ANNEX IV

Categories and definitions of target animals and indication of the minimum duration of efficacy studies

1. Table. Animal categories: Pigs

| Category | Definition of the | Approximate age) | duration perio | od (weight/ | Minimum duration of |
|--|---|---------------------|---|--|---|
| | animal category | Period/age | Age | Weight | long term efficacy studies |
| Piglets (suckling) | Young porcine animals getting milk from sows | From birth | Up to 21-42 days | Up to 6-11 kg | 14 days |
| Piglets (weaned) | Young porcine animals having completed the suckling period and being reared for reproduction or meat production | From 21-42 days | Up to 120 days | Up to 35 kg | 42 days |
| Piglets (suckling and weaned piglets) | Young porcine animal from birth being reared for reproduction or meat production purposes | From birth | Up to 120 days | Up to 35 kg | 58 days |
| Pigs for fattening | Porcine animals having completed the weaning period and intended for meat production until day of transport to slaughterhouse | From 60-120 days | Up to 120-250 days (or according to local custom) | 80-150 kg (or according to local custom) | Until slaughter weight, but not less than 70 days |

| Sows for reproduction | Female porcine animals having been inseminated/ mated at least once | From first insemination | | From insemination to the end of the second weaning period (two cycles) |
|---|---|-------------------------|--|--|
| Sows, in order to have benefit in piglets | Female porcine animals having been inseminated/ mated at least once | | | At least two weeks before the parturition until the end of weaning period |

2. Table. Animal categories: Poultry

| Category | Definition of the | Approximate age) | Approximate duration period (weight/ | | |
|----------------------------------|--|------------------|---|---|---|
| | animal category | Period | Age | Weight | long term studies for efficacy |
| Chickens for fattening | Birds raised for fattening | From hatching | Up to 35 days | Up to ~1 600 g(up to 2 kg) | 35 days |
| Chickens reared for laying | Female birds being reared for consumer egg production or for breeding purposes | From hatching | Up to ~16 weeks (up to 20 weeks) | | 112 days (if the efficacy data are not available for chickens for fattening) |
| Laying hens | Productive female birds held for egg production purposes | From 16-21 weeks | Up to ~13 months (up to 18 months) | From 1 200 g (white) 1 400 g (brown) | 168 days |
| Turkeys for fattening | Birds raised for fattening | From hatching | 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 for breeding purposes | Female and male birds held for | Whole period | From 30 weeks up to ~ 60 weeks | Hens: from ~15 000 g Cocks: from ~30 000 g | At least six months |

| | breeding purposes | | | | |
|-----------------------------------|--|---------------|----------------|---|---|
| Turkeys reared for breeding | Young female and male birds reared for breeding purposes | From hatching | Up to 30 weeks | Hens: up to ~15 000 g Cocks: up to ~30 000 g | Whole period (if the efficacy data are not available for turkeys for fattening) |

3. Table. Animal categories: Bovines (domestic bovine animals including bubalus and bison species)

| Category | Definition of the | Approximate age) | Minimum duration of | | |
|--------------------------------------|---|--|---------------------|--------------------------------|--|
| | animal category | Period | Age | Weight | long term studies for efficacy |
| Calves for rearing | Calves which are reared for reproduction or for beef production | From birth | Up to 4 months | Up to 60-80 kg up to 145 kg) | 56 days |
| Calves for fattening | Calves for veal production | From birth | Up to 6 months | Up to 180 kg (up to 250 kg) | Until slaughter but not less than 84 days |
| Cattle for fattening | Bovine animals that have completed the weaning period and are destined for meat production until day of transport to slaughterhouse | From full development of rumination | Up to 10-36 months | Up to 350-700 kg | 168 days |
| Dairy cows for milk production | Female bovine animals that have produced at least one calf. | | | | 84 days (total lactation period shall be reported) |
| Cows for reproduction | Female bovine animals that have been | From first insemination to the end of second | | | Two cycles (if the reproduction |

| r | nseminated/ nated at least | | parameters are requested) |
|---|-------------------------------|--|---------------------------|
| C | once | | |

4. Table. Animal categories: Sheep

| Category | Definition of the | PF | | | | |
|---|---|--|---------------------------|-------------|---|--|
| | animal category | Period | Age | Weight | long term studies for efficacy | |
| Lambs for rearing | Lambs reared for future reproduction | From birth | Up to 3 months | 15-20 kg | 56 days | |
| Lambs for fattening | Lambs that are reared for lamb meat production. | From birth | Up to 6 months (or older) | up to 55 kg | Until slaughter weight but not less than 56 days | |
| Dairy sheep (for milk production) | Sheep that have produced at least one lamb | | | | 84 days (total lactation period shall be reported) | |
| Ewes for reproduction | Female sheep that have been inseminated/ mated at least once | From first insemination to the end of second weaning period | | | Two cycles (if the reproduction parameters are requested) | |

5. Table. Animal categories: Goats

| Category | Definition of the | Approximate duration period (weight/age) | | | Minimum duration of |
|--------------------|--|--|----------------|----------|--------------------------------------|
| | animal category | Period | Age | Weight | long term studies for efficacy |
| Kids for rearing | Young goats reared for future reproduction | From birth | Up to 3 months | 15-20 kg | At least 56 |
| Kids for fattening | Young goats that are reared for goat meat production | From birth | Up to 6 months | | At least 56 days |

| Dairy goats (for milk production) | Goats that have produced at least one kid | | | 84 days (total lactation period shall be reported) |
|---|---|--|--|---|
| Goats for reproduction | Female goats that have been inseminated/ mated at least once | From first insemination to the end of second weaning period | | Two cycles (if the reproduction parameters are requested) |

6. Table. Animal categories: Fish

| Category | Definition of the | Approximate age) | Minimum duration of | | |
|------------------|--------------------|--|---------------------|-----------|--|
| | animal category | Period | Age | Weight | long term studies for efficacy |
| Salmon and trout | | | | 200-300 g | 90 days or until initial body weight is doubled. |
| Salmon and trout | Brood stock | As close to the spawning period as possible | | | 90 days |

7. Table. Animal categories: Rabbits

| Category | Definition of the | Approximate age) | Approximate duration period (weight/age) | | | |
|-----------------------------------|---|---|--|--------|--|--|
| | animal category | Period | Age | Weight | long term studies for efficacy | |
| Rabbits suckling and weaned | | Beginning one week after birth | | | 56 days | |
| Rabbits for fattening | Rabbits that are reared for meat production | After weaning period | Up to 8-11 weeks | | 42 days | |
| Breeding does (for reproduction) | Does, that have been inseminated/ mated at least once | From the insemination to the end of the second weaning period | | | Two cycles (if the reproduction parameters are requested). | |

| Breeding does (in order to have benefits to young rabbits) | Does, that have been inseminated at least once | From first insemination | | At least 2 weeks before parturition until the end of the weaning period (e.g. for micro- organism product) |
|--|---|-------------------------|--|--|
| | | | | product) |

Table. Animal Categories: horses 8.

| Category | Definition of the animal category | Approximate duration period (weight/age) | | | Minimum duration of |
|----------|--|--|-----|--------|--------------------------------------|
| | | Period | Age | Weight | long term studies for efficacy |
| Horses | All categories | | | | 56 days |