REGULATION REGARDING THE USE OF FEED ADDITIVES SUBSTANCES IN ANIMAL NUTRITION

PART ONE
Objective, Scope, Basis and Definitions

Objective and Scope

ARTICLE 1 – (1) This Regulation has been prepared with the intention of establishing procedure and principles for the rules governing the approval of the placing on the market and use of feed additives and to lay down rules for the supervision and labeling 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' and consumers' interests in relation to feed additives.

(2) This regulation does not cover veterinary health products other than coccidiostats and histomonostats which are used as processing aids and feed additive substances.

Basis

ARTICLE 2 – (1) This Regulation is based on ;

a) has been prepared based on articles 21, 22, 24, 25, 26 and 43 of the Law for Veterinary Services, Plant Health, Food and Feed Law dated 11/6/2010 number 5996,

b) and in parallel with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition,

c) **COMMISSION REGULATION (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council.**

Definitions

ARTICLE 3 – (1) The terminology used in this Regulation is defined as follows;

a) "antibiotic" means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the reproduction of other micro-organisms,

b) "antimicrobials" means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms such as bacteria, viruses or fungi, or of parasites, in particular protozoa,

c) Ministry: the Ministry of Food, Agriculture and Livestock,

ç) "daily ration" means the average total quantity of feed calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs,

d) "processing aids" means any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfill a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed,

e) Traceability: the ability to trace and follow the trail of a substances throughout the production, processing and distribution phases which are intended or anticipated to be present in the food and feed, animals or plants from which food is generated,

f) compound feedingstuffs: a compound of at least two feed substances with or without additives fed orally to animals as full or supplementary feed,

g) "coccidiostats" and "histomonostats" means substances intended to kill or inhibit protozoa,

ğ) "maximum residue limit (MRL)" means the acceptable maximum concentration of residue resulting from the use of an additive in animal nutrition as being legally permitted or recognized as acceptable in or on animal feed,

h) "micro-organism" means: colony-forming micro-organisms,

ı) Placing on the market: placing any of the feed additives substances within the scope of this Regulation on the market for a fee or without charge,

i) "first placing on the market" means the initial placing on the market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed,

j) "premixtures" means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals,

k) complete feedingstuffs: A feed mixture which is sufficient for a daily ration in terms of its composition,

l) complementary feedingstuffs: a compound feed with a content which is rich in terms of certain substances and when used together with another feed fulfills the daily ration,

m)Feed: Any processed, partially processed or un-processed material or products including feed additives used to feed animals orally,

n) feed materials: various products of plant or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, with or without additives, 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 and fulfill the nutritional needs of animals,

o) 'feed business operator' means the natural or legal persons responsible for ensuring that the legislative requirements regarding the relevant controls for the manufacturing, processing and storage, transport and marketing of animal feed by public organizations and agencies or natural or legal entities on a profit or non-profit basis are maintained including the production, processing and storage of feed for the animals in the operator's establishment,

ö) "feed additives" means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(6).

PART TWO
Putting Feed Additives on the Market, their Processing Usage, Approval, categories, Commissions and Inspections

Putting on the market, processing and usage

ARTICLE 4 – (1) The following conditions must be fulfilled in order to put feed additives on the market, process and use them;

a) They must be approved according to the provisions of this Regulation,

b) They must fulfill the conditions indicated in this Regulation including the overall usage conditions indicated in Annex-4,

c) They must comply with the labeling rules indicated in this Regulation. Feed additives which do not conform to these conditions cannot be marketed, processed or used.

(2) Feed additives which have not been approved by the Ministry need a permission from the Ministry to be used for scientific purposes. The Ministry may allow the use of feed additive substances other than antibiotics to be used in scientific studies under certain conditions and after necessary investigations have been made. The Ministry shall supervise any such granted permissions if necessary. The animals used in scientific trials may be used in food production provided this will not have a negative impact on human health, animal health and the environment.

(3) Feed additive substances belonging to the categories indicated in subparagraphs (ç) and (d) of the first paragraph of article 6 and feed additive substances which are included in the legislation covering feed additive substances which are produced from genetically modified organisms (GDO), generated from these organisms or products containing these organisms can be placed first on the market only by the natural or legal entities, their heirs or authorized officers of those who have obtained an approval for the relevant feed additive substances in their name.

(4) The sale of mixing additives directly to the end-user shall be allowed, subject to compliance with the conditions for use laid down in the approval of each single feed additive.

(5) Mixtures comprising approved feed additive substances do not need an additional approval.

(6) If deemed necessary due to changing circumstances, scientific development or technological advancement the general conditions in Annex-4 may be re-regulated.

Approval conditions

ARTICLE 5 – (1) Any person seeking an approval for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

(2) An approval shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation, or in accordance with emergency procedures indicated in Article 26 of the Law for Veterinary Services, Plant Health, Food and Feed Law dated number 5996.

(3) The approval applicant or the representative must be resident in the country.

(4) A feed additive substances shall not be approved if the requirements indicated in article 7 regarding the use of the feed additive substance have not been fulfilled by the applicant and if all of the conditions indicated in the fifth paragraph of this article as well as if at least one of the features indicated in the sixth paragraph cannot be fulfilled.

(5) Feed additive substances must avoid the following properties;

a) not have an adverse effect on animal health, human health or the environment,

b) should not be presented in a manner which may mislead the user,

c) should not harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.

(6) Feed additive substances should have at least one of the following properties;

a) have a favorable impact on the characteristics of feed,

b) have a favorable impact on the characteristics of products of animal origin,

c) have a favorable impact on the colors of ornamental fish and birds,

ç) fulfill the nutrition requirements of animals,

d) have a favorable impact on the environmental consequences of animal production,

e) have a favorable impact on the animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs,

f) have a coccidiostatic or histomonostatic impact.

(7) Antibiotics, other than coccidiostats or histomonostats, shall not be approved as feed additives.

(8) The feed additive substances updated and approved by the European Union shall be accepted as approved within the scope of this Regulation provided that the prohibitions and restrictions indicated in the Biosecurity Law dated 18/3/2010 and number 5977 as well as the provisions of the Regulation regarding Genetically Modified Organisms and their Products published in the Official Gazette dated 13/8/2010 and number 27671 are without prejudice.

Feed additive substance categories

ARTICLE 6 – (1) A feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, in accordance with the procedure set out at Articles 7, 8 and 9.

a) technological additives: any substance added to feed for a technological purpose.

b) sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals.

c) nutritional feed additives: additive substances indicated in article three of Annex-1 to this Regulation.

ç) zootechnical additives: any additive used to affect favorably the performance of animals in good health or used to have a favorable impact on the environment.

d) coccidiostats and histomonostats feed additive substances.

(2) Within the categories referred to in paragraph 1, feed additives shall further be allocated within one or more of the functional groups mentioned in Annex I, depending on their function or functions, in accordance with the procedure specified in Articles 7 and 8.

(3) Where necessary as a result of technological progress or scientific development, additional feed additive categories and functional groups may be established.

Approval application

ARTICLE 7 – (1)Application for the approval of feed additive substances shall be directed to the Ministry.

(2)The applicant shall apply to the Ministry with the following information and documents.

a) his name and address,

b) the identification of the feed additive, a proposal for its classification by category and functional group under Article 6, and its specifications and purity criteria where applicable,

c) a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food,

ç) a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(5) and (6);

d) proposed conditions for placing the feed additive on the market, including labeling requirements and, where appropriate, specific conditions for use and handling including known incompatibilities, use levels in complementary feedingstuffs and animal species and categories for which the feed additive is intended,

e) a written statement that samples of the feed additive have been sent by the applicant to a reference laboratory,

f) a traceability plan for the post-market monitoring of additives which, according to the proposal under paragraph one of Article 6 do not belong to either category (a) or category (b) and for additives falling within the scope of products consisting of, containing or produced from GMOs,

g) a summary containing the information indicated under points (a) to (f) of this paragraph,

ğ) for additives falling within the scope of legislation relating to the marketing of products consisting of GMOs, details of any approval granted in accordance with the applicable legislation.

(3) The Ministry may determine rules regarding the preparation and presentation of applications in terms of this article if deemed necessary.

(4) After the Ministry has assessed the application additional rules regarding the application of this article may be enforced. These rules may differentiate between requirements for feed additives in respect of food-producing animals and requirements in respect of other animals, in particular pets. The implementing rules shall include provisions which allow for simplified procedures for the approval of additives which have been approved for use in food.

(5) If necessary the Ministry shall prepare a guidebook regarding the approval procedures of additive substances indicated in the first paragraph of article 6. The Ministry shall determine matters related to the preparation and presentation of an application file in order to inform applicants.

Ministerial decision

ARTICLE 8 – (1) The Ministry shall inform the applicant of the decision within six months after receiving the legal applications. However, if the Ministry demands for additional information and documents within this time this time shall not be taken into consideration in the calculation of the six month period.

(2) The Ministry may request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority after consultation with the applicant.

(3) In order to form an opinion the Ministry shall;

a) verify that the particulars and documents submitted by the applicant are in accordance with Article 7 and undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5,

b) verify the report of the Reference Laboratory.

(4) In the event that the Ministry forms a favorable opinion in regarding the feed additive, the opinion shall also include the following elements;

a) the name and address of the applicant,

b) the designation of the feed additive including its categorization and allocation within functional groups provided for in Article 6, its technical specifications, including, where applicable, purity criteria and method of analysis,

c) depending on the outcome of the assessment, specific conditions or restrictions in relation to processing, post-market monitoring requirements and use, including animal species and categories of animal species for which the additive is to be used,

ç) specific additional requirements for the labeling of the feed additive necessary as a result of conditions and restrictions imposed under subparagraph (c) of this paragraph,

d) a plan for the establishment of Maximum Residues Limits (MRLs) in the relevant foodstuffs of animal origin, unless the opinion of the Ministry concludes that the establishment of MRLs is not necessary for the protection of consumers or MRLs have already been established in The Regulation regarding the Classification of Pharmacological Active Substances and Maximum Residue Limits in Food of Animal Origin of the Turkish Food Codex published in the Official Gazette dated 4/5/2012 and number 28282.

(5) The Ministry shall prepare a report stating the assessment results of the feed additive substance and state the reasons which had an impact on this decision.

(6) The Ministry shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 17(2).

(7) An application for feed additive substances with GMO must include decisions and permissions enacted in accordance with the provisions of the Biosecurity Law and the Regulation regarding Genetically Modified Organisms and their Products.

(8) Feed additive substance approval applications for the categories indicated in subparagraphs (ç) and (d) of the first paragraph of article 6 of this Regulation shall be accompanied with the name of the proprietor of the approval and the descriptive number of the additive substance.

(9) Where the levels of residues of an additive in food from animals fed with that additive might have a detrimental effect on human health, the approval granted within the scope of this Regulation shall include MRLs for the active substance or for its metabolites in the relevant foodstuffs of animal origin. In this case the active components shall be considered for the purposes of MRLs and where an MRL for the substance concerned has already been established that MRL shall also apply to residues of the active substance or its metabolites originating from the use of the substance as a feed additive.

(10) The approval granted in accordance with the procedure laid down in this Regulation which is not included in the EU feed additives substances registration list shall be valid for 10 years and shall be renewable in accordance with Article 13. Approved feed additive shall be registered according to article 16. Each registration entry shall state the approval status as well as the particulars referred to in paragraphs 4, 7 and 8 of this article.

(11) The granting of approval shall be without prejudice to the civil and criminal liability of feed operators in respect of the feed additive concerned.

Approval Commission

ARTICLE 9 – (1) The feed additive substances approval application submitted to the Ministry shall be examined by the Feed Additive Substances Approval Commission. When deemed necessary the views of the risk assessment of the feed commission established within the scope of the Regulation regarding the Working Principles and Procedures of Risk Assessment Committees and Commissions published in the Official Gazette dated 24/12/2011 and number 28152 shall be sought. Additional opinions of relevant organizations and agencies shall be sought if deemed necessary by the Approval Commission. After the feed additive substances approval commission has completed its investigation the approval application shall be decided.

(2) The feed additive substance approval commission shall be established by the General Directorate of Food and Control of the Ministry and be comprised of the relevant department director and experts employed in the Ministry.

(3) The Commission shall convene with a two-thirds majority as a minimum and a simple majority shall decide. The decision taken by members of the Commission shall be written into a protocol and signed by the members. Views to the contrary shall be indicated in a protocol.

The status of current products

ARTICLE 10 – (1) The feed additive substances and premixes which were approved by the Ministry before the enactment of this Regulation can remain on the market for two years after the enactment of the Regulation. In order to obtain a re-approval for products which have been

approved before the enactment of this Regulation, persons who intend to place these products on the market for the first time must apply to the Ministry within one year after the enactment of the Regulation. When the Ministry approved feed additive substances which are not on the feed additive substances list these additive substances shall be included in the list indicated in article 16. This list shall include the expiry date of the approval of the feed additive substance, if any.

Inspection

ARTICLE 11 – (1) After the approval of a feed additive substance according to this Regulation persons or parties using this additive or using or marketing a feed which contains the feed additive shall comply with the conditions or restrictions related to the delivery, usage and maintaining of the feed additive substance.

(2) The Ministry shall carry out the inspection and control procedures of feed additive substances-premixes.

(3) In circumstances which require tracing, the approval owner shall ensure that the tracing is executed and shall present a tracing report commensurate with the approval to the Ministry.

Modification, suspension and revocation of approvals

ARTICLE 12 – (1) If the Ministry deems necessary or a demand is made, a new assessment as to whether or not the conditions within the Regulation framework in terms of an approval are maintained. As a result of the executed assessment, measures such as a modification regarding the approval of an additive substance or a suspension of the approval or a revocation of the approval may be taken.

(2) If the holder of the approval proposes changing the terms of the approval by submitting an application to the Ministry accompanied with the relevant data supporting the request for the change, the Ministry shall assess the application and make a decision and transmit this decision to the applicant.

(3) The registration list of approved feed additives substances may be changed if deemed necessary.

(4) The provisions of the first and second paragraphs of article 7 and the provisions of article 8 shall be applied in this process.

Renewal of the approval

ARTICLE 13 – (1) The approvals of the feed additive substances included in the list for allowed feed additive substances indicated in article 16 of this Regulation shall remain valid until the date on the list. Feed additive substances which are not on the list and which receive approval for a determined period shall be renewable after ten years. An application for renewal for feed additive substances which are not on the EU feed additive substances registry list but which have been approved by the Ministry shall be forwarded to the Ministry at least one year before the expiry date for renewal. When the expiry date of feed additive substances for which no renewal application has been made is due the feed additive substance shall be removed from the registry list. In situations where the approval has not been made on behalf of any particular company the entity or other relevant parties who put the feed additive substance on the market for the first time can apply to the Ministry and such entities shall be considered application holders.

(2) The Application holder shall submit the following information and documents to the Ministry for application:

a) a copy of the approval for placing the feed additive on the market for the first time,

b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the approval,

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,

ç) where appropriate, a proposal for amending or supplementing the conditions of the original approval in addition to conditions concerning future monitoring.

(3) The conditions indicated in the first, second, fourth and fifth subparagraphs of article 7 and the contents of article 8 shall be applicable for approval renewal applications.

(4) Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an approval before its expiry date, the period of approval of the product shall automatically be extended until

the Ministry takes a decision. Information on this extension of the approval shall be made available to the public in the feed additive registry list referred to in Article 16.

Rapid approval

ARTICLE 14 – (1) In specific cases where urgent approval is needed to ensure the protection of animal welfare, the Ministry may provisionally approve the use of an additive for a maximum period of five years. Under such special circumstances the approval procedures of the feed additive substances are carried out within a timeframe to be determined by the feed additive substances approval commission with a view on the urgency of the situation and the approval conditions are valid.

PART THREE
Labeling and Packaging

The labeling and packaging of feed additive substances and premixes

ARTICLE 15 – (1) No entity shall place on the market a feed additive or a premix shall be put on the market unless its packaging or container is labeled under the responsibility of a producer, packer, importer, seller or distributor established within the country and bears the following information, in a conspicuous, clearly legible and indelible manner on the label in Turkish;

a) the specific name given to the additives upon approval, preceded by the name of the functional group as mentioned in the approval,

b) the name, commercial title and address of the establishment or entities responsible for labeling,

c) the net weight of solid or granulated feed additive substances and premixes or, in the case of liquid additives and premixes, either the net volume or the net weight,

ç) the approval number or registration number given to the producer of the feed additive substance or the entity putting it on the market in accordance with the Feed Hygiene Regulation published in the Official Gazette dated 27/12/2011 and number 28155,

d) directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the approval, including animal species and categories for which the additive or premix is intended,

e) identification number,

f) batch reference number and date of manufacture.

(2) It is not necessary to have the information indicated in subparagraphs (b), (ç), (d) and (f) of the first paragraph for each additive substance included in the premix compounds of the labels.

(3) For flavoring compounds, the list of additives may be replaced by the words "mixture of flavoring compounds" instead of a list with each single feed additive substance. This shall not apply to flavoring compounds subject to a quantitative limitation when used in feed and drinking water.

(4) In addition to the information specified in paragraph 1, the packaging or container of an additive or premix comprised of these feed additive substances belonging to a functional group specified in Annex 3 must bear the information, presented in a conspicuous, clearly legible and indelible manner, indicated in that Annex.

(5) Moreover, if premixes are used the word "PREMIX" (in capital letters) must appear clearly on the label, and the carrier substance must be declared. If water is used as a carrier the humidity content of the premix must be indicated. The minimum storage life and most appropriate storage conditions shall be indicated on the premix; there is no need to indicate the minimum storage life of each additive substance in the premix.

(6) Additives and premixes shall be marketed only in closed packages or closed containers that when they are opened they cannot be closed again and put on the market as closed packages or closed containers.

(7) The Ministry shall modify Annex-3 in view of scientific developments and technological advances.

PART FOUR
Miscellaneous and Final Provisions

Feed additive substance registry list

ARTICLE 16 – (1) The Ministry shall prepare a list of feed additive substances which are allowed for use and shall update this list when any changes occur. The registry list shall be published on the official website of the Ministry.

Confidentiality

ARTICLE 17 – (1) The applicant may indicate which information submitted under this Regulation he wishes to be treated as confidential on the ground that its disclosure might significantly harm his competitive position. Verifiable reasons must be presented in such cases.

(2) After obtaining the opinions of the applicant in writing the Ministry shall decide which information other than the information in the third paragraph of this article should be kept confidential and inform the applicant of its decision.

(3) The following information shall not be considered confidential;

a) name and composition of the feed additive and if micro-organisms are present then the indication of the production strain,

b) physico-chemical and biological properties of the feed additive,

c) conclusions of the study results on the effects of the feed additive on human and animal health and on the environment,

ç) conclusions of the study results on the effects of the feed additive on the characteristics of animal products and its nutritional properties,

d) methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

(4) Without prejudice to the provisions of the second paragraph of this article, provided the applicant withdraws his application the Ministry shall comply with the confidentiality of commercial and industrial information including information regarding research and development.

Protection of Data

ARTICLE 18 – (1) The scientific data and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of 10 years from the date of approval unless the applicant has agreed with the previous applicant that such data and information may be used.

(2) After the 10-year data protection period for minor species for additives has expired the use of which have been approved for other species shall be extended by one year for each minor species for which a use extension approval has been granted.

(3) The applicant and the previous applicant should take all necessary steps to reach an agreement on sharing the use of information, in order not to repeat toxicological tests on vertebrates. If, however, no such agreement can be reached on sharing the information, the feed commission of the Ministry shall make the necessary assessment in order to avoid repeating toxicological tests on vertebrates and make the final decision based on these assessments. The Ministry shall ensure a reasonable balance between the interests of the parties concerned.

(4) On the expiry of the 10-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 Ministry for the benefit of another applicant.

Reference laboratories

ARTICLE 19 – (1) The Ministry shall determine the reference laboratories which shall execute the analysis procedures of feed additive substances. The relevant tasks and duties of reference laboratories are indicated in Annex-2.

(2) Applicants are obliged to pay a fee to the reference laboratories for the analysis they commission. The analysis fees shall be determined by the Ministry.

Sanctions

ARTICLE 20 – (1) Any violations of the provisions of this Regulation shall be processed in accordance with the relevant articles of the Law for Veterinary Services, Plant Health, Food and Feed number 5996.

Transitional provisions

PROVISIONAL ARTICLE 1 – (1) Feed additive substances and premixes which had approval before the enactment date of this Regulation can remain on the market for two years following the enactment of this Regulation.

(2) Feed operators may use the current labels which are compliant with the previous relevant feed legislation for one year after the enactment of this Regulation. Feed additive substances and premixes carrying these labels may be put on the market for two years following the enactment of this Regulation.

Entry into Force

ARTICLE 21 – (1) This Regulation shall come into force six months after its publication.

Execution

ARTICLE 22 – (1) The provisions of this Regulation are executed by the Minister of Food, Agriculture and Livestock.

Annex-1
FEED ADDITIVE SUBSTANCES FUNCTIONAL GROUPS

(1) In the category "technological additives", the following functional groups are included:

a) preservatives: substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites,

b) antioxidants: substances prolonging the storage life of feedingstuffs and feed materials by protecting them against deterioration caused by oxidation,

c) emulsifiers: substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feedingstuffs,

ç) stabilizers: substances which make it possible to maintain the physico-chemical state of feedingstuffs,

d) thickeners: substances which increase the viscosity of feedingstuffs,

e) gelling agents: substances which give a feedingstuff texture through the formation of a gel,

f) binders: substances which increase the tendency of particles of feedingstuffs to adhere,

g) substances for control of radionucleide contamination: substances that suppress absorption of radionucleides or promote their excretion,

ğ) anticaking agents: substances that reduce the tendency of individual particles of a feedingstuff to adhere,

h) acidity regulators: substances which adjust the pH of feedingstuffs,

ı) silage additives: substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage,

i) denaturants: substances which, when used for the manufacture of processed feedingstuffs, allow the identification of the origin of specific food or feed materials,

j) Substances which decrease the mycotoxin contamination of feed: substances which repress or decrease the absorption of mycotoxins, enhance excretion or change the form of impact.

(2) In the category "sensory additives", the following functional groups are included:

a) colorants;

1) substances that add or regulate color in feedingstuffs,

2) substances which, when fed to animals, add colors to food of animal origin,

3) substances which favorably affect the color of ornamental fish or birds,

b) flavoring compounds: substances the inclusion of which in feedingstuffs increases feed smell and palatability.

(3) In the category "nutritional additives", the following functional groups are included:

a) vitamins, pro-vitamins and chemically defined substances having a similar effect,

b) compounds of trace elements,

c) amino acids, their salts and analogues,

ç) urea and its derivatives.

(4) In the category "zootechnical additives", the following functional groups are included:

a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials,

b) gut flora stabilizers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora,

c) feed additive substances which favorably affect the environment,

ç) other zootechnical additives.

(5) ‘‘coccidiostats and histomonostats’’ category.

Annex-2

DUTIES AND TASKS OF REFERENCE LABORATORIES

(1) The main tasks of reference laboratories regarding applications for feed additive substance approvals are the following:

a) the reception, preparation, storage and maintenance of the reference samples;

b) the testing and evaluation or validation of the method for detection;

c) evaluating the data provided by the applicant for approval to place the feed additive on the market, for the purpose of testing and evaluation or validation of the method for detection;

ç) submitting full evaluation reports to the Ministry.

Annex-3
SPECIAL LABELING CONDITIONS FOR CERTAIN FEED ADDITIVE SUBSTANCES AND PREMIXES

(1) Zootechnical additives, coccidiostats and histomonostats;

a) expiry date of the guarantee or the storage life from the date of manufacture,

b) directions for use,

c) concentration of the product.

(2) Enzymes, in addition to the abovementioned indications;

a) the specific names of the active component or components in accordance with their enzyme activities, in conformity with the given approval given,

b) International Union of Biochemistry identification number,

c) instead of concentration: units of activity (units of activity per gram or units of activity per milliliter).

(3) Micro-organisms;

a) expiry date of the guarantee or the storage life from the date of manufacture,

b) directions for use,

c) strain identification number,

ç) number of colony-forming units per gram.

(4) Nutritional additive substances;

a) active substance level,

b) expiry date of the guarantee for the indicated level or shelf life from the date of manufacture.

(5) Technological and sensory additives with the exception of flavoring compounds;

a) active substance level.

(6) Flavoring additive substances;

a) incorporation rate in premixes.

Annex-4
GENERAL CONDITIONS OF USE

(1) With this Regulation the quantity of additives that exist in the natural state in certain feed materials shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the approval.

(2) Mixing of additives shall be permitted in premixes and feedingstuffs where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

(3) 'Supplementary feedingstuffs' diluted as specified, may not contain levels of the additives which exceed those fixed for complete feedingstuffs.

(4) In the case of premixes containing silage additives the words "CONTAINS SILAGE ADDITIVES" must clearly be added on the label after "PREMIX".