COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.7.2003
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OPINION OF THE COMMISSION
pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty,
on the European Parliament’s amendments
to the Council’s common position regarding the
proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL

on additives for use in animal nutrition

AMENDING THE PROPOSAL OF THE COMMISSION
pursuant to Article 250 (2) of the EC Treaty
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1. INTRODUCTION

Article 251(2), third subparagraph, point (c) of the EC Treaty provides that the
Commission is to deliver an opinion on the amendments proposed by the European
Parliament at second reading. The Commission sets out its opinion on the
amendments proposed by Parliament.

2. BACKGROUND

– Adoption of the proposal by the Commission: 22 March 2002\(^1\)
– Opinion of the European Economic
  and Social Committee: 18 September 2002\(^2\)
– Date of political agreement in Council: 16 December 2002
– Date of adoption of the amended proposal: 18 December 2002
– Date of adoption of the common position: 17 March 2003\(^3\)
– Adoption by Parliament of the Recommendation
  for a second reading: 19 June 2003

\(^2\) OJ C 61, 14.03.2003 p. 43.
\(^3\) OJ C 113E, 13.05.2003, p. 1.
3. **PURPOSE OF THE PROPOSAL**

With a view to bringing coherence to Community legislation in a “farm to table” approach, the objectives of the proposal, which results from the White Paper on Food Safety, are:

- To distinguish clearly between the risk evaluation (to take into account the entry into force of the European Food Safety Authority (hereunder called “the Authority” - EFSA) and the risk management (Comitology)
- To simplify the existing rules regarding the authorisation procedure of additives in feedingstuffs
- To lay down provisions for the phasing out of antibiotics used as growth promoters.
- To maintain the use of coccidiostats as feed additives.
- To consolidate EU provisions on additives for use in animal nutrition.

The European Food Safety Authority (EFSA) will have the competence and the responsibility to provide a single framework for dossier evaluation for all feed additives. It will bring clarity (guidelines will be updated and adapted to the various types of additives), efficiency (a single evaluation) and transparency (adoption of an assessment report and public consultation) to the process.

A definition of feed additives is provided by this Regulation. The list of authorised additives will be divided into a restricted number of broad additive categories. Processing aids and veterinary medicines are not covered within the scope of this regulation.

Except for coccidiostats fed to healthy animals during their entire productive life, compounds used in disease prevention, namely antibiotics, are not authorised as feed additives.

In its opinion adopted on 28 May 1999, the Scientific Steering Committee (SSC) recommended that the use of antimicrobials as growth promoting agents, belonging to classes that are or may be used in human or veterinary medicine, should be phased out as soon as possible and ultimately abolished.

A second opinion of the SSC on anti-microbial resistance adopted on 10-11 May 2001 confirmed the need to plan and co-ordinate the phase-out process and to make efforts to replace those antimicrobials by alternative products.

In order to comply with the SSC recommendation, the following steps are now being taken:

- exclusion of the antibiotics from the scope of the new legislation on feed additives, i.e. the request for authorisation of antibiotic feed additives will no longer be permitted;
- Adoption of a transitional period for the phasing out of the four remaining antibiotics in order to allow animal production practices to be adapted. These substances will be prohibited from 1.1.2006.
4. **Opinion of the Commission on the Amendments by the European Parliament**

The Commission considers that the amendments improve the text of its proposal and therefore it accepts all the amendments voted by the Parliament:

- Amendment 7 provides that the opinion of the European Food Safety Authority is made public.
- Amendment 9 on the renewal of authorisations for feed additives considers that efficacy studies are not necessary to obtain a renewal of the authorisation.
- Amendments 14 to 20 are compromise amendments previously discussed and accepted by COREPER. They concern:
  - a reference to the General Food Law (Regulation 178/2002) in a recital,
  - a priority order for the re-evaluation of additives,
  - a report from the Commission before 2008 on the use of coccidiostats as feed additives and available alternatives,
  - specific rules for the labelling of flavours,
  - provisional authorisation of an additive by the Commission.

5. **Conclusions**

Pursuant to Article 250 (2) of the Treaty, the Commission amends its proposal as set out above.