EUROPEAN PARLIAMENT

1999 *2004*

Session document

FINAL
A5-0176/2003

21 May 2003

***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a European Parliament and Council regulation on additives for use in animal nutrition
(15776/2/2002 – C5-0132/2003 – 2002/0073(COD))

Committee on Agriculture and Rural Development

Rapporteur: Hedwig Keppelhoff-Wiechert

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

PROCEDURAL PAGE

At the sitting of 21 November 2002 Parliament adopted its position at first reading on the proposal for a European Parliament and Council regulation on additives for use in animal nutrition (COM(2002) 153 – 2002/0073 (COD)).

At the sitting of 27 March 2003 the President of Parliament announced that the common position had been received and referred to the Committee on Agriculture and Rural Development (15776/2/2002 – C5-0132/2003).

The committee had appointed Hedwig Keppelhoff-Wiechert rapporteur at its meeting of 17 April 2002.

It considered the common position and draft recommendation for second reading at its meetings of 28 April 2003 and 20 May 2003.

At the latter meeting it adopted the draft legislative resolution by 35 votes to 0, with 2 abstentions.

The following were present for the vote: Joseph Daul, chairman; Friedrich-Wilhelm Graefe zu Baringdorf, Albert Jan Maat and María Rodríguez Ramos, vice-chairmen; Hedwig Keppelhoff-Wiechert, rapporteur; Gordon J. Adam, Danielle Auroi, Alexandros Baltas (for María Izquierdo Rojo), Carlos Bautista Ojeda, Niels Busk, Giorgio Celli, Arlindo Cunha, Michl Ebner, Christel Fiebiger, Francesco Fiori, Christos Folias, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, María Esther Herranz García (for Encarnación Redondo Jiménez), Liam Hyland, Elisabeth Jeggle, Salvador Jové Peres, Heinz Kindermann, Wolfgang Kreissl-Dörfler (for Willi Görlach), Vincenzo Lavarra, Jean-Claude Martinez, Véronique Mathieu, Xaver Mayer, Jan Mulder (for Giovanni Procacci), Karl Erik Olsson, Neil Parish, Mikko Pesälä, Christa Prets (for António Campos), Agnes Schierhuber, Dominique F.C. Souchet and Robert William Sturdy.

The recommendation for second reading was tabled on 21 May 2003.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council regulation on additives for use in animal nutrition (COM15776/2/2002 – C5-0132/2003 – 2002/0073(COD))
(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (15776/2/2002 – C5-0132/2003),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2002) 153),

– having regard to the Commission's amended proposal (COM(2002) 771),[2]

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on Agriculture and Rural Development (A5-0176/2003),

1. Amends the common position as follows;

2. Instructs its President to forward its position to the Council and Commission.

[1] OJ C 203 E, 27.8.2002, p. 10.
[2] Not yet published in the OJ.

Council common position	Amendments by Parliament

Amendment 1
Recital 4 a (new)

	(4a) Conditions for imports from third countries of additives for use in animal nutrition must be at least as strict as those which the same Member States apply in order to safeguard human and animal health and Community trade. This shall also apply to imports of meat and animal products from animals which have consumed feed containing additives not approved for use in the EU.

Justification

Legal controls for imports from third countries should be equivalent to those for intra-Community trade so as not to compromise Member States.

Amendment 2
Recital 16 a (new)

	(16a) Over and above the ban on antibiotics as feed additives, it is necessary to establish stricter rules on the prophylactic use of antibiotics as veterinary medicinal products.

Justification

Parliament has been calling for phasing-out of antibiotics as growth-promoting feed additives for several years. In order to prevent antibiotics from being widely prescribed prophylactically as veterinary medicines, the Commission should lay down stricter rules in connection with the Regulation on veterinary medical products ((EEC) No 2309/93) and the Directive on medicated feed (90/167/EEC).

Amendment 3
Recital 25 a (new)

(25a) To achieve effective monitoring of the use of growth-promoting substances, the manufactured quantity of these substances must be registered by the industry, together with sales and distribution channels through to the end-user (substance flow control). The monitoring authorities must have access to the register kept by the manufacturers and traders at any time.

Justification

To prevent antibiotics ending up illegally in feed or their prescription on a large scale as prophylactic veterinary medicines, the industry must register the quantity of the substances manufactured and the substance flow of the products must be monitored. This is the only way to prevent illegal use of the kind familiar from the case of clenbuterol, a growth-promoting hormone which was authorised as cough medicine. The Commission should submit a proposal to this end within a year.

Amendment 4
Article 2, paragraph 2, point (a)

(a) 'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);	(a) 'feed additives' means ***chemically defined or described*** substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);

Justification

This definition, which was also incorporated into the Commission's amended proposal, enables a clearer distinction to be made between feed materials and feed additives and will result in greater legal certainty when the regulation is applied.

Amendment 5

Article 10, paragraph 2, sentence 1

An application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period***, and within a maximum of seven years after the entry into force of this Regulation for*** additives authorised without a time limit or pursuant to Directive 82/471/EEC.	An application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period***. For*** additives authorised without a time limit or pursuant to Directive 82/471/EEC***, a list of those additives which require re-evaluation and their priority order for re-evaluation shall be adopted in accordance with the procedure referred to in Article 21(2). The European Food Safety Authority shall be consulted in drawing up the list. An application shall be submitted in accordance with Article 8 within a maximum of seven years of the adoption of the list***.

Justification

There are over 300 substances currently authorised without a time limit, including generic substances, which might require re-evaluation. Many of these are innocuous substances, some of which are already authorised for use in human foods. It may not be necessary to carry out a detailed assessment of all these substances, involving an application in accordance with Article 7. The European Food Safety Authority will be responsible for the assessment of additives and may have an opinion on which additives require re-evaluation and on priorities for re-evaluation.

Amendment 6
Article 11

Phasing out By way of derogation from Article 10 and without prejudice to Article 13, antibiotics, other than coccidiostats and histomonostats, may be marketed and used as feed additives only until 31 December 2005; as from 1 January	Phasing out By way of derogation from Article 10 and without prejudice to Article 13, antibiotics, other than coccidiostats and histomonostats, may be marketed and used as feed additives only until 31 December 2005; as from 1 January

2006, those substances shall be deleted from the Register.	2006, those substances shall be deleted from the Register. ***Coccidiostats and histomonostats may be used as feed additives until 31 December 2008. If, by 1 January 2009, no legal instrument concerning further use is in force, the coccidiostats and histomonostats still authorised shall be deleted from the Register.*** ***Before 1 January 2008, the Commission shall submit a report on the use of these substances as feed additives together, where appropriate, with a legislative proposal concerning further use..***

Justification

To ensure that coccidiostats and histomonostats, which at present are virtually essential in poultry farming, are not used as additives in future, they should be authorised for a limited period only. That is the only way to develop sufficient pressure for developing suitable alternative products or vaccines. Moreover, only if there is temporary authorisation can Parliament retain its right to codecision on any future assessment as to whether coccidiostats and histomonostats should continue to be allowed as additives. There is no reason why the Commission should take decisions alone on this important health policy question in the future.

Amendment 7
Article13, paragraph 1

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation.	1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. ***The opinion shall be made public.***

Justification

Self-explanatory. The principle behind this amendment, which was not incorporated by the Council, can be found in the Commission's amended proposal, too.

Amendment 8
Article14, paragraph 1, subparagraph 2

In the case of authorisations not issued to a specific holder, ***any person*** who ***first places the additive on the market or any other interested party may submit*** the application to the ***Commission*** and shall be considered as the applicant.	In the case of authorisations not issued to a specific holder, ***each operator*** who ***imports or produces the products referred to in this Article will be responsible for submitting the information or*** the application to the ***Authority*** and shall be considered as the applicant**.**

Justification

Self-explanatory.

Amendment 9
Article14, paragraph 2, point (c)

(c) any other new information which has become available with regard to the evaluation of the safety in use ***and the efficacy*** of the feed additive and the risks of the feed additive to animals, humans or the environment;	(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;

Justification

The amendment was not taken into consideration by the Council, probably by mistake. The re-

evaluation should only relate to the safety aspects and the risks to humans, animals and the environment. The question of efficacy is for regulation by economic operators via the market.

Amendment10
Article15, paragraph 1, subparagraph 1 a (new)

Mixtures and premixtures containing flavourings and appetite stimulants shall be exempt from the labelling requirement for each additive. This shall not apply to flavourings and appetite stimulants subject to a quantitative limitation when used in feed and drinking water.

Justification

Unlike all other feed additives, the final formulations of flavourings are nearly always for use in the form of mixtures and premixtures. Open declarations of the flavourings contained in mixtures and premixtures would disclose corporate know-how which should be protected. For the industry concerned, this would entail crucial economic disadvantages.

Amendment11
Article 19, paragraph 2, subparagraph 1 a (new)

In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the Commission may, by special derogation, provisionally authorise the use of an additive for a maximum period of five years.

Justification

In cases where no appropriate additive is on the market, and in cases where an unacceptable situation arises for either public health or animal health and welfare (such as new diseases,

cases where the registered products required to deal with a crisis are not available for the species affected or cannot be imported from elsewhere), the Commission should be able to license a product for a limited period only, within the confines of strict post-marketing monitoring arrangements, as provided for in Article 11 of this Regulation.

Amendment12
Annexe I, paragraph 3, point (c)

(c) amino acids, their salts and analogues; ***deleted***

Justification

There is no discernible reason why amino acids should be covered by legislation on feed additives. A distinction should be made between these products and other food additives, as is occasionally the case, even if they are subject to a specific authorisation procedure pursuant to Directive 82/471/EEC concerning certain products used in animal nutrition.

Amendment13
Annexe III, point (e)

(e) Technological and sensory additives: – the active-substance level.	Technological and sensory additives: – the active-substance level***; this shall not apply to mixtures and premixtures containing flavouring and appetite stimulants, except those subject to a quantitative limitation when used in feed and drinking water***.

Justification

Unlike all other feed additives, the final formulations of flavourings are nearly always for use in the form of mixtures and premixtures. Open declarations of the flavourings contained in mixtures and premixtures would disclose corporate know-how which should be protected. For the industry concerned, this would entail crucial economic disadvantages.

Neither is there any provision in the flavouring directive for food (Council Directive

88/388/EEC of 22 June 1988, Article 9) for an open declaration except for substances which are subject to a quantitative limitation when used in food.

On 8 November 2002, the Commission presented a proposal for a new Parliament-Council regulation on flavourings used in or on food (DG Sanco Working Document WGF/002/02, 'Draft proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on flavourings and food ingredients with flavouring properties for use in and on food').

With regard to the declaration, the proposal for a regulation on food flavourings provides in future, too, for only a list of flavouring categories in descending order by weight which are present in a mixture (WGF/002/02-rev1, Article 13(1)(d)), with the exception of substances subject to a quantitative limitation when used in food (Article 13(1)(e)).