given by three short term efficacy studies with animals showing significant beneficial effects. The studies shall take into consideration the possibility of an adaptive response to the additive.

4.2.5. *Section V: post-market monitoring plan*

This section shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.

5. COCCIDIOSTATS AND HISTOMONOSTATS

5.1. Section I: summary of the dossier

The whole of Section I of Annex II applies

5.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The whole of Section II of Annex II applies

5.3. Section III: studies concerning the safety of the additives

5.3.1. *Studies concerning the safety of use of the additive for target animals*

The whole of the subsection 3.1 of Annex II applies

5.3.2. *Studies concerning the safety of use of the additive for consumer*

The whole of the subsection 3.2 of Annex II applies

5.3.3. *Studies concerning the safety of use of the additive for users/workers*

The whole of the subsection 3.3 of Annex II applies

5.3.4. *Studies concerning the safety of use of the additive for environment*

The whole of the subsection 3.4 of Annex II applies

5.4. Section IV: studies concerning the efficacy of the additive

These additives protect the animals from the results of an invasion of *Eimeria* spp. or *Histomonas meleagridis*. Importance shall be attached to evidence of the specific effects of the additive (e.g. species controlled) and its prophylactic properties (e.g. reduction in morbidity, mortality, oocyst count and lesion score). Information on the effect on growth and feed conversion (fattening birds, replacement layers and rabbits), effects on hatchability (breeding birds) shall be provided, as appropriate.

The required efficacy data shall derive from three types of target animal experiments:

— artificial single and mixed infections

— natural/artificial infection to simulate use conditions

— actual use conditions in field trials

Experiments with artificial single and mixed infections (e.g. battery cages for poultry) are intended to demonstrate the relative effectiveness against the parasites and do not require replication. Three significant results are required for studies simulating use conditions (e.g. floor pen studies with poultry, battery cage studies with rabbits). Three field studies in which a degree of natural infection is present are also required.

5.5. Section V: post-market monitoring plan

This section of Annex II shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.

6. EXTRAPOLATION FROM MAJOR TO MINOR SPECIES

Minor species are defined in Article 1(2) of this Regulation.

A more limited submission will normally be accepted for a proposed extension of the authorised use to a species which is physiologically comparable to one in which the use of the additive has already been granted.

The following requirements apply only to requested authorisations for minor species of additives already authorised for major species. For requested authorisations for new feed additives requested only for minor species, all sections fully apply, depending on the category/functional group of the additive (see corresponding specific requirements of Annex III).

6.1. Section I: summary of the dossier

The whole of Section I of Annex II applies.

6.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives subject to a specific holder of the authorisation, the whole of Section II applies,

— for other additives the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply.

6.3. Section III: studies concerning the safety of the use of the additive

6.3.1. *Studies concerning the safety of use of the additive for the target animals*

6.3.1.1. Tolerance of the target species

The requirements for the different categories/functional groups of additives apply.

In principle, tolerance studies for minor species are not required if the additive showed a wide margin of safety (at least a factor of 10) in the relevant physiologically similar major species.

If three major target species (including monogastric and ruminant mammals and poultry) showed a similar and wide margin of safety, no additional tolerance studies would be required for non-physiologically similar minor species (e.g. horses or rabbits). Where tolerance is required, the duration of the studies for minor species (except rabbits) shall be at least 28 days for growing animals and 42 days for adult animals. For rabbits, the following durations apply: rabbits for fattening: 28 days; breeding does: one cycle (from insemination to the end of the weaning period). If rabbits suckling and weaned are applied for, a period of 49 days (beginning one week after birth) would be considered sufficient and must include the does until weaning. For fish (other than salmonidae) a 90-day period is required.

6.3.2. *Studies concerning the safety of use of the additive for the human consumers*

6.3.2.1. Metabolic studies

The requirements for the different categories and functional groups of additives apply.

In addition, metabolic studies are not required if the additive is already authorised for use in a species which is physiologically comparable to the minor species for which the authorisation is sought. In the absence of physiological similarity, a comparison of metabolic profile based on *in vitro* studies (e.g. performed in hepatocytes using labelled compound) is considered sufficient to assess metabolic proximity.

If the minor species is not physiologically similar to a major species, then an indication of the metabolic fate of the additive shall be obtained in the minor species.

6.3.2.2. Residue studies

Only marker residue quantification in edible tissues and products is needed when metabolic proximity is given or demonstrated. In all other cases, subsection 3.2.1.2 of Annex II fully applies.

6.3.2.3. Assessment of consumer safety

Proposal for Maximum Residue Limits (MRLs)

Setting of MRLs can be done by assuming that no significant differences in the content of residues occur in the edible tissues of minor species compared to a similar major species.

MRLs can be extrapolated within classes of animals as follows:

— from major growing ruminants to all growing ruminants;

— from milk of dairy cows to milk of other dairy ruminants;

— from pigs to all monogastric mammals, excluding horses;

— from chickens or turkeys to other poultry;

— from laying hens to other laying birds; and

— from Salmonidae to all fin fish.

MRLs for horses could be extrapolated when MRLs for a major ruminant and a major monogastric mammal exist.

If identical MRLs were derived in cattle (or sheep), pigs and chicken (or poultry), which represent major species with different metabolic capacities and tissue composition, the same MRLs can also be set for ovine, equidae and rabbits, which means an extrapolation is considered possible to all food-producing animals except fish. Considering the Committee for Medicinal Products for Veterinary Use (CVMP) guideline ([10]) on the establishment of MRLs for *Salmonidae* and other finfish, which already allows an extrapolation from MRLs in muscle of a major species to *Salmonidae* and other finfish provided that the parent substances is acceptable as marker residue for the MRL in muscle and skin, MRLs can be extrapolated to all-food-producing animals.

Analytical methods shall be available for monitoring residues in edible tissue and products of all food-producing animals.

6.3.3. *Studies concerning the safety of use of the additive for users/workers*

The whole of subsection 3.3 of Annex II applies.

6.3.4. *Studies concerning the safety of use of the additive for the environment*

Environmental risk assessment can be extrapolated from the assessment performed for the physiologically comparable major species. For additives intended to be used in rabbits, the whole section applies taking into consideration the requirements for each category/functional group of additives.

6.4. **Section IV: studies concerning the efficacy of the additive**

Where the additive is already approved for a physiologically comparable major species for the same function and where the mode of action of the additive is known or demonstrated, evidence of the same mode of action in the minor species can be taken as evidence of efficacy. Where no such link can be made, efficacy shall be demonstrated following the general rules for Section IV in Annex II. In some cases it may be appropriate to combine animal species in the same productive stage (e.g. goats and sheep used for milk production). Significance should be demonstrated in each study ($P \leq 0,1$) or, if possible, by meta-analysis ($P \leq 0,05$).

([10]) Note for guidance of the establishment of maximum residue limits for *Salmonidae* and other fin fish. The European Agency for the Evaluation of Medicinal Products. *Veterinary Medicines Evaluation Unit*. EMEA/CVMP/153b/97-FINAL.

If efficacy demonstration is required, the duration of efficacy studies shall be analogous to the comparable production stages of the physiologically comparable major species. In other cases, the minimum study duration shall follow the relevant provisions in subsection 4.4 of Annex II and Annex IV.

6.5. **Section V: post-market monitoring plan**

This section of Annex II shall apply under provision of Article 7(3) (g) of Regulation (EC) No 1831/2003.

7. **PETS AND OTHER NON FOOD-PRODUCING ANIMALS**

Pets and other non food-producing animals are defined in Article 1(1) of this Regulation.

7.1. **Section I: summary of the dossier**

The whole of Section I of Annex II applies.

7.2. **Section II: identity, characterisation and conditions of use of the additive; methods of analysis**

The Section II of Annex II applies as following:

— for additives subject to a specific holder of the authorisation, the while of Section II applies

— for other additives the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2., 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply.

7.3. **Section III: studies concerning the safety of the additive**

7.3.1. *Studies concerning the safety of use of the additive for the target animals*

The requirements for the different categories/functional groups of additives apply. Where a tolerance study is required, its duration shall be at least 28 days.

A tolerance study is not required if the additive has shown a comparable and wide margin of safety in three major species (including monogastric and ruminant mammals and poultry).

7.3.2. *Studies concerning the safety of use of the additive for consumers*

This subsection is not usually required. Consideration shall be given to the safety of the owner.

7.3.3. *Studies concerning the safety of use of the additive for users/workers*

The whole of subsection 3.3 of Annex II applies.

7.3.4. *Studies concerning the safety of use of the additive for the environment*

Subsection 3.4 of Annex II is not required.

7.4. **Section IV: studies concerning the efficacy of the additive**

The requirements for the different categories/functional group of additives apply.

When the additive, for which animal studies are required, has been previously authorised for other physiological similar species, no further demonstration of efficacy is required provided the requested effect and mode of action are the same. If the additive has not been previously authorised, the requested effect, or the mode of action are different than former authorisation, efficacy shall be demonstrated following the general rules for Section IV in Annex II.

The duration of the long term efficacy trials shall be at least 28 days.

7.5. **Section V: post-market monitoring plan**

This section of Annex II shall apply under provision of Article 7(3) (g) of Regulation (EC) No 1831/2003.

8. **ADDITIVES ALREADY AUTHORISED FOR USE IN FOOD**

8.1. **Section I: summary of the dossier**

The whole of Section I of Annex II applies.

8.2. **Section II: identity, characterisation and conditions of use of the additive; methods of analysis**

The Section II of Annex II applies as following:

— for additives subject to a specific holder of the authorisation, the whole of Section II applies,

— for other additives the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2., 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply.

8.3. **Section III: studies concerning the safety of the additives**

The most recent formal assessments of the safety of the food additive shall be included and shall be supplemented with any subsequently produced data.

For those additives which are authorised as food additives or approved as components for foodstuffs in the European Union without any restriction, studies concerning the safety for the consumer and the workers are generally not necessary.

Subsections 3.1, 3.2 and 3.3 of Annex II shall be provided considering the present knowledge on the safety of these substances when used in food. Accordingly, such substances also used in food can be classified as:

— ADI not specified (without an explicit indication of the upper limit of intake, assigned to substances of very low toxicity),

— ADI or UL established, or

— no ADI allocated (applicable to substances for which the available information is not sufficient to establish their safety).

8.3.1. *Studies concerning the safety of use of the additive for the target animals*

If the use level as for the feed additive is similar to that used in food, the safety for target species can be assessed based on the *in vivo* toxicological data available, a consideration of chemical structure and the metabolic capacity of the target species. If the use level in feed is considerably higher than the corresponding use in food, a tolerance study in the target animal may be required, depending on the nature of the substance.

8.3.2. *Studies concerning the safety of use of the additive for consumers*

If the use as a feed additive results in a higher consumer exposure, or to a different pattern of metabolites than that resulting from use in food, then further toxicological and residue data will be required.

8.3.2.1. Food additives for which an ADI is not specified

Assessment of the safety for consumers is not required, except when the use of the additive in feed leads to a different pattern of metabolites than when used in food.

8.3.2.2. Food additives with an established ADI or UL

Consumer safety must be assessed taking into consideration the additional exposure from feed use, or specific exposure related to metabolites arising from the target species. This can be done by extrapolating residue data from literature.

Where residue studies are necessary, the requirement is limited to a comparison of the tissue or product levels in an untreated group to the group supplemented with the highest dose that is claimed.

8.3.2.3. Food additives for which no ADI is allocated

The reasons why an ADI was not allocated shall be clearly specified. If concerns arise from this, and the use of the additive in feed would contribute to a significant increase in consumer exposure, a full toxicological evaluation is required.

Additional exposure from feed use can be extrapolated from residue data from the literature.

Where residue studies are necessary, the requirement is limited to a comparison of the levels in tissues or products in an untreated group with the group supplemented with the highest dose that is claimed.

8.3.3. *Studies concerning the safety of use of the additive for users/workers*

The whole of the subsection 3.3 of Annex II applies.

Precautionary measures set for handling these substances used in food shall be taken into account when considering user safety for the feed additive.

8.3.4. *Studies concerning the safety of use of the additive for the environment*

Subsection 3.4 of Annex II is required.

8.4. **Section IV: studies concerning the efficacy of the additive**

Where the function requested for feed is the same as that used in food, no further demonstration of efficacy might be necessary. Otherwise the requirements for efficacy are as those shown in Section IV of Annex II.

8.5. **Section V: post-market monitoring plan**

This section of Annex II shall apply under provision of Article 7(3)(g) of Regulation (EC) No 1831/2003.

9. **MODIFICATION OF THE AUTHORISATIONS**

Since reliance can be placed on the evaluation of the data supplied for previous authorisations, a dossier prepared for an application under Article 13(3) of Regulation (EC) No 1831/2003 needs to comply only with the requirements listed below.

An application for modification of the terms included in an existing authorisation Regulation, such as the identification, the characterisation or the conditions of use of the additive, shall demonstrate that the modification does not have any harmful effect on the target species, the consumer, the user or the environment. An additive can be considered as identical for this purpose if the active substance(s) or agent(s) and the conditions of use are the same, its purity is essentially similar and no new components of concern have been introduced. For such products an abridged application may be submitted as it will normally not be necessary to repeat studies to demonstrate the safety for the target species, the consumer and the environment and efficacy.

The application shall address the following requirements:

1. the whole of Annex I applies — this includes details of the modification requested;

2. the whole of Section II of Annex II applies;

3. data must be provided indicating that the, chemical or biological characteristics of the additive are essentially the same to those of the established product;

4. where appropriate, evidence for bioequivalence shall be provided either by specification, or by published literature or from specific studies. Where bioequivalence is not fully demonstrated, conformity of the withdrawal period with the MRL has to be demonstrated;

5. evidence shall be presented that in the light of current scientific knowledge that the additive remains safe under the approved conditions for target species, consumers, workers and the environment;

6. a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation, shall be provided; and

7. the specific data supporting the request for change must be submitted in compliance with the relevant parts of Sections III, IV and V of Annex II.

10. RENEWAL OF AUTHORISATIONS

Applications for renewal of authorisation under Article 14 of Regulation (EC) No.1831/2003 shall comply with the following requirements:

10.1. Section I: summary of the dossier

The whole of Section I of Annex II applies. A copy of the original Community authorisation for placing the feed additive on the market, or the last renewal of authorisation, shall be provided. An updated dossier shall be prepared according to the most up-to-date requirements and a list providing all variations since the original authorisation, or the last renewal of authorisation shall be submitted. The applicant has to provide a summary of the dossier, detailing the scope of the application, and any new information that has become available since the previous authorisation/renewal in terms of identity and safety.

10.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives subject to a specific holder of the authorisation, the whole of the Section II applies,

— for other additives the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply.

Evidence shall be presented to show that the additive has not been significantly changed or altered in composition, purity or activity in respect of the additive that was authorised. Any change in the manufacturing process shall be reported.

10.3. Section III: studies concerning the safety of the additives

Evidence shall be presented that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, workers and the environment. A safety update for the period since the original authorisation, or the last renewal of authorisation with information on the following items shall be presented:

— reports on adverse effects including accidents (previously unknown effects, severe effects of any type, increased incidence of known effects) for target animals, consumers, users and the environment. The report on adverse effects shall include the nature of the effect, number of affected individuals/organisms, outcome, conditions of use, and causality assessment,

— reports on previously unknown interactions and cross-contaminations,

— data from residue monitoring, where appropriate,

— data from epidemiologic and/or toxicological studies,

— any other information concerning the safety of the additive and risks of the additive to animals, humans, and environment.

If no further information is provided on any of these issues, the reasons for this shall be clearly identified.

A report on the results of the post-market monitoring program shall be provided, if such a monitoring requirement is included in the previous authorisation.

Where, as provided for in Article 14(2)(d) of Regulation (EC) No 1831/2003, the application for renewal of the authorisation includes a proposal for amending or supplementing the conditions of the original authorisation, *inter alia*, the conditions concerning future monitoring, the specific data supporting the proposal for amendment must be submitted in compliance with the relevant parts of Sections III, IV and V of Annex II.

11. RE-EVALUATION OF CERTAIN ADDITIVES ALREADY AUTHORISED UNDER DIRECTIVE 70/524/EEC

The additives concerned by this point 11 are additives which were authorised under Directive 70/524/EEC and are to be re-evaluated in accordance with Article 10(2) of Regulation (EC) No 1831/2003 and which belong to the following groups:

— antioxidant substances,

— flavouring and appetising substances,

— emulsifying and stabilising substances, thickeners and gelling agents,

— colourants, including pigments,

— preservatives,

— vitamins, provitamins and chemically well-defined substances having similar effect,

— trace elements,

— binder, anti-caking agents and coagulants,

— acidity regulators, and

— radionuclide binders.

The level and quality of risk evaluation for these additives shall be similar to other additives. However, due to their long history of safe use, data from studies already published may be used, under provisions provided by this Regulation, to show that the additive remains safe under the approved conditions for the target species, consumers, users and the environment.

11.1. Section I: summary of the dossier

The whole of Section I of Annex II applies.

11.2. Section II: identity, characterisation and conditions of use of the additive; methods of analysis

The Section II of Annex II applies as following:

— for additives not subject to a specific holder of the authorisation the paragraphs 2.1.2, 2.1.3, 2.1.4, 2.1.4.2, 2.2, 2.3.1, 2.3.2, 2.4.1, 2.4.2, 2.4.4, 2.5, 2.6 apply;

— for other additives subject to a specific holder of the authorisation, the whole of Section II applies.

11.3. **Section III: studies concerning the safety of the additives**

Where an additive has been assessed for safety for target species, consumers, users/workers and the environment, a summary of the safety studies submitted for the previous authorisation, plus any new information arising since the previous authorisation shall be provided. Where a formal safety assessment has not been undertaken for the use of the substance as a feed additive, studies and data from the scientific literature can be used provided it is equivalent to that which would be required in a new application. Otherwise, a complete set of safety studies shall be provided.

11.4. **Section IV: studies concerning the efficacy of the additive**

Where appropriate, the compliance with the requirement of efficacy provided for in Article 5(3) of Regulation (EC) No 1831/2003 may be demonstrated by submission of material other than studies, in particular relating to the long history of use.

11.5. **Section V: post-market monitoring plan**

This section of Annex II shall apply under provision of Article 7(3) (g) of Regulation (EC) No 1831/2003.

ANNEX IV

Categories and definitions of target animals and indication of the minimum duration of efficacy studies

1. Table. Animal categories: Pigs

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term efficacy studies
		Period/age	Age	Weight	
Piglets (suckling)	Young porcine animals getting milk from sows	From birth	Up to 21-42 days	Up to 6-11 kg	14 days
Piglets (weaned)	Young porcine animals having completed the suckling period and being reared for reproduction or meat production	From 21-42 days	Up to 120 days	Up to 35 kg	42 days
Piglets (suckling and weaned piglets)	Young porcine animal from birth being reared for reproduction or meat production purposes	From birth	Up to 120 days	Up to 35 kg	58 days
Pigs for fattening	Porcine animals having completed the weaning period and intended for meat production until day of transport to slaughterhouse	From 60-120 days	Up to 120-250 days (or according to local custom)	80-150 kg (or according to local custom)	Until slaughter weight, but not less than 70 days
Sows for reproduction	Female porcine animals having been inseminated/ mated at least once	From first insemination			From insemination to the end of the second weaning period (two cycles)
Sows, in order to have benefit in piglets	Female porcine animals having been inseminated/ mated at least once				At least two weeks before the parturition until the end of weaning period

2. Table. Animal categories: Poultry

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Chickens for fattening	Birds raised for fattening	From hatching	Up to 35 days	Up to ~1 600 g(up to 2 kg)	35 days
Chickens reared for laying	Female birds being reared for consumer egg production or for breeding purposes	From hatching	Up to ~16 weeks (up to 20 weeks)	—	112 days (if the efficacy data are not available for chickens for fattening)

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Laying hens	Productive female birds held for egg production purposes	From 16-21 weeks	Up to ~13 months (up to 18 months)	From 1 200 g (white) 1 400 g (brown)	168 days
Turkeys for fattening	Birds raised for fattening	From hatching	Up to ~14 weeks (up to 20 weeks) Up to ~16 weeks (up to 24 weeks)	Hens: up to ~7 000 g (up to 10 000 g) Cocks: up to ~12 000 g (up to 20 000 g)	84 days
Turkeys for breeding purposes	Female and male birds held for breeding purposes	Whole period	From 30 weeks up to ~ 60 weeks	Hens: from ~15 000 g Cocks: from ~30 000 g	At least six months
Turkeys reared for breeding	Young female and male birds reared for breeding purposes	From hatching	Up to 30 weeks	Hens: up to ~15 000 g Cocks: up to ~30 000 g	Whole period (if the efficacy data are not available for turkeys for fattening)

3. Table. Animal categories: Bovines (domestic bovine animals including bubalus and bison species)

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Calves for rearing	Calves which are reared for reproduction or for beef production	From birth	Up to 4 months	Up to 60-80 kg up to 145 kg)	56 days
Calves for fattening	Calves for veal production	From birth	Up to 6 months	Up to 180 kg (up to 250 kg)	Until slaughter but not less than 84 days
Cattle for fattening	Bovine animals that have completed the weaning period and are destined for meat production until day of transport to slaughterhouse	From full development of rumination	Up to 10-36 months	Up to 350-700 kg	168 days

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Dairy cows for milk production	Female bovine animals that have produced at least one calf.				84 days (total lactation period shall be reported)
Cows for reproduction	Female bovine animals that have been inseminated/mated at least once	From first insemination to the end of second weaning period			Two cycles (if the reproduction parameters are requested)

4. Table. Animal categories: Sheep

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Lambs for rearing	Lambs reared for future reproduction	From birth	Up to 3 months	15-20 kg	56 days
Lambs for fattening	Lambs that are reared for lamb meat production.	From birth	Up to 6 months (or older)	up to 55 kg	Until slaughter weight but not less than 56 days
Dairy sheep (for milk production)	Sheep that have produced at least one lamb				84 days (total lactation period shall be reported)
Ewes for reproduction	Female sheep that have been inseminated/mated at least once	From first insemination to the end of second weaning period			Two cycles (if the reproduction parameters are requested)

5. Table. Animal categories: Goats

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Kids for rearing	Young goats reared for future reproduction	From birth	Up to 3 months	15-20 kg	At least 56

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Kids for fattening	Young goats that are reared for goat meat production	From birth	Up to 6 months		At least 56 days
Dairy goats (for milk production)	Goats that have produced at least one kid				84 days (total lactation period shall be reported)
Goats for reproduction	Female goats that have been inseminated/mated at least once	From first insemination to the end of second weaning period			Two cycles (if the reproduction parameters are requested)

6. Table. Animal categories: Fish

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Salmon and trout				200-300 g	90 days or until initial body weight is doubled.
Salmon and trout	Brood stock	As close to the spawning period as possible			90 days

7. Table. Animal categories: Rabbits

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Rabbits suckling and weaned		Beginning one week after birth			56 days
Rabbits for fattening	Rabbits that are reared for meat production	After weaning period	Up to 8-11 weeks		42 days

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Breeding does (for reproduction)	Does, that have been inseminated/mated at least once	From the insemination to the end of the second weaning period			Two cycles (if the reproduction parameters are requested).
Breeding does (in order to have benefits to young rabbits)	Does, that have been inseminated at least once	From first insemination			At least 2 weeks before parturition until the end of the weaning period (e.g. for micro-organism product)

8. Table. Animal Categories: horses

Category	Definition of the animal category	Approximate duration period (weight/age)			Minimum duration of long term studies for efficacy
		Period	Age	Weight	
Horses	All categories				56 days

DIRECTIVES

DIRECTIVE 2008/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 April 2008

on credit agreements for consumers and repealing Council Directive 87/102/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Council Directive 87/102/EEC of 22 December 1986 for the approximation of the laws, regulations and administrative provisions of the Member States concerning consumer credit [3] lays down rules at Community level concerning consumer credit agreements.

(2) In 1995, the Commission presented a report on the operation of Directive 87/102/EEC and undertook a broad consultation of the interested parties. In 1997, the Commission presented a summary report of reactions to the 1995 report. A second report was produced in 1996 on the operation of Directive 87/102/EEC.

(3) Those reports and consultations revealed substantial differences between the laws of the various Member States in the field of credit for natural persons in general and consumer credit in particular. An analysis of the national laws transposing Directive 87/102/EEC shows that Member States use a variety of consumer protection mechanisms, in addition to Directive 87/102/EEC, on account of differences in the legal or economic situation at national level.

(4) The *de facto* and *de jure* situation resulting from those national differences in some cases leads to distortions of competition among creditors in the Community and creates obstacles to the internal market where Member States have adopted different mandatory provisions more stringent than those provided for in Directive 87/102/EEC. It restricts consumers' ability to make direct use of the gradually increasing availability of cross-border credit. Those distortions and restrictions may in turn have consequences in terms of the demand for goods and services.

(5) In recent years the types of credit offered to and used by consumers have evolved considerably. New credit instruments have appeared, and their use continues to develop. It is therefore necessary to amend existing provisions and to extend their scope, where appropriate.

(6) In accordance with the Treaty, the internal market comprises an area without internal frontiers in which the free movement of goods and services and freedom of establishment are ensured. The development of a more transparent and efficient credit market within the area without internal frontiers is vital in order to promote the development of cross-border activities.

(7) In order to facilitate the emergence of a well-functioning internal market in consumer credit, it is necessary to make provision for a harmonised Community framework in a number of core areas. In view of the continuously developing market in consumer credit and the increasing mobility of European citizens, forward-looking Community legislation which is able to adapt to future forms of credit and which allows Member States the appropriate degree of flexibility in their implementation should help to establish a modern body of law on consumer credit.

[1] OJ C 234, 30.9.2003, p. 1.

[2] Opinion of the European Parliament of 20 April 2004 (OJ C 104 E, 30.4.2004, p. 233), Council common position of 20 September 2007 (OJ C 270 E, 13.11.2007, p. 1) and Position of the European Parliament of 16 January 2008 (not yet published in the Official Journal). Council Decision of 7 April 2008.

[3] OJ L 42, 12.2.1987, p. 48. Directive as last amended by Directive 98/7/EC of the European Parliament and of the Council (OJ L 101, 1.4.1998, p. 17).

(8) It is important that the market should offer a sufficient degree of consumer protection to ensure consumer confidence. Thus, it should be possible for the free movement of credit offers to take place under optimum conditions for both those who offer credit and those who require it, with due regard to specific situations in the individual Member States.

(9) Full harmonisation is necessary in order to ensure that all consumers in the Community enjoy a high and equivalent level of protection of their interests and to create a genuine internal market. Member States should therefore not be allowed to maintain or introduce national provisions other than those laid down in this Directive. However, such restriction should only apply where there are provisions harmonised in this Directive. Where no such harmonised provisions exist, Member States should remain free to maintain or introduce national legislation. Accordingly, Member States may, for instance, maintain or introduce national provisions on joint and several liability of the seller or the service provider and the creditor. Another example of this possibility for Member States could be the maintenance or introduction of national provisions on the cancellation of a contract for the sale of goods or supply of services if the consumer exercises his right of withdrawal from the credit agreement. In this respect Member States, in the case of open-end credit agreements, should be allowed to fix a minimum period needing to elapse between the time when the creditor asks for reimbursement and the day on which the credit has to be reimbursed.

(10) The definitions contained in this Directive determine the scope of harmonisation. The obligation on Member States to implement the provisions of this Directive should therefore be limited to its scope as determined by those definitions. However, this Directive should be without prejudice to the application by Member States, in accordance with Community law, of the provisions of this Directive to areas not covered by its scope. A Member State could thereby maintain or introduce national legislation corresponding to the provisions of this Directive or certain of its provisions on credit agreements outside the scope of this Directive, for instance on credit agreements involving amounts less than EUR 200 or more than EUR 75 000. Furthermore, Member States could also apply the provisions of this Directive to linked credit which does not fall within the definition of a linked credit agreement as contained in this Directive. Thus, the provisions on linked credit agreements could be applied to credit agreements that serve only partially to finance a contract for the supply of goods or provision of a service.

(11) In the case of specific credit agreements to which only some provisions of this Directive are applicable, Member States should not be allowed to adopt national legislation implementing other provisions of this Directive. However, Member States should remain free to regulate, in their national legislation, such types of credit agreements as regards other aspects not harmonised by this Directive.

(12) Agreements for the provision on a continuing basis of services or for the supply of goods of the same kind, where the consumer pays for them for the duration of their provision by means of instalments, may differ considerably, in terms of the interests of the contractual parties involved, and the modalities and performance of the transactions, from credit agreements covered by this Directive. Therefore, it should be clarified that such agreements are not regarded as credit agreements for the purposes of this Directive. Such types of agreement include, for example, an insurance contract where the insurance is paid for in monthly instalments.

(13) This Directive should not apply to certain types of credit agreement, such as deferred debit cards, under the terms of which the credit has to be repaid within three months and only insignificant charges are payable.

(14) Credit agreements covering the granting of credit secured by real estate should be excluded from the scope of this Directive. That type of credit is of a very specific nature. Also, credit agreements the purpose of which is to finance the acquisition or retention of property rights in land or in an existing or projected building should be excluded from the scope of this Directive. However, credit agreements should not be excluded from the scope of this Directive only because their purpose is the renovation or increase of value of an existing building.

(15) The provisions of this Directive apply irrespective of whether the creditor is a legal person or a natural person. However, this Directive does not affect the right of Member States to limit, in conformity with Community law, the provision of credit for consumers to legal persons only or to certain legal persons.

(16) Certain provisions of this Directive should apply to natural and legal persons (credit intermediaries) who, in the course of their trade, business or profession, for a fee, present or offer credit agreements to consumers, assist consumers by undertaking preparatory work in respect of credit agreements or conclude credit agreements with consumers on behalf of the creditor. Organisations which allow their identity to be used in promoting credit products, such as credit cards, and which may also recommend those products to their members should not be regarded as credit intermediaries for the purposes of this Directive.

(17) This Directive regulates only certain obligations of credit intermediaries in relation to consumers. Member States should therefore remain free to maintain or introduce

additional obligations incumbent on credit intermediaries, including the conditions under which a credit intermediary may receive fees from a consumer who has requested his service.

(18) Consumers should be protected against unfair or misleading practices, in particular with respect to the disclosure of information by the creditor, in line with Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market ('Unfair Commercial Practices Directive) ([1]). However, this Directive should contain specific provisions on advertising concerning credit agreements as well as certain items of standard information to be provided to consumers in order to enable them, in particular, to compare different offers. Such information should be given in a clear, concise and prominent way by means of a representative example. A ceiling should be provided where it is not possible to indicate the total amount of credit as the total sums made available, in particular where a credit agreement gives the consumer freedom of drawdown with a limitation with regard to the amount. The ceiling should indicate the upper limit of credit which can be made available to the consumer. In addition, Member States should remain free to regulate information requirements in their national law regarding advertising which does not contain information on the cost of the credit.

(19) In order to enable consumers to make their decisions in full knowledge of the facts, they should receive adequate information, which the consumer may take away and consider, prior to the conclusion of the credit agreement, on the conditions and cost of the credit and on their obligations. To ensure the fullest possible transparency and comparability of offers, such information should, in particular, include the annual percentage rate of charge applicable to the credit, determined in the same way throughout the Community. As the annual percentage rate of charge can at this stage be indicated only through an example, such example should be representative. Therefore, it should correspond, for instance, to the average duration and total amount of credit granted for the type of credit agreement under consideration and, if applicable, to the goods purchased. When determining the representative example, the frequency of certain types of credit agreement in a specific market should also be taken into account. As regards the borrowing rate, the frequency of instalments and the capitalisation of interest, creditors should use their conventional method of calculation for the consumer credit concerned.

(20) The total cost of the credit to the consumer should comprise all the costs, including interest, commissions, taxes, fees for credit intermediaries and any other fees which the consumer has to pay in connection with the credit agreement, except for notarial costs. Creditors' actual knowledge of the costs should be assessed objectively, taking into account the requirements of professional diligence.

(21) Credit agreements in which a borrowing rate is periodically revised in line with changes occurring in a reference rate referred to in the credit agreement should not be regarded as credit agreements with a fixed borrowing rate.

(22) Member States should remain free to maintain or introduce national provisions prohibiting the creditor from requiring the consumer, in connection with the credit agreement, to open a bank account or conclude an agreement in respect of another ancillary service, or to pay the expenses or fees for such bank accounts or other ancillary services. In those Member States where such combined offers are allowed, consumers should be informed before the conclusion of the credit agreement about any ancillary services which are compulsory in order for the credit to be obtained in the first place or on the terms and conditions marketed. The costs payable in respect of those ancillary services should be included in the total cost of the credit; alternatively, if the amount of such costs cannot be determined in advance, consumers should receive adequate information about the existence of costs at a pre-contractual stage. The creditor must be presumed to have knowledge of the costs of the ancillary services which he offers to the consumer himself, or on behalf of a third party, unless the price thereof depends on the specific characteristics or situation of the consumer.

(23) For specific types of credit agreements, however, it is appropriate, in order to ensure an adequate level of consumer protection without placing an excessive burden on creditors or, where applicable, credit intermediaries, to restrict the pre-contractual information requirements of this Directive, taking into account the specific character of such types of agreements.

(24) The consumer needs to be given comprehensive information before he concludes the credit agreement, regardless of whether or not a credit intermediary is involved in the marketing of the credit. Therefore, in general, the pre-contractual information requirements should also apply to credit intermediaries. However, where suppliers of goods and services act as credit intermediaries in an ancillary capacity, it is not appropriate to burden them with the legal obligation to provide the pre-contractual information in accordance with this Directive. Suppliers of goods and services may be deemed, for example, to be acting as credit intermediaries in an ancillary capacity if their activity as credit intermediaries is not the main purpose of their trade, business or profession. In those cases, a sufficient level of consumer protection is still achieved since the creditor is responsible for ensuring that the consumer receives the full pre-contractual information, either from the intermediary, if the creditor and the intermediary so agree, or in some other appropriate manner.

(25) The potentially binding character of the information to be provided to the consumer prior to the conclusion of the credit agreement and the period of time during which the creditor is to be bound by it may be regulated by the Member States.

(26) Member States should take appropriate measures to promote responsible practices during all phases of the

([1]) OJ L 149, 11.6.2005, p. 22.

credit relationship, taking into account the specific features of their credit market. Those measures may include, for instance, the provision of information to, and the education of, consumers, including warnings about the risks attaching to default on payment and to over-indebtedness. In the expanding credit market, in particular, it is important that creditors should not engage in irresponsible lending or give out credit without prior assessment of creditworthiness, and the Member States should carry out the necessary supervision to avoid such behaviour and should determine the necessary means to sanction creditors in the event of their doing so. Without prejudice to the credit risk provisions of Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions ([1]), creditors should bear the responsibility of checking individually the creditworthiness of the consumer. To that end, they should be allowed to use information provided by the consumer not only during the preparation of the credit agreement in question, but also during a long-standing commercial relationship. The Member States' authorities could also give appropriate instructions and guidelines to creditors. Consumers should also act with prudence and respect their contractual obligations.

(27) Despite the pre-contractual information to be provided, the consumer may still need additional assistance in order to decide which credit agreement, within the range of products proposed, is the most appropriate for his needs and financial situation. Therefore, Member States should ensure that creditors provide such assistance in relation to the credit products which they offer to the consumer. Where appropriate, the relevant pre-contractual information, as well as the essential characteristics of the products proposed, should be explained to the consumer in a personalised manner so that the consumer can understand the effects which they may have on his economic situation. Where applicable, this duty to assist the consumer should also apply to credit intermediaries. Member States could determine when and to what extent such explanations are to be given to the consumer, taking into account the particular circumstances in which the credit is offered, the consumer's need for assistance and the nature of individual credit products.

(28) To assess the credit status of a consumer, the creditor should also consult relevant databases; the legal and actual circumstances may require that such consultations vary in scope. To prevent any distortion of competition among creditors, it should be ensured that creditors have access to private or public databases concerning consumers in a Member State where they are not established under non-discriminatory conditions compared with creditors in that Member State.

(29) Where a decision to reject an application for credit is based on the consultation of a database, the creditor should inform the consumer of this fact and of the particulars of the database consulted. However, the creditor should not be obliged to give such information when this is prohibited by other Community legislation, for example legislation on money laundering or the financing of terrorism. Furthermore, such information should not be given if this would be contrary to objectives of public policy or public security, such as the prevention, investigation, detection or prosecution of criminal offences.

(30) This Directive does not regulate contract law issues related to the validity of credit agreements. Therefore, in that area, the Member States may maintain or introduce national provisions which are in conformity with Community law. Member States may regulate the legal regime governing the offer to conclude the credit agreement, in particular when it is to be given and the period during which it is to be binding on the creditor. If such an offer is made at the same time as the pre-contractual information provided for by this Directive is given, it should, like any additional information the creditor may wish to give to the consumer, be provided in a separate document which may be annexed to the Standard European Consumer Credit Information.

(31) In order to enable the consumer to know his rights and obligations under the credit agreement, it should contain all necessary information in a clear and concise manner.

(32) In order to ensure full transparency, the consumer should be provided with information concerning the borrowing rate, both at a pre-contractual stage and when the credit agreement is concluded. During the contractual relationship, the consumer should further be informed of changes to the variable borrowing rate and changes to the payments caused thereby. This is without prejudice to provisions of national law not related to consumer information which lay down conditions for, or prescribe the consequences of, changes, other than changes concerning payments, in borrowing rates and other economic conditions governing the credit, for instance rules providing that the creditor may change the borrowing rate only where there is a valid reason for such change or that the consumer may terminate the contract should there be a change in the borrowing rate or in some other economic condition concerning the credit.

(33) The contracting parties should have the right to effect a standard termination of an open-end credit agreement. In addition, if agreed in the credit agreement, the creditor should have the right to suspend the consumer's right to draw down on an open-end credit agreement for objectively justified reasons. Such reasons may include, for instance, suspicion of an unauthorised or fraudulent use of the credit or a significantly increased risk of the consumer being unable to fulfil his obligation to repay the credit. This Directive does not affect national law in the area of contract law regulating the rights of the contracting parties to terminate the credit agreement on the basis of a breach of contract.

([1]) OJ L 177, 30.6.2006, p. 1. Directive as last amended by Directive 2008/24/EC (OJ L 81, 20.3.2008, p. 38).

(34) In order to approximate the procedures for exercising the right of withdrawal in similar areas, it is necessary to make provision for a right of withdrawal without penalty and with no obligation to provide justification, under conditions similar to those provided for by Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services ([1]).

(35) Where a consumer withdraws from a credit agreement in connection with which he has received goods, in particular from a purchase in instalments or from a hiring or leasing agreement providing for an obligation to purchase, this Directive should be without prejudice to any regulation by Member States of questions concerning the return of the goods or any related questions.

(36) In some cases, national legislation already provides that funds cannot be made available to the consumer before the expiry of a specific deadline. In these cases, consumers may wish to ensure that they receive the goods or services purchased early. Therefore, in the case of linked credit agreements, Member States may exceptionally provide that, if the consumer explicitly wishes early receipt, the deadline for the exercise of the right of withdrawal could be reduced to the same deadline before which funds cannot be made available.

(37) In the case of linked credit agreements, a relationship of interdependence exists between the purchase of goods or services and the credit agreement concluded for that purpose. Therefore, where the consumer exercises his right of withdrawal in respect of the purchase agreement, based on Community law, he should no longer be bound by the linked credit agreement. This should not affect national law applicable to linked credit agreements in cases where a purchase agreement has been voided or where the consumer has exercised his right of withdrawal based on national law. Nor should this affect the rights of consumers granted by national provisions according to which no commitment may be entered into between the consumer and a supplier of goods or services, nor any payment made between those persons, as long as the consumer has not signed the credit agreement to finance the purchase of the goods or services.

(38) Under certain conditions, the consumer should be allowed to pursue remedies against the creditor in the event of problems related to the purchase agreement. However, Member States should determine to what extent and under what conditions the consumer is required to pursue his remedies against the supplier, in particular by bringing an action against the latter, before being in a position to pursue them against the creditor. This Directive should not deprive consumers of their rights under national provisions attaching joint and several liability to the seller or supplier of services and to the creditor.

(39) The consumer should have the right to discharge his obligations before the date agreed in the credit agreement. In the case of early repayment, either in part or in full, the creditor should be entitled to compensation for the costs directly linked to the early repayment, taking into account also any savings thereby made by the creditor. However, in order to determine the method of calculating the compensation, it is important to respect several principles. The calculation of the compensation due to the creditor should be transparent and comprehensible to consumers already at the pre-contractual stage and in any case during the performance of the credit agreement. In addition, the calculation method should be easy for creditors to apply, and supervisory control of the compensation by the responsible authorities should be facilitated. Therefore, and due to the fact that consumer credit is, given its duration and volume, not financed by long-term funding mechanisms, the ceiling for the compensation should be fixed in terms of a flat-rate amount. This approach reflects the special nature of credits for consumers and should not prejudice the possibly different approach in respect of other products which are financed by long-term funding mechanisms, such as fixed-rate mortgage loans.

(40) Member States should have the right to provide that compensation for early repayment may be claimed by the creditor only on condition that the amount repaid over a 12-month period exceeds a threshold defined by Member States. When fixing that threshold, which should not exceed EUR 10 000, Member States should for instance take into account the average amount of consumer credits in their market.

(41) Assignment of the creditor's rights under a credit agreement should not have the effect of placing the consumer in a less favourable position. The consumer should also be properly informed when the credit agreement is assigned to a third party. However, where the initial creditor, in agreement with the assignee, continues to service the credit vis-à-vis the consumer, the consumer has no significant interest in being informed of the assignment. Therefore, a requirement at EU level that the consumer be informed of the assignment in such cases would be excessive.

(42) Member States should remain free to maintain or introduce national rules providing for collective forms of communication when this is necessary for purposes relating to the effectiveness of complex transactions such as securitisations or liquidation of assets that take place in the compulsory administrative liquidation of banks.

(43) In order to promote the establishment and functioning of the internal market and to ensure a high degree of protection for consumers throughout the Community, it is necessary to ensure the comparability of information relating to annual percentage rates of charge throughout the Community. Despite the uniform mathematical formula for its calculation, the annual percentage rate of charge provided for in Directive 87/102/EEC is not yet fully

([1]) OJ L 271, 9.10.2002, p. 16. Directive as last amended by Directive 2007/64/EC (OJ L 319, 5.12.2007, p. 1).

comparable throughout the Community. In individual Member States different cost factors are taken into account in the calculation thereof. This Directive should therefore clearly and comprehensively define the total cost of a credit to the consumer.

(44) In order to ensure market transparency and stability, and pending further harmonisation, Member States should ensure that appropriate measures for the regulation or supervision of creditors are in place.

(45) This Directive respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In particular, this Directive seeks to ensure full respect for the rules on protection of personal data, the right to property, non-discrimination, protection of family and professional life, and consumer protection pursuant to the Charter of Fundamental Rights of the European Union.

(46) Since the objective of this Directive, namely the establishment of common rules for certain aspects of the laws, regulations and administrative provisions of the Member States concerning consumer credit, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(47) Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. While the choice of penalties remains within the discretion of the Member States, the penalties provided for should be effective, proportionate and dissuasive.

(48) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(49) In particular, the Commission should be empowered to adopt additional assumptions for the calculation of the annual percentage rate of charge. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(50) In accordance with point 34 of the Interinstitutional Agreement on better law-making ([2]), Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(51) Accordingly, taking account of the number of amendments that need to be made to Directive 87/102/EEC due to the evolution of the consumer credit sector and in the interests of the clarity of Community legislation, that Directive should be repealed and replaced by this Directive,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

The purpose of this Directive is to harmonise certain aspects of the laws, regulations and administrative provisions of the Member States concerning agreements covering credit for consumers.

Article 2

Scope

1. This Directive shall apply to credit agreements.

2. This Directive shall not apply to the following:

(a) credit agreements which are secured either by a mortgage or by another comparable security commonly used in a Member State on immovable property or secured by a right related to immovable property;

(b) credit agreements the purpose of which is to acquire or retain property rights in land or in an existing or projected building;

(c) credit agreements involving a total amount of credit less than EUR 200 or more than EUR 75 000;

(d) hiring or leasing agreements where an obligation to purchase the object of the agreement is not laid down either by the agreement itself or by any separate agreement; such an obligation shall be deemed to exist if it is so decided unilaterally by the creditor;

(e) credit agreements in the form of an overdraft facility and where the credit has to be repaid within one month;

(f) credit agreements where the credit is granted free of interest and without any other charges and credit agreements under the terms of which the credit has to be repaid within three months and only insignificant charges are payable;

(g) credit agreements where the credit is granted by an employer to his employees as a secondary activity free of interest or at annual percentage rates of charge lower than those prevailing on the market and which are not offered to the public generally;

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

([2]) OJ C 321, 31.12.2003, p. 1.

(h) credit agreements which are concluded with investment firms as defined in Article 4(1) of Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments ([1]) or with credit institutions as defined in Article 4 of Directive 2006/48/EC for the purposes of allowing an investor to carry out a transaction relating to one or more of the instruments listed in Section C of Annex I to Directive 2004/39/EC, where the investment firm or credit institution granting the credit is involved in such transaction;

(i) credit agreements which are the outcome of a settlement reached in court or before another statutory authority;

(j) credit agreements which relate to the deferred payment, free of charge, of an existing debt;

(k) credit agreements upon the conclusion of which the consumer is requested to deposit an item as security in the creditor's safe-keeping and where the liability of the consumer is strictly limited to that pledged item;

(l) credit agreements which relate to loans granted to a restricted public under a statutory provision with a general interest purpose, and at lower interest rates than those prevailing on the market or free of interest or on other terms which are more favourable to the consumer than those prevailing on the market and at interest rates not higher than those prevailing on the market.

3. In the case of credit agreements in the form of an overdraft facility and where the credit has to be repaid on demand or within three months, only Articles 1 to 3, Article 4(1), Article 4(2)(a) to (c), Article 4(4), Articles 6 to 9, Article 10(1), Article 10(4), Article 10(5), Articles 12, 15, 17 and Articles 19 to 32 shall apply.

4. In the case of credit agreements in the form of overrunning, only Articles 1 to 3, 18, 20 and 22 to 32 shall apply.

5. Member States may determine that only Articles 1 to 4, 6, 7 and 9, Article 10(1), points (a) to (h) and (l) of Article 10(2), Article 10(4) and Articles 11, 13 and 16 to 32 shall apply to credit agreements which are concluded by an organisation which:

(a) is established for the mutual benefit of its members;

(b) does not make profits for any other person than its members;

(c) fulfils a social purpose required by domestic legislation;

(d) receives and manages the savings of, and provides sources of credit to, its members only; and

(e) provides credit on the basis of an annual percentage rate of charge which is lower than that prevailing on the market or subject to a ceiling laid down by national law,

and whose membership is restricted to persons residing or employed in a particular location or employees and retired employees of a particular employer, or to persons meeting other qualifications laid down under national law as the basis for the existence of a common bond between the members.

Member States may exempt from the application of this Directive credit agreements concluded by such an organisation where the total value of all existing credit agreements entered into by the organisation is insignificant in relation to the total value of all existing credit agreements in the Member State in which the organisation is based and the total value of all existing credit agreements entered into by all such organisations in the Member State is less than 1 % of the total value of all existing credit agreements entered into in that Member State.

Member States shall each year review whether the conditions for the application of any such exemption continue to exist and shall take action to withdraw the exemption where they consider that the conditions are no longer met.

6. Member States may determine that only Articles 1 to 4, 6, 7, 9, Article 10(1), points (a) to (i), (l) and (r) of Article 10(2), Article 10(4), Articles 11, 13, 16 and Articles 18 to 32 shall apply to credit agreements which provide for arrangements to be agreed by the creditor and the consumer in respect of deferred payment or repayment methods, where the consumer is already in default on the initial credit agreement and where:

(a) such arrangements would be likely to avert the possibility of legal proceedings concerning such default; and

(b) the consumer would not thereby be subject to terms less favourable than those laid down in the initial credit agreement.

However, if the credit agreement falls within the scope of paragraph 3, only the provisions of that paragraph shall apply.

Article 3

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) 'consumer' means a natural person who, in transactions covered by this Directive, is acting for purposes which are outside his trade, business or profession;

(b) 'creditor' means a natural or legal person who grants or promises to grant credit in the course of his trade, business or profession;

([1]) OJ L 145, 30.4.2004, p. 1. Directive as last amended by Directive 2008/10/EC (OJ L 76, 19.3.2008, p. 33).

(c) 'credit agreement' means an agreement whereby a creditor grants or promises to grant to a consumer credit in the form of a deferred payment, loan or other similar financial accommodation, except for agreements for the provision on a continuing basis of services or for the supply of goods of the same kind, where the consumer pays for such services or goods for the duration of their provision by means of instalments;

(d) 'overdraft facility' means an explicit credit agreement whereby a creditor makes available to a consumer funds which exceed the current balance in the consumer's current account;

(e) 'overrunning' means a tacitly accepted overdraft whereby a creditor makes available to a consumer funds which exceed the current balance in the consumer's current account or the agreed overdraft facility;

(f) 'credit intermediary' means a natural or legal person who is not acting as a creditor and who, in the course of his trade, business or profession, for a fee, which may take a pecuniary form or any other agreed form of financial consideration:

(i) presents or offers credit agreements to consumers;

(ii) assists consumers by undertaking preparatory work in respect of credit agreements other than as referred to in (i); or

(iii) concludes credit agreements with consumers on behalf of the creditor;

(g) 'total cost of the credit to the consumer' means all the costs, including interest, commissions, taxes and any other kind of fees which the consumer is required to pay in connection with the credit agreement and which are known to the creditor, except for notarial costs; costs in respect of ancillary services relating to the credit agreement, in particular insurance premiums, are also included if, in addition, the conclusion of a service contract is compulsory in order to obtain the credit or to obtain it on the terms and conditions marketed;

(h) 'total amount payable by the consumer' means the sum of the total amount of the credit and the total cost of the credit to the consumer;

(i) 'annual percentage rate of charge' means the total cost of the credit to the consumer, expressed as an annual percentage of the total amount of credit, where applicable including the costs referred to in Article 19(2);

(j) 'borrowing rate' means the interest rate expressed as a fixed or variable percentage applied on an annual basis to the amount of credit drawn down;

(k) 'fixed borrowing rate' means that the creditor and the consumer agree in the credit agreement on one borrowing rate for the entire duration of the credit agreement or on several borrowing rates for partial periods using exclusively a fixed specific percentage. If not all borrowing rates are determined in the credit agreement, the borrowing rate shall be deemed to be fixed only for the partial periods for which the borrowing rates are determined exclusively by a fixed specific percentage agreed on the conclusion of the credit agreement;

(l) 'total amount of credit' means the ceiling or the total sums made available under a credit agreement;

(m) 'durable medium' means any instrument which enables the consumer to store information addressed personally to him in a way accessible for future reference for a period of time adequate for the purposes of the information and which allows the unchanged reproduction of the information stored;

(n) 'linked credit agreement' means a credit agreement where

(i) the credit in question serves exclusively to finance an agreement for the supply of specific goods or the provision of a specific service, and

(ii) those two agreements form, from an objective point of view, a commercial unit; a commercial unit shall be deemed to exist where the supplier or service provider himself finances the credit for the consumer or, if it is financed by a third party, where the creditor uses the services of the supplier or service provider in connection with the conclusion or preparation of the credit agreement, or where the specific goods or the provision of a specific service are explicitly specified in the credit agreement.

CHAPTER II

INFORMATION AND PRACTICES PRELIMINARY TO THE CONCLUSION OF THE CREDIT AGREEMENT

Article 4

Standard information to be included in advertising

1. Any advertising concerning credit agreements which indicates an interest rate or any figures relating to the cost of the credit to the consumer shall include standard information in accordance with this Article.

This obligation shall not apply where national legislation requires the indication of the annual percentage rate of charge in advertising concerning credit agreements which does not indicate an interest rate or any figures relating to any cost of credit to the consumer within the meaning of the first subparagraph.

2. The standard information shall specify in a clear, concise and prominent way by means of a representative example:

(a) the borrowing rate, fixed or variable or both, together with particulars of any charges included in the total cost of the credit to the consumer;

(b) the total amount of credit;

(c) the annual percentage rate of charge; in the case of a credit agreement of the kind referred to in Article 2(3), Member States may decide that the annual percentage rate of charge need not be provided;

(d) if applicable, the duration of the credit agreement;

(e) in the case of a credit in the form of deferred payment for a specific good or service, the cash price and the amount of any advance payment; and

(f) if applicable, the total amount payable by the consumer and the amount of the instalments.

3. Where the conclusion of a contract regarding an ancillary service relating to the credit agreement, in particular insurance, is compulsory in order to obtain the credit or to obtain it on the terms and conditions marketed, and the cost of that service cannot be determined in advance, the obligation to enter into that contract shall also be stated in a clear, concise and prominent way, together with the annual percentage rate of charge.

4. This Article shall be without prejudice to Directive 2005/29/EC.

Article 5

Pre-contractual information

1. In good time before the consumer is bound by any credit agreement or offer, the creditor and, where applicable, the credit intermediary shall, on the basis of the credit terms and conditions offered by the creditor and, if applicable, the preferences expressed and information supplied by the consumer, provide the consumer with the information needed to compare different offers in order to take an informed decision on whether to conclude a credit agreement. Such information, on paper or on another durable medium, shall be provided by means of the Standard European Consumer Credit Information form set out in Annex II. The creditor shall be deemed to have fulfilled the information requirements in this paragraph and in Article 3, paragraphs (1) and (2) of Directive 2002/65/EC if he has supplied the Standard European Consumer Credit Information.

The information in question shall specify:

(a) the type of credit;

(b) the identity and the geographical address of the creditor as well as, if applicable, the identity and geographical address of the credit intermediary involved;

(c) the total amount of credit and the conditions governing the drawdown;

(d) the duration of the credit agreement;

(e) in the case of a credit in the form of deferred payment for a specific good or service and linked credit agreements, that good or service and its cash price;

(f) the borrowing rate, the conditions governing the application of the borrowing rate and, where available, any index or reference rate applicable to the initial borrowing rate, as well as the periods, conditions and procedure for changing the borrowing rate; if different borrowing rates apply in different circumstances, the abovementioned information on all the applicable rates;

(g) the annual percentage rate of charge and the total amount payable by the consumer, illustrated by means of a representative example mentioning all the assumptions used in order to calculate that rate; where the consumer has informed the creditor of one or more components of his preferred credit, such as the duration of the credit agreement and the total amount of credit, the creditor shall take those components into account; if a credit agreement provides different ways of drawdown with different charges or borrowing rates and the creditor uses the assumption set out in point (b) of Part II of Annex I, he shall indicate that other drawdown mechanisms for this type of credit agreement may result in higher annual percentage rates of charge;

(h) the amount, number and frequency of payments to be made by the consumer and, where appropriate, the order in which payments will be allocated to different outstanding balances charged at different borrowing rates for the purposes of reimbursement;

(i) where applicable, the charges for maintaining one or several accounts recording both payment transactions and drawdowns, unless the opening of an account is optional, together with the charges for using a means of payment for both payment transactions and drawdowns, any other charges deriving from the credit agreement and the conditions under which those charges may be changed;

(j) where applicable, the existence of costs payable by the consumer to a notary on conclusion of the credit agreement;

(k) the obligation, if any, to enter into an ancillary service contract relating to the credit agreement, in particular an insurance policy, where the conclusion of such a contract is compulsory in order to obtain the credit or to obtain it on the terms and conditions marketed;

(l) the interest rate applicable in the case of late payments and the arrangements for its adjustment, and, where applicable, any charges payable for default;

(m) a warning regarding the consequences of missing payments;

(n) where applicable, the sureties required;

(o) the existence or absence of a right of withdrawal;

(p) the right of early repayment, and, where applicable, information concerning the creditor's right to compensation and the way in which that compensation will be determined in accordance with Article 16;

(q) the consumer's right to be informed immediately and free of charge, pursuant to Article 9(2), of the result of a database consultation carried out for the purposes of assessing his creditworthiness;

(r) the consumer's right to be supplied, on request and free of charge, with a copy of the draft credit agreement. This provision shall not apply if the creditor is at the time of the request unwilling to proceed to the conclusion of the credit agreement with the consumer; and

(s) if applicable, the period of time during which the creditor is bound by the pre-contractual information.

Any additional information which the creditor may provide to the consumer shall be given in a separate document which may be annexed to the Standard European Consumer Credit Information form.

2. However, in the case of voice telephony communications, as referred to in Article 3(3) of Directive 2002/65/EC, the description of the main characteristics of the financial service to be provided pursuant to the second indent of Article 3(3)(b) of that Directive shall include at least the items referred to in points (c), (d), (e), (f) and (h) of paragraph (1) of this Article, together with the annual percentage rate of charge illustrated by means of a representative example and the total amount payable by the consumer.

3. If the agreement has been concluded at the consumer's request using a means of distance communication which does not enable the information to be provided in accordance with paragraph 1, in particular in the case referred to in paragraph 2, the creditor shall provide the consumer with the full pre-contractual information using the Standard European Consumer Credit Information form immediately after the conclusion of the credit agreement.

4. Upon request, the consumer shall, in addition to receiving the Standard European Consumer Credit Information, be supplied free of charge with a copy of the draft credit agreement. This provision shall not apply if the creditor is at the time of the request unwilling to proceed to the conclusion of the credit agreement with the consumer.

5. In the case of a credit agreement under which payments made by the consumer do not give rise to an immediate corresponding amortisation of the total amount of credit, but are used to constitute capital during periods and under conditions laid down in the credit agreement or in an ancillary agreement, the pre-contractual information required under paragraph 1 shall include a clear and concise statement that such credit agreements do not provide for a guarantee of repayment of the total amount of credit drawn down under the credit agreement, unless such a guarantee is given.

6. Member States shall ensure that creditors and, where applicable, credit intermediaries provide adequate explanations to the consumer, in order to place the consumer in a position enabling him to assess whether the proposed credit agreement is adapted to his needs and to his financial situation, where appropriate by explaining the pre-contractual information to be provided in accordance with paragraph 1, the essential characteristics of the products proposed and the specific effects they may have on the consumer, including the consequences of default in payment by the consumer. Member States may adapt the manner by which and the extent to which such assistance is given, as well as by whom it is given, to the particular circumstances of the situation in which the credit agreement is offered, the person to whom it is offered and the type of credit offered.

Article 6

Pre-contractual information requirements for certain credit agreements in the form of an overdraft facility and for certain specific credit agreements

1. In good time before the consumer becomes bound by any credit agreement or offer concerning a credit agreement as referred to in Article 2(3), (5) or (6), the creditor and, where applicable, the credit intermediary shall, on the basis of the credit terms and conditions offered by the creditor and, if applicable, the preferences expressed and information supplied by the consumer, provide the consumer with the information needed to compare different offers in order to take an informed decision on whether to conclude a credit agreement.

The information in question shall specify:

(a) the type of credit;

(b) the identity and geographical address of the creditor as well as, if applicable, the identity and geographical address of the credit intermediary involved;

(c) the total amount of credit;

(d) the duration of the credit agreement;

(e) the borrowing rate; the conditions governing the application of that rate, any index or reference rate applicable to the initial borrowing rate, the charges applicable from the time the credit agreement is concluded, and, where applicable, the conditions under which those charges may be changed;

(f) the annual percentage rate of charge, illustrated by means of representative examples mentioning all the assumptions used in order to calculate that rate;

(g) the conditions and procedure for terminating the credit agreement;

(h) in the case of credit agreements as referred to in Article 2(3), where applicable, an indication that the consumer may be requested to repay the amount of credit in full at any time;

(i) the interest rate applicable in the case of late payments and the arrangements for its adjustment, and, where applicable, any charges payable for default;

(j) the consumer's right to be informed immediately and free of charge, pursuant to Article 9(2), of the result of a database consultation carried out for the purposes of assessing his creditworthiness;

(k) in the case of credit agreements as referred to in Article 2(3), information about the charges applicable from the time such agreements are concluded and, if applicable, the conditions under which those charges may be changed;

(l) if applicable, the period of time during which the creditor is bound by the pre-contractual information.

Such information shall be provided on paper or on another durable medium and all information shall be equally prominent. It may be provided by means of the European Consumer Credit Information form set out in Annex III. The creditor shall be deemed to have fulfilled the information requirements in this paragraph and in Article 3(1) and (2) of Directive 2002/65/EC if he has supplied the European Consumer Credit Information.

2. In the case of a credit agreement of the kind referred to in Article 2(3), Member States may decide that the annual percentage rate of charge need not be provided.

3. In the case of a credit agreement as referred to in Article 2(5) and (6), the information provided to the consumer in accordance with paragraph 1 of this Article shall also include:

(a) the amount, number and frequency of payments to be made by the consumer and, where appropriate, the order in which payments will be allocated to different outstanding balances charged at different borrowing rates for the purposes of reimbursement; and

(b) the right of early repayment, and, where applicable, information concerning the creditor's right to compensation and the way in which that compensation will be determined.

However, if the credit agreement falls within the scope of Article 2(3), only the provisions of paragraph 1 of this Article shall apply.

4. However, in the case of voice telephony communications and where the consumer requests that the overdraft facility be made available with immediate effect, the description of the main characteristics of the financial service shall include at least the items referred to in points (c), (e), (f) and (h) of paragraph 1. In addition, in credit agreements of the kind referred to in paragraph 3, the description of the main characteristics shall include a specification of the duration of the credit agreement.

5. Notwithstanding the exclusion provided for in Article 2(2)(e), the Member States shall apply at least the requirements of the first sentence of paragraph 4 of this Article to credit agreements in the form of an overdraft facility and where the credit has to be repaid within one month.

6. Upon request, the consumer shall, in addition to receiving the information referred to in paragraphs 1 to 4, be supplied free of charge with a copy of the draft credit agreement containing the contractual information provided for by Article 10 insofar as that Article is applicable. This provision shall not apply if the creditor is at the time of the request unwilling to proceed to the conclusion of the credit agreement with the consumer.

7. If the agreement has been concluded at the consumer's request using a means of distance communication which does not enable the information to be provided in accordance with paragraphs 1 and 3, including in the cases referred to in paragraph 4, the creditor shall immediately after the conclusion of the credit agreement fulfil his obligations under paragraphs 1 and 3 by providing the contractual information pursuant to Article 10 insofar as that Article is applicable.

Article 7

Exemptions from the pre-contractual information requirements

Articles 5 and 6 shall not apply to suppliers of goods or services acting as credit intermediaries in an ancillary capacity. This is without prejudice to the creditor's obligation to ensure that the consumer receives the pre-contractual information referred to in those Articles.

Article 8

Obligation to assess the creditworthiness of the consumer

1. Member States shall ensure that, before the conclusion of the credit agreement, the creditor assesses the consumer's creditworthiness on the basis of sufficient information, where appropriate obtained from the consumer and, where necessary, on the basis of a consultation of the relevant database. Member States whose legislation requires creditors to assess the creditworthiness of consumers on the basis of a consultation of the relevant database may retain this requirement.

2. Member States shall ensure that, if the parties agree to change the total amount of credit after the conclusion of the credit agreement, the creditor updates the financial information at his disposal concerning the consumer and assesses the consumer's creditworthiness before any significant increase in the total amount of credit.

CHAPTER III

DATABASE ACCESS

Article 9

Database access

1. Each Member State shall in the case of cross-border credit ensure access for creditors from other Member States to databases used in that Member State for assessing the creditworthiness of consumers. The conditions for access shall be non-discriminatory.

2. If the credit application is rejected on the basis of consultation of a database, the creditor shall inform the consumer immediately and without charge of the result of such consultation and of the particulars of the database consulted.

3. The information shall be provided unless the provision of such information is prohibited by other Community legislation or is contrary to objectives of public policy or public security.

4. This Article shall be without prejudice to the application of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1].

CHAPTER IV

INFORMATION AND RIGHTS CONCERNING CREDIT AGREEMENTS

Article 10

Information to be included in credit agreements

1. Credit agreements shall be drawn up on paper or on another durable medium.

All the contracting parties shall receive a copy of the credit agreement. This Article shall be without prejudice to any national rules regarding the validity of the conclusion of credit agreements which are in conformity with Community law.

2. The credit agreement shall specify in a clear and concise manner:

(a) the type of credit;

(b) the identities and geographical addresses of the contracting parties as well as, if applicable, the identity and geographical address of the credit intermediary involved;

(c) the duration of the credit agreement;

(d) the total amount of credit and the conditions governing the drawdown;

(e) in case of a credit in the form of deferred payment for a specific good or service or in the case of linked credit agreements, that good or service and its cash price;

(f) the borrowing rate, the conditions governing the application of that rate and, where available, any index or reference rate applicable to the initial borrowing rate, as well as the periods, conditions and procedures for changing the borrowing rate and, if different borrowing rates apply in different circumstances, the abovementioned information in respect of all the applicable rates;

(g) the annual percentage rate of charge and the total amount payable by the consumer, calculated at the time the credit agreement is concluded; all the assumptions used in order to calculate that rate shall be mentioned;

(h) the amount, number and frequency of payments to be made by the consumer and, where appropriate, the order in which payments will be allocated to different outstanding balances charged at different borrowing rates for the purposes of reimbursement;

(i) where capital amortisation of a credit agreement with a fixed duration is involved, the right of the consumer to receive, on request and free of charge, at any time throughout the duration of the credit agreement, a statement of account in the form of an amortisation table.

The amortisation table shall indicate the payments owing and the periods and conditions relating to the payment of such amounts; the table shall contain a breakdown of each repayment showing capital amortisation, the interest calculated on the basis of the borrowing rate and, where applicable, any additional costs; where the interest rate is not fixed or the additional costs may be changed under the credit agreement, the amortisation table shall indicate, clearly and concisely, that the data contained in the table will remain valid only until such time as the borrowing rate or the additional costs are changed in accordance with the credit agreement;

(j) if charges and interest are to be paid without capital amortisation, a statement showing the periods and conditions for the payment of the interest and of any associated recurrent and non-recurrent charges;

(k) where applicable, the charges for maintaining one or several accounts recording both payment transactions and drawdowns, unless the opening of an account is optional, together with the charges for using a means of payment for both payment transactions and drawdowns, and any other charges deriving from the credit agreement and the conditions under which those charges may be changed;

(l) the interest rate applicable in the case of late payments as applicable at the time of the conclusion of the credit agreement and the arrangements for its adjustment and, where applicable, any charges payable for default;

[1] OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(m) a warning regarding the consequences of missing payments;

(n) where applicable, a statement, that notarial fees will be payable;

(o) the sureties and insurance required, if any;

(p) the existence or absence of a right of withdrawal, the period during which that right may be exercised and other conditions governing the exercise thereof, including information concerning the obligation of the consumer to pay the capital drawn down and the interest in accordance with Article 14(3)(b) and the amount of interest payable per day;

(q) information concerning the rights resulting from Article 15 as well as the conditions for the exercise of those rights;

(r) the right of early repayment, the procedure for early repayment, as well as, where applicable, information concerning the creditor's right to compensation and the way in which that compensation will be determined;

(s) the procedure to be followed in exercising the right of termination of the credit agreement;

(t) whether or not there is an out-of-court complaint and redress mechanism for the consumer and, if so, the methods for having access to it;

(u) where applicable, other contractual terms and conditions;

(v) where applicable, the name and address of the competent supervisory authority.

3. Where paragraph 2(i) applies, the creditor shall make available to the consumer, free of charge and at any time throughout the duration of the credit agreement, a statement of account in the form of an amortisation table.

4. In the case of a credit agreement under which payments made by the consumer do not give rise to an immediate corresponding amortisation of the total amount of credit, but are used to constitute capital during periods and under conditions laid down in the credit agreement or in an ancillary agreement, the information required under paragraph 2 shall include a clear and concise statement that such credit agreements do not provide for a guarantee of repayment of the total amount of credit drawn down under the credit agreement, unless such a guarantee is given.

5. In the case of credit agreements in the form of overdraft facilities as referred to in Article 2(3), the following shall be specified in a clear and concise manner:

(a) the type of credit;

(b) the identities and geographical addresses of the contracting parties as well as, if applicable, the identity and geographical address of the credit intermediary involved;

(c) the duration of the credit agreement;

(d) the total amount of the credit and the conditions governing the drawdown;

(e) the borrowing rate, the conditions governing the application of the borrowing rate and, where available, any index or reference rate applicable to the initial borrowing rate, as well as the periods, conditions and procedure for changing the borrowing rate and, if different borrowing rates apply in different circumstances, the abovementioned information in respect of all the applicable rates;

(f) the annual percentage rate of charge and the total cost of the credit to the consumer, calculated at the time the credit agreement is concluded; all the assumptions used in order to calculate that rate as referred to in Article 19(2) in conjunction with Article 3(g) and (i) shall be mentioned; Member States may decide that the annual percentage rate of charge need not be provided;

(g) an indication that the consumer may be requested to repay the amount of credit in full on demand at any time;

(h) conditions governing the exercise of the right of withdrawal from the credit agreement; and

(i) information concerning the charges applicable from the time such agreements are concluded and, if applicable, the conditions under which those charges may be changed.

Article 11

Information concerning the borrowing rate

1. Where applicable, the consumer shall be informed of any change in the borrowing rate, on paper or another durable medium, before the change enters into force. The information shall state the amount of the payments to be made after the entry into force of the new borrowing rate and, if the number or frequency of the payments changes, particulars thereof.

2. However, the parties may agree in the credit agreement that the information referred to in paragraph 1 is to be given to the consumer periodically in cases where the change in the borrowing rate is caused by a change in a reference rate, the new reference rate is made publicly available by appropriate means and the information concerning the new reference rate is also kept available in the premises of the creditor.

Article 12

Obligations in connection with credit agreement in the form of an overdraft facility

1. Where a credit agreement covers credit in the form of an overdraft facility, the consumer shall be kept regularly informed

by means of a statement of account, on paper or on another durable medium, containing the following particulars:

(a) the precise period to which the statement of account relates;

(b) the amounts and dates of drawdowns;

(c) the balance from the previous statement, and the date thereof;

(d) the new balance;

(e) the dates and amounts of payments made by the consumer;

(f) the borrowing rate applied;

(g) any charges that have been applied;

(h) where applicable, the minimum amount to be paid.

2. In addition, the consumer shall be informed on paper or another durable medium of increases in the borrowing rate, or in any charges payable, before the change in question enters into force.

However, the parties may agree in the credit agreement that information concerning changes in the borrowing rate is to be given in the manner provided for in paragraph 1 in cases where the change in the borrowing rate is caused by a change in a reference rate, the new reference rate is made publicly available by appropriate means and the information concerning the new reference rate is also kept available in the premises of the creditor.

Article 13

Open-end credit agreements

1. The consumer may effect standard termination of an open-end credit agreement free of charge at any time unless the parties have agreed on a period of notice. Such a period may not exceed one month.

If agreed in the credit agreement, the creditor may effect standard termination of an open-end credit agreement by giving the consumer at least two months' notice drawn up on paper or on another durable medium.

2. If agreed in the credit agreement, the creditor may, for objectively justified reasons, terminate the consumer's right to draw down on an open-end credit agreement. The creditor shall inform the consumer of the termination and the reasons for it on paper or on another durable medium, where possible before the termination and at the latest immediately thereafter, unless the provision of such information is prohibited by other Community legislation or is contrary to objectives of public policy or public security.

Article 14

Right of withdrawal

1. The consumer shall have a period of 14 calendar days in which to withdraw from the credit agreement without giving any reason.

That period of withdrawal shall begin

(a) either from the day of the conclusion of the credit agreement, or

(b) from the day on which the consumer receives the contractual terms and conditions and information in accordance with Article 10, if that day is later than the date referred to in point (a) of this subparagraph.

2. Where in the case of a linked credit agreement, as defined in Article 3(n), national legislation at the time of the entry into force of this Directive already provides that funds cannot be made available to the consumer before the expiry of a specific period, Member States may exceptionally provide that the period referred to in paragraph 1 of this Article may be reduced to this specific period at the explicit request of the consumer.

3. If the consumer exercises his right of withdrawal, he shall:

(a) in order to give effect to the withdrawal before the expiry of the deadline referred to in paragraph 1, notify this to the creditor in line with the information given by the creditor pursuant to Article 10(2)(p) by means which can be proven in accordance with national law. The deadline shall be deemed to have been met if that notification, if it is on paper or on another durable medium that is available and accessible to the creditor, is dispatched before the deadline expires; and

(b) pay to the creditor the capital and the interest accrued thereon from the date the credit was drawn down until the date the capital is repaid, without any undue delay and no later than 30 calendar days after the despatch by him to the creditor of notification of the withdrawal. The interest shall be calculated on the basis of the agreed borrowing rate. The creditor shall not be entitled to any other compensation from the consumer in the event of withdrawal, except compensation for any non-returnable charges paid by the creditor to any public administrative body.

4. If an ancillary service relating to the credit agreement is provided by the creditor or by a third party on the basis of an agreement between the third party and the creditor, the consumer shall no longer be bound by the ancillary service contract if the consumer exercises his right of withdrawal from the credit agreement in accordance with this Article.

5. If the consumer has a right of withdrawal under paragraphs 1, 3 and 4, Articles 6 and 7 of Directive 2002/65/EC and Article 5 of Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises ([1]) shall not apply.

6. Member States may provide that paragraphs 1 to 4 of this Article shall not apply to credit agreements which by law are required to be concluded through the services of a notary, provided that the notary confirms that the consumer is guaranteed the rights provided for under Articles 5 and 10.

7. This Article shall be without prejudice to any rule of national law establishing a period of time during which the performance of the contract may not begin.

Article 15

Linked credit agreements

1. Where the consumer has exercised a right of withdrawal, based on Community law, concerning a contract for the supply of goods or services, he shall no longer be bound by a linked credit agreement.

2. Where the goods or services covered by a linked credit agreement are not supplied, or are supplied only in part, or are not in conformity with the contract for the supply thereof, the consumer shall have the right to pursue remedies against the creditor if the consumer has pursued his remedies against the supplier but has failed to obtain the satisfaction to which he is entitled according to the law or the contract for the supply of goods or services. Member States shall determine to what extent and under what conditions those remedies shall be exercisable.

3. This Article shall be without prejudice to any national rules rendering the creditor jointly and severally liable in respect of any claim which the consumer may have against the supplier where the purchase of goods or services from the supplier has been financed by a credit agreement.

Article 16

Early repayment

1. The consumer shall be entitled at any time to discharge fully or partially his obligations under a credit agreement. In such cases, he shall be entitled to a reduction in the total cost of the credit, such reduction consisting of the interest and the costs for the remaining duration of the contract.

2. In the event of early repayment of credit the creditor shall be entitled to fair and objectively justified compensation for possible costs directly linked to early repayment of credit provided that the early repayment falls within a period for which the borrowing rate is fixed.

Such compensation may not exceed 1 % of the amount of credit repaid early, if the period of time between the early repayment and the agreed termination of the credit agreement exceeds one year. If the period does not exceed one year, the compensation may not exceed 0,5 % of the amount of credit repaid early.

3. Compensation for early repayment shall not be claimed:

(a) if the repayment has been made under an insurance contract intended to provide a credit repayment guarantee;

(b) in the case of overdraft facilities; or

(c) if the repayment falls within a period for which the borrowing rate is not fixed.

4. Member States may provide that:

(a) such compensation may be claimed by the creditor only on condition that the amount of the early repayment exceeds the threshold defined by national law. That threshold shall not exceed EUR 10 000 within any period of 12 months;

(b) the creditor may exceptionally claim higher compensation if he can prove that the loss he suffered from early repayment exceeds the amount determined under paragraph 2.

If the compensation claimed by the creditor exceeds the loss actually suffered, the consumer may claim a corresponding reduction.

In this case, the loss shall consist of the difference between the initially agreed interest rate and the interest rate at which the creditor can lend out the amount repaid early on the market at the time of early repayment, and shall take into account the impact of early repayment on administrative costs.

5. Any compensation shall not exceed the amount of interest the consumer would have paid during the period between the early repayment and the agreed date of termination of the credit agreement.

Article 17

Assignment of rights

1. In the event of assignment to a third party of the creditor's rights under a credit agreement or the agreement itself, the consumer shall be entitled to plead against the assignee any

([1]) OJ L 372, 31.12.1985, p. 31.

defence which was available to him against the original creditor, including set-off where the latter is permitted in the Member State concerned.

2. The consumer shall be informed of the assignment referred to in paragraph 1 except where the original creditor, by agreement with the assignee, continues to service the credit vis-à-vis the consumer.

Article 18

Overrunning

1. In the case of an agreement to open a current account, where there is a possibility that the consumer is allowed an overrun, the agreement shall contain in addition the information referred to in Article 6(1)(e). The creditor shall in any case provide that information on paper or another durable medium on a regular basis.

2. In the event of a significant overrunning exceeding a period of one month, the creditor shall inform the consumer without delay, on paper or on another durable medium,

(a) of the overrunning;

(b) of the amount involved;

(c) of the borrowing rate;

(d) of any penalties, charges or interest on arrears applicable.

3. This Article shall be without prejudice to any rule of national law requiring the creditor to offer another kind of credit product when the duration of the overrunning is significant.

CHAPTER V

ANNUAL PERCENTAGE RATE OF CHARGE

Article 19

Calculation of the annual percentage rate of charge

1. The annual percentage rate of charge, equating, on an annual basis, to the present value of all commitments (drawdowns, repayments and charges), future or existing, agreed by the creditor and the consumer, shall be calculated in accordance with the mathematical formula set out in Part I of Annex I.

2. For the purpose of calculating the annual percentage rate of charge, the total cost of the credit to the consumer shall be determined, with the exception of any charges payable by the consumer for non-compliance with any of his commitments laid down in the credit agreement and charges other than the purchase price which, for purchases of goods or services, he is obliged to pay whether the transaction is effected in cash or on credit.

The costs of maintaining an account recording both payment transactions and drawdowns, the costs of using a means of payment for both payment transactions and drawdowns, and other costs relating to payment transactions shall be included in the total cost of credit to the consumer unless the opening of the account is optional and the costs of the account have been clearly and separately shown in the credit agreement or in any other agreement concluded with the consumer.

3. The calculation of the annual percentage rate of charge shall be based on the assumption that the credit agreement is to remain valid for the period agreed and that the creditor and the consumer will fulfil their obligations under the terms and by the dates specified in the credit agreement.

4. In the case of credit agreements containing clauses allowing variations in the borrowing rate and, where applicable, charges contained in the annual percentage rate of charge but unquantifiable at the time of calculation, the annual percentage rate of charge shall be calculated on the assumption that the borrowing rate and other charges will remain fixed in relation to the initial level and will remain applicable until the end of the credit agreement.

5. Where necessary, the additional assumptions set out in Annex I may be used in calculating the annual percentage rate of charge.

If the assumptions set out in this Article and in Part II of Annex I do not suffice to calculate the annual percentage rate of charge in a uniform manner or are not adapted any more to the commercial situation at the market, the Commission may determine the necessary additional assumptions for the calculation of the annual percentage rate of charge, or modify existing ones. These measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(2).

CHAPTER VI

CREDITORS AND CREDIT INTERMEDIARIES

Article 20

Regulation of creditors

Member States shall ensure that creditors are supervised by a body or authority independent from financial institutions, or regulated. This shall be without prejudice to Directive 2006/48/EC.

Article 21

Certain obligations of credit intermediaries vis-à-vis consumers

Member States shall ensure that:

(a) a credit intermediary indicates in advertising and documentation intended for consumers the extent of his powers, in particular whether he works exclusively with one or more creditors or as an independent broker;

(b) the fee, if any, payable by the consumer to the credit intermediary for his services is disclosed to the consumer, and agreed between the consumer and the credit intermediary on paper or another durable medium before the conclusion of the credit agreement;

(c) the fee, if any, payable by the consumer to the credit intermediary for his services is communicated to the creditor by the credit intermediary, for the purpose of calculation of the annual percentage rate of charge.

CHAPTER VII

IMPLEMENTING MEASURES

Article 22

Harmonisation and imperative nature of this Directive

1. Insofar as this Directive contains harmonised provisions, Member States may not maintain or introduce in their national law provisions diverging from those laid down in this Directive.

2. Member States shall ensure that consumers may not waive the rights conferred on them by the provisions of national law implementing or corresponding to this Directive.

3. Member States shall further ensure that the provisions they adopt in implementation of this Directive cannot be circumvented as a result of the way in which agreements are formulated, in particular by integrating drawdowns or credit agreements falling within the scope of this Directive into credit agreements the character or purpose of which would make it possible to avoid its application.

4. Member States shall take the necessary measures to ensure that consumers do not lose the protection granted by this Directive by virtue of the choice of the law of a third country as the law applicable to the credit agreement, if the credit agreement has a close link with the territory of one or more Member States.

Article 23

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

Article 24

Out-of-court dispute resolution

1. Member States shall ensure that adequate and effective out-of-court dispute resolution procedures for the settlement of consumer disputes concerning credit agreements are put in place, using existing bodies where appropriate.

2. Member States shall encourage those bodies to cooperate in order to also resolve cross-border disputes concerning credit agreements.

Article 25

Committee procedure

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 26

Information to be supplied to the Commission

Where a Member State makes use of any of the regulatory choices referred to in Article 2(5) and 2(6), Article 4(1), Article 4(2)(c), Article 6(2), Article 10(1), Article 10(2)(g), Article 14(2) and Article 16(4), it shall inform the Commission thereof as well as of any subsequent changes. The Commission shall make that information public on a website or in another easily accessible way. Member States shall take the appropriate measures to diffuse that information amongst national creditors and consumers.

Article 27

Transposition

1. Before 12 May 2010 Member States shall adopt and publish the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 12 May 2010.

When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. The Commission shall undertake, every five years and for the first time 12 May 2013, a review of the thresholds laid down in this Directive and its annexes and the percentages used to calculate the compensation payable in the event of early repayment, assessing them in the light of economic trends in the Community and the situation of the market concerned. The Commission shall also monitor the effect of the existence of the regulatory choices referred to in Article 2(5) and 2(6), Article 4(1), Article 4(2)(c), Article 6(2), Article 10(1), Article 10(2)(g), Article 14(2) and Article 16(4) on the internal market and consumers. The results shall be made known to the European Parliament and the Council, accompanied where appropriate by a proposal to modify the thresholds and percentages as well as the abovementioned regulatory choices accordingly.

Article 28

Conversion of amounts expressed in euro into national currency

1. For the purposes of this Directive, those Member States who convert the amounts expressed in euro into their national currency shall initially use in the conversion the exchange rate prevailing on the date of adoption of this Directive.

2. Member States may round off the amounts resulting from the conversion provided that such rounding off does not exceed EUR 10.

CHAPTER VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 29

Repeal

Directive 87/102/EEC shall be repealed with effect from 12 May 2010.

Article 30

Transitional measures

1. This Directive shall not apply to credit agreements existing on the date when the national implementing measures enter into force.

2. However, Member States shall ensure that Articles 11, 12, 13 and 17, the second sentence of Article 18(1), and Article 18(2) are applied also to open-end credit agreements existing on the date when the national implementing measures enter into force.

Article 31

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 32

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 23 April 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J. LENARČIČ

ANNEX I

I. The basic equation expressing the equivalence of drawdowns on the one hand and repayments and charges on the other.

The basic equation, which establishes the annual percentage rate of charge (APR), equates, on an annual basis, the total present value of drawdowns on the one hand and the total present value of repayments and payments of charges on the other hand, i.e.:

$$\sum_{k=1}^{m} C_k(1+X)^{-t_k} = \sum_{l=1}^{m'} D_l(1+X)^{-s_l}$$

where:

— X is the APR,

— m is the number of the last drawdown,

— k is the number of a drawdown, thus $1 \leq k \leq m$,

— C_k is the amount of drawdown k,

— t_k is the interval, expressed in years and fractions of a year, between the date of the first drawdown and the date of each subsequent drawdown, thus $t_{1=0}$,

— m' is the number of the last repayment or payment of charges,

— l is the number of a repayment or payment of charges,

— D_l is the amount of a repayment or payment of charges,

— s_l is the interval, expressed in years and fractions of a year, between the date of the first drawdown and the date of each repayment or payment of charges.

Remarks:

(a) The amounts paid by both parties at different times shall not necessarily be equal and shall not necessarily be paid at equal intervals.

(b) The starting date shall be that of the first drawdown.

(c) Intervals between dates used in the calculations shall be expressed in years or in fractions of a year. A year is presumed to have 365 days (or 366 days for leap years), 52 weeks or 12 equal months. An equal month is presumed to have 30,41666 days (i.e. 365/12) regardless of whether or not it is a leap year.

(d) The result of the calculation shall be expressed with an accuracy of at least one decimal place. If the figure at the following decimal place is greater than or equal to 5, the figure at that particular decimal place shall be increased by one.

(e) The equation can be rewritten using a single sum and the concept of flows (A_k), which will be positive or negative, in other words either paid or received during periods 1 to k, expressed in years, i.e.:

$$S = \sum_{k=1}^{n} A_k(1+X)^{-t_k},$$

S being the present balance of flows. If the aim is to maintain the equivalence of flows, the value will be zero.

II. Additional assumptions for the calculation of the annual percentage rate of charge

(a) if a credit agreement gives the consumer freedom of drawdown, the total amount of credit shall be deemed to be drawn down immediately and in full;

(b) if a credit agreement provides different ways of drawdown with different charges or borrowing rates, the total amount of credit shall be deemed to be drawn down at the highest charge and borrowing rate applied to the most common drawdown mechanism for this type of credit agreement;

(c) if a credit agreement gives the consumer freedom of drawdown in general but imposes, amongst the different ways of drawdown, a limitation with regard to the amount and period of time, the amount of credit shall be deemed to be drawn down on the earliest date provided for in the agreement and in accordance with those drawdown limits;

(d) if there is no fixed timetable for repayment, it shall be assumed:

(i) that the credit is provided for a period of one year; and

(ii) that the credit will be repaid in 12 equal instalments and at monthly intervals;

(e) if there is a fixed timetable for repayment but the amount of such repayments is flexible, the amount of each repayment shall be deemed to be the lowest for which the agreement provides;

(f) unless otherwise specified, where the credit agreement provides for more than one repayment date, the credit is to be made available and the repayments made on the earliest date provided for in the agreement;

(g) if the ceiling applicable to the credit has not yet been agreed, that ceiling is assumed to be EUR 1 500;

(h) in the case of an overdraft facility the total amount of credit shall be deemed to be drawn down in full and for the whole duration of the credit agreement. If the duration of the credit agreement is not known the annual percentage rate of charge shall be calculated on the assumption that the duration of the credit is three months;

(i) if different interest rates and charges are offered for a limited period or amount, the interest rate and the charges shall be deemed to be the highest rate for the whole duration of the credit agreement;

(j) for consumer credit agreements for which a fixed borrowing rate is agreed in relation to the initial period, at the end of which a new borrowing rate is determined and subsequently periodically adjusted according to an agreed indicator, the calculation of the annual percentage rate shall be based on the assumption that, at the end of the fixed borrowing rate period, the borrowing rate is the same as at the time of calculating the annual percentage rate, based on the value of the agreed indicator at that time.

ANNEX II

STANDARD EUROPEAN CONSUMER CREDIT INFORMATION

1. **Identity and contact details of the creditor/credit intermediary**

Creditor Address Telephone number (*) E-mail address (*) Fax number (*) Web address (*)	[Identity] [Geographical address to be used by the consumer]
If applicable Credit intermediary Address Telephone number (*) E-mail address (*) Fax number (*) Web address (*)	 [Identity] [Geographical address to be used by the consumer]

(*) This information is optional for the creditor.

Wherever 'if applicable' is indicated, the creditor must fill in the box if the information is relevant to the credit product or delete the respective information or the entire row if the information is not relevant for the type of credit considered.

Indications between square brackets provide explanations for the creditor and must be replaced with the corresponding information.

2. **Description of the main features of the credit product**

The type of credit	
The total amount of credit *This means the ceiling or the total sums made available under the credit agreement.*	
The conditions governing the drawdown *This means how and when you will obtain the money.*	
The duration of the credit agreement	
Instalments and, where appropriate, the order in which instalments will be allocated	You will have to pay the following: [The amount, number and frequency of payments to be made by the consumer] Interest and/or charges will be payable in the following manner:
The total amount you will have to pay *This means the amount of borrowed capital plus interest and possible costs related to your credit.*	[Sum of total amount of credit and total cost of credit]
If applicable The credit is granted in the form of a deferred payment for a good or service or is linked to the supply of specific goods or the provision of a service Name of good/service Cash price	

If applicable Sureties required *This is a description of the security to be provided by you in relation to the credit agreement.*	[Kind of sureties]
If applicable *Repayments do not give rise to immediate amortisation of the capital.*	

3. **Costs of the credit**

The borrowing rate or, if applicable, different borrowing rates which apply to the credit agreement	[% — fixed or, — variable (with the index or reference rate applicable to the initial borrowing rate), — periods],
Annual Percentage Rate of Charge (APR) *This is the total cost expressed as an annual percentage of the total amount of credit.* *The APR is there to help you compare different offers.*	[% A representative example mentioning all the assumptions used for calculating the rate to be set out here]
Is it compulsory, in order to obtain the credit or to obtain it on the terms and conditions marketed, to take out — an insurance policy securing the credit, or — another ancillary service contract, *If the costs of these services are not known by the creditor they are not included in the APR.*	 Yes/no [if yes, specify the kind of insurance] Yes/no [if yes, specify the kind of ancillary service]
Related costs	
If applicable Maintaining one or more accounts is required for recording both payment transactions and drawdowns	
If applicable Amount of costs for using a specific means of payment (e.g. a credit card)	
If applicable Any other costs deriving from the credit agreement	
If applicable Conditions under which the abovementioned costs related to the credit agreement can be changed	
If applicable Obligation to pay notarial fees	
Costs in the case of late payments *Missing payments could have severe consequences for you (e.g. forced sale) and make obtaining credit more difficult.*	You will be charged […… (applicable interest rate and arrangements for its adjustment and, where applicable, default charges)] for missing payments.

4. **Other important legal aspects**

Right of withdrawal *You have the right to withdraw from the credit agreement within a period of 14 calendar days.*	Yes/no

Early repayment *You have the right to repay the credit early at any time in full or partially.*	
If applicable The creditor is entitled to compensation in the case of early repayment	[Determination of the compensation (calculation method) in accordance with the provisions implementing Article 16 of Directive 2008/48/EC]
Consultation of a database *The creditor must inform you immediately and without charge of the result of a consultation of a database, if a credit application is rejected on the basis of such a consultation. This does not apply if the provision of such information is prohibited by European Community law or is contrary to objectives of public policy or public security.*	
Right to a draft credit agreement *You have the right, upon request, to obtain a copy of the draft credit agreement free of charge. This provision does not apply if the creditor is at the time of the request unwilling to proceed to the conclusion of the credit agreement with you.*	
If applicable The period of time during which the creditor is bound by the pre-contractual information	This information is valid from … until …

If applicable

5. **Additional information in the case of distance marketing of financial services**

(a) concerning the creditor	
If applicable Representative of the creditor in your Member State of residence Address Telephone number (*) E-mail address (*) Fax number (*) Web address (*)	[Identity] [Geographical address to be used by the consumer]
If applicable Registration	[The trade register in which the creditor is entered and his registration number or an equivalent means of identification in that register]
If applicable The supervisory authority	
(b) concerning the credit agreement	
If applicable Exercise of the right of withdrawal	[Practical instructions for exercising the right of withdrawal indicating, *inter alia*, the period for exercising the right, the address to which notification of exercise of the right of withdrawal should be sent and the consequences of non-exercise of that right]
If applicable The law taken by the creditor as a basis for the establishment of relations with you before the conclusion of the credit contract	

If applicable Clause stipulating the governing law applicable to the credit agreement and/or the competent court	[Relevant clause to be set out here]
If applicable Language regime	Information and contractual terms will be supplied in [specific language]. With your consent, we intend to communicate in [specific language/languages] during the duration of the credit agreement.
(c) concerning redress	
Existence of and access to out-of-court complaint and redress mechanism	[Whether or not there is an out-of-court complaint and redress mechanism for the consumer who is party to the distance contract and, if so, the methods of access to it]

(*) This information is optional for the creditor.

ANNEX III

EUROPEAN CONSUMER CREDIT INFORMATION FOR

(1) **overdrafts**

(2) **consumer credit offered by certain credit organisations (Article 2(5) of Directive 2008/48/EC)**

(3) **debt conversion**

1. **Identity and contact details of the creditor/credit intermediary**

Creditor Address Telephone number (*) E-mail address (*) Fax number (*) Web address (*)	[Identity] [Geographical address to be used by the consumer]
If applicable Credit intermediary Address Telephone number (*) E-mail address (*) Fax number (*) Web address (*)	 [Identity] [Geographical address to be used by the consumer]

(*) This information is optional for the creditor.

Wherever 'if applicable' is indicated, the creditor must fill in the box if the information is relevant to the credit product or delete the respective information or the entire row if the information is not relevant for the type of credit considered.

Indications between square brackets provide explanations for the creditor and must be replaced with the corresponding information.

2. **Description of the main features of the credit product**

The type of credit	
The total amount of credit *This means the ceiling or the total sums made available under the credit agreement.*	
The duration of the credit agreement	
If applicable You may be requested to repay the amount of credit in full on demand at any time.	

3. **Costs of the credit**

The borrowing rate or, if applicable, different borrowing rates which apply to the credit agreement	[% — fixed or, — variable (with the index or reference rate applicable to the initial borrowing rate)],

If applicable The annual percentage rate of charge (APR) (*) *This is the total cost of credit expressed as an annual percentage of the total amount of credit. The APR is there to help you compare different offers.*	[% A representative example mentioning all the assumptions used for calculating the rate to be set out here]
If applicable Costs If applicable The conditions under which those costs may be changed	[The costs applicable from the time the credit agreement is concluded]
Costs in the case of late payments	You will be charged […… (applicable interest rate and arrangements for its adjustment and, where applicable, default charges)] for missing payments.

(*) Not applicable to European Consumer Credit Information for overdrafts in those Member States which decide on the basis of Article 6(2) of Directive 2008/48/EC that the APR need not be provided for overdrafts.

4. **Other important legal aspects**

Termination of the credit agreement	[The conditions and procedure for terminating the credit agreement]
Consultation of a database *The creditor must inform you immediately and without charge of the result of a consultation of a database if a credit application is rejected on the basis of such a consultation. This does not apply if the provision of such information is prohibited by European Community law or is contrary to objectives of public policy or public security.*	
If applicable The period of time during which the creditor is bound by the pre-contractual information	This information is valid from … until…

If applicable

5. **Additional information to be given where the pre-contractual information is provided by certain credit organisations (Article 2(5) of Directive 2008/48/EC or relates to a consumer credit for debt conversion**

Instalments and, where appropriate, the order in which instalments will be allocated	You will have to pay the following: [Representative example of an instalment table including the amount, number and frequency of payments to be made by the consumer]
The total amount you will have to pay	
Early repayment *You have the right to repay the credit early at any time in full or partially.* If applicable The creditor is entitled to compensation in the case of early repayment	[Determination of the compensation (calculation method) in accordance with the provisions implementing Article 16 of Directive 2008/48/EC]

If applicable

6. **Additional information to be given in the case of distance marketing of financial services**

(a) concerning the creditor	
If applicable Representative of the creditor in your Member State of residence	[Identity]
Address Telephone number (*) E-mail address (*) Fax number (*) Web address (*)	[Geographical address to be used by the consumer]
If applicable Registration	[The trade register in which the creditor is entered and his registration number or an equivalent means of identification in that register]
If applicable The supervisory authority	
(b) concerning the credit agreement	
Right of withdrawal *You have the right to withdraw from the credit agreement within a period of 14 calendar days.* If applicable Exercise of the right of withdrawal	Yes/no [Practical instructions for exercising the right of withdrawal indicating, inter alia, the address to which notification of exercise of the right of withdrawal should be sent and the consequences of non-exercise of that right]
If applicable The law taken by the creditor as a basis for the establishment of relations with you before the conclusion of the credit contract	
If applicable Clause stipulating the law applicable to the credit agreement and/or the competent court	[Relevant clause to be set out here]
If applicable Language regime	Information and contractual terms will be supplied in [specific language]. With your consent, we intend to communicate in [specific language/languages] during the duration of the credit agreement.
(c) concerning redress	
Existence of and access to out-of-court complaint and redress mechanism	[Whether or not there is an out-of-court complaint and redress mechanism for the consumer who is party to the distance contract and, if so, the methods of access to it]

(*) This information is optional for the creditor.