ANNEX I

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

1. APPLICATION FORM
EUROPEAN COMMISSIONHEALTH AND CONSUMER PROTECTIONDIRECTORATE-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:

…

…

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 %

…

…

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.

(**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).

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

(**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).