

EN

SANCO/10060/2006 (POOL/D1/2006/10060/10060-EN.doc)

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

**GUIDELINES FOR APPLICATIONS FOR NEW
ALTERNATIVE METHODS OF DISPOSAL OR USE OF
ANIMAL BY-PRODUCTS UNDER REGULATION (EC) NO
1774/2002**

Prepared jointly by

The Health and Consumer Protection Directorate-General and

The European Food Safety Authority

1. INTRODUCTION

Under Regulation (EC) No 1774/2002 on animal by-products not intended for human consumption of 3 October 2002¹ (the “Animal By-products Regulation”), alternative methods of disposal or use of animal by-products may be approved by the Commission after consultation of the appropriate scientific committee (now: the European Food Safety Authority - EFSA).

Before a process can be approved, EFSA has to examine whether the process can be regarded as safe, i. e. if it minimises the possible risks to public and animal health and provides for safe process conditions. In order to proceed with this scientific assessment, EFSA needs sufficient information on the material to be processed, the process parameters and the safety measures in place.

It is the purpose of the current guidelines to assist the applicants in the preparation and presentation of their applications in order to speed up the procedure at Commission level. In addition, assistance provided by specialised experts as well as Member States’ competent authorities could be helpful for applications to be prepared according to the necessary standards.

As the Commission favours the development of scientifically safe disposal technologies, it has developed the current guidelines jointly with EFSA in order to facilitate approval procedures. The guidelines are also based on the experience gained during the approval of alternative methods which has led to the adoption of Commission Regulation (EC) No 92/2005 of 19 January 2005².

The Commission and EFSA highly recommend the use of these guidelines.

¹ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 416/2005 of 11 March 2005, OJ L 66, 12.3.2005, p. 66.

² OJ L 19, 21.1.2005, p. 27.

2. PROCEDURE FOR SUBMISSION OF APPLICATIONS

2.1. Applicable legal provisions

Articles 4 (2) (e), 5 (2) (g) and 6 (2) (i) respectively of the Animal By-products Regulation allow the Commission to lay down rules on alternative methods of disposal after consultation of the appropriate scientific committee (now: EFSA) and following the Regulatory Committee procedure laid down in Article 33 (2) of the Regulation, i.e. following an opinion of the Standing Committee of the Food Chain and Animal Health. Therefore, according to the legislation in force, an EFSA opinion is necessary before the Commission can propose a legislative measure to the Standing Committee.

The tasks of EFSA in general are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002³. The procedure applied by EFSA to requests for scientific opinions is laid down in Commission Regulation (EC) No 1304/2003⁴.

2.2. Recommended preparation procedure

2.2.1. Preparation of application

It is recommended to develop applications in close cooperation with the competent authorities of Member States, if appropriate taking into account technical/scientific knowledge provided by specialised independent experts.

The competent authority can assist in advising the operator how he can best put forward his application on the basis of its experience and exchanges of view with the Commission and other Member States' competent authorities. Member States have communicated the addresses of contact points which are able, should the need arise, to direct applicants to the competent authority responsible for their application (see list of contact points in Annex 2).

Member States' competent authorities could assist operators so that applications are submitted in the format recommended (see Point 3.2) on the basis of their experience. Competent authorities will also examine whether a Community approval of the new method is required or whether, according to legislation in force, in particular Commission Regulation (EC) No 92/2005, it may issue a national approval as the process submitted consists only of a modification of certain process parameters of alternative methods already approved.

³ OJ L 21, 1.2.2002, p. 1, as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).
⁴ OJ L 185, 24.7.2003, p. 6.

If appropriate and/or necessary, specialised scientific and/ or technical experts could also be consulted in the preparation of an application. In so far as research and tests are required as evidence, the consultation of such experts may be important. Experts may include consultants operating in accordance with relevant international standards (e.g. ISO) or consultants approved under national legislation and other experts with technical knowledge in the relevant field. In this context the current rules on independence and absence of conflicts of interest for experts acting as Members of EFSA Panels and Working Groups, in particular Article 37 of Regulation (EC) No 178/2002, should also be noted.

2.2.2. Submission of application

The application should be forwarded to the competent authority of the Member State in which the applicant intends to use the new process in question. The competent authority should carry out a first scrutiny in examining whether the application responds to the basic presentation requirements set out under (3.) and lay down its findings in a documentary report.

The competent authority should then forward the application and their report to EFSA for assessment with a copy to the Commission Service for information (see addresses in Annex 1). The competent authority should indicate a time limit for the delivery of the assessment, which should normally allow at least six months. If no time limit is indicated or if EFSA cannot meet the time limit indicated, a time limit will be set by EFSA in accordance with the procedure laid down in Article 7 (1) of Commission Regulation (EC) No 1304/2003⁵.

2.2.3. Assessment of application, decision

EFSA examines the application according to the criteria laid down under (3.) and will contact the applicant (with copies to the competent authority and the Commission) in case further information has to be provided on specific aspects of the application. EFSA will then proceed in dealing with the application in accordance with Commission Regulation (EC) No 1304/2003, i. e. forward it to the Panel responsible which may further ask a Technical Working Group to evaluate the submission.

The Panel will then give an opinion and transmit the result to the relevant Member State authority and the Commission Service. The Commission, as foreseen by the relevant articles in the Regulation, then proceeds to discussion of the process submitted with Member States' experts and, eventually, adoption of a legislative measure authorising the use of the process Community-wide, after a favourable opinion of the Standing Committee on the Food Chain and Animal Health.

⁵ Commission Regulation (EC) No 1304/2003 of 11 July 2003, OJ L 185, 24.7.2003, p. 6.

3. RECOMMENDED CONTENT OF APPLICATIONS

3.1. General scope of applications

In order to provide for a structured approach to the assessment of the safety of alternative methods of disposal and use, applications should be submitted in a standard format (for details see (3.2.) below), accompanied by documentary evidence. The applicant should state how the process eliminates risks to public and animal health with regard to the possible presence of pathogenic agents.

3.2. Elements to be included

The elements to be included in the process description are based on the criteria which have until present been used by EFSA (and its predecessor, the Scientific Steering Committee) for the evaluation of alternative methods⁶. In particular, the following should be mentioned:

(a) Risk categories

The categories of materials to be processed should be identified, in accordance with the categories laid down in Articles 4, 5, and 6 of the Animal By-products Regulation.

(b) Identification and characterisation of risk materials

Significant risk materials should be identified separately. For each material, the likelihood of human and animal exposure under normal and emergency/ abnormal operating conditions should be assessed. In case of significant exposure, the potential risk should be assessed.

(c) Agent risk reduction

The risk reduction for human and animal health which can be achieved by the process should be estimated on the basis of direct measurements. In case no direct measurement is available, modelling or extrapolation from other processes may also be used. Estimates should be accompanied by evidence. This includes – for measurements – information on the methodology used (sensitivity and reliability of the methods used, nature of samples which have been analysed and evidence that samples are representative (relevant real samples, number of tests performed).

If surrogates for prion measurement are used, an explanation should be given of their relevance. In any case it is necessary to provide an evaluation of the validity with the uncertainties involved.

⁶ Opinion on a framework for the assessment of the risk from different options for the safe disposal or use of animal by-products which might be contaminated with microbiological agents, including TSE, adopted by the Scientific Steering Committee at its meeting of 10-11 April 2003 (still available at http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html).

(d) Risk containment

The likely effectiveness of the technical measures used to ensure that the risks are contained should be analysed. This analysis should reflect normal and abnormal/ emergency operating conditions including a breakdown of the process. Monitoring and surveillance procedures to demonstrate containment should be specified. If full containment is not achievable, an assessment is required of any potential risk.

(e) Identification of interdependent processes

Possible indirect impacts which may influence the risk reduction capacity of a particular process should be evaluated. Indirect impacts may arise from transport, storage and safe disposal of end-products and by-products of a process.

(f) Intended end-use of the products

The intended end use of products and by-products of a process should be specified. The likely risks involved should be calculated from the risk reduction estimated in accordance with (c), which may arise to human and animal health.

3.3. Documentary evidence

Documentary evidence should include a flow diagram showing the functioning of the process, the evidence indicated under (3.2 (c)), as well as other evidence aiming to substantiate the explanation given under the framework set out under (3.2).

3.4. Contact address

The application should include a contact address (name and full address, telephone, fax and electronic mail address of a particular contact person responsible as or on behalf of the applicant).

ANNEX 1: ADDRESS FOR SUBMISSION OF APPLICATIONS

THE APPLICATION SHOULD BE SENT FOR ASSESSMENT TO:

European Food Safety Authority
ABP Unit
Scientific Panel on Biological Hazards
Largo N. Palli 5/A
I-43100 Parma
Italy

Telephone: (39) 0521 036111

Fax:(39) 0521 036110

mailto: abp@efsa.eu.int

A COPY OF THE APPLICATION SHOULD BE SENT FOR INFORMATION TO:

European Commission
Directorate General for Health and Consumer Protection
Unit D 1 – Animal Health and Standing Committees
B-1049 Brussels
Belgium

Fax: (32-2) 29 53144

e-mail: sanco-abp@ec.europa.eu

ANNEX 2 : CONTACT POINTS FOR APPLICATIONS IN MEMBER STATES

BELGIË/ BELGIQUE

Federaal Agentschap voor de Veiligheid van de Voedselketen (FAVV) DG Controlebeleid WTC III Simon Bolivarlaan, 30 1000 Brussel <u>Attention of:</u> Mr Christophe KEPPENS Tel.: +32 2 208 38 74 Fax: +32 2 208 38 66 E-mail: christophe.keppens@favv.be	Agence fédérale pour la Sécurité de la Chaîne alimentaire (AFSCA) DG Politique de Contrôle WTC III Boulevard Simon Bolivar, 20 1000 Bruxelles <u>Attention of:</u> Mr Christophe KEPPENS Tel.: +32 2 208 38 74 Fax: +32 2 208 38 66 E-mail: christophe.keppens@favv.be
---	--

ČESKA REPUBLIKA

State Veterinary Administration of the Czech Republic
Slezská 7
120 00 Praha 2

Tel.: +420 227 010 142
E-mail: kom@svscr.cz
e.podatelna@svscr.cz

DANMARK

Danish Food and Veterinary Administration
Animal Health Division
Mørkhøj Bygade 19
DK-2860 Søborg

Tel.: +45 33 95 60 00
Fax: +45 39 67 52 48
E-mail: 1kontor@fvst.dk

DEUTSCHLAND

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Rochusstr. 65
53123 Bonn

Tel.: +49 1888 6198-0
Fax: +49 1888 6198-120
E-mail: poststelle@bvl.bund.de

EESTI

Dr Toomas KALJA
Chief Specialist
Animal Health Office
Animal Health and Welfare Department
Veterinary and Food Board

Tel.: +372 605 1731

Fax: +372 605 1737

E-mail: toomas.kalja@vet.agri.ee

ΕΛΛΑΣ

Hellenic Republic
Ministry of Rural Development and Food
Veterinary Directorate of Public Health
Animal Waste Management Office
Attention of: Mr Konstantinos KOUTSOMPINAS
2 Acharnon Str,
101 76 Athens

Tel.: +30 210 21 25 712

Fax: +30 210 82 29 188

E-mail: ka6u006@minagric.gr

ESPAÑA

Secretaria de la Comisión Nacional de Subproductos No Destinados Al Consumo Humano
Ministerio de Agricultura, Pesca y Alimentación
(Dirección General de Ganadería - Subdirección General de Porcino, Avicultura y otras producciones ganaderas)
C/ Alfonso XII, 62
8070 Madrid

Tel.: +34 91 34 76 632

Fax: +34 91 34 74 080

E-mail: sandach@mapa.es

FRANCE

Ministère de l'Agriculture et de la Pêche
Direction Générale de l'Alimentation
Bureau de la Pharmacie Vétérinaire et de l'Alimentation Animale
251, rue de Vaugirard
75015 PARIS

Tel. : +33 1 49 55 83 77

+33 1 49 55 84 68

Fax : +33 1 49 55 40 22

E-Mail : karen.bucher@agriculture.gouv.fr

Jean-pierre.orand@agriculture.gouv.fr

IRELAND

Department of Agriculture and Food
Meat Hygiene/ Animal By-Products Division
Agriculture House (3C)
Kildare Street
Dublin 2
Attention of: Mr Michael MC NAMARA

Tel.: +352 1 6072342

Fax: +352 1 6072845

E-mail: Michael.mcnamara@agriculture.gov.ie

ITALIA

Ministero della Salute
Dipartimento per la sanità pubblica veterinaria, la nutrizione e la sicurezza degli alimenti - ex
Ufficio IX
Attention of: Dott.ssa Claudia MADDALUNO
Piazzale Marconi, 25
00144 Roma

Tel.: +39 06. 59 94 38 37

Fax: +39 06. 59 94 66 57

E-mail: c.maddaluno@sanita.it

KYIΠOΣ

Andreas PAPAEFSTATHIOU
Veterinary Services
Ministry of Agriculture, Natural Resources and Environment
1417 Nicosia

Tel.: +357 22805201
Fax: +357 22332803
E-mail: apapaevstathiou@vs.moa.gov.cy

LATVIJA

Ministry of Agriculture
Veterinary and Food Department
Attention of: Mr Juris ZINARS
Republikas laukums 2
Riga, LV-1981

Tel.: +371 7027294
Fax: +371 7027205
E-mail: Juris.Zinars@zm.gov.lv

LIETUVA (LITHUANIA)

State Food and Veterinary Service
Attention of: Mr. Vaidotas KIUDULAS
Head of Animal Health Department
Siesiku str. 19
Vilnius, LT – 07170

Tel.: +370 5 2491627
Fax: +370 5 2404362

LUXEMBOURG

Ministère de l'Agriculture, de la Viticulture et du
Développement Rural
Administration des Services Vétérinaires
BP 1403
L-1014 Luxembourg

Tel.: +352 478 2539
Fax: +352 40 75 45
E-mail: roger.schmit@asv.etat.lu
felix.wildschutz@asv.etat.lu

MAGYARORSZÁG

Ministry of Agriculture and Rural Development
Animal Health and Food Control Department
Budapest
Kossuth Lajos sqr. 11
H-1055
Attention of : Mr Lajos BOGNÁR, DVM

Tel.: +36 1 301 4498
Fax: +36 1 301 4669
E-mail: allategeszsegugyifo@fvm.hu

MALTA

Food and Veterinary Regulation Division
Ministry for Rural Affairs and the Environment
Attention of: Dr. Mireille VELLA
Alberttown, Marsa
Malta

Tel.: +356 21225930 ext. 379
+356 99420381
Fax: +356 21238105
E-mail: mireille.vella@gov.mt

NEDERLAND

Ministerie van Landbouw, Natuur en Voedselkwaliteit
Directie Voedselkwaliteit en Diergezondheid
Dossier dierlijke bijproducten
Postbus 20401
2500 EK Den Haag

Tel.: +31 70 37 85 928
Fax: +31 70 37 86 141
E-mail: vdabp@minlnv.agro.nl

ÖSTERREICH

Bundesministerium für Gesundheit und Frauen
Abteilung IV/B/7
c/o Mag. Rudolf SCHERZER
Radetzkystraße 2
A-1030 Wien

Tel.: +43 (0) 1 711 00
+43 (0) 1 711 4345
Fax: +43 (0) 1 710 41 51
E-mail: rudolf.scherzer@bmgf.gv.at

POLSKA

Krzysztof BEDNARCZYK
Specialist
Feedingstuffs, Rendering and Pharmacy Office
General Veterinary Inspectorate
Wspólna 30
PL - 00 – 930 Warsaw

Tel.: +48 22 623 26 70
Fax: +48 22 623 14 08
E-mail: krzysztof.bednarczyk@wetgiw.gov.pl

PORTUGAL

Ministério da Agricultura do Desenvolvimento Rural e das Pescas
Direcção Geral da Veterinária
Largo da Academia Nacional de Belas Artes, 2
1249-105 LISBOA

Tel.: +351 21 3 23 95 00
Fax: +351 21 346 35 18
E-mail: dirgeral@dgv.min-agricultura.pt

SLOVENIJA

Ministry of Agriculture, Forestry and Food
Veterinary Administration of the Republic of Slovenia
Parmova 53
SI-1000 LJUBLJANA

Tel.: +386 1 300 13 00
Fax: +386 1 300 13 56
E-mail: yurs@gov.si

REPUBLIKA SLOVENSKA

State Veterinary and Food Administration of Slovak Republic
CVO Prof. Jozef Bires, DVM, DrSci.
Botanicka 17
Bratislava
842 13 – SK

Contact point:
Martin BENKA, DVM
Tel.: +421-2-602 57 225
Fax.: +421-2-654 11 159
E-mail: benka@svsrsk

SUOMI

Ministry of Agriculture and Forestry
Department of Food and Health
Mariankatu 23
Helsinki
PO BOX 30
FI-00023 Government

Tel.: +358 9 160 01
Fax: +358 9 160 53 338
E-mail: cvo.finland@mmm.fi

SVERIGE

Statens jordbruksverket
551 82 Jönköping

Tel.: +46 36 155000
Fax: +46 36 308182
E-mail: foderkvalitetsenheten@sjv.se

UNITED KINGDOM

DEFRA
Animal By-Products Technical Branch
BSE and Animal By-Products Division
Area 304
1A Page Street
London
SW1P 4PQ

Tel.: +44 20 7904 6176
Fax: +44 20 7904 6272
E-mail: animal-by-products@defra.gsi.gov.uk