Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2002/0073(COD)	Procedure completed
Food safety: additive in feedingstuffs and in drinking water for animal nutrition Amended by 2008/0050(COD) Amended by 2018/0088(COD) Subject 3.10.08.01 Feedingstuffs, animal nutrition 4.60.04.04 Food safety		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	AGRI Agriculture and Rural Development		17/04/2002
		PPE-DE KEPPELHOFF-WIECHERT Hedwig	
	Former committee responsible		
	AGRI Agriculture and Rural Development		17/04/2002
		PPE-DE KEPPELHOFF-WIECHERT Hedwig	
	Former committee for opinion		
	BUDG Budgets	The committee decided not to give an opinion.	
	ENVI Environment, Public Health, Consumer Policy		23/04/2002
		PPE-DE FLEMMING Marialiese	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2524	22/07/2003
	Agriculture and Fisheries	2494	17/03/2003
	Agriculture and Fisheries	2486	20/02/2003
	Agriculture and Fisheries	2476	16/12/2002
	Agriculture and Fisheries	2422	22/04/2002
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events

21/03/2002	Legislative proposal published	COM(2002)0153	Summary
08/04/2002	Committee referral announced in Parliament, 1st reading		
22/04/2002	Debate in Council	2422	
05/11/2002	Vote in committee, 1st reading		Summary
04/11/2002	Committee report tabled for plenary, 1st reading	A5-0373/2002	
20/11/2002	Debate in Parliament		
21/11/2002	Decision by Parliament, 1st reading	T5-0560/2002	Summary
17/12/2002	Modified legislative proposal published	COM(2002)0771	Summary
16/03/2003	Council position published	15776/2/2002	Summary
27/03/2003	Committee referral announced in Parliament, 2nd reading		
20/05/2003	Vote in committee, 2nd reading		Summary
19/05/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0176/2003	
19/06/2003	Debate in Parliament		
19/06/2003	Decision by Parliament, 2nd reading	T5-0286/2003	Summary
22/07/2003	Act approved by Council, 2nd reading		
22/09/2003	Final act signed		
22/09/2003	End of procedure in Parliament		
18/10/2003	Final act published in Official Journal		

Technical information

Procedure reference	2002/0073(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2008/0050(COD) Amended by 2018/0088(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152; EC Treaty (after Amsterdam) EC 037
Stage reached in procedure	Procedure completed
Committee dossier	AGRI/5/16968

Documentation gateway

Legislative proposal		COM(2002)0153 OJ C 203 27.08.2002, p. 0010 E	22/03/2002	EC	Summary
Economic and Social Committee: opinion, report		CES1014/2002 OJ C 061 14.03.2003, p. 0043	18/09/2002	ESC	

Committee report tabled for plenary, 1st reading/single reading		A5-0373/2002	05/11/2002	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0560/2002 OJ C 025 29.01.2004, p. 0222-0342 E	21/11/2002	EP	Summary
Modified legislative proposal		COM(2002)0771	18/12/2002	EC	Summary
Council statement on its position		06715/2003	26/02/2003	CSL	
Council position		15776/2/2002 OJ C 113 13.05.2003, p. 0001-0020 E	17/03/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)0375	25/03/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0176/2003	20/05/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0286/2003	19/06/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2003)0447	16/07/2003	EC	Summary
Implementing legislative act		32005R0378 OJ L 059 05.03.2005, p. 0008-0015	04/03/2005	EU	Summary
Follow-up document		COM(2008)0233	05/05/2008	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Regulation 2003/1831
OJ L 268 18.10.2003, p. 0029-0043 Summary

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

PURPOSE: To consolidate EU provisions on additives for use in animal nutrition. CONTENT: Existing provisions on the regulation of additives for use in animal nutrition stem from a variety of (frequently outdated) Directives. So far, the basic legislation (Directive 70/524/EEC) has undergone five major amendments and numerous modifications of the annexes (over 100). The Directive has never been consolidated and provisions for authorisation contain many faults. Recognised problems include, no clear separation for risk evaluation or risk management, too much dependence on Member States who tend not be impartial and time-consuming, intransparent procedures. In light of these short comings the general objective of this proposed Regulation is to re-haul the entire regulatory process taking into account new products, feeding techniques and the short-coming of existing legislation. The Regulation will incorporate additives in feeding-stuffs and drinking water as well as the use of additives in silage. Only those additives which do not present a risk to human health, animal health or the environment may be included. Importantly, responsibility for authorisation will rest in the hands of the European Food Safety Authority (EFSA). The advantages are that the EFSA will provide a single framework for dossier evaluation for all feed additives, will bring clarity through guidelines which will be updated and adopted to various types of additives, efficiency through a single evaluation and transparency through the adoption of an assessment report and public consultation. Specifically, the Regulation contains the following elements: - In terms of scope the Regulation seeks to define "feed additives" Processing aids and veterinary medicines will not be covered by the Regulation. Only additives covered by an authorisation under the terms of the Regulation will be allowed to be put on the market, used or processed. Further, the borderline between veterinary medicinal products and feed additives is clarified. Thus, antibiotics are not authorised as feed additives. The use of coccidiostats as feed additives will be given limited authority depending on strict Maximum Residue Limits (MRLs). - The list of authorised additives will be divided into a restricted number of categories including technological additives; sensory additives; nutritional additives; zootechnical additives; coccidiostats. Additionally, a number of antibiotic feed additives will be withdrawn including avoparcin, tylosin phosphate, spiramycin, virginiamycin and bacitracin zinc. The Scientific Steering Committee recommends that the use of anti-microbials as growth promoting agents should be phased out as soon as possible and ultimately abolished. - In terms of registration, a positive list is maintained whereby only the additives listed in a register are allowed to be placed on the market, used or processed. Strict guidelines on the authorisation procedure are outlined. - On labelling rules the following will be required: the labelling of all additives; the name of the additive, the name and address of the person responsible for placing the product on the market, the net weight of the active component, directions for use and safety recommendations. The labelling will also indicate whether the additive is intended to be incorporated in feeding-stuffs or in drinking water. Lastly, the Commission will be responsible for implementation in accordance with Council Decision 1999/468/EC.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The committee adopted the report by Hedwig KEPPELHOFF-WIECHERT (EPP-ED, D) broadly approving the proposal under the 1st reading of the codecision procedure, subject to a number of amendments: - it should be specified that the directive applies not only to feed additives but also to premixtures; - the proposed deadline for withdrawing the remaining authorised antibiotic growth promoters in animal feed should be brought forward by one year to 1 January 2005 from the date of 1 January 2006 proposed by the Commission; - rather than allowing an open-ended derogation for coccidiostats and histomonostats (two specific substances used to treat poultry diseases), the committee proposed that they be used until the end of 2008 and set a final deadline of 1 January 2009 for banning them, provided no legislation had been passed to continue their use on the basis of a report to be submitted by 1 January 2008; - with regard to labelling, the person or business responsible for the information to be displayed on packaging or containers, relating to each additive contained in the material, should be resident or have their registered place of business in the EU; moreover, labelling should include details of the batch reference number and the date of manufacture, to ensure product traceability; - specific guidelines should be drawn up in cooperation with the EFSA for the authorisation of each category of additive; - 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; - the use of the banned additives (except antibiotics) should be allowed in scientific experiments provided there is adequate official supervision.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The European Parliament adopted a resolution drafted by Hedwig KEPPELHOFF - WIECHERT (EPP-ED, Germany) on additives in animal nutrition. (Please refer to the document dated 5/11/02.) Parliament also added the following amendments: -unless otherwise specified, the mixing of additives to be sold directly to the end user will be allowed, subject to compliance with the conditions for use laid down in the authorisation for each single additive. The mixing of additives does not, therefore, require specific authorisation other than the requirements laid down in Directive 95/69/EC. -if no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation is automatically extended until the Commission takes a decision. -mixtures and premixtures containing flavourings and appetite stimulants will be exempt from the labelling requirement for each additive. This does not apply to flavouring and appetite stimulants subject to a quantitative limitation when used in feed and water. -the ten-year data protection period will be extended by one year for each new species of additives for which use extension authorisation is granted. In specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the commission may, by special derogation, provisionally authorise use for a maximum of five years, with the possibility of extension subject to a satisfactory outcome of the post-market monitoring programme.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The Commission can accept 24 amendments out of 57 adopted by the European Parliament at first reading. These amendments improve or bring more clarification to the Commission's initial proposal. They refer in particular to: - the clarification of the status of coccidiostats - (inclusion of histomonostats and presentation of a report on the use of and coccidiostats and histomonostats before 1 January 2008); - the flexibility of the authorisation procedure, in particular concerning the extension to minor species and the extension to further categories of animals; - the clarification of the authorisation procedure, in particular concerning the steps and delays to be followed by the applicant, the Commission and the EFSA; - the improvement of transparency and traceability of additives and facilitates communication during the authorisation procedure; - indication of specific provisions for additives in pet food; - mixtures of feedingstuffs to be sold directly to the final user. Concerning the amendments accepted in principle, in part and/or subject to re-wording, these concern: - the extension to other substances : this amendment foresees in its first part, an extension for silage agents. This extension can be accepted because the scope of Directive 70/524/EEC is vague and therefore there is no uniform application in the MS concerning silage agents; - phasing out of antibiotics used as growth promoters : this amendment indicates that the antibiotics used as growth promoters still authorised on the date of entry into force of the Regulation shall be deleted from the Register from that date; - improvement of transparency : improves the transparency of the procedure. It is important that the applicant is involved in all decisions concerning his application and particularly concerning the time frame of the risk assessment and the provision of new information. On the other hand, the amendments not accepted by the Commission are considered to undermine the aim to sustain the overall Community legislation as more transparent, less complex and efficient. Lastly, certain technical changes have been made to the text to ensure its conformity with the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The Council's common position broadly agrees with the positions taken by the Commission and the European Parliament, in as much as it: - confirms the objectives and most of the arrangements proposed by the Commission and supported by the European parliament; - includes a large number of the amendments passed at first reading by the European Parliament. In particular, the Council has retained the legal form of a Regulation with a view to consolidating existing provisions on the regulation of additives for use in animal nutrition which stem from a variety of Directives. The basic legislation (Directive 70/524/EEC) which it is intended to replace has undergone five major amendments and numerous modifications of the annexes, making its application increasingly difficult for operators and authorities. The Council felt appropriate to introduce a number of amendments, many of them at the suggestion of the Parliament. - Status of coccidiostats - Inclusion of histomonostats - Report of use of coccidiostats and histomonostats : the Council included histomonostats in the same category of feed additives as coccidiostats, thus maintaining these two groups within the framework of the feed additives legislation. While not prejudging the future use of these substances at the present time, the Council also followed Parliament in asking the Commission to present a report on the use of coccidiostats and histomonostats as feed additives before 1 January 2008, where appropriate together with a legislative proposal concerning further use. - Scope of the Regulation and authorisation procedure : the Council decided to adapt several provisions regarding the scope of the Regulation and the authorisation procedure, in particular concerning the steps and time limits to be followed by the applicant, the Commission and the EFSA. Further, a new paragraph has been included that specifies that applicants for authorisation of additives shall contribute to support the

implied cost of the tasks carried out by the Community reference laboratory and the consortium of national reference laboratories. - Improvement of transparency and traceability - Administrative review : the Council decided to introduce amendments to certain provisions in order to improve the traceability of additives and facilitate communication during the authorisation procedure and the availability of information to the public. New Articles on confidentiality and on the administrative review of decisions or failures to act by the EFSA were included in the Common position. In the interest of animal welfare, a new paragraph was included on data protection, providing rules for the sharing of information in order to avoid repeating toxicological tests on vertebrates. - Minor species - Animal categories : the Council decided to introduce more flexibility in the authorisation procedure for minor species and the extension to further categories of animals. Specific conditions were added regarding data protection when applying for authorisations for minor species. - Specific requirements for pets : the Council decided to modify the text in order to provide that specific provisions for additives in pet food are appropriate. - Definitions and general conditions : the Council considered itappropriate in the interest of legal clarity to include several additional definitions, in particular one of "feed additives". Various clarifications proposed by Parliament regarding mixtures of additives have been included. Likewise, the additive groups in Annex I have been completed. A new Annex IV gives room for establishing conditions of use applicable to all feed additives. - Silage agents : the Council added an extension for silage agents. This extension, accompanied by a transitional arrangement for silage agents which are currently marketed and used in the Community without an authorisation pursuant to Directive 70/524/EEC, was considered necessary because there is no uniform application in the Member States concerning silage agents. - Phasing out of antibiotics used as growth promoters : following the Parliament's suggestion, the common position clarifies that all antibiotics, other than coccidiostats and histomonostats, shall be deleted from the Register as from 1 January 2006, the Council followed the Commission proposal and rejected the amendments of the Parliament for another date for the phasing out of antibiotic growth promoters.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The Commission considers that the amendments introduced by the Council constitute an improvement to the original Commission proposal and, therefore, supports the common position adopted by the Council.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The committee adopted the report by Hedwig KEPPELHOFF-WIECHERT (EPP-ED, D) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated a number of amendments adopted by Parliament at 1st reading, as follows: - the definition of "feed additives" was modified by adding the words "chemically defined or described" substances, mirco-organisms or preparations etc. (the committee pointed out that the Commission had incorporated the amended definition proposed by Parliament at 1st reading into its amended proposal); - as regards the status of existing products, the procedure for reassessment should be simplified: thus, for additives authorised without a time limit, a list of additives which require re-evaluation and their priority order for re-evaluation should be drawn up under the commitology procedure, after the European Food Safety Authority has been consulted. An application for authorisation shall be submitted no later than 7 years after the adoption of that list. The committee pointed out that many of the substances currently authorised without a time limit are innocuous substances already authorised for use in human foods, and it may not therefore be necessary to carry out a detailed assessment of all of them involving an application as provided for in the regulation; - rather than allowing an open-ended derogation for coccidiostats and histomonostats, it was specified that those two substances may be used until the end of 2008, and a final deadline of 1 January 2009 was set for banning them. Moreover, the Commission should submit a report before 1 January 2008 on the use of these substances as feed additives together, where appropriate, with a legislative proposal concerning future use; - to protect corporate know-how, mixtures and premixtures containing flavourings and appetite stimulants should be exempt from the labelling requirement for each additive. This should not apply, however, to flavourings and appetite stimulants subject to a quantitative limitation when used in feed and drinking water; - 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 5 years.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The European Parliament adopted the report drafted by Hedwig KEPPELHOFF-WIECHERT (EPP-ED, Germany) and made some amendments to the common position. (Please see the document dated 20/05/03.) The amendments are as follows: - a new recital recalls the principle of Community food law enshrined in Regulation 178/2002/EC, whereby food and feed imported for placing on the market must comply with Community legislation. It is therefore necessary to subject imports of third countries of additives for use in animal nutrition to requirements equivalent to those which apply to additives produced in the EC; - for additives authorised without a time limit, a list of additives which require re-evaluation and their priority order for re-evaluation should be drawn up, after the European Food Safety Authority has been consulted. An application for authorisation shall be submitted no later than 7 years after the adoption of that list; - with a view to a decision on the phasing out of the use of coccidiostats and histomonostats as feed additives by 31/12/12, the Commission must submit a report on the use of these substances as feed additives and available alternatives by 01/01/08. This should be accompanied, where appropriate by legislative proposals; - to protect corporate know-how, mixtures and premixtures containing flavourings and appetite stimulants should be exempt from the labelling requirement for each additive. This should not apply, however, to flavourings and appetite stimulants subject to a quantitative limitation when used in feed and drinking water; - in specific cases where urgent authorisation is needed to ensure the protection of animal welfare, the Commission may, provisionally authorise the use of an additive for a maximum period of 5 years.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

The Commission considers that the amendments improve the text of its proposal and therefore it accepts all the amendments voted by the Parliament: - provides that the opinion of the European Food Safety Authority is made public; - on the renewal of authorisations for feed additives considers that efficacy studies are not necessary to obtain a renewal of the authorisation; - a few 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.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

PURPOSE : to establish a Community procedure for authorising the placing on the market and use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures. LEGISLATIVE ACT : Regulation 1831/2003/EC on additives for use in animal nutrition. CONTENT : in order to protect human health, animal health and the environment, this regulation provides that feed additives must undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community. The main points of the Regulation are as follows: - imports from third countries of additives for use in animal nutrition are subjected to requirements equivalent to those applying to additives produced in the Community; - mixtures of additives sold to the end-user are covered by this Regulation. The marketing and use of those mixtures must comply with the conditions laid down in the authorisation of each single additive; - premixtures are not regarded as preparations covered by the definition of additives; - the basic principle is only those additives approved under the procedure provided for in this Regulation may be placed on the market, used and processed in animal feeding under conditions set out in the authorisation; - categories of feed additives are defined in order to facilitate the assessment procedure with a view to authorisation. Amino acids, their salts and analogues, and urea and its derivatives, which are currently covered by Council Directive 82/471/EEC are included as a category of feed additives and therefore transferred from the scope of that Directive to this Regulation; - a harmonised scientific assessment of feed additives will be carried out by the European Food Safety Authority. Applications will be supplemented by residue studies in order to assess the establishment of Maximum Residues Limits (MRLs); - the Commission will establish guidelines for the authorisation of feed additives in cooperation with the European Food Safety Authority, paying attention to the possibility of extrapolating the results of the studies carried out on major species to minor species; - there is a simplified authorisation procedure for those additives which have successfully undergone the authorisation procedure for food use provided for in Council Directive 89/107/EEC; - the authorisation of an additive will be granted by the Commission; - applicants are encouraged to seek authorisation extensions for minor species by being granted one year's additional data protection in addition to the 10 years' data protection for all species for which the additive is authorised; - there is an obligation for the holder of the authorisation to implement a post-market monitoring plan in order to trace and identify any unforeseen effect resulting from the use of feed additives on human or animal health or the environment; - a register of authorised feed additives will be established, including product-specific information and detection methods. Non-confidential data will be made available to the public. - there are transitional rules to take into account additives which are already on the market and which were authorised under Directive 70/524/EEC, and amino acids, their salts and analogues, urea and its derivatives, currently authorised under Directive 82/471/EEC, and silage agents, as well as additives for which the authorisation procedure is in progress. Such products may remain on the market only insofar as notification with a view to their evaluation has been submitted to the Commission within one year after the entry into force of the Regulation; - there are transitional provisions for silage additives which are currently marketed and used in the Community without an authorisation granted pursuant to Directive 70/524/EEC; - with a view to a decision on the phasing out of the use of coccidiostats and histomonostats as feed additives by 31 December 2012, the Commission will submit to the European Parliament and the Council before 1 January 2008 a report on the use of these substances as feed additives and available alternatives; - 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 will be deleted from the Register; - there are provisions on labeling of the product and for simplified labelling requirements for flavouring compounds; - Directive 70/524/EEC is repealed. However labelling provisions applicable to compound feedingstuffs incorporating additives are maintained until a revision of Council Directive 79/373/EEC; - until the rules of this Regulation are applicable, the substances already authorised may remain on the market and be used under the conditions of the current legislation. ENTRY INTO FORCE : 07/11/03. DATE OF APPLICATION : 18/10/04.?

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

ACT : Commission Regulation 378/2005/EC on detailed rules for the implementation of Regulation 1831/2003/EC of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives.

CONTENT : this Regulation lays down detailed rules for the implementation of Regulation 1831/2003/EC as regards:

(a) applications for authorisation of a feed additive or for a new use of a feed additive as provided for in Article 4(1) of that Regulation (the application); and

(b) the duties and tasks of the Community Reference Laboratory (the CRL).

ENTRY INTO FORCE : 25/03/2005.

Food safety: additive in feedingstuffs and in drinking water for animal nutrition

Provisions set out in Regulation (EC) No 1831/2003 on additives for use in animal nutrition require the Commission to prepare a report on the use of coccidiostats and histomonostats as feed additives with a view to a decision on the phasing out of these substances as feed additives by 31 December 2012. In presenting this report to both the Council and the European Parliament the Commission is fulfilling its obligations. As well as considering the phasing-out of coccidiostats and histomonostats as feed additives, the report addresses what alternatives may be available. It is accompanied, where appropriate with legislative proposals.

To recall, coccidiostats and histomonostats are chemicals, either obtained by synthesis or produced by micro-organisms, which inhibit or destroy protozoan parasites which cause coccidiosis or histomoniasis in farmed animals. Coccidiostats may also have a secondary and residual activity against the micro flora of the gut, but they are different from antibiotics as growth promoters, which have their primary action on the gut micro flora. The use of those antibiotics as growth promoters has been forbidden in the European Community since 1 January 2006.

The condition, coccidiosis in farmed animals has been controlled in the Community by adding substances to feed. As a feed additive it is regulated under Directive 70/524/EEC on additives in feeding stuffs. Regulation (EC) No 1831/2003 is a major overhaul of the existing EU legislation on feed additives. Coccidiosis affects all wild and domestic birds. It is widely acknowledged that the parasites are present in all commercial herds. The nature of the parasitic infestation is such that coccidiosis is present on all poultry farms, even in the presence of high sanitary standards and good management, with a high potential impact on animal welfare. The disease histomoniasis is also caused by a protozoan parasite ? the most sever effects are seen in turkey (black head) although a broad spectrum of birds can be affected.

At present there are 11 different coccidiostats which have been granted 28 different authorisations for different species and under certain conditions of use. Generally coccidiostats inhibit reproduction and do not fully eliminate the parasite from the intestine of the animal. The authorised synthetic chemicals play a vital role in conjunction with ionophores. In order to minimise immunity to the parasite the products are switched from production cycle to production cycle in order to use them in so-called ?shuttle? programmes. Thus, the availability and the continuous preventive use of coccidiostats have contributed significantly to the development of poultry production with a high level of health and welfare of the animals. As regards histomonostats, although no products belonging to this category are currently authorised in the EU, the mechanism exists for authorising them if an application for authorisation of a product were to be submitted with enough data supporting its safety for the animals, the consumer and the environment.

More recently the European Food Safety Authority (EFSA) has assessed extensively the safety of coccidiostats. In preparing this report the Commission requested information from both Member States and operators. A number of organisations responded to the report including the International Federation for Animal Health Europe, the European Feed Manufactures? Federation, the European poultry producers and traders associations and the Association of Veterinary Consultants ? as did fifteen EU Member States. All have indicated that, at present, there are no better alternatives to the current regulatory and inspection system in place namely MLRs, feed hygiene rules, registration and approval of establishments handling coccidiostats and traceability.

Based on the above analysis and the responses from stakeholders and Member States, the Commission concludes that at present, the use of coccidiostats as a preventive measure for the control of coccidiosis in modern poultry production is essential. The practice contributes significantly to the protection of both animal health and animal welfare by preventing a disease that is present on all farms. Alternatives, such as vaccines or herbal remedies do not offer the same advantages as the use of coccidiostats as feed additives. As regards histomoniasis, since there are currently no alternative treatments, the specific category should be maintained under the Regulation to open the option of authorising future products for the prevention of the disease, on condition that they meet high safety and efficacy criteria. The Regulatory framework established by Regulation 1831/2003 is effective and the Commission is of the view that it would be inappropriate to change the existing situation at present.