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***I
REPORT

on the proposal for a European Parliament and Council regulation on additives for use in animal nutrition
(COM(2002) 153 – C5-0143/2002 – 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.

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PROCEDURAL PAGE

By letter of 22 March 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Articles 37 and 152(4)(b) of the EC Treaty, 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 28 April 2002 the President of Parliament announced that he had referred this proposal to the Committee on Agriculture and Rural Development as the committee responsible and to the Committee on Budgets and the Committee on the Environment, Public Health and Consumer Policy for their opinions (C5-0143/2002).

The Committee on Agriculture and Rural Development appointed Hedwig Keppelhoff-Wiechert rapporteur at its meeting of 17 April 2002.

It considered the Commission proposal and the draft report at its meetings of 11 September 2002, 2 October 2002 and 5 November 2002.

At the last meeting it adopted the draft legislative resolution by 30 votes in favour, with 4 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, María del Pilar Ayuso González (for Encarnación Redondo Jiménez), Carlos Bautista Ojeda, Niels Busk, Arlindo Cunha, Christel Fiebiger, Francesco Fiori, Christos Folias, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, Willi Görlach, Liam Hyland, María Izquierdo Rojo, Elisabeth Jeggle, Salvador Jové Peres, Heinz Kindermann, Dimitrios Koulourianos, Wolfgang Kreissl-Dörfler (for Vincenzo Lavarra), Véronique Mathieu, Xaver Mayer, Karl Erik Olsson, Mikko Pesälä, Giacomo Santini (for Michl Ebner), Agnes Schierhuber, Dominique F.C. Souchet, Robert William Sturdy and Eurig Wyn (for Giorgio Celli).

The opinion of the Committee on the Environment, Public Health and Consumer Policy is attached; the Committee on Budgets decided on 17 April 2002 not to deliver an opinion.

The report was tabled on 7 November 2002.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council regulation on additives for use in animal nutrition (COM(2002) 153 – C5-0143/2002 – 2002/0073(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the proposal by the Commission to the European Parliament and the Council (COM(2002) 153)[1],

– having regard to Articles 251(2), 37 and 152(4)(b) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0143/2002),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on Agriculture and Rural and the opinion of the Committee on the Environment, Public Health and Consumer Policy (A5-0373/2002),

1. Approves the Commission proposal as amended;

2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;

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

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 3	
(3) In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community.	(3) In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. ***Since pet food is not part of the human food chain and has no environmental impact on arable land, specific provisions for additives in pet food are appropriate.***

[1] OJ C 203 E, 27.8.2002, p. 10.

Justification

Self-explanatory.

Amendment 2
Recital 4 a (new)

(4a) Conditions for imports from third countries of additives for use in animal nutrition must at least be 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, without prejudice to existing Community legislation on third-country imports of meat and animal products and provisions therein relating to animal welfare and food safety.

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 3
Recital 6 a (new)

(6a) This Regulation should also cover mixtures of nutritional additives sold to the end user and the marketing and use of those mixtures needs to respect the conditions laid down on the authorisation of each single additive.

Justification

For clarification.

Amendment 4
Recital 9 a (new)

(9a) The Commission should establish the guidelines for the authorisation of feed additives in cooperation with the EFSA. In establishing these guidelines, attention should be paid to the possibility to extrapolate the results of the studies carried out on major species to minor species.

Justification

In order to ensure the widest supply of animal products from different animal species, it is essential to enable minor species to benefit from the same technical progress as major species. One of the solutions which would make it possible to minimise the authorisation costs for minor species could be the extrapolation of certain results obtained on major species to minor species. Such an approach has been validated by the EMEA for the establishment of MRLs for certain medicinal substances.

Amendment 5
Recital 10 a (new)

(10a) The effort for obtaining an approval for an additive is, in certain cases, prohibitive for applicants to generate scientific data for "minor species". In order to assure the necessary level of protection for animal welfare and consumer safety, applicants are encouraged to submit approval extensions for minor species by granting one year additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised.

Justification

Self-explanatory.

Amendment 6
Recital 12

(12) It is necessary to introduce, where appropriate, an obligation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment.	(12) It is necessary to introduce, where appropriate, an obligation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment ***using a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law.***

Justification

Self-explanatory.

Amendment 7
Recital 13

(13) In order to allow technical and scientific progress to be taken into account it is necessary to ***revise*** regularly the authorisations of feed additives. ***Time limited authorisations will allow this review.***	(13) In order to allow technical and scientific progress to be taken into account it is necessary to ***update*** regularly the authorisations of feed additives. ***Results of post market monitoring reports are essential for the updating of authorisations.***

Justification

Self-explanatory.

Amendment 8
Recital 15

(15) It is necessary to establish rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids currently authorised under Directive 82/471/EEC, as well as for additives for which the authorisation procedure is in progress.	(15) It is necessary to establish rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids currently authorised under Directive 82/471/EEC, as well as for additives for which the authorisation procedure is in progress. ***It is also necessary to provide for a simplified authorisation procedure for those additives which have successfully undergone the authorisation procedure for food use provided for in Directive 1989/107/EEC.***

Justification

In line with the basic principle of consistency and interaction between the food and the feed legislations, a link should be established which would provide for a simplified authorisation procedure for those feed additives, which have successfully undergone the authorisation procedure for food use.

Amendment 9
Recital 16 a (new)

(16a) Beyond the ban on antibiotics as feed additives, it necessary to establish stronger rules on the prophylactic use of antibiotics as veterinary medicinal products.

Justification

The EP has called for a phasing-out of antibiotics as growth-promoting feed additives for several years. In order to prevent antibiotics from being prescribed prophylactically on a broad scale as veterinary medicines, the Commission should lay down stronger rules in the regulation on veterinary medical products ((EEC) No 2309/93) and the directive on medicated feed (90/167/EEC).

Amendment 10
Recital 16 b (new)

(16b) 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 11
Recital 17

(17) Certain substances with coccidiostatic effects should be considered as ***feed additives for the purpose of*** this Regulation.	(17) Certain substances with coccidiostatic ***and histomonal*** effects should be considered as ***veterinary medicines and therefore do not fall within the scope of*** this Regulation.

Justification

According to the Commission's explanatory memorandum, the aim of the proposed regulation is to clarify the dividing line between veterinary medicines and feed additives. Coccidiostats and histomonostats should not continue to be regarded as exceptions. The systematic use of coccidiostats and histomonostats as feed additives also involves the risk that hygiene problems on farms are not taken seriously as they can be concealed through the use of these products. The use of these substances should therefore be regulated by means of legislation on veterinary medicines.

Amendment 12
Article 1

Subject matter

1. The purpose of this Regulation is to establish a Community procedure for authorisation and supervision of feed additives and to lay down rules to ensure labelling of feed additives in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.	1. The purpose of this Regulation is to establish a Community procedure for authorisation and supervision of feed additives ***and premixtures*** and to lay down rules to ensure labelling of feed additives ***and premixtures*** in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market.

Justification

It should be made clear that the regulation applies not only to feed additives but also to premixtures.

Amendment 13
Article 2, paragraph 1

1. This Regulation shall apply to chemically *defined* substances or micro-organisms not normally used as feed materials which are intentionally added to feedingstuffs or drinking water, hereinafter referred to as "feed additives".	1. This Regulation shall apply to chemically *defined* ***or described*** substances or micro-organisms not normally used as feed materials which are intentionally added to feedingstuffs or drinking water, hereinafter referred to as "feed additives".

Justification

This enables a clearer distinction to be made between feed materials and feed additives but, unlike the Commission's text, includes substances derived from materials of animal or vegetable origin.

Amendment 14
Article 2, paragraph 2, subparagraph (a)

Does not affect English version.

Justification

Amendment 15
Article 3, paragraphs (a), (b) and (d)

Definitions

The following definitions shall also apply:	The following definitions shall also apply:
(a) 'feed materials' means ***products as defined in Article 2(a) of Council Directive 96/25/EC[1] ;***	(a) 'feed materials' means ***various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;***
(b) 'complementary feedingstuffs' means ***products as defined in Article 2(e) of***	(b) 'complementary feedingstuffs' means ***mixtures of feedingstuffs which have a***

[1] OJ L 125, 13.5.1996, p. 35; Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

Directive 79/373/EEC;	***high content of certain substances but which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs;***
(d) 'compound feedingstuffs' means ***products as defined in Article 2 (b) of Directive 79/373/EEC ;***	(d) 'compound feedingstuffs' means ***organic or inorganic substances in mixtures, whether or not containing additives, for oral animal feeding in the form of complete feedingstuffs or complementary feedingstuffs;***

Justification

In addition to the definitions used in the basic regulation, No 178/2002, the fundamental terms of the regulation should be defined in the text of the regulation itself for clarification. For paragraphs (b) and (d) the changes are editorial. Paragraph (a) must be amended as the definition of 'feed materials' in Directive 96/25/EEC itself contains the term additive and would therefore render the definition of 'additives' in this regulation a circular one.

Amendment 16
Article 3, paragraph 2, subparagraph (f)

(f) 'processing aids' means any substances not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing ***and which do not remain in the final product***;	(f) 'processing aids' means any substances not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing ***which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished feed;***

Justification

The definition of processing aids in feed should be similar to the one used in food, for consistency reasons and legal certainty.

Amendment 17
Article 3, paragraph 2, subparagraph (j) a (new)

	(ja) 'Coccidiostats and histomonostats'

means substances with a coccidiostatic or histomonal effect.

Justification

The definition of coccidiostats should come under this article and not Article 6.

Amendment 18
Article 4, paragraph 1, second paragraph (new)

For experiments for scientific purposes, Member States may authorise the use, as additives, of substances which are not authorised at Community level, with the exception of antibiotics, provided the experiments are carried out in accordance with the principles and conditions laid down in Directive 87/153/EEC, Directive 83/228/EEC or the guidelines in Article 8(4) and provided that there is adequate official supervision. The animals concerned may only be used for food production if the authorities establish that no health risk exists.

Justification

The regulation should not be used to prevent scientific research into additives. An exemption is therefore necessary.

Amendment 19
Article 4, paragraph 2 a (new)

2a. Unless otherwise specified, the mixing of nutritional additives to be sold directly to the end user will be allowed, when respecting the use for use laid down in the authorisation for each single additive. Consequently, the mixing of authorised additives should not be subject to specific authorisations other than the requirements provided under Directive 95/69/EEC.

Justification

The fact that mixing of authorised additives will not be subject to any specific authorisation is clearly stated in the explanatory memorandum. The point is however important enough to be clearly stated in an Article in the Regulation.

Amendment 20
Article 6, paragraph 1

1. No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that, when used in accordance with conditions to be set out in the Regulation authorising the use of the additive, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3.	1. No feed additive shall be authorised unless the applicant for such authorisation has demonstrated, ***according to guidelines defined in Article 8(4), adapted to each additive category,*** that when used in accordance with conditions to be set out in the Regulation authorising the use of the additive, it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3.

Justification

To ensure that no availability crisis emerges for additives and to prevent unnecessary paperwork, guidelines should be defined which enable thorough analysis by the Food Safety Authority, but that limit the dossier costs for relatively "harmless" additives.

Amendment 21
Article 6, paragraph 2

2. The feed additive must not:	2. The feed additive must not:
(a) present a risk to animal health, human health or the environment,	(a) present a risk to animal health, human health or the environment,
(b) ***mislead the user,***	(b) ***be presented in a manner which may mislead the user,***
(c) harm the consumer by impairing the distinctive features of animal products.	(c) harm the consumer by impairing the distinctive features of animal products ***or mislead the consumer in regard to the distinctive features of animal products.***

Justification

Self-explanatory.

Amendment 22
Article 6, paragraphs 4 and 5
Conditions for authorisation

4. Antibiotics shall not be authorised as feed additives.	4. Antibiotics shall not be authorised as feed additives. ***This does not apply to coccidiostats and histomonostats presented for continuous use mixed in feed or drinking water.***
5. By derogation of paragraph 4 certain substances with a coccidiostatic effect and presented for continuous use mixed in feed or drinking water, referred to hereafter as coccidiostats, are considered as feed additives for the purpose of this Regulation.	***5. Deleted***

Justification

Coccidiostats and histomonostats which are also antibiotics should continue to be authorised as feed additives at least temporarily. Coccidiosis in chickens and blackhead in turkeys are practically unavoidable in poultry farming, particularly intensive farming. The use of coccidiostats in poultry breeding is therefore still essential to prevent a higher death rate. When used as a feed additive, an appropriate dosage of coccidiostats is authorised. If the use of coccidiostats as feed additives is prohibited, coccidiostats would possibly appear in feed as a form of preventive medicine via veterinary prescriptions, combined with higher costs and possibly in higher doses. However, less intensive use of coccidiostats cannot be expected as a result of their being subject to prescription. Nevertheless, the status of coccidiostats as feed additives requires a reassessment of these substances within a maximum of five years following the entry into force of this regulation. The amendment seeks to include histomonostats and is otherwise of an editorial nature.

Amendment 23
Article 7, paragraph 1, point (a)

Does not affect English version.

Justification

Amendment 24
Article 7, paragraph 1, point (e)

(e) coccidiostats	(e) coccidiostats ***and histomonostats***

Justification

For the sake of clarity, products related to coccidiostats (e.g. anti-histomoniasis products) should be mentioned.

Amendment 25
Article 8, paragraph 3, point (b)
Application for authorisation

3. The application shall be accompanied by the following particulars and documents:	3. The application shall be accompanied by the following particulars and documents:
(b) the designation of the feed additive, including a proposal for its classification by category and functional group under Article 7, and its specifications, including purity criteria;	(b) the designation of the feed additive, including a proposal for its classification by category and functional group under Article 7, and its specifications, including purity criteria***, where appropriate***;

Justification

Additives for pet food require different purity standards from food additives. Directive 1999/29/EC on undesirable substances and products in animal nutrition lays down maximum contents of contaminants in end products, which effectively precludes the use of contaminated additives.

Amendment 26
Article 8, paragraph 4

	4. ***After consultation of the Authority, specific guidelines for the authorisation of additives shall be established for each category of additive referred to in Article 7(1) in accordance with the procedure laid down in Article 21(2). These guidelines shall take account of the possibility of extrapolating the results of the studies carried out on target species to minor species.***
After consultation of the Authority, rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 21(2).	After consultation of the Authority, ***further*** rules for the implementation of this Article may be established in accordance with the procedure referred to in Article 21(2). ***These implementing rules should, where appropriate, differentiate between standards for feed additives in respect of animals for production and standards in***

	respect of other animals, in particular pets. The implementing rules shall include provisions which allow for simplified procedures for the authorisation of additives which have been authorised for use in food.
Until the adoption of these implementing rules the application shall be made in accordance with the Annex of Directive 87/153/EEC.	Until the adoption of these implementing rules the application shall be made in accordance with the Annex of Directive 87/153/EEC.

Justification

Specific guidelines should be drawn up in cooperation with the European Food Safety Authority for each category of additive and each additive must be evaluated on the basis of those guidelines. The guidelines should state the information to be submitted and the criteria to be used for evaluating the additives. To obtain the broadest possible spectrum of animal products from different species, minor species (non-target species) must also be able to benefit from the development of new feed additives. In order to ensure the availability of new additives for these species, it is therefore appropriate to provide for the possibility of extrapolating certain results for major species to minor species. A comparable approach has already been used by the European Agency for the Evaluation of Medicinal Products to establish maximum residue limits for medicinal substances.

Since pets are not normally for human consumption, all rules on feed additives designed to protect human health should be applicable to pet food only to a restricted extent or not at all.

A simplified procedure for additives which have been authorised for use in food should be established. Furthermore rules for extrapolating results to other species should be specified.

Amendment 27
Article 8, paragraph 5

5. The ***Authority*** shall ***publish*** detailed ***guidance*** concerning the preparation, presentation, and validation of the applications***, not later than one year after the entry into force of this Regulation***.	5. The ***implementing rules*** shall ***contain*** detailed ***guidelines*** concerning the ***proportionate and appropriate*** preparation, presentation, and validation of the applications.

Justification

To ensure no availability crisis emerges for additives and to prevent unnecessary paperwork, guidelines should be defined which enable thorough analysis by the Food Safety Authority, but that limit the dossier costs for relatively "harmless" additives. Hence the addition of the words "appropriate and proportionate". When application requirements lead to considerable costs this might hamper submission of applications for many additives. On the other hand certain categories of additives require very thorough analysis reminiscent of medicinal products.

Amendment 28
Article 9, paragraph 2

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that the information has been provided. Likewise, the applicant may at the request of the Authority, or on his own initiative prepare oral or written explanations within a specified time limit.	2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority***, after agreement with the applicant***. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that the information has been provided. Likewise, the applicant may at the request of the Authority, or on his own initiative prepare oral or written explanations within a specified time limit.

Justification

It is very important that the applicant is involved in all decisions concerning his application and specifically concerning the time frame of the risk assessment and the provision of new information.

Amendment 29
Article 9, paragraph 3, subparagraph (d)

(d) shall make the summary of the dossier mentioned in Article 8(3) (h) available to the public.	(d) shall make the summary of the dossier mentioned in Article 8(3) (h) available to the public ***in accordance with the confidentiality precautions laid down in Article 18(2)***.

Justification

The applicant / marketing authorisation holder should be involved in the decisions regarding what is confidential information since they developed the data.

Amendment 30
Article 9, paragraph 4, subparagraph (b)
Opinion of the Authority

4. In the event of an opinion in favour of authorising the feed additive, the opinion shall also include the following elements:	4. In the event of an opinion in favour of authorising the feed additive, the opinion shall also include the following elements:
b) the designation of the feed additive including its categorisation and allocation within functional groups provided for in Article 7, its specification, including purity criteria and method of analysis;	b) the designation of the feed additive including its categorisation and allocation within functional groups provided for in Article 7, its specification, including purity criteria***, where appropriate,*** and method of analysis;

Justification

Additives for pet food require other purity standards than food additives. Directive 1999/29/EC on the undesirable substances and products in animal nutrition lays down maximum contents of contaminants in end products, which effectively excludes contaminated additives.

Amendment 31
Article 11, paragraph 2

2. An application shall be submitted in accordance with Article 8, at the latest one year before the expiry date of the authorisation given pursuant with 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. For the substances belonging to the category of coccidiostats, an application shall be submitted within a maximum of four years after the entry into force of this Regulation.*** A detailed calendar listing the priority order for the re-evaluation of the different classes of additives may be adopted in accordance with the procedure referred to in Article 21 (2).	2. An application shall be submitted in accordance with Article 8, at the latest one year before the expiry date of the authorisation given pursuant with Directive 70/524/EEC for additives with a limited authorisation period. A detailed calendar listing the priority order for the re-evaluation of the different classes of additives may be adopted in accordance with the procedure referred to in Article 21 (2).

For the substances belonging to the category of coccidiostats and histomonostats, an application shall be submitted within a maximum of four years after the entry into force of this Regulation. Before 1 January 2008, the Commission shall submit a report on the use of these substances as feed additives.

For additives authorised without a time limit 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

Coccidiostats and histomonostats which are also antibiotics should continue to be authorised as feed additives. The use of coccidiostats and histomonostats is still essential in modern poultry and turkey farming to prevent a higher death rate If the use of coccidiostats as feed additives is prohibited, coccidiostats would possibly appear in feed as a form of preventive medicine via veterinary prescriptions at a higher costs, possibly at higher doses and with further administrative constraints. Furthermore, feed companies have developed from in-situ experience procedures to ensure a rotation in the use of molecules in order to avoid the development of resistances by the targeted parasites. If these substances should require prescription by veterinarians, such a control would no longer be possible. Alternative products may replace coccidiostats from antibiotic origin but their development still requires a long time. The report provided for in the above amendment aims at clarifying the situation as regards the user of coccidiostats and histomonostats, to update on alternative products and to assess the economic impact of a withdrawal of coccidiostats on the poultry chain as well as the impact on animal welfare and health.

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 8. 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 32
Article 11, paragraph 4

4. In case of authorisations not issued to a specific holder, any person who imports or manufactures the products referred to in this Article shall submit the information or the application to the Authority.	4. In case of authorisations not issued to a specific holder, any person who imports or manufactures the products referred to in this Article shall submit the information ***that is to accompany notification pursuant to paragraph 1*** or the application ***referred to in paragraph 2*** to the Authority.

Justification

To clarify the procedure.

Amendment 33
Article 11, paragraph 5 a (new)

	5a. The preceding paragraphs (1-5) shall also apply to:
	(a) chemically defined substances, enzymes and micro-organisms used as silage agents; and
	(b) chemically defined substances used in animal nutrition, other than in feedingstuffs.
	For these substances, the deadline for application as referred to in paragraph 2 shall be seven years after the entry into force of this Regulation.

Justification

Silage agents, which are additives used in the ensilage process of grass or forage, would come within the scope of the controls for the first time. The effect of the Commission's proposal would mean that detailed assessments would have to be carried out on these products by the time the Regulation comes into force - possibly in two years' time. Otherwise, they would become illegal. This period is too short for manufacturers to carry out trials, especially as the EFSA will need to draw up guidelines for such trials.

Similarly, additives administered orally to animals other than in feedingstuffs will need a transitional period.

Amendment 34
Article 11, paragraph 5 b (new)

	5b. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. The Commission shall inform the applicant of this extension of the authorisation.

Justification

It should be stated that where no decision is taken before the expiry date and for reasons beyond the control of the applicant, the period of authorisation of the product is extended.

Amendment 35
Article 12
Phasing out

By derogation from Article 5 and Article 11, the placing on the market and use as antibiotic growth promoters ***of the following substances mentioned in Annex B under A of Chapters I and II of Directive 70/524/EEC: sodium monensin, sodium-salinomycin, flavophospholipol and avilamycin, shall be prohibited from 1 January 2006 and, from that date, those substances shall be deleted from the Register***.	***1.*** By derogation from Article 5 and Article 11 ***and without prejudice to Article 14***, the placing on the market and use ***of*** antibiotic growth promoters shall be prohibited from 1 January ***2005. Antibiotic growth promoters still authorised on the date that this regulation enters into force shall be deleted from the Register from that date***. ***2. Coccidiostats and histomonostats may, however, be used as feed additives until 31 December 2008. Before 1 January 2008, the Commission shall submit a report on the use of these substances as feed additives, where appropriate together with a legal proposal concerning further use. 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.***

Justification

For legal reasons, there should be no reference to antibiotic growth promoters which are currently still authorised.

The ban should apply from 2005 since the scientific steering committee had already called for a

ban in 1999 on antibiotics as growth promoters as soon as possible. The transitional period to 2005 allows sufficient time for such antibiotics to be replaced by alternative products.

The aim of preventing the development of resistance, which is an aspect of the ban on antibiotic growth promoters, would be undermined by authorising the same antibiotics as coccidiostats to some extent even if they were used as a preventive medical measure, as opposed to the use of growth promoters. Antibiotic coccidiostats should therefore be replaced as far as possible by vaccination or other appropriate substances. However, this requires a longer period of time. This amendment requires Parliament to be involved in any future decision-making on this matter.

Amendment 36
Article 14, paragraph 1

1. ***Where,*** on its own initiative or following a request from a Member State or from the Commission, ***the Authority concludes that an authorisation granted in accordance with this Regulation should be modified, suspended or revoked, it shall forthwith transmit this opinion to the Commission.***	1. ***The Authority shall,*** on its own initiative or following a request from a Member State or the Commission, ***deliver an opinion on compliance with the conditions laid down in this Regulation.*** ***It shall forward this opinion to the Commission, the authorisation holder and the Member States. The opinion shall be made public.***

Justification

Self-explanatory.

Amendment 37
Article 15, paragraph 1

1. Authorisations under this Regulation shall be ***renewable for ten-year periods***, on application to the Authority by the applicant at the latest ***one year before the expiry date of the authorisation***.	1. Authorisations under this Regulation shall be ***subject to re-evaluation at least every ten years***, on application to the Authority by the applicant at the latest ***nine years after the first authorisation or last evaluation***.
In case of authorisations not issued to a specific holder, ***any person*** who imports or produces the products referred to in this Article ***may submit*** the information or the application to the Authority and shall be considered as the applicant.	In 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.
The Authority shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The	The Authority shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The

acknowledgement shall state the date of receipt of the application.	acknowledgement shall state the date of receipt of the application.

Justification

The procedure proposed by the Commission, limiting authorisation to ten years, is replaced by a procedure under which a re-evaluation is carried out every ten years.

Amendment 38
Article 15, paragraph 2, subparagraph (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 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.

Amendment 39
Article 15, paragraph 5

5. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. The Commission shall inform the applicant of this extension of the authorisation.	***Delete***

Justification

This provision is no longer needed if the re-evaluation system is used instead of authorisation limited to ten years. In this case, the authorisation is retained in any case.

Amendment 40
Article 15, paragraph 7

7. The Authority shall publish detailed ***guidance*** concerning the preparation and the presentation of the application.	7. The Authority shall***, no later than one year after the entry into force of this Regulation,*** publish detailed ***guidelines adapted to each additive category provided for in Article 7(1)*** concerning the preparation and the presentation of the application. ***These guidelines shall take account of specific circumstances relating to the authorisation of additives for 'minor species'.***

Justification

Each additive should be assessed on the basis of guidelines specifically relating to its use in animal feed. These guidelines, which should be drawn up at the earliest opportunity, will contain the information required in order to authorise a feed additive. They can also be adjusted to take account of new technical and scientific knowledge.

Without prejudice to their quality, safety and efficacy, provision should be made for the authorisation of additives for 'minor species' in compliance with requirements specially tailored to the specific circumstances of such species. Unless this is done, gaps in the law would exist to the detriment of the health and welfare of such animals. This would be the case for species such as goats, rabbits, game birds (partridges, quail, pheasants) and farmed fish.

Amendment 41
Article 16, paragraph 1, subparagraph (b)

No person shall place on the market a feed additive, a mixture of feed additives or a premixture of additives, unless its packaging or container bears the following information, in a conspicuous, clearly legible and indelible manner, in relation to each additive contained in the material:	No person shall place on the market a feed additive, a mixture of feed additives or a premixture of additives, unless its packaging or container bears the following information, in a conspicuous, clearly legible and indelible manner, in relation to each additive contained in the material:
(a) the specific name given to the additives upon authorisation preceded, by the name of the functional group as mentioned in the authorisation ;	(a) the specific name given to the additives upon authorisation preceded, by the name of the functional group as mentioned in the authorisation;
(b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;	(b) the name or business name and the address or registered place of business ***in the European Community*** of the person responsible for the particulars referred to in this paragraph;

Justification

The person or business responsible for the particulars should be resident or have their registered place of business in the EC if these provisions are to be effectively used when the occasion arises.

Amendment 42
Article 16, paragraph 1, subparagraph (e) b (new)

(eb) Mixtures and premixtures containing flavouring and appetite stimulants shall be exempt from the labelling requirement for each additive. This shall not apply to flavouring 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 flavouring 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.

Furthermore, Regulation (EC) No. 2232/96 (Article 3, paragraph 2c) and Commission recommendation 98/282/EC of 21 April refer to the specific protection of the flavouring manufacturer's intellectual property rights.

This provision should also apply to flavouring for use in feed provided the flavouring is in mixtures or premixtures since, in these cases, it is usually a question of complicated recipes in which numerous individual substances are mixed together in quite specific proportions to obtain the flavouring profile of such products as full-cream milk or strawberries. This work is extremely time-consuming and requires a great deal of expertise and experience. Open declarations would bring these company secrets into the public domain. Once the recipes were not subject to any form of protection, they could be copied by anyone.

Amendment 43
Article 16, paragraph 1, subparagraph (e) a (new)

(ea) the batch reference number and the date of manufacture.

Justification

Details of the batch reference number and the date of manufacture must be made compulsory for

all additives in order to ensure product traceability.

Amendment 44
Article 19

Data Protection	*Data Protection*
The scientific data and other information in the application dossier required under Article 8 may not be used for the benefit of another applicant for a period of ten years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used. On expiry of the ten-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant.	The scientific data and other information in the application dossier required under Article 8 may not be used for the benefit of another applicant for a period of ten years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used. On expiry of the ten-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant. ***In order to stimulate efforts to obtain approvals for new species for additives whose use is authorised for other species, the 10 year data protection period shall be extended by one year for each new species for which a use extension authorisation is granted.*** ***In specific cases where urgent approval 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 5 years, with the possible extension of authorisation subject to a satisfactory outcome of the post-approval monitoring programme.***

Justification

For 'minor species' (other than broiler chickens, pigs and bovines), the investment required to research and develop products is not commercially justified. With a view to promoting the development of products in this area and ensuring the health of such species, incentives must be given for research, in the form of longer protection periods for the data obtained.

Furthermore, 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 Recital 12 and Article 11(2) of this Regulation.

Amendment 45
Annex I, paragraph 1, points (i) and (j) (new)

(i) binders: ….

(j) coagulants: ….

Justification

Need to cover all recognised categories of technological additives in Annex L to the current legislation.

Amendment 46
Annex I, paragraph 3, point (c)

(c) amino acids	***Delete***

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.

Amendment 47
Annex I, paragraph 4 (c) a (new)

(ca) substances which have a positive effect on the environmental impact of animal production.

Justification

While Articles 6 and 7 mention the positive effects of additives on the environment, the annex does not. In view of the possible relevance of such substances to the quality and environmental impact of fertiliser, they should be clearly referred to in the annex.

Amendment 48
Annex III, paragraph (e)

(e) Technological and sensory additives: the active-substance level.	(e) Technological and sensory additives: the active-substance level. ***This shall not apply to flavouring 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 flavouring 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.

Furthermore, Regulation (EC) No. 2232/96 (Article 3, paragraph 2(c)) and Commission recommendation 98/282/EC of 21 April refer to the specific protection of the flavouring manufacturer's intellectual property rights.

This provision should also apply to flavouring for use in feed provided the flavouring is in mixtures or premixtures since, in these cases, it is usually a question of complicated recipes in which numerous individual substances are mixed together in quite specific proportions to obtain the flavouring profile of such products as full-cream milk or strawberries. This work is extremely time-consuming and requires a great deal of expertise and experience. Open declarations would bring these company secrets into the public domain. Once the recipes were not subject to any form of protection, they could be copied by anyone.

EXPLANATORY STATEMENT

This proposal aims to consolidate existing rules on additives in feedingstuffs and clarifies certain procedural aspects related to dossier evaluation and the types of authorisation granted to feed additives.

So far, the basic legislation (Council Directive 70/524/EEC) has undergone five major amendments and numerous minor modifications of the annexes (over 100). The Directive has never been consolidated.

The current legislation is very complex. The existence of different types of authorisation (provisional, for ten years or with no time limit, linked to the applicant company or not) complicates the implementation of EC rules on this matter.

The Commission proposes the following changes and improvements in relation to the current situation:

- a ban from 2006 on the four antibiotic growth promoters still authorised;
- new authorisations for feed additives to be issued for a period of ten years only;
- reassessment of feed additives authorised under current law within the next seven years;
- obligation on companies to prove the efficacy of the product and their harmlessness to human and animal health and the environment;
- assessment of applications for authorisation for additives by the European Food Safety Authority;
- maximum residue values for some feed additives and monitoring of compliance after placing on the market;
- a clear, transparent authorisation procedure;
- stricter conditions for coccidiostats derived from antibiotics; the applicants to submit a new dossier for reassessment within four years.

An aspect of fundamental political significance in this proposal is the ban from 2006 of the four antibiotic growth promoters still authorised. This ban may be based on the relevant reports of the Scientific Food Committee and is consistent with medical opinion in general.

The rapporteur is, in principle, in favour of the Commission's proposal but considers some amendments to be essential or expedient. Particularly in regard to the problems associated with antibiotics, it is not appropriate to give the go-ahead for unrestricted use of coccidiostats in the future. It is not plausible to ban antibiotics on health policy grounds while ignoring the use of antibiotics as coccidiostats on economic grounds. In this regard, pressure must be brought to bear by granting temporary authorisation only so that other methods, such as appropriate vaccines, are developed.

9 October 2002

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND CONSUMER POLICY

for the Committee on Agriculture and Rural Development

on the proposal for a Council regulation on additives for use in animal nutrition
(COM(2002) 153 – C5-0143/2002 – 2002/0073(COD))

Draftsman: Marialiese Flemming

PROCEDURE

The Committee on the Environment, Public Health and Consumer Policy appointed Marialiese Flemming draftsman at its meeting of 23 April 2002.

It considered the draft opinion at its meetings of 10 September 2002 and 8 October 2002.

At the latter meeting it adopted the following amendments by 25 votes to 7.

The following were present for the vote: Mauro Nobilia, chairman; Per-Arne Arvidsson, María del Pilar Ayuso González, Hans Blokland, David Robert Bowe, Alexander de Roo, Anne Ferreira, Cristina García-Orcoyen Tormo, Laura González Álvarez, Jutta D. Haug (for Dorette Corbey), Heidi Anneli Hautala (for Hiltrud Breyer), Anneli Hulthén, Marie Anne Isler Béguin, Hedwig Keppelhoff-Wiechert (for Marialiese Flemming), Bernd Lange, Paul A.A.J.G. Lannoye (for Patricia McKenna), Giorgio Lisi (for John Bowis), Minerva Melpomeni Malliori, Rosemarie Müller, Mihail Papayannakis, Encarnación Redondo Jiménez (for Martin Callanan), María Rodríguez Ramos (for Torben Lund), Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Catherine Stihler, Astrid Thors and Phillip Whitehead.

SHORT JUSTIFICATION

On 22 March 2002, the Commission adopted a proposal for a regulation amending the procedure for the authorisation of additives. As well as prohibiting the four remaining antibiotic performance enhancers from the beginning of 2006, the proposal provides for a fundamentally new procedure for the authorisation of all feed additives. The European Food Safety Authority will have a key role to play in this, as it will be responsible for assessing the dossiers (applications for authorisation). The authorisation of an additive, valid for a maximum of 10 years, is issued pursuant to the Commission regulation. Under the proposal, compounds used in disease prevention, namely antibiotics, are not authorised as feed additives, though coccidiostats are an exception. As recommended by the Scientific Steering Committee, an adequate transitional period is laid down for the phasing-out of the four remaining antibiotics, to allow animal production practices to be adapted and the antimicrobials to be replaced by alternative products. These substances are to be prohibited with effect from 1 January 2006.

The Council, under the Spanish Presidency, initially considered the proposal on 16 May 2002 and continued on 4 June. Further Council working parties are planned under the Danish Presidency. The proposal was submitted to the Agriculture Council on 22 April 2002. Further consideration at Coreper and Council level is scheduled for November 2002. In the European Parliament, the Agriculture Committee is the committee responsible.

Under the Spanish Presidency, the proposal was considered in terms of the following subjects:

1. Authorisation procedures
2. Status of existing products
3. Phasing-out of antibiotics
4. Classification of additives

1. Authorisation procedures

Discussion here centred in particular on the participation of Member States. Almost all Member States have in principle come out in favour of assessment of authorisation applications by the European Food Safety Authority. Some Member States, however, wish to see national administrative or scientific bodies involved in the assessment of applications.

2. Status of existing products

The Commission proposal provides for re-evaluation of all authorised additives, including those which have been authorised for an indefinite period. As the number of manufacturers and marketers of additives is very high, the need for such re-evaluation was questioned. The practicalities of re-evaluation and, in particular, the issue of which businesses would have to bear the cost of re-evaluation, were addressed.

3. Phasing-out of antibiotics

Most Member States want to see antibiotic performance enhancers banned from 2006.

The Commission pointed out that, at best, the regulation would enter into force at the beginning of 2004, but that entry into force at the beginning of 2005 was likely.

From a legal point of view, the Council's Legal Service recommended imposing a ban without naming the specific substances. This would be more advisable in view of possible legal action in the European Court of Justice.

4. Classification of additives

The Commission undertook to revise the categories because they are not entirely compatible with the current system (e.g. binding agents).

Some Member States wanted a definition of the term 'additive'. The Commission rejected this because the dividing line between medicinal product and additive is blurred. A definition should therefore only be available via the positive list, i.e. the list of authorised additives.

Coccidiostats:

The Commission pointed out that, compared with legislation on veterinary medicinal products, EC legislation on feed displayed greater harmonisation, as there was an EC positive list and an EC authorisation procedure. According to reports by the FVO in Dublin, there are major shortcomings as regards the application of veterinary medicinal product legislation. For that reason, coccidiostats should initially continue to be authorised in feed legislation. A new feature, however, is that maximum residue limits are laid down for all coccidiostats. Alignment with legislation on medicinal products is thus taking place in practice and will also be taken into consideration in the legal context in a few years.

AMENDMENTS

The Committee on the Environment, Public Health and Consumer Policy calls on the Committee on Agriculture and Rural Development, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Recital 12	
(12) It is necessary to introduce, where appropriate, an obligation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment.	(12) It is necessary to introduce, where appropriate, an obligation to implement a post-market monitoring plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment ***using a similar product tracing***

[1] OJ C 203, 27.8.2002, p. 10.

framework that already exists in other sectors.

Justification

An effective in-use monitoring and surveillance scheme will allow the withdrawal of a product immediately if and when necessary. This is more effective in protecting public health and animal health than requiring all products to undergo a periodic renewal. Such schemes already exist in other sectors – for example, in the veterinary pharmaceutical field. These could either serve as a blueprint or the same mechanisms could be used to ensure that human health and animal health are protected.

Amendment 2
Recital 16 a (new)

(16a) Beyond the ban on antibiotics as feed additives, it necessary to establish stronger rules on the prophylactic use of antibiotics as veterinary medicinal products.

Justification

The EP has called for a phasing-out of antibiotics as growth-promoting feed additives for several years. In order to avoid that antibiotics will be prescribed prophylactically on a broad scale as veterinary medicines, the Commission should lay down stronger rules in the regulation on veterinary medical products ((EEC) No 2309/93) and the directive on medicated feed (90/167/EEC).

Amendment 3
Recital 17

(17) ***Certain*** substances with coccidiostatic effects should be considered as ***feed additives for the purpose of this Regulation.***	(17) Substances with coccidiostatic effects should be considered as ***veterinary medicinal products.***

Justification

Coccidiostats are widely used in intensive poultry husbandry. The Commission wants to keep coccidiostats authorised as feed additives, as their use 'is, according to operators, indispensable'. But even in intensive farming systems, veterinary medical substances should be treated as such by legislation and their use should be subject to a veterinarian's control.

Amendment 4
Recital 28 a (new)

(28a) The effort for obtaining an approval for an additive is, in certain cases, prohibitive for applicants to generate scientific data for "minor species". In order to assure the necessary level of protection for animal welfare and consumer safety, applicants are encouraged to submit approval extensions for minor species by granting one year's additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised.

Justification

Any research that leads to a marketing authorisation is subject to a form of 'data protection' that enables companies to invest in developing the research. This additional year's data protection is already envisaged in other areas to promote medicines availability for so-called 'minor species', in particular the pharmaceutical legislation currently under review, which also provides for other mechanisms to encourage development for 'minor species' or 'minor indications.'.

Amendment 5
Article 6, paragraph 5

5. By derogation of paragraph 4 certain substances with a coccidiostatic effect and presented for continuous use mixed in feed or drinking water, referred to hereafter as coccidiostats, are considered as feed additives for the purpose of this Regulation.	***deleted***

Justification

Coccidiostats are widely used in intensive poultry husbandry. The Commission wants to keep coccidiostats authorised as feed additives, as their use 'is, according to operators, indispensable'. But even in intensive farming systems, veterinary medical substances should be treated as such by legislation and their use should be subject to a veterinarian's control.

Amendment 6
Article 7, paragraph 1, point (e)

(e) coccidiostats.	***deleted***

Justification

Coccidiostats are widely used in intensive poultry husbandry. The Commission wants to keep coccidiostats authorised as feed additives, as their use 'is, according to operators, indispensable'. But even in intensive farming systems, veterinary medical substances should be treated as such by legislation and their use should be subject to a veterinarian's control.

Amendment 7
Article 8, paragraph 1

1. An application for an authorisation as provided for in Article 5 shall be submitted to ***the European Food Safety Authority, hereinafter referred to as "the Authority"***.	1. An application for an authorisation as provided for in Article 5 shall be submitted to ***the Commission.***

Justification

Risk evaluation and risk management must be clearly separated between the Authority and the Commission.

Amendment 8
Article 8, paragraph 2

2. ***The Authority*** shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.	2. ***The Commission*** shall acknowledge receipt of the application, in writing, to the applicant within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application.

Justification

Cf. Am. 7 (to Article 8, paragraph 1).

Amendment 9

Article 11, paragraph 1, point (a)

(a) within one year of the entry into force of this Regulation, each person who places the feed additive on the market shall notify this fact to the ***Authority***. This notification shall be accompanied by the particulars mentioned in Article 8(3)(a) to (c);	(a) within one year of the entry into force of this Regulation, each person who places the feed additive on the market shall notify this fact to the ***Commission***. This notification shall be accompanied by the particulars mentioned in Article 8(3)(a) to (c) ***and shall be forwarded to the Authority and the Member States;***

Justification

Cf. Am. 7 (to Article 8, paragraph 1).

Amendment 10
Article 11, paragraph 5 a (new)

	5a. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. The Commission shall inform the applicant of this extension of the authorisation.

Justification

It should be stated that the period of authorisation of the product is extended if, for reasons beyond the applicant's control, no decision has been taken before the authorisation expires.

Amendment 11
Article 12

By derogation from Article 5 and Article 11, the placing on the market and use as antibiotic growth promoters of the following substances mentioned in Annex B under A of Chapters I and II of Directive 70/524/EEC: sodium monensin, sodium-salinomycin, flavophospholipol and avilamycin, shall be prohibited from ***1 January 2006*** and, from that date, those substances shall be deleted from the Register.	By derogation from Article 5 and Article 11, the placing on the market and use as antibiotic growth promoters of the following substances mentioned in Annex B under A of Chapters I and II of Directive 70/524/EEC: sodium monensin, sodium-salinomycin, flavophospholipol and avilamycin, shall be prohibited from ***1 January 2004*** and, from that date, those substances shall be deleted from the Register.

Justification

The EP has called for a phasing-out of antibiotics as growth-promoting feed additives for several years. As there is a certain risk of new resistances to antibiotics, the deadline for prohibition of the remaining four substances should not be set later than 1 January 2004.

Amendment 12
Article 13, paragraph 1

1. After an additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a feedingstuff into which it has been incorporated shall ensure that any conditions or restrictions which have been imposed on the placing on the market, use and handling of the additive or feedingstuffs containing it, are respected. Where monitoring requirements, as referred to in Article 9(4)(c) have been imposed, the authorisation holder shall ensure that it is carried out and shall submit reports to the ***Authority*** in accordance with the authorisation.	1. After an additive has been authorised in accordance with this Regulation, any person using or placing on the market that substance, or a feedingstuff into which it has been incorporated shall ensure that any conditions or restrictions which have been imposed on the placing on the market, use and handling of the additive or feedingstuffs containing it, are respected. Where monitoring requirements, as referred to in Article 9(4)(c) have been imposed, the authorisation holder shall ensure that it is carried out and shall submit reports to the ***Commission*** in accordance with the authorisation.

Justification

Cf. Am. 7 (to Article 8, paragraph 1).

Amendment 13
Article 13, paragraph 2

2. The authorisation holder shall forthwith communicate to the ***Authority*** any new information that might influence the evaluation of the safety in use of the feed additive, in particular health sensitivities of specific categories of consumers. The authorisation holder shall forthwith inform the ***Authority*** of any prohibition or restriction imposed by the competent authority of any third country in which the feed additive is placed on the market.	2. The authorisation holder shall forthwith communicate to the ***Commission*** any new information that might influence the evaluation of the safety in use of the feed additive, in particular health sensitivities of specific categories of consumers. The authorisation holder shall forthwith inform the ***Commission*** of any prohibition or restriction imposed by the competent authority of any third country in which the feed additive is placed on the market.

Justification

Cf. Am. 7 (to Article 8, paragraph 1).

Amendment 14
Article 14, paragraph 1

1. ***Where, on its own initiative or following a request from a Member State or from the Commission, the Authority concludes that an authorisation granted in accordance with this Regulation should be modified, suspended or revoked, it shall forthwith transmit this opinion to the Commission.***	1. ***The Authority shall, on its own initiative or following a request from a Member State or the Commission, deliver an opinion on compliance with the conditions laid down in this Regulation.*** ***It shall forward this opinion to the Commission, the authorisation holder and the Member States. The opinion shall be made public.***

Justification

Cf. Am. 7 (to Article 8, paragraph 1).

Amendment 15
Article 14, paragraph 2

2. If the authorisation holder proposes to modify the terms of the authorisation, he shall submit an application to the ***Authority***, which includes the relevant data supporting the request for the change. The Authority shall give an opinion on the proposal.	2. If the authorisation holder proposes to modify the terms of the authorisation, he shall submit an application to the ***Commission***, which includes the relevant data supporting the request for the change. The ***Authority*** shall give an opinion on the proposal.

Justification

Cf. Am. 7 (to Article 8, paragraph 1).

Amendment 16
Article 19, paragraph 1 a (new)

	1a. In order to stimulate efforts to obtain approvals for new species for additives where the use is linked to a certain species, the 10-year data will be extended by one year for each additional species for which a use extension authorisation is granted.

Justification

For species other than broiler chickens, bovines and pigs, the investment required to research and develop products is not justified. This proposal for extension by one year of data protection per species is in line with measures proposed elsewhere to combat, for example, the medicines availability crisis. Lack of research into so-called 'minor species' risks leading to unacceptable public health risks and/or animal suffering.