

EN**ANNEX I**

Annexes I, II, III and IV to Regulation (EC) No 429/2008 are amended as follows:

1. Annex I is replaced by the following:

'ANNEX I

APPLICATION FORM REFERRED TO IN ARTICLE 2(1)

APPLICATION FORM

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Subject: Application for authorisation of a feed additive in accordance with Regulation (EC) No 1831/2003.

Submission date:

I. TYPE OF SUBMISSION

- Application for authorisation of a new feed additive (Article 4(1) of Regulation (EC) No 1831/2003)
- Application for authorisation of a new use and/or modification and/or renewal of the authorisation of a feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003):
 - New use (Article 4 of Regulation (EC) No 1831/2003)
 - Modification of an existing authorisation (Article 13(3) of Regulation (EC) No 1831/2003)
 - Renewal of a feed additive authorisation (Article 14 of Regulation (EC) No 1831/2003)
- Submission of complementary information following Authority's inconclusive opinion

II. SUBJECT OF THE APPLICATION

1. **Subject of the request: provide the name of the substance, preparation or micro-organism;**
 - if the application is submitted for the modification of an existing authorisation

under Article 13(3), explain the modification that is requested;

- if the application is submitted for the renewal of an existing authorisation under Article 14, explain any proposal for amending or supplementing the conditions of the original authorisation in accordance with Article 14(2)(d), as appropriate:

2. Identification and characterisation of the additive as defined in subsections 2.2.1.1 and 2.2.1.2 of Annex II to Regulation (EC) No 429/2008

Additive type(s) to be placed on the market:

- Substance
- Micro-organism
- Preparation

Name of additive:

Trade name of the additive (required only for coccidiostats and histomonostats):

Identifiers of the substance:

3. Category/ies and functional group/s of additives ⁽¹⁾

Category:

Functional group:

⁽¹⁾ For the functional groups 1(m) substances for reduction of the contamination of feed by mycotoxins, 1(n) hygiene condition enhancers, 1(o) other technological additives, 4(c) substances which favourably affect the environment, 4(d) other zootechnical additives, and 4(e) physiological condition stabilisers, it shall be necessary to define clearly, including in the public summary, which specific function is sought for the additive.

4. Target animal species and category(ies) as designated in Annex IV to Regulation (EC) No 429/2008

Species:

Category:

Additional precision or comment on the species / category:

5. Proposed mode of use in animal nutrition

- Use in feed
- Use in water for drinking
- Special conditions of use

6. Existing authorisations, if applicable

Existing authorisation in the EU feed legislation:

Eur-Lex link:

Functional group in which the feed additive is currently authorised:

Identification number of the feed additive as currently authorised:

Existing authorisation under the GMO legislation

Unique identifier (Commission Regulation (EC) No 65/2004 (2) (where appropriate):

Has any authorisation been granted in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council?

- Yes
- No

Is there any pending application for authorisation under Regulation (EC) No 1829/2003 of the European Parliament and of the Council?

- Yes
- No

(2) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5, ELI: <http://data.europa.eu/eli/reg/2004/65/oj>).

III. REFERENCE SAMPLES

Community Reference Laboratory (CRL) sample number (if applicable):

IV. ADMINISTRATIVE DATA

1. Applicant's administrative data

Applicant name (to be retained as the name of the authorisation holder, if applicable):

Email:

Phone number:

Website:

Address:

Post code:

Country:

2. Applicant's EU representative contact details (as necessary)

EU Representative name:

Email:

Phone number:

Website:

Address:

Post code:

Country:

3. Contact person/Person responsible for the dossier contact details

Name of contact person / person responsible:

Name of the entity/organization:

Email:

Phone number:

Website:

Address:

Post code:

Country:,'

2. Annex II is amended as follows:

(1) in point 3.1.1.2., Table 2, Table 5 and Table 7 are replaced by the following:

Table 2
Duration of tolerance trials: Poultry

Target animals	Duration of the studies	Characteristic of the target animals
Chickens for fattening and	35 days	From hatching

chickens reared for laying or reproduction		
Laying hens	56 days	Preferably during the first third of the laying period
Turkeys for fattening	42 days	From hatching

Tolerance data from chickens for fattening or turkeys for fattening can be used to demonstrate tolerance for chickens or turkeys reared for laying/reproduction respectively.';

*'Table 5
Duration of tolerance trials: Salmonids'*

Target animals	Duration of the studies	Characteristic of the target animals
Salmon and trout	90 days	

As an alternative to a 90-day duration, a study could be performed where the finfish increase their initial body weight at the start of the trial by least a factor of two.

If the additive is intended to be used for brood stock only, the tolerance tests shall be carried out as close to the spawning period as possible. The tolerance tests shall last for 90 days and attention shall be paid to the egg quality and survival of the eggs.';

*'Table 7
Duration of tolerance trials: Rabbits'*

Target animals	Duration of the studies	Characteristic of the target animals
Rabbits for fattening	28 days	
Rabbit does	1 cycle	From insemination to the end of the weaning period

If rabbits suckling and weaned are applied for, a period of 49 days (beginning one week after birth) would be considered sufficient and must include the does until weaning.'

(2) in point 3.2.1.2., the fifth subparagraph is replaced by the following:

'For the determination of a withdrawal period, the suggested minimum number of animals sampled and/or products at each time point are the following:

- edible tissues:
 - bovines, sheep, pigs and minor species: 4;
 - poultry: 6;
 - salmonids and other food-producing finfish: 10.
- products:

- milk: 8 samples per time point;
- eggs: 10 eggs per time point;
- honey: 8 samples per time point. ’;

(3) in point 3.2.3.3., the third subparagraph is replaced by the following:

‘For additives intended for multi-species, the exposure from tissues shall be independently calculated for mammals, poultry and food-producing finfish and the highest value taken. Where appropriate, exposure from milk and eggs shall be added to this figure. For example, where an additive is applied for lactating mammals and laying birds, the respective highest edible tissue values are added to those for milk and egg consumption. Where the additive is applied for food-producing finfish and laying birds and lactating mammals, the respective highest edible tissue values are added to those for egg and milk consumption. Other combinations shall be envisaged in the same way. ’;

(4) in point 3.2.3.3., the title of the third column of Table 1 is replaced by ‘Poultry’ and the title of the fourth column of Table 1 is replaced by ‘Food-producing finfish’;

(5) in point 3.4.1.2., the first subparagraph is replaced by the following:

‘Feed additives used in aquaculture can result in contamination of sediment and water. The compartment of concern for the environmental risk assessment for food-producing finfish farmed in cages is assumed to be the sediment. For food-producing finfish farmed in land-based systems the effluent flowing to surface water is considered to pose the major environmental risk. ’;

(6) point 3.4.2.1. is replaced by the following:

‘Phase II A

In addition to the compartments considered in Phase I, the PEC for surface water has to be calculated considering runoff and drainage.

Based on data not considered in Phase I, a more refined PEC can be calculated for each environmental compartment of concern. In ascertaining the refined PEC, account shall be taken of:

- (a) the concentration of active substance(s)/metabolites of concern in manure/finfish faeces following administration of the additive to animals at the proposed dose level. This calculation shall include consideration of dosage rates and amount of excreta produced;
- (b) the potential degradation of the excreted active substance(s)/metabolites of concern during normal manure processing practice and storage prior to its application to land;
- (c) the adsorption/desorption of the active substance(s)/metabolites of concern onto soil or sediment for aquaculture, preferentially determined by studies in soil/sediment (OECD 106);
- (d) degradation in soil and water/sediment systems (OECD 307 and 308, respectively); and

(e) other factors such as hydrolysis, photolysis, evaporation, dilution through ploughing.

The highest value for the PEC obtained from these calculations for each environmental compartment of concern shall be adopted for Phase II risk assessment purposes.

If a high persistence in soil/sediment is anticipated (time to degradation of 90 % of original concentration of the compound: DT₉₀ > 1 year), the potential for accumulation shall be considered.

The concentrations of additives (or metabolites) producing serious adverse effects for various trophic levels in the environmental compartments of concern shall be determined. These tests are mostly acute tests and should follow OECD or similar well-established guidelines. Studies for the terrestrial environment shall include: toxicity to earthworms; three terrestrial plants; and soil micro-organisms (e.g. effects on nitrogen fixation). Studies for the fresh water environment shall include: toxicity to finfish; Daphnia magna; algae; and a sediment dwelling organism. In case of sea cages, three species of different taxa of sediment dwelling organisms shall be studied.

Calculation of the PNEC value shall be carried out for each compartment of concern. The PNEC is normally derived from the lowest toxicity value observed in the above tests and dividing by a safety factor of at least 100 depending on the endpoint and number of test species used.

The potential for bioaccumulation can be estimated from the value of the n-octanol/water partition coefficient, Log K_{ow}. Values ≥ 3 indicate that the substance may bioaccumulated. In order to assess the risk for secondary poisoning it shall be considered whether to carry out a bioconcentration factor (BCF) study at Phase II B.'

(7) point 4.4. is replaced by the following:

‘4.4. Duration of long term efficacy studies with target animals

In principle, the duration of efficacy trials shall correspond to the application period claimed.

Efficacy trials shall be carried out according to farming practices in the Union and be of the minimum duration as stated by Annex IV.

For minor species for which a minimum duration period of studies is not established in Annex IV, the minimum duration shall correspond to that of the physiologically related major species, as applicable. For other animal species and categories for which a minimum duration period of studies is not established in Annex IV, the minimum duration shall be 42 days for growing animals (from birth to slaughter or to entry in the reproduction period) and 56 days for adult animals (from entry in the reproduction period).

If an additive is applied for a specific and shorter period than normally applicable for the animal species or category, it shall be administered according to the proposed conditions of use. However, the observation period shall not be shorter than 28 days and shall involve the relevant end-points (e.g., for sows the number of piglets born alive when considering the gestation period, or the number and weight of weaned piglets when considering the lactation period).’;

3. Annex III is amended as follows:

(1) in point 2.1.3., subparagraph (3) is replaced by the following:

‘(3) For substances which favourably affect the colour of ornamental aquatic species or ornamental birds, studies concerning Section III subsection 3.1 of Annex II are required and shall be performed on animals receiving the additive at the recommended dose. Evidence can also be provided by reference to existing scientific literature. However, subsections 3.2 and 3.4 are not required.’;

(2) in point 2.1.4., subparagraph (c) is replaced by the following:

‘(c) For substances which favourably affect the colour of ornamental aquatic species and birds:

studies demonstrating the effect(s) shall be performed on animals receiving the additive at the recommended levels of use. Colour changes shall be measured using the appropriate methodology. Evidence of efficacy may also be provided by other experimental studies (e.g. bioavailability) or by reference to scientific literature.’;

(3) in point 5.4., the first subparagraph is replaced by the following:

‘These additives protect the animals from the results of an invasion of *Eimeria* spp. or *Histomonas meleagridis*. Importance shall be attached to evidence of the specific effects of the additive (e.g. species controlled) and its prophylactic properties (e.g. reduction in morbidity, mortality, oocyst count and lesion score). Information on the effect on growth and feed conversion (fattening birds, replacement layers and rabbits), effects on hatchability (birds for reproduction) shall be provided, as appropriate.’;

(4) in point 6., the first subparagraph is replaced by the following:

‘Major species and minor species are defined in Article 1(2) and (3) of this Regulation.’

(5) in point 6.3.1.1., the third subparagraph is replaced by the following:

‘If three major target species (including monogastric and ruminant mammals and poultry) showed a similar and wide margin of safety, no additional tolerance studies is required for non-physiologically similar minor species (e.g. horses or rabbits). Where tolerance is required, the duration of the studies for minor species (except rabbits) shall be at least 28 days for growing animals and 42 days for adult animals. For rabbits, the following durations apply: rabbits for fattening: 28 days; rabbit does: one cycle (from insemination to the end of the weaning period). If rabbits suckling and weaned are applied for, a period of 49 days (beginning one week after birth) is considered sufficient and must include the does until weaning. For food-producing finfish (other than salmonids) a 90-day period is required.’;

(6) point 6.3.2.3. is replaced by the following:

‘6.3.2.3. Assessment of consumer safety

Proposal for Maximum Residue Limits (MRLs)

Setting of MRLs can be done by assuming that no significant differences in the content of residues occur in the edible tissues of minor species compared to a similar major species.

MRLs can be extrapolated within classes of animals as follows:

- from major growing ruminants to all growing ruminants;
- from milk of dairy cows to milk of other dairy ruminants;
- from pigs to all monogastric mammals, excluding horses;
- from chickens or turkeys to other poultry;
- from laying hens to other laying birds; and
- from salmonids to all food-producing finfish.

MRLs for horses could be extrapolated when MRLs for a major ruminant and a major monogastric mammal exist.

If identical MRLs were derived in cattle (or sheep), pigs and chicken (or poultry), which represent major species with different metabolic capacities and tissue composition, the same MRLs can also be set for ovines, equines and rabbits, which means an extrapolation is considered possible to all food-producing animals except food-producing aquatic animals. Considering the Committee for Medicinal Products for Veterinary Use (CVMP) guideline ^(x) on the establishment of MRLs for salmonids and other food-producing finfish, which already allows an extrapolation from MRLs in muscle of a major species to salmonids and other food-producing finfish provided that the parent substances is acceptable as marker residue for the MRL in muscle and skin, MRLs can be extrapolated to all food-producing animals.

Analytical methods shall be available for monitoring residues in edible tissue and products of all food-producing animals.

^(x) Note for guidance of the establishment of maximum residue limits for *Salmonidae* and other fin fish. The European Agency for the Evaluation of Medicinal Products. Veterinary Medicines Evaluation Unit. EMEA/CVMP/153b/97-FINAL.’;

4. Annex IV is replaced by the following:

'ANNEX IV'

DESIGNATION OF THE TARGET ANIMAL CATEGORIES AND MINIMUM DURATION OF THE LONG TERM EFFICACY STUDIES

1. Porcine species (Suidae)

Animal species	Animal category	Definition of the animal category	Approximate weight/age in the category			Minimum duration of long-term efficacy studies
			Period/age	Age	Weight	
Pigs	Suckling piglets	Piglets getting milk from sows, reared for reproduction or meat production, from birth until weaning		Up to 21-42 days	Up to 6-11 kg	
	Weaned piglets	Piglets reared for reproduction or meat production, having completed the suckling period until the end of the post-weaning period (transition period)	From 21-42 days	Up to 120 days	Up to 35 kg	42 days 35 days, if the growth rate is $\geq 0,5$ kg/day
	Piglets	Piglets reared for reproduction or meat production, from birth until the end of the post-weaning period (transition period)		Up to 120 days	Up to 35 kg	
	Pigs for fattening	Pigs for meat production, from the end of the post-weaning period (transition period) until date of slaughter	From 60-120 days	Up to 120-250 days (or according to local custom)	80-150 kg (or according to local custom)	Until slaughter, but not less than 70 days
	Pigs reared for reproduction	Females (gilts) and males reared for reproduction, from the end of the post-weaning period (transition period) until entry in the reproduction period				
	Sows	Females for reproduction, which				Two full reproduction

		have mated or have been inseminated at least once				cycles
	Sows, in order to have benefit in piglets	Females for reproduction, which have mated or have been inseminated at least once. For cases where the benefit of feeding the additive to the sows will be claimed in the piglets.				No later than from parturition until the end of the weaning period (but no less than 28 days)
	Boars	Males for reproduction, from entry in the reproduction period				
	Pigs	All categories of pigs				
Minor porcine species	Suckling piglets of minor porcine species	Piglets of all minor porcine species getting milk from sows, reared for reproduction or meat production, from birth until weaning				
	Weaned piglets of minor porcine species	Piglets of all minor porcine species reared for reproduction or meat production, having completed the suckling period until the end of the post-weaning period (transition period)				
	Piglets of minor porcine species	Piglets of all minor porcine species reared for reproduction or meat production, from birth until the end of the post-weaning period (transition period)				
	Minor porcine species for fattening	Animals of all minor porcine species for meat production, from the end of the post-weaning period (transition period) until date of slaughter				
	Minor porcine species reared for reproduction	Animals of all minor porcine species reared for reproduction, from the end of the post-weaning period (transition period) until entry in the reproduction period				

	Sows of minor porcine species	Females of all minor porcine species for reproduction, which have mated or have been inseminated at least once				
	Boars of minor porcine species	Males of all minor porcine species for reproduction, from entry in the reproduction period				
	Minor porcine species	All species and categories of all minor porcine species				
Porcine species	Suckling piglets of porcine species	Piglets of all porcine species getting milk from sows, reared for reproduction or meat production, from birth until weaning				
	Weaned piglets of porcine species	Piglets of all porcine species reared for reproduction or meat production, having completed the suckling period until the end of the post-weaning period (transition period)				
	Piglets of porcine species	Piglets of all porcine species reared for reproduction or meat production, from birth until the end of the post-weaning period (transition period)				
	Porcine species for fattening	Animals of all porcine species for meat production, from the end of the post-weaning period (transition period) until date of slaughter				
	Porcine species reared for reproduction	Animals of all porcine species reared for reproduction, from the end of the post-weaning period (transition period) and until entry in the reproduction period				
	Sows of porcine species	Females of all porcine species for reproduction, which have mated or				

		have been inseminated at least once				
Boars of porcine species		Males of all porcine species for reproduction, from entry in the reproduction period				
Porcine species		All species and categories of all porcine species				

2. Poultry

Species	Animal category	Definition of the animal category	Approximate weight/age in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Chickens	Chickens for fattening	Broilers for meat production, from hatching to slaughter		Up to 35 days	Up to ~1 600 g (up to 2 kg)	35 days
	Chickens reared for laying or reproduction	Females and males reared for laying (consumer egg production) or reproduction, from hatching until entry in the laying or reproduction period		Up to ~16 weeks (up to 20 weeks)		
	Hens	Hens, from entry in the laying (consumer egg production) or reproduction period	From 16-21 weeks	Up to ~13 months (up to 18 months)	From 1 200 g (white) 1 400 g (brown)	84 days
	Roosters	Roosters, from entry in the reproduction period				
	Chickens	All categories of chickens				
Turkeys	Turkeys for fattening	Turkeys for meat production, from hatching to slaughter		Up to ~14 weeks (up to 20 weeks) Up to ~16 weeks (up to 24 weeks)	Hens: up to ~7 000 g (up to 10 000 g) Cocks: up to ~12 000 g (up to 20 000 g)	84 days
	Turkeys reared for reproduction	Females and males reared for reproduction, from hatching until entry in the reproduction period		Up to 30 weeks	Hens: up to ~15 000 g Cocks: up to	

				~30 000 g	
	Turkeys for reproduction	Female and male birds held for breeding purposes		From 30 weeks up to ~ 60 weeks	Hens: from ~15 000 g Cocks: from ~30 000 g
	Turkeys	All categories of turkeys			
Minor poultry	Minor poultry for fattening	Females and males of all minor poultry species for meat production, from hatching to slaughter			
	Minor poultry reared for laying or reproduction	Females and males of all minor poultry species reared for laying (consumer egg production) or reproduction, from hatching until entry in the laying or reproduction period			
	Minor poultry for laying or reproduction	Females and males of all minor poultry species, from entry in the laying (consumer egg production) or reproduction period			
	Minor poultry	All species and categories of minor poultry			
Poultry	Poultry for fattening	Females and males of all poultry species for meat production, from hatching to slaughter			
	Poultry reared for laying or reproduction	Females and males of all poultry species reared for laying (consumer egg production) or reproduction, from hatching until entry in the laying or reproduction period			
	Poultry for laying or reproduction	Females and males of all poultry species, from entry in the laying (consumer egg production) or reproduction period			
	Poultry	All species and categories of poultry			

3. Ruminants

Species	Animal category	Definition of the animal category	Approximate weight/age in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Cattle	Calves for fattening	Calves for veal production, from birth until date of slaughter		Up to 6 months	Up to 180 kg (up to 250 kg)	84 days
	Calves for rearing	Calves reared for milk production/reproduction or for meat production, from birth up to 4 months			Up to 60-80 kg (up to 145 kg)	56 days
	Cattle for fattening	Cattle for meat production, other than calves for fattening and calves for rearing, until date of slaughter	From full development of rumination	Up to 10-36 months	Up to 350-700 kg	84 days
	Cattle reared for milk production / reproduction	Heifers and young bulls, other than calves for rearing, reared for milk production/reproduction, until entry in the reproduction period				
	Cows	Cows for milk production (dairy cows)/reproduction, which have mated or have been inseminated at least once				84 days Two cycles, if the reproduction parameters are requested.
	Bulls	Bulls for reproduction, from entry in the reproduction period				
	Cattle	All categories of cattle				
Minor bovine species	Calves of minor bovine species for fattening	In all minor bovine species, calves for veal production, from birth until date of slaughter				
	Calves of minor bovine species for rearing	In all minor bovine species, calves reared for milk production/reproduction or for meat production, from birth up to 4 months				

	Minor bovines for fattening	In all minor bovine species, animals for meat production other than calves for fattening and calves for rearing, until date of slaughter				
	Minor bovines reared for milk production/reproduction	In all minor bovine species, heifers and young bulls other than calves for rearing, reared for milk production/reproduction, until entry in the reproduction period				
	Cows of minor bovine species	In all minor bovine species, cows for milk production/reproduction, which have mated or have been inseminated at least once				
	Bulls of minor bovine species	In all minor bovine species, bulls for reproduction, from entry in the reproduction period				
	Minor bovines	All species and categories of minor bovines				
Bovines	Calves of bovine species for fattening	In all bovine species, calves for veal production, from birth until date of slaughter				
	Calves of bovine species for rearing	In all bovine species, calves reared for milk production/reproduction or for meat production, from birth up to 4 months				
	Bovines for fattening	In all bovine species, animals for meat production other than calves for fattening and calves for rearing, until date of slaughter				
	Bovines reared for milk production/reproduction	In all bovine species, heifers and young bulls other than calves for rearing, reared for milk production/reproduction, until entry in the reproduction period				
	Cows of bovine	In all bovine species, cows for milk				

	species	production/reproduction, which have mated or have been inseminated at least once				
	Bulls of bovine species	In all bovine species, bulls for reproduction, from entry in the reproduction period				
	Bovines	All species and categories of bovines				
Sheep	Lambs for fattening	Lambs for lamb meat production, from birth until date of slaughter		Up to 6 months (or older)	up to 55 kg	56 days
	Lambs for rearing	Lambs reared for milk production/reproduction, from birth up to 3 months			15-20 kg	56 days
	Sheep for fattening	Sheep for meat production other than lambs for fattening, until date of slaughter				
	Sheep reared for milk production / reproduction	Young sheep other than lambs for rearing, females and males, reared for milk production/reproduction, until entry in the reproduction period				
	Ewes	Ewes for milk production (dairy sheep)/reproduction, which have mated or have been inseminated at least once				84 days Two cycles, if the reproduction parameters are requested.
	Rams	Rams for reproduction, from entry in the reproduction period				
	Sheep	All categories of sheep				
Ovines	Lambs of ovine species for fattening	In all ovine species, lambs for meat production, from birth until date of slaughter				
	Lambs of ovine species for rearing	In all ovine species, lambs reared for milk production/reproduction, from birth up to 3 months				
	Ovines for	In all ovine species, ovines for meat				

	fattening	production other than lambs for fattening, until date of slaughter				
	Ovines reared for milk production/reproduction	In all ovine species, young animals other than lambs for rearing, females and males, reared for milk production/reproduction, until entry in the reproduction period				
	Ewes of ovine species	In all ovine species, ewes for milk production/reproduction, which have mated or have been inseminated at least once				
	Rams of ovine species	In all ovine species, rams for reproduction, from entry in the reproduction period				
	Ovines	All species and categories of ovines				
Goats	Kids for fattening	Kids for meat production, from birth until date of slaughter		Up to 6 months		56 days
	Kids for rearing	Kids reared for milk production/reproduction, from birth up to 3 months			15-20 kg	56 days
	Goats for fattening	Goats for meat production other than kids for fattening, until date of slaughter				
	Goats reared for milk production / reproduction	Young goats other than kids for rearing, females and males, reared for milk production/reproduction, until entry in the reproduction period				
	Goat does	Female goats for milk production (dairy goats)/reproduction, which have mated or have been inseminated at least once				84 days Two cycles, if the reproduction parameters are requested.
	Goat bucks	Bucks (billy goats) for reproduction, from entry in the reproduction period				
	Goats	All categories of goats				

Caprines	Kids of caprine species for fattening	In all caprine species, kids for meat production, from birth until date of slaughter				
	Kids of caprine species for rearing	In all caprine species, kids reared for milk production/reproduction), from birth up to 3 months				
	Caprines for fattening	In all caprine species, caprines for meat production other than kids for fattening, until date of slaughter				
	Caprines reared for milk production/reproduction	In all caprine species, young goats other than kids for rearing, females and males, reared for milk production/reproduction, until entry in the reproduction period				
	Does of caprine species	In all caprine species, female goats for milk production/reproduction, which have mated or have been inseminated at least once				
	Bucks of caprine species	In all caprine species, bucks for reproduction, from entry in the reproduction period				
	Caprines	All species and categories of caprines				
Cervids		All species of cervids				
Ruminants	Young ruminants for fattening	In all ruminant species, calves, lambs, kids, etc. for meat production, from birth until date of slaughter				
	Young ruminants for rearing	In all ruminant species, calves, lambs, kids, etc. reared for milk production/reproduction, from birth up to 4 months (bovines) or up to 3 months (ovines, caprines and cervids)				
	Ruminants for fattening	In all ruminant species, animals for meat production other than young				

		ruminants for fattening, until date of slaughter				
Ruminants reared for milk production/reproduction	In all ruminant species, female and male animals other than young ruminants for rearing, reared for milk production or reproduction, until entry in the reproduction period					
Ruminants for milk production/reproduction	In all ruminant species, females which have mated or have been inseminated at least once, and adult males from entry in the reproduction period					
Ruminants	All species and categories of ruminants					

4. Food-producing aquatic animals

Species	Animal category	Definition of the animal category	Approximate weight/age in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Food-producing finfish	Salmonids				200-300 g	84 days
	Food-producing finfish other than salmonids	All species of food-producing finfish other than salmonids				
	Food-producing finfish	All species of food-producing finfish				
Food-producing molluscs		All species of food-producing molluscs				
Food-producing crustaceans		All species of food-producing crustaceans				
Other food-producing aquatic invertebrates		All species of other food-producing aquatic invertebrates				
Food-producing		All species and categories of food-				

aquatic animals		producing aquatic animals				
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5. Leporids (Leporidae)

Species	Animal category	Definition of the animal category	Approximate weight/age in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Rabbits	Growing rabbits	Females and males of: -kits getting milk from rabbit does, reared for reproduction or meat production from birth until weaning (suckling rabbits), -rabbits for fattening, from the end of the weaning period until slaughter, -young rabbits reared for reproduction, from the end of the weaning period until entry in the reproduction period				42 days
	Rabbit does	Females for reproduction, which have mated or have been inseminated at least once				Two cycles, if the reproduction parameters are requested. No later than from parturition until the end of the weaning period, if the application is in order to have benefit in kits.
	Rabbit bucks	Males for reproduction, from entry in the reproduction period				
	Rabbits	All categories of rabbits				
Leporids	Growing leporids	Females and males of: -leporid kits getting milk from				

		leporid does, reared for reproduction or meat production from birth until weaning (suckling leporids), - leporids for fattening, from the end of the weaning period until slaughter, - young leporids reared for reproduction, from the end of the weaning period until entry in the reproduction period				
	Leporid does	Females for reproduction, which have mated or have been inseminated at least once				
	Leporid bucks	Males for reproduction, from entry in the reproduction period				
	Leporids	All species and categories of leporids				

6. Equines (Equidae)

Species	Animal category	Definition of the animal category	Approximate weight/age in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Horses						
Equines		All species of equines				

7. Other food-producing animals

Species	Animal category	Definition of the animal category	Approximate duration period (weight/age) in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Camelids	Camelid calves for fattening	In all camelid species, calves for meat production				

	Camelid calves for rearing	In all camelid species, calves reared for milk production/reproduction				
	Camelids for fattening	In all camelid species, animals for meat production other than calves for fattening				
	Camelids reared for milk production or reproduction	In all camelid species, young female and male animals other than calves for rearing, reared for milk production or reproduction, until entry in the reproduction period				
	Camelids for milk production or reproduction	In all camelid species, females which have mated or have been inseminated at least once and adult males				
	Camelids	All species and categories of camelids				
Food-producing insects	Honeybees					28 days
	Food-producing insect species other than honeybees	All food-producing insect species other than honeybees				Whole production cycle
	Food-producing insects	All species of food-producing insects				Whole production cycle
Other food-producing animals		Only for species that are not covered in the previous entries. For example: snails, frogs, crocodiles...				

8. Pets and other non-food producing animals

Species	Animal category	Definition of the animal category	Approximate duration period (weight/age) in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
Pets	Dogs					28 days
	Cats					28 days
	Ornamental birds					28 days

	Ornamental aquatic species				28 days
	Other pets	Other pet species: ferrets, rodents, ornamental amphibian species, ornamental reptile species or ornamental terrestrial invertebrate species			28 days
Other non-food producing animals		All species of non-food producing animals, other than pets			28 days
Pets and other non-food producing animals		All species of non-food producing animals			28 days

9. All animal species

Species	Animal category	Definition of the animal category	Approximate duration period (weight/age) in the category			Minimum duration of long term studies for efficacy
			Period	Age	Weight	
All terrestrial animal species						
All aquatic animal species						
All animal species						

ANNEX II

The following Annex V is added to Regulation (EC) No 429/2008:

'ANNEX V

DEFINITION OF RESPECTIVE ANIMAL SPECIES AND DIFFERENTIATION BETWEEN MAJOR AND MINOR SPECIES AS REGARDS FOOD-PRODUCING ANIMAL SPECIES

1. Porcine species (Suidae)

Animals of species which, within the family *Suidae* genus *Babyrousa* ssp., *Hylochoerus* ssp., *Phacochoerus* ssp., *Porcula* ssp., *Potamochoerus* ssp. and *Sus* ssp., and the offsprings of the crossing of those species, are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Major species: pigs (*Sus scrofa domesticus*).

Minor species: porcine species, other than pigs (*Sus scrofa domesticus*).

2. Poultry

Birds of species which are fed, bred or kept for the production of food for human consumption, including restocking supplies of game birds, and including birds that are not used for the production of food for human consumption but belong to species which are normally used for human consumption in the Union.

Major species: chickens (including laying hens) (*Gallus gallus domesticus*) and turkeys (*Meleagris gallopavo*).

Minor species: poultry, other than chickens and turkeys, including quails (e.g. *Coturnix japonica*, *Coturnix coturnix*), ducks (e.g. *Anas platyrhynchos*, *Cairina moschata*), geese (e.g. *Anser anser*), Guinea fowls (*Numida meleagris*), pigeons (e.g. *Columba livia domestica*), pheasants (e.g. *Phasianus colchicus*), Indian peafowls (*Pavo cristatus*), partridges (e.g. *Perdix perdix*, *Alectoris rufa*), ratites including ostrich (*Struthio* sp.), emu (*Dromaius novaehollandiae*), rhea (*Rhea* sp.).

3. Ruminants

Bovine, ovine and caprine and cervid animals, as defined below.

(a) **Bovines**: animals of species of ungulates which, within the genus *Bison*, *Bos* (including the subgenus *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*), and the offsprings of the crossing of those species, are fed, bred or kept for the

production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Major species: cattle (*Bos taurus*).

Minor species: all bovines other than cattle (*Bos taurus*), including buffalo (*Bubalus bubalis*) and bison (*Bison bison*).

(b) **Ovines**: animals of species of ungulates which, within the genus *Ovis*, and the offsprings of the crossing of those species, are fed, bred or kept for the production of food for human consumption, animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Major species: sheep (*Ovis aries*) for meat production (meat animals).

Minor species: ovines other than sheep (*Ovis aries*) for meat production.

(c) **Caprines**: animals of the species of ungulates which, within the genus *Capra*, and the offsprings of the crossing of those species, are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Minor species: all caprines.

(d) **Cervids (Cervidae)**: animals of the species of ungulates which, within the family *Cervidae*, and the offsprings of the crossing of those species, are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Minor species: all cervids.

4. Food-producing aquatic animals

Animals of the species which, within the following:

- (a) finfish, belonging to the classes *Chondrichthyes*, *Sarcopterygii*, *Actinopterygii*, and *Hyperoartia*
- (b) aquatic molluscs, belonging to the phylum *Mollusca*,
- (c) aquatic crustaceans, belonging to the subphylum *Crustacea*,
- (d) other aquatic invertebrates,

are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Major species: salmonids (Salmonidae), including salmon (*Salmo*) and trout (*Oncorhynchus*).

Minor species: all food-producing aquatic animals other than salmonids.

5. Leporids (Leporidae)

Animals of species which, within the family *Leporidae*, are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Minor species: all leporids, including rabbits (*Oryctolagus cuniculus*) and hares (*Lepus europaeus*).

6. Equines (Equidae)

Animals of species which, within the genus *Equus*, and the offspring of crossings of those species, are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Minor species: all equines, including horses (*Equus caballus*) and asses (*Equus asinus*).

7. Other food-producing animals

Animals of species, other than porcine species, poultry, ruminants, food-producing aquatic species, leporids and equines as defined above, and the offsprings of the crossing of those species, which, within the following:

- (a) Camelids (Camelidae): animals, belonging to the family *Camelidae*, including dromedary camels (*Camelus dromedarius*), Bactrian camels (*Camelus bactrianus*), wild Bactrian camels (*Camelus ferus*), llamas (*Lama glama*), alpacas (*Lama pacos*), vicuñas (*Lama vicugna*) and guanacos (*Lama guanicoe*),
- (b) Honeybees (*Apis mellifera*),
- (c) Food-producing insect species, other than honeybees,
- (d) Other food-producing animals,

are fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption but belong to the species which, among the above-mentioned group of species, are normally used for human consumption in the Union.

Minor species: all species of other food-producing animals.

8. Pets and other non-food producing animals

In accordance with the definition set out in Article 1(1), pets and non-food producing animals include the following species:

- (a) Pets:
 - i. Dogs (*Canis lupus familiaris*);
 - ii. Cats (*Felis silvestris catus*);
 - iii. Ferrets (*Mustela putoris furo*);
 - iv. Rodents: animals belonging to the order *Rodentia*;

- v. Ornamental birds: avian species other than poultry, including wild birds;
- vi. Ornamental aquatic species: aquatic species other than those listed in “food-producing aquatic animals”;
- vii. Ornamental amphibian species: amphibian species other than those that are normally used for human consumption in the Union;
- viii. Ornamental reptile species: reptile species other than those that are normally used for human consumption in the Union;
- ix. Ornamental terrestrial invertebrate species: terrestrial invertebrate species other than those listed in “other food-producing animals” and other than those that are normally used for human consumption in the Union.

(b) Other non-food producing animals:

- x. Fur animals (mink, fox, racoon);
- xi. Other, including zoo, circus and laboratory animals, other than those belonging to species normally used for human consumption in the Union.

Rabbits and horses, including animals thereof that are not used for human consumption, do not belong to the group of pets and non-food producing animals but to that of leporids (*Leporidae*) and equines (*Equidae*), respectively.

9. All animal species

Animals of:

- (a) all terrestrial animal species: porcine species, poultry, ruminants, leporids, equines, other food-producing animals, pets and other non-food producing animals except ornamental aquatic species.
- (b) all aquatic animal species: food-producing aquatic animals and ornamental aquatic species.

ANNEX III

CONCORDANCE TABLE OF ANIMAL SPECIES AND CATEGORIES

Terms commonly used for the designation of animal species and categories in authorisations granted before [date of entry into application of this Regulation. To be completed by the Service responsible for the publication]	Terms designating the corresponding animal species and categories in accordance with this Implementing Regulation (alternatives may be considered appropriate on a case-by-case basis) <small>[Animal species/category (additional precision)]</small>
All animal species	All animal species
All avian species	Poultry + Ornamental birds
All avian species for fattening	Poultry for fattening

All avian species for laying	Poultry for laying or reproduction
All avian species reared for breeding	Poultry reared for laying or reproduction
All avian species reared for laying	Poultry reared for laying or reproduction
All crustaceans	Food-producing crustaceans + Ornamental aquatic species (crustaceans)
All fin fish	Food-producing finfish + Ornamental aquatic species (finfish)
All fish	Food-producing finfish + Ornamental aquatic species (finfish)
All laying poultry	Poultry for laying or reproduction
All minor avian species for fattening	Minor poultry for fattening
All minor avian species reared for laying	Minor poultry reared for laying or reproduction
All minor porcine species	Minor porcine species
All minor poultry species for laying	Minor poultry for laying or reproduction
All minor ruminant species for rearing	Calves of minor bovine species for rearing + Minor bovines reared for milk production/reproduction + Lambs of ovine species for rearing + Ovines reared for milk production/reproduction + Kids of caprine species for rearing + Caprines reared for milk production/reproduction + Cervids (animals for rearing)
All minor ruminant species for fattening	Calves of minor bovine species for fattening + Minor bovines for fattening + Lambs of ovine species for fattening (except sheep) + Ovines for fattening (except sheep) + Kids of caprine species for fattening + Caprines for fattening + Cervids (animals for fattening)
All pigs	Pigs
All porcine species	Porcine species
All porcine species weaned	Weaned piglets of porcine species
All porcine species for breeding	Sows of porcine species + Boars of porcine species
All poultry	Poultry
All poultry species	Poultry
All poultry species for fattening	Poultry for fattening
All poultry species for laying	Poultry for laying or reproduction
All poultry species reared for breeding	Poultry reared for laying or reproduction
All poultry species reared for laying	Poultry reared for laying or reproduction
All species	All animal species
All species or categories of animals	All animal species
All Suidae	Porcine species
All Suidae for fattening	Porcine species for fattening
All Suidae for reproduction purposes	Sows of porcine species + Boars of porcine species
All turkeys	Turkeys
Aquatic animals	All aquatic animal species
Bovines	Bovines
Breeder hens	Hens
Breeding hens	Hens
Calves	Calves for fattening + Calves for rearing
Calves (milk replacer)	Calves for fattening + Calves for rearing

Calves for fattening	Calves for fattening
Calves for rearing	Calves for rearing
Camelids for rearing	Camelid calves for rearing + Camelids reared for milk production or reproduction
Camelids for fattening	Camelid for fattening
Canaries	Ornamental birds (canaries)
Canidae	Dogs + Other non-food producing animals (Canidae)
Carp	Food-producing finfish other than salmonids (carp)
Cats	Cats
Cattle	Cattle
Cattle for fattening	Cattle for fattening
Chickens	Chickens
Chickens for fattening	Chickens for fattening
Chickens reared for breeding	Chickens reared for laying or reproduction
Chickens reared for laying	Chickens reared for laying or reproduction
Cows for reproduction	Cows + Cattle reared for milk production/reproduction
Crustaceans	Food-producing crustaceans + Ornamental aquatic species (crustaceans)
Dairy buffaloes	Cows of minor bovine species (buffaloes)
Dairy cows	Cows
Dairy cows of minor bovine species	Cows of minor bovine species
Dairy goats	Goat does
Dairy ruminants	Ruminants for milk production/reproduction
Dairy sheep	Ewes
Dogs	Dogs
Ducks	Minor poultry (ducks)
Ducks for fattening	Minor poultry for fattening (ducks)
Equidae	Equines
Fattening Suidae	Porcine species for fattening
Felidae	Cats + Other non-food producing animals (Felidae)
Finfish	Food-producing finfish + Ornamental aquatic species (finfish)
Fish	Food-producing finfish + Ornamental aquatic species (finfish)
Fish species	Food-producing finfish + Ornamental aquatic species (finfish)
Food-producing animals	Porcine species + Poultry + Ruminants + Food-producing aquatic animals + Leporids + Equines + Other food producing animals
Game birds	Minor poultry (target bird species to be detailed)
Goats	Goats
Goats for fattening	Goats for fattening
Grain-eating ornamental birds	Ornamental birds (grain-eating birds)
Guinea fowl	Minor poultry (Guinea fowls (<i>Numida meleagris</i>)))
Guinea fowl for breeding	Minor poultry for laying or reproduction (Guinea fowls (<i>Numida meleagris</i>)))
Guinea fowl for fattening	Minor poultry for fattening (Guinea fowls (<i>Numida</i>

	<i>meleagris))</i>
Guinea pigs	Other pets (Guinea pigs)
Horses	Horses
Kids	Kids for fattening + Kids for rearing
Kids for fattening	Kids for fattening
Kids for rearing	Kids for rearing
Lactating sows	Sows
Lactating sows of all Suidae species	Sows of porcine species
Lagomorphs	Leporids
Lambs	Lambs for fattening + Lambs for rearing
Lambs for fattening	Lambs for fattening
Lambs for rearing	Lambs for rearing
Laying birds	Poultry for laying or reproduction
Laying hens	Hens
Laying poultry	Poultry for laying or reproduction
Mammals	Porcine species + Ruminants + Leporids + Equines + Camelids + Dogs + Cats + Other pets (Mammals) + Other non-food producing animals (Mammals)
Marine animals	Food-producing aquatic animals (marine animals) + Other pets (marine animals) + Other non-food producing animals (marine animals)
Minor avian species	Minor poultry
Minor avian species for fattening	Minor poultry for fattening
Minor avian species for laying	Minor poultry for laying or reproduction
Minor avian species reared for laying	Minor poultry reared for laying or reproduction
Minor dairy ruminant species	Cows of minor bovine species + Minor bovines reared for milk production/reproduction + Ewes of ovine species + Ovines reared for milk production/reproduction + Does of caprine species + Caprines reared for milk production/reproduction
Minor finfish	Food-producing finfish other than salmonids
Minor porcine species (suckling and weaned)	Piglets of minor porcine species
Minor porcine species (suckling piglets)	Suckling piglets of minor porcine species
Minor porcine species (weaned)	Weaned piglets of minor porcine species
Minor porcine species for fattening	Minor porcine species for fattening
Minor porcine species for reproduction	Sows of minor porcine species + Boars of minor porcine species
Minor poultry for fattening	Minor poultry for fattening
Minor poultry for laying	Minor poultry for laying or reproduction
Minor poultry species	Minor poultry
Minor poultry species for breeding	Minor poultry for laying or reproduction
Minor poultry species for fattening	Minor poultry for fattening
Minor poultry species for laying	Minor poultry for laying or reproduction
Minor poultry species reared for breeding	Minor poultry reared for laying or reproduction
Minor poultry species reared for laying	Minor poultry reared for laying or reproduction

Minor ruminant species for fattening	Calves of minor bovine species for fattening + Minor bovines for fattening + Lambs of ovine species for fattening (except sheep) + Ovines for fattening (except sheep) + Kids of caprine species for fattening + Caprines for fattening + Cervids (animals for fattening)
Minor ruminant species for rearing	Calves of minor bovine species for rearing + Minor bovines reared for milk production/reproduction + Lambs of ovine species for rearing + Ovines reared for milk production/reproduction + Kids of caprine species for rearing + Caprines reared for milk production/reproduction + Cervids (animals for rearing)
Minor ruminants for dairy production	Cows of minor bovine species + Minor bovines reared for milk production/reproduction + Ewes of ovine species + Ovines reared for milk production/reproduction + Does of caprine species + Caprines reared for milk production/reproduction
Minor ruminants for fattening	Calves of minor bovine species for fattening + Minor bovines for fattening + Lambs of ovine species for fattening (except sheep) + Ovines for fattening (except sheep) + Kids of caprine species for fattening + Caprines for fattening + Cervids (animals for fattening)
Mustelidae	Other pets (ferrets) + Other non-food producing animals (Mustelidae)
Non-food producing animals	Pets and other non-food producing animals
Ornamental birds	Ornamental birds
Ornamental fish	Ornamental aquatic species
Ovines	Ovines
Partridges	Minor poultry (partridges)
Pets	Dogs + Cats + Ornamental birds + Ornamental aquatic species + Other pets
Pheasants	Minor poultry (pheasants)
Piglets	Piglets
Piglets (suckling and weaned)	Piglets
Piglets (weaned)	Weaned piglets
Piglets of all Suidae species	Piglets of porcine species
Piglets of minor porcine species	Piglets of minor porcine species
Piglets of minor porcine species (suckling and weaned)	Piglets of minor porcine species
Piglets of minor Suidae	Piglets of minor porcine species
Pigs	Pigs
Pigs for fattening	Pigs for fattening
Pigs for fattening of all Suidae species	Porcine species for fattening
Pigs for fattening of minor Suidae	Minor porcine species for fattening
Porcine species (suckling and weaned)	Piglets of porcine species
Poultry	Poultry
Poultry for breeding	Poultry for laying or reproduction
Poultry for fattening	Poultry for fattening
Poultry for laying	Poultry for laying or reproduction
Poultry reared for breeding	Poultry reared for laying or reproduction

Poultry reared for laying	Poultry reared for laying or reproduction
Poultry species for fattening	Poultry for fattening
Poultry species for laying	Poultry reared for laying or reproduction
Quails	Minor poultry (quails)
Rabbits	Rabbits
Rabbits for fattening	Growing rabbits
Reptiles	Other food producing animals (reptiles) + Other pets (reptiles)
Rodents	Other pets (rodents)
Ruminants	Ruminants
Ruminants for fattening	Young ruminants for fattening + Ruminants for fattening
Ruminants with a functional rumen	Ruminants (with a functional rumen)
Ruminants with a non-functional rumen	Ruminants (with a non-functional rumen)
Salmon	Salmonids (salmons)
Salmonids	Salmonids
Sheep	Sheep
Sheep for fattening	Sheep for fattening
Sows	Sows
Sows for reproduction	Sows
Sows of all Suidae species	Sows of porcine species
Sows, in order to have benefit in piglets	Sows, in order to have benefit in piglets
Suckling piglets	Suckling piglets
Suckling piglets of all Suidae species	Suckling piglets of porcine species
Suckling rabbits	Growing rabbits
Suckling Suidae piglets	Suckling piglets of porcine species
Trout	Salmonids (trout)
Turkeys	Turkeys
Turkeys for fattening	Turkeys for fattening
Turkeys reared for breeding	Turkeys reared for reproduction
Weaned minor porcine species	Weaned piglets of minor porcine species
Weaned piglets	Weaned piglets
Weaned piglets of all Suidae	Weaned piglets of porcine species
Weaned piglets of minor porcine species	Weaned piglets of minor porcine species
Weaned Suidae	Weaned piglets of porcine species
Weaned Suidae piglets	Weaned piglets of porcine species
Zoo mammals	Other non-food producing animals (zoo mammals)