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| From:            | Secretary-General of the European Commission,<br>signed by Mr Jordi AYET PUIGARNAU, Director |
| date of receipt: | 6 December 2013  |
| To:              | Mr Uwe CORSEPIUS, Secretary-General of the Council of the European<br>Union                  |

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Delegations will find attached document SWD(2013) 497 final PART 4/5.

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Brussels, 5.12.2013  
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PART 4/5

**COMMISSION STAFF WORKING DOCUMENT**

**Accompanying document to the  
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT**

**Seventh Report on the Statistics on the Number of Animals used for Experimental and  
other Scientific Purposes in the Member States of the European Union**

{ COM(2013) 859 final }

**COMMISSION STAFF WORKING DOCUMENT**

**Accompanying document to the  
REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT  
Seventh Report on the Statistics on the Number of Animals used for Experimental and  
other Scientific Purposes in the Member States of the European Union**

**PART B III: DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE  
MEMBER STATES**



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# FRANCE

## Statistical data submitted

The statistical data were submitted by the '*Ministère de l'Enseignement Supérieur et de la Recherche*' (Ministry for Higher Education and Research).

## Comments of the French authorities

This study was realized by the IsoCL Company (formerly Eficom Marketudes) for the Research and Higher Education Ministry.

In France, 2.2 million animals were used for scientific purposes in 2010, whereas 2.3 million were used in 2007. It appears that the number of animals used showed a steady state since 1999 with about 2.2 million. It represents a decrease of 40% in comparison with the figures of the first statistical study in 1990.

1,326,274 of the animals used were mice (60%). Fish accounted for 354,039 (16%) of the animals used, rats for 252,589 (11%), and rabbits for 125,913 (6%).

Cool-blooded animals (fish, amphibian and reptiles) accounted for 357,392 (16%) of the animals used.

Non-human primates accounted for 1,810 animals, 0.08% of the animals used, a reduction of 34% compared with 2007. Most of the non-human primates used were cercopithecoidea (86%) and more precisely *Macaca cynomolgus* (70%). Similarly to previous years, no apes were used for scientific purposes.

Since 2007, rodents (1,622,840) showed a reduction of 20%, whereas rabbits (125,913) and fish (354,039) presented an increase of 31% and 1650%, respectively.

Concerning the purpose, 1,103,214 animals (50%) were used for research purposes: 598,532 animals (27%) were used for fundamental biology studies and 504,682 (23%) were used for research and development and production and quality control relating to human medicine, dentistry and veterinary medicine. 403,426 animals (18%) were used for production and quality control of products and devices for human medicine and dentistry.

Toxicological or other safety evaluations used 78,041 animals (3.5%).

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 1 326 274    | 1 193 758   | 20 682   | 39 110  | 72 724                                   | 914                    |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 252 589      | 244 910   | 674  | 1 030   | 5 975                                    | 2 132                  |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 35 543       | 31 181  | 3 857  | 410   | 95                                       | 0                      |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 8 210        | 6 805   | 243  | 0   | 1 162                                    | 0                      |
| 1.e. Other Rodents (other <i>Rodentia</i> )              | 224          | 0   | 0  | 0   | 0  | 0                      |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 125 913      | 125 912   | 0  | 1   | 0  | 1 102                  |
| 1.g. Cats ( <i>Felis catus</i> )                         | 569          | 479   | 69   | 0   | 21                                       | 130                    |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 3 032        | 1 840   | 373  | 129   | 690                                      | 825                    |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 351          | 0   | 0  | 0   | 351                                      | 72                     |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          | 0            | 0   | 0  | 0   | 0  | 0                      |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) | 373          | 0   | 0  | 0   | 0  | 0                      |
| 1.l. Pigs ( <i>Sus</i> )                                 | 7 364        | 0   | 0  | 0   | 0  | 0                      |
| 1.m. Goats ( <i>Capra</i> )                              | 710          | 0   | 0  | 0   | 0  | 0                      |
| 1.n. Sheep ( <i>Ovis</i> )                               | 5 491        | 0   | 0  | 0   | 0  | 0                      |
| 1.o. Cattle ( <i>Bos</i> )                               | 2 362        | 0   | 0  | 0   | 0  | 0                      |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 83           | 83  | 0  | 0   | 0  | 83                     |
| 1.q. New World Monkeys ( <i>Cebioidea</i> )              | 163          | 160   | 3  | 0   | 0  | 156                    |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 1 564        | 666   | 63   | 0   | 835                                      | 514                    |
| 1.s. Apes ( <i>Hominidea</i> )                           | 0            | 0   | 0  | 0   | 0  | 0                      |
| 1.t. Other Mammals (other <i>Mammalia</i> )              | 2            | 0   | 0  | 0   | 0  | 0                      |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 122          | 122   | 0  | 0   | 0  | 0                      |
| 1.v. Other birds (other <i>Aves</i> )                    | 71 821       | 0   | 0  | 0   | 0  | 0                      |
| 1.w. Reptiles ( <i>Reptilia</i> )                        | 74           | 0   | 0  | 0   | 0  | 0                      |
| 1.x. Amphibians ( <i>Amphibia</i> )                      | 3 279        | 0   | 0  | 0   | 0  | 0                      |
| 1.y. Fish ( <i>Pisces</i> )                              | 354 039      |   |  |   |  |                        |
| 1.z. TOTAL   | 2 200 152    | 1 605 916   | 25 964   | 40 680  | 81 853                                   | 5 928                  |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2



**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 547 843   | 347 485   | 312 483  | 13 527  | 22 074   | 2 879                       | 10 722                        | 69 261       | 1 326 274     |
| 2.b. Rats                             | 45 681  | 130 052   | 3 638  | 163   | 41 799   | 152                         | 10 105                        | 20 999       | 252 589       |
| 2.c. Guinea-Pigs                      | 464   | 4 816   | 25 829   | 750   | 2 609  | 0                           | 75                            | 1 000        | 35 543        |
| 2.d. Hamsters                         | 567   | 3 361   | 0  | 1 416   | 542  | 0                           | 80                            | 2 244        | 8 210         |
| 2.e. Other Rodents                    | 118   | 100   | 0  | 0   | 0  | 0                           | 6                             | 0            | 224           |
| 2.f. Rabbits                          | 1 343   | 6 922   | 53 613   | 1 015   | 3 733  | 8                           | 424                           | 58 855       | 125 913       |
| 2.g. Cats                             | 40  | 317   | 0  | 132   | 68   | 0                           | 0                             | 12           | 569           |
| 2.h. Dogs                             | 125   | 1 012   | 0  | 375   | 1 483  | 0                           | 6                             | 31           | 3 032         |
| 2.i. Ferrets                          | 36  | 288   | 4  | 0   | 20   | 0                           | 3                             | 0            | 351           |
| 2.j. Other Carnivores                 | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.k. Horses, donkeys and cross breeds | 3   | 96  | 94   | 5   | 0  | 0                           | 10                            | 165          | 373           |
| 2.l. Pigs                             | 136   | 1 759   | 0  | 681   | 245  | 4                           | 1 951                         | 2 588        | 7 364         |
| 2.m. Goats                            | 78  | 35  | 0  | 0   | 0  | 7                           | 0                             | 590          | 710           |
| 2.n. Sheep                            | 18  | 510   | 10   | 808   | 161  | 0                           | 5                             | 3 979        | 5 491         |
| 2.o. Cattle                           | 3   | 443   | 0  | 108   | 239  | 0                           | 19                            | 1 550        | 2 362         |
| 2.p. Primates                         | 83  | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 83            |
| 2.q. New World Monkeys                | 31  | 125   | 0  | 0   | 6  | 0                           | 0                             | 1            | 163           |
| 2.r. Old World Monkeys                | 110   | 484   | 86   | 0   | 811  | 0                           | 0                             | 73           | 1 564         |
| 2.s. Apes                             | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.t. Other Mammals                    | 2   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 2             |
| 2.u. Quail                            | 122   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 122           |
| 2.v. Other birds                      | 294   | 3 818   | 7 669  | 38 277  | 45   | 0                           | 58                            | 21 660       | 71 821        |
| 2.w. Reptiles                         | 74  | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 74            |
| 2.x. Amphibians                       | 1 016   | 12  | 0  | 0   | 0  | 0                           | 2 238                         | 13           | 3 279         |
| 2.y. Fish                             | 345   | 3 047   | 0  | 0   | 4 206  | 0                           | 418                           | 346 023      | 354 039       |
| 2.z. TOTAL                            | 598 532   | 504 682   | 403 426  | 57 257  | 78 041   | 3 050                       | 26 120                        | 529 044      | 2 200 152     |

**TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Products versus species**

| 3.1<br>Species                        | 3.2<br>Products/<br>substances or<br>devices for<br>human<br>medicine and<br>dentistry and<br>for veterinary<br>medicine | 3.3<br>Products/<br>substances<br>used or<br>intended to<br>be used<br>mainly in<br>agriculture | 3.4<br>Products/<br>substances<br>used or<br>intended to<br>be used<br>mainly in<br>industry | 3.5<br>Products/<br>substances<br>used or<br>intended to<br>be used<br>mainly in<br>the<br>household | 3.6<br>Products/<br>substances<br>used or<br>intended to<br>be used<br>mainly as<br>cosmetics<br>or toiletries | 3.7<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>human<br>consumption | 3.8<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>animal<br>consumption | 3.9<br>Potential or<br>actual contami-<br>nants in the<br>general envi-<br>ronment which<br>do not appear in<br>other columns | 3.10<br>Other toxico-<br>logical or<br>safety<br>evaluations | 3.11<br>Total |
|---------------------------------------|--|---|--|--|--|---|--|---|--|---------------|
| 3.a. Mice                             | 9 604  | 3 122   | 1 765  | 0  | 0  | 52  | 0  | 872   | 6 659  | 22 074        |
| 3.b. Rats                             | 15 019   | 5 979   | 4 235  | 0  | 40   | 70  | 54   | 756   | 15 646   | 41 799        |
| 3.c. Guinea-Pigs                      | 914  | 750   | 150  | 0  | 0  | 0   | 0  | 0   | 795  | 2 609         |
| 3.d. Hamsters                         | 254  | 73  | 21   | 0  | 0  | 0   | 0  | 0   | 194  | 542           |
| 3.e. Other Rodents                    | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.f. Rabbits                          | 1 043  | 397   | 212  | 0  | 0  | 0   | 0  | 0   | 2 081  | 3 733         |
| 3.g. Cats                             | 68   | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 68            |
| 3.h. Dogs                             | 693  | 88  | 0  | 0  | 0  | 0   | 0  | 0   | 702  | 1 483         |
| 3.i. Ferrets                          | 20   | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 20            |
| 3.j. Other Carnivores                 | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.k. Horses, donkeys and cross breeds | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.l. Pigs                             | 112  | 0   | 0  | 0  | 0  | 0   | 0  | 3   | 130  | 245           |
| 3.m. Goats                            | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.n. Sheep                            | 0  | 0   | 0  | 0  | 0  | 0   | 21   | 140   | 0  | 161           |
| 3.o. Cattle                           | 233  | 0   | 0  | 0  | 0  | 0   | 6  | 0   | 0  | 239           |
| 3.p. Prosimians                       | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.q. New World Monkeys                | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 6  | 6             |
| 3.r. Old World Monkeys                | 242  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 569  | 811           |
| 3.s. Apes                             | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.t. Other Mammals                    | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.u. Quail                            | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.v. Other birds                      | 45   | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 45            |
| 3.w. Reptiles                         | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.x. Amphibians                       | 0  | 0   | 0  | 0  | 0  | 0   | 0  | 0   | 0  | 0             |
| 3.y. Fish                             | 86   | 2 049   | 0  | 0  | 0  | 0   | 0  | 0   | 2 071  | 4 206         |
| 3.z. TOTAL                            | 28 333   | 12 458  | 6 383  | 0  | 40   | 122   | 81   | 1 771   | 28 853   | 78 041        |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             | 94 767                                  | 142 675                                      | 178 443  | 261 176                     | 221 146                                       | 898 207      |
| 4.b. Rats                             | 38 018                                  | 78 662                                       | 4 392  | 53 274                      | 1 539   | 175 885      |
| 4.c. Guinea-Pigs                      | 652                                     | 281  | 26   | 4 028                       | 293   | 5 280        |
| 4.d. Hamsters                         | 506                                     | 0  | 72   | 1 109                       | 2 241   | 3 928        |
| 4.e. Other Rodents                    | 0                                       | 0  | 0  | 80                          | 138   | 218          |
| 4.f. Rabbits                          | 1 438                                   | 184  | 79   | 6 483                       | 89  | 8 273        |
| 4.g. Cats                             | 0                                       | 19   | 0  | 44                          | 294   | 357          |
| 4.h. Dogs                             | 68                                      | 41   | 1  | 286                         | 741   | 1 137        |
| 4.i. Ferrets                          | 0                                       | 0  | 0  | 273                         | 51  | 324          |
| 4.j. Other Carnivores                 | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.k. Horses, donkeys and cross breeds | 0                                       | 0  | 0  | 0                           | 99  | 99           |
| 4.l. Pigs                             | 544                                     | 29   | 0  | 549                         | 777   | 1 899        |
| 4.m. Goats                            | 0                                       | 0  | 0  | 31                          | 89  | 120          |
| 4.n. Sheep                            | 170                                     | 0  | 0  | 69                          | 289   | 528          |
| 4.o. Cattle                           | 4                                       | 0  | 0  | 3                           | 439   | 446          |
| 4.p. Prosimians                       | 0                                       | 58   | 0  | 25                          | 0   | 83           |
| 4.q. New World Monkeys                | 0                                       | 0  | 0  | 156                         | 0   | 156          |
| 4.r. Old World Monkeys                | 343                                     | 12   | 0  | 194                         | 45  | 594          |
| 4.s. Apes                             | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.t. Other Mammals                    | 0                                       | 0  | 2  | 0                           | 0   | 2            |
| 4.u. Quail                            | 0                                       | 0  | 0  | 122                         | 0   | 122          |
| 4.v. Other birds                      | 0                                       | 0  | 0  | 299                         | 3 813   | 4 112        |
| 4.w. Reptiles                         | 0                                       | 0  | 0  | 24                          | 50  | 74           |
| 4.x. Amphibians                       | 36                                      | 40   | 0  | 67                          | 885   | 1 028        |
| 4.y. Fish                             | 0                                       | 0  | 0  | 3 127                       | 265   | 3 392        |
| 4.z. TOTAL                            | 136 546                                 | 222 001                                      | 183 015  | 331 419                     | 233 283                                       | 1 106 264    |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>(1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements)<br>(2) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|---|---|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             | 24 926  | 49 841  | 2 162   | 0                        | 223 452   | 25 629                               | 326 010      |
| 5.b. Rats                             | 3 282   | 243   | 0   | 0                        | 274   | 2                                    | 3 801        |
| 5.c. Guinea-Pigs                      | 0   | 3 064   | 0   | 280                      | 23 235  | 0                                    | 26 579       |
| 5.d. Hamsters                         | 0   | 1 416   | 0   | 0                        | 0   | 0                                    | 1 416        |
| 5.e. Other Rodents                    | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.f. Rabbits                          | 488   | 27 006  | 0   | 0                        | 2 338   | 24 796                               | 54 628       |
| 5.g. Cats                             | 0   | 132   | 0   | 0                        | 0   | 0                                    | 132          |
| 5.h. Dogs                             | 118   | 257   | 0   | 0                        | 0   | 0                                    | 375          |
| 5.i. Ferrets                          | 0   | 0   | 0   | 0                        | 4   | 0                                    | 4            |
| 5.j. Other Carnivores                 | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.k. Horses, donkeys and cross breeds | 0   | 99  | 0   | 0                        | 0   | 0                                    | 99           |
| 5.l. Pigs                             | 0   | 681   | 0   | 0                        | 0   | 0                                    | 681          |
| 5.m. Goats                            | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.n. Sheep                            | 0   | 818   | 0   | 0                        | 0   | 0                                    | 818          |
| 5.o. Cattle                           | 0   | 108   | 0   | 0                        | 0   | 0                                    | 108          |
| 5.p. Prosimians                       | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.q. New World Monkeys                | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.r. Old World Monkeys                | 0   | 0   | 0   | 0                        | 86  | 0                                    | 86           |
| 5.s. Apes                             | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.t. Other Mammals                    | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.u. Quail                            | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.v. Other birds                      | 0   | 45 916  | 0   | 0                        | 0   | 30                                   | 45 946       |
| 5.w. Reptiles                         | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.x. Amphibians                       | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.y. Fish                             | 0   | 0   | 0   | 0                        | 0   | 0                                    | 0            |
| 5.z. TOTAL                            | 28 814  | 129 581   | 2 162   | 280                      | 249 389   | 50 457                               | 460 683      |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement **Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

5.3 - UK is testing according to EC legislation **not to the body which has issued the actual test method, guideline or protocol.**

5.4 - Spain is testing due to a Norwegian requirement **Example:** a test required by French legislation and carried out in Belgium according to an

5.5 – Poland is testing due to a US specific requirement **ISO protocol must be coded as a national (FR) legislative requirement and be**

5.6 – Germany is testing due to a Swiss requirement (also an EC requirement) **entered into column 5.2 in the tables submitted by Belgium.**

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Regulatory requirements versus species**

| 6.1<br>Species                        | 6.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 6.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 6.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 6.5<br>Other legislation | 6.6<br>Any combination of<br>6.2/ 6.3/ 6.4/ 6.5 | 6.7<br>No regulatory<br>requirements | 6.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 6.a. Mice                             | 7 193  | 3 680  | 0   | 4 092                    | 5 029   | 2 080                                | 22 074       |
| 6.b. Rats                             | 10 268   | 3 372  | 162   | 9 058                    | 16 064  | 2 875                                | 41 799       |
| 6.c. Guinea-Pigs                      | 610  | 954  | 0   | 745                      | 163   | 137                                  | 2 609        |
| 6.d. Hamsters                         | 21   | 62   | 0   | 174                      | 285   | 0                                    | 542          |
| 6.e. Other Rodents                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.f. Rabbits                          | 873  | 684  | 250   | 1 336                    | 469   | 121                                  | 3 733        |
| 6.g. Cats                             | 0  | 0  | 0   | 0                        | 68  | 0                                    | 68           |
| 6.h. Dogs                             | 270  | 28   | 0   | 428                      | 757   | 0                                    | 1 483        |
| 6.i. Ferrets                          | 0  | 0  | 0   | 0                        | 20  | 0                                    | 20           |
| 6.j. Other Carnivores                 | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.k. Horses, donkeys and cross breeds | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.l. Pigs                             | 0  | 0  | 0   | 120                      | 125   | 0                                    | 245          |
| 6.m. Goats                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.n. Sheep                            | 21   | 0  | 0   | 0                        | 0   | 140                                  | 161          |
| 6.o. Cattle                           | 6  | 8  | 0   | 0                        | 225   | 0                                    | 239          |
| 6.p. Prosimians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.q. New World Monkeys                | 0  | 0  | 0   | 0                        | 6   | 0                                    | 6            |
| 6.r. Old World Monkeys                | 170  | 0  | 0   | 348                      | 270   | 23                                   | 811          |
| 6.s. Apes                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.t. Other Mammals                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.u. Quail                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.v. Other birds                      | 0  | 0  | 0   | 0                        | 45  | 0                                    | 45           |
| 6.w. Reptiles                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.x. Amphibians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.y. Fish                             | 0  | 0  | 0   | 2 071                    | 2 049   | 86                                   | 4 206        |
| 6.z. TOTAL                            | 19 432   | 8 788  | 412   | 18 372                   | 25 575  | 5 462                                | 78 041       |

**Examples:**

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Norwegian requirement

6.5 – Poland is testing due to a US specific requirement

6.6 – Germany is testing due to a Swiss requirement (also an EC requirement)

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

**Footnotes:**

- 1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus species**

| 7.1<br>Species                           | 7.2<br>Acute and sub-acute toxicity testing methods<br>(including limit test) |       |                                  | 7.3<br>Skin<br>irritation | 7.4<br>Skin<br>sensitisation | 7.5<br>Eye<br>irritation | 7.6<br>Sub-<br>chronic and<br>chronic<br>toxicity | 7.7<br>Carcino-<br>genicity | 7.8<br>Develop-<br>mental<br>toxicity | 7.9<br>Muta-<br>genicity | 7.10<br>Repro-<br>ductive<br>toxicity | 7.11<br>Toxicity<br>to aquatic<br>vertebra-<br>tes not<br>included<br>in other<br>columns | 7.12<br>Other | 7.13<br>Total |  |
|--|---|-------|----------------------------------|---------------------------|------------------------------|--------------------------|---|-----------------------------|---------------------------------------|--------------------------|---------------------------------------|---|---------------|---------------|--|
|  | 7.2.1.<br>LD50,<br>LC50   |       | 7.2.2<br>Other lethal<br>methods |                           |                              |                          |   |                             |                                       |                          |                                       |   |               |               | 7.2.3<br>Non lethal<br>clinical signs<br>methods |
|  | 7.a   | 7.b   | 7.c                              |                           |                              |                          |   |                             |                                       |                          |                                       |   |               |               | 7.d  |
| 7.a. Mice                                | 364   | 1 593 | 2 575                            | 28                        | 2 307                        | 0                        | 5 996   | 2 226                       | 702                                   | 220                      | 0                                     | 0   | 6 063         | 22 074        |  |
| 7.b. Rats                                | 102   | 2 195 | 2 652                            | 0                         | 0                            | 0                        | 10 494  | 1 273                       | 2 579                                 | 1 633                    | 1 089                                 | 0   | 19 782        | 41 799        |  |
| 7.c. Guinea-Pigs                         | 0   | 13    | 0                                | 0                         | 1 130                        | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 1 466         | 2 609         |  |
| 7.d. Hamsters                            | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 265   | 0                           | 0                                     | 0                        | 0                                     | 0   | 277           | 542           |  |
| 7.e. Other Rodents                       | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.f. Rabbits                             | 0   | 0     | 260                              | 348                       | 0                            | 295                      | 16  | 0                           | 424                                   | 0                        | 0                                     | 0   | 2 390         | 3 733         |  |
| 7.g. Cats                                | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 68            | 68            |  |
| 7.h. Dogs                                | 0   | 0     | 78                               | 0                         | 0                            | 0                        | 563   | 0                           | 0                                     | 0                        | 0                                     | 0   | 842           | 1 483         |  |
| 7.i. Ferrets                             | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 20            | 20            |  |
| 7.j. Other Carnivores                    | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.k. Horses, donkeys and cross<br>breeds | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.l. Pigs                                | 0   | 0     | 15                               | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 230           | 245           |  |
| 7.m. Goats                               | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.n. Sheep                               | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 161           | 161           |  |
| 7.o. Cattle                              | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 239           | 239           |  |
| 7.p. Prosimians                          | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.q. New World Monkeys                   | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 6             | 6             |  |
| 7.r. Old World Monkeys                   | 0   | 0     | 31                               | 0                         | 0                            | 0                        | 216   | 0                           | 0                                     | 0                        | 0                                     | 0   | 564           | 811           |  |
| 7.s. Apes                                | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.t. Other Mammals                       | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.u. Quail                               | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.v. Other birds                         | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 45            | 45            |  |
| 7.w. Reptiles                            | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.x. Amphibians                          | 0   | 0     | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.y. Fish                                | 0   | 0     | 86                               | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 2 071         | 4 206         |  |
| 7.z. TOTAL                               | 466   | 3 801 | 5 697                            | 376                       | 3 437                        | 295                      | 17 550  | 3 499                       | 3 705                                 | 1 853                    | 1 089                                 | 2 049   | 34 224        | 78 041        |  |

**TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus products**

| 8.1<br>Products   | 8.2<br>Acute and sub-acute toxicity testing methods (including limit test) |                               |  | 8.3<br>Skin irritation | 8.4<br>Skin sensitisation | 8.5<br>Eye irritation | 8.6<br>Sub-chronic and chronic toxicity | 8.7<br>Carcinogenicity | 8.8<br>Developmental toxicity | 8.9<br>Mutagenicity | 8.10<br>Reproductive toxicity | 8.11<br>Toxicity to aquatic vertebrates not included in other columns | 8.12<br>Other | 8.13<br>Total |
|---|--|-------------------------------|--|------------------------|---------------------------|-----------------------|---|------------------------|-------------------------------|---------------------|-------------------------------|---|---------------|---------------|
|   | 8.2.1.<br>LD50, LC50   | 8.2.2<br>Other lethal methods | 8.2.3<br>Non lethal clinical signs methods |                        |                           |                       |   |                        |                               |                     |                               |   |               |               |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine        | 226  | 1 053                         | 5 657                                      | 85                     | 864                       | 40                    | 8 426                                   | 1 701                  | 1 120                         | 1 330               | 447                           | 0   | 7 384         | 28 333        |
| 8.b. Products/substances used or intended to be used mainly in agriculture                              | 0  | 1 596                         | 0  | 160                    | 750                       | 144                   | 5 085                                   | 1 798                  | 664                           | 70                  | 142                           | 2 049   | 0             | 12 458        |
| 8.c. Products/substances used or intended to be used mainly in industry                                 | 0  | 211                           | 0  | 116                    | 1 823                     | 96                    | 0                                       | 0                      | 840                           | 371                 | 0                             | 0   | 2 926         | 6 383         |
| 8.d. Products/substances used or intended to be used mainly in the household                            | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 0             |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries                  | 0  | 0                             | 40   | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 40            |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption  | 0  | 70                            | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 52            | 122           |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 54                  | 0                             | 0   | 27            | 81            |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns   | 0  | 153                           | 0  | 0                      | 0                         | 0                     | 1 267                                   | 0                      | 0                             | 28                  | 0                             | 0   | 323           | 1 771         |
| 8.i. Other toxicological or safety evaluations  | 240  | 718                           | 0  | 15                     | 0                         | 15                    | 2 772                                   | 0                      | 1 081                         | 0                   | 500                           | 0   | 23 512        | 28 853        |
| 8.j. TOTAL  | 466  | 3 801                         | 5 697                                      | 376                    | 3 437                     | 295                   | 17 550                                  | 3 499                  | 3 705                         | 1 853               | 1 089                         | 2 049   | 34 224        | 78 041        |

# ITALY

## Statistical data submitted

The statistical data were submitted by Ministry of Health, Directorate General for Animal Health and Veterinary Medicinal Products, Office VI, Animal Welfare.

## Comments of the Italian authorities

The data collected have been used for the '*EU harmonised statistical tables*' produced by the competent national EU authorities for 1997.

In general the trend of an overall decrease in the numbers of the animals used for experiments has been confirmed and from 1999 the numbers have been consistently under 1 million animals.

This said, there has been a significant increase in percentage terms in the use of mice (+ 2.01) and fish (+ 5.01) with regard to 2008.

The tables also show data on the animals used for in vitro studies (euthanized to remove organs, tissues and cells).

**88.99 %** of the species of animals used were rodents or rabbits.

**53.78 %** of animals were used in basic biological studies.

**33.87 %** of animals were used for research and development, for the production and quality control of products and appliances for human medicine, orthodontics and veterinary medicine.

**7.82 %** of animals were used in toxicological studies.

**4.53 %** of animals were used to diagnose illnesses, for teaching and other purposes.

In general a decrease has been noted in the number of animals used for the production and quality control of products and appliances for human medicine, orthodontics and veterinary medicine and for toxicological studies (- 4.22% with regard to 2008).

Article 24 of Directive 86/609/EEC, which was transposed into Italian law with Legislative Decree No 116/92, has allowed the introduction of stricter measures which concern, in particular, the use of non-human primates, dogs and cats as stipulated in Article 3(2) of the above-mentioned Legislative Decree: '**as regards non-human primates, dogs and cats, the authorisation referred to in Article 8(1)(b) is also required.**'

However the use of **non-human primates, dogs and cats** is permitted only after obtaining specific prior authorisation from the Ministry of Health.

All this has resulted in non-human primates, dogs and cats accounting overall for **0.11%** of the total animals used.





**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| I.a. Mice ( <i>Mus musculus</i> )                        |              | 515946  | 486030   | 13639   | 117                                      | 16160                  |
| I.b. Rats ( <i>Rattus norvegicus</i> )                   |              | 155136  | 153134   | 1067  | 0  | 935                    |
| I.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              |              | 13784   | 11155  | 2629  | 0  | 0                      |
| I.d. Hamsters ( <i>Mesocricetus</i> )                    |              | 517   | 517  | 0   | 0  | 0                      |
| I.e. Other Rodents (other <i>Rodentia</i> )              |              | 1946  |  |   |  |                        |
| I.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            |              | 8392  | 7847   | 545   | 0  | 0                      |
| I.g. Cats ( <i>Felis catus</i> )                         |              | 0   | 0  | 0   | 0  | 0                      |
| I.h. Dogs ( <i>Canis familiaris</i> )                    |              | 408   | 214  | 154   | 0  | 40                     |
| I.i. Ferrets ( <i>Mustela putorius furo</i> )            |              | 0   | 0  | 0   | 0  | 0                      |
| I.j. Other Carnivores (other <i>Carnivora</i> )          |              | 0   |  |   |  |                        |
| I.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) |              | 34  |  |   |  |                        |
| I.l. Pigs ( <i>Sus</i> )                                 |              | 2486  |  |   |  |                        |
| I.m. Goats ( <i>Capra</i> )                              |              | 34  |  |   |  |                        |
| I.n. Sheep ( <i>Ovis</i> )                               |              | 243   |  |   |  |                        |
| I.o. Cattle ( <i>Bos</i> )                               |              | 27  |  |   |  |                        |
| I.p. Prosimians ( <i>Prosimia</i> )                      |              | 0   | 0  | 0   | 0  | 0                      |
| I.q. New World Monkeys ( <i>Ceboidae</i> )               |              | 79  | 68   | 11  | 0  | 0                      |
| I.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       |              | 371   | 40   | 291   | 2  | 38                     |
| I.s. Apes ( <i>Hominioidea</i> )                         |              | 0   | 0  | 0   | 0  | 0                      |
| I.t. Other Mammals (other <i>Mammalia</i> )              |              | 184   |  |   |  |                        |
| I.u. Quail ( <i>Coturnix coturnix</i> )                  |              | 4   | 4  | 0   | 0  | 0                      |
| I.v. Other birds (other <i>Aves</i> )                    |              | 29305   |  |   |  |                        |
| I.w. Reptiles ( <i>Reptilia</i> )                        |              | 239   |  |   |  |                        |
| I.x. Amphibians ( <i>Amphibia</i> )                      |              | 894   |  |   |  |                        |
| I.y. Fish ( <i>Pisces</i> )                              |              | 51786   |  |   |  |                        |
| I.z. TOTAL   | 864318       | 781815  |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 307552  | 112340  | 35049  | 1821  | 29226  | 25026                       | 25                            | 4907         | 515946        |
| 2.b. Rats                             | 60920   | 23858   | 53323  | 880   | 14109  | 857                         | 639                           | 550          | 155136        |
| 2.c. Guinea-Pigs                      | 1206  | 2812  | 2671   | 518   | 6531   | 21                          | 0                             | 25           | 13784         |
| 2.d. Hamsters                         | 327   | 28  | 0  | 0   | 161  | 0                           | 0                             | 1            | 517           |
| 2.e. Other Rodents                    | 92  | 493   | 0  | 0   | 0  | 1361                        | 0                             | 0            | 1946          |
| 2.f. Rabbits                          | 556   | 398   | 4681   | 659   | 1918   | 161                         | 0                             | 19           | 8392          |
| 2.g. Cats                             | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.h. Dogs                             | 0   | 49  | 0  | 0   | 359  | 0                           | 0                             | 0            | 408           |
| 2.i. Ferrets                          | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.j. Other Carnivores                 | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.k. Horses, donkeys and cross breeds | 23  | 0   | 0  | 0   | 0  | 0                           | 0                             | 3            | 34            |
| 2.l. Pigs                             | 319   | 350   | 7  | 840   | 453  | 1                           | 473                           | 43           | 2486          |
| 2.m. Goats                            | 3   | 3   | 0  | 0   | 0  | 28                          | 0                             | 0            | 34            |
| 2.n. Sheep                            | 108   | 109   | 0  | 0   | 18   | 0                           | 0                             | 8            | 243           |
| 2.o. Cattle                           | 5   | 0   | 0  | 20  | 2  | 0                           | 0                             | 0            | 27            |
| 2.p. Primates                         | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.q. New World Monkeys                | 0   | 68  | 0  | 0   | 11   | 0                           | 0                             | 0            | 79            |
| 2.r. Old World Monkeys                | 19  | 55  | 35   | 0   | 262  | 0                           | 0                             | 0            | 371           |
| 2.s. Apes                             | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.t. Other Mammals                    | 184   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 184           |
| 2.u. Quail                            | 4   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 4             |
| 2.v. Other birds                      | 3694  | 664   | 5  | 19778   | 4124   | 956                         | 0                             | 84           | 29305         |
| 2.w. Reptiles                         | 238   | 0   | 0  | 0   | 0  | 0                           | 0                             | 1            | 239           |
| 2.x. Amphibians                       | 894   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 894           |
| 2.y. Fish                             | 44307   | 1660  | 0  | 1600  | 3986   | 0                           | 0                             | 233          | 51786         |
| 2.z. TOTAL                            | 420451  | 142887  | 95771  | 26116   | 61160  | 28419                       | 1137                          | 5874         | 781815        |

**TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Products versus species**

| 3.1<br>Species                        | 3.2<br>Products/<br>substances or<br>devices for<br>human<br>medicine and<br>dentistry and<br>for veterinary<br>medicine | 3.3<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>agriculture | 3.4<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>industry | 3.5<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>the<br>household | 3.6<br>Products/<br>substances<br>intended to<br>be used<br>mainly as<br>cosmetics<br>or toiletries | 3.7<br>Products/<br>substances<br>intended to be<br>used mainly<br>as additives in<br>food for<br>human<br>consumption | 3.8<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>animal<br>consumption | 3.9<br>Potential or<br>actual<br>contaminants in<br>the general<br>environment<br>which do not<br>appear in other<br>columns | 3.10<br>Other toxico-<br>logical or<br>safety<br>evaluations | 3.11<br>Total |
|---------------------------------------|--|--|---|---|---|--|--|--|--|---------------|
| 3.a. Mice                             | 5390   | 0  | 90  | 0   | 0   | 0  | 160  | 0  | 23586  | 29226         |
| 3.b. Rats                             | 10041  | 603  | 2228  | 0   | 0   | 311  | 0  | 0  | 926  | 14109         |
| 3.c. Guinea-Pigs                      | 5992   | 468  | 0   | 0   | 0   | 0  | 0  | 0  | 71   | 6531          |
| 3.d. Hamsters                         | 153  | 0  | 0   | 8   | 0   | 0  | 0  | 0  | 0  | 161           |
| 3.e. Other Rodents                    | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.f. Rabbits                          | 1812   | 69   | 21  | 0   | 0   | 0  | 0  | 4  | 12   | 1918          |
| 3.g. Cats                             | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.h. Dogs                             | 359  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 359           |
| 3.i. Ferrets                          | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.j. Other Carnivores                 | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.k. Horses, donkeys and cross breeds | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.l. Pigs                             | 309  | 0  | 0   | 0   | 0   | 0  | 144  | 0  | 0  | 453           |
| 3.m. Goats                            | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.n. Sheep                            | 18   | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 18            |
| 3.o. Cattle                           | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 2  | 2             |
| 3.p. Prosimians                       | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.q. New World Monkeys                | 11   | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 11            |
| 3.r. Old World Monkeys                | 262  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 262           |
| 3.s. Apes                             | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.t. Other Mammals                    | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.u. Quail                            | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.v. Other birds                      | 3620   | 0  | 0   | 0   | 0   | 0  | 504  | 0  | 0  | 4124          |
| 3.w. Reptiles                         | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.x. Amphibians                       | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0  | 0  | 0             |
| 3.y. Fish                             | 310  | 0  | 1866  | 0   | 0   | 0  | 0  | 1810   | 0  | 3986          |
| 3.z. TOTAL                            | 28277  | 1140   | 4205  | 8   | 0   | 311  | 808  | 1814   | 24597  | 61160         |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             | 17852                                   | 53875  | 88910  | 124413                      | 17426   | 302476       |
| 4.b. Rats                             | 3670                                    | 27783  | 5572   | 18448                       | 606   | 56079        |
| 4.c. Guinea-Pigs                      | 58                                      | 376  | 0  | 3330                        | 0   | 3764         |
| 4.d. Hamsters                         | 28                                      | 90   | 0  | 158                         | 0   | 276          |
| 4.e. Other Rodents                    | 0                                       | 0  | 0  | 1197                        | 749   | 1946         |
| 4.f. Rabbits                          | 122                                     | 43   | 3  | 545                         | 179   | 892          |
| 4.g. Cats                             | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.h. Dogs                             | 15                                      | 24   | 140  | 82                          | 0   | 261          |
| 4.i. Ferrets                          | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.j. Other Carnivores                 | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.k. Horses, donkeys and cross breeds | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.l. Pigs                             | 73                                      | 0  | 9  | 165                         | 1   | 248          |
| 4.m. Goats                            | 0                                       | 0  | 0  | 0                           | 31  | 31           |
| 4.n. Sheep                            | 14                                      | 0  | 2  | 59                          | 33  | 108          |
| 4.o. Cattle                           | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.p. Prosimians                       | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.q. New World Monkeys                | 0                                       | 57   | 0  | 11                          | 0   | 68           |
| 4.r. Old World Monkeys                | 4                                       | 10   | 42   | 50                          | 0   | 106          |
| 4.s. Apes                             | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.t. Other Mammals                    | 0                                       | 0  | 0  | 0                           | 5   | 5            |
| 4.u. Quail                            | 0                                       | 0  | 0  | 0                           | 4   | 4            |
| 4.v. Other birds                      | 0                                       | 0  | 0  | 0                           | 120   | 120          |
| 4.w. Reptiles                         | 0                                       | 0  | 0  | 0                           | 99  | 99           |
| 4.x. Amphibians                       | 0                                       | 41   | 0  | 7                           | 0   | 48           |
| 4.y. Fish                             | 0                                       | 0  | 0  | 21151                       | 120   | 21271        |
| 4.z. TOTAL                            | 21836                                   | 82299  | 94678  | 169616                      | 19373   | 387802       |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             | 3477   | 13930  | 0   | 100                      | 14863   | 4500                                 | 36870        |
| 5.b. Rats                             | 72   | 4662   | 0   | 0                        | 49469   | 0                                    | 54203        |
| 5.c. Guinea-Pigs                      | 536  | 203  | 0   | 0                        | 2450  | 0                                    | 3189         |
| 5.d. Hamsters                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.e. Other Rodents                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.f. Rabbits                          | 363  | 4063   | 0   | 0                        | 914   | 0                                    | 5340         |
| 5.g. Cats                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.h. Dogs                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.i. Ferrets                          | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.j. Other Carnivores                 | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.k. Horses, donkeys and cross breeds | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.l. Pigs                             | 121  | 692  | 0   | 0                        | 34  | 0                                    | 847          |
| 5.m. Goats                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.n. Sheep                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.o. Cattle                           | 0  | 20   | 0   | 0                        | 0   | 0                                    | 20           |
| 5.p. Primates                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.q. New World Monkeys                | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.r. Old World Monkeys                | 0  | 0  | 0   | 0                        | 35  | 0                                    | 35           |
| 5.s. Apes                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.t. Other Mammals                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.u. Quail                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.v. Other birds                      | 1249   | 18534  | 0   | 0                        | 0   | 0                                    | 19783        |
| 5.w. Reptiles                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.x. Amphibians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.y. Fish                             | 1600   | 0  | 0   | 0                        | 0   | 0                                    | 1600         |
| 5.z. TOTAL                            | 7418   | 42104  | 0   | 100                      | 67765   | 4500                                 | 121887       |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Norwegian requirement

5.5 – Poland is testing due to a US specific requirement

5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

**Example:** a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Regulatory requirements versus species**

| 6.1<br>Species                        | 6.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 6.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 6.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 6.5<br>Other legislation | 6.6<br>Any combination of<br>6.2/ 6.3/ 6.4/ 6.5 | 6.7<br>No regulatory<br>requirements | 6.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 6.a. Mice                             | 21297  | 3702   | 10  | 0                        | 4212  | 5                                    | 29226        |
| 6.b. Rats                             | 3640   | 7086   | 0   | 0                        | 2961  | 422                                  | 14109        |
| 6.c. Guinea-Pigs                      | 93   | 4962   | 30  | 0                        | 1444  | 2                                    | 6531         |
| 6.d. Hamsters                         | 0  | 150  | 0   | 0                        | 11  | 0                                    | 161          |
| 6.e. Other Rodents                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.f. Rabbits                          | 136  | 1409   | 0   | 0                        | 311   | 62                                   | 1918         |
| 6.g. Cats                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.h. Dogs                             | 227  | 132  | 0   | 0                        | 0   | 0                                    | 359          |
| 6.i. Ferrets                          | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.j. Other Carnivores                 | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.k. Horses, donkeys and cross breeds | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.l. Pigs                             | 0  | 453  | 0   | 0                        | 0   | 0                                    | 453          |
| 6.m. Goats                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.n. Sheep                            | 0  | 18   | 0   | 0                        | 0   | 0                                    | 18           |
| 6.o. Cattle                           | 2  | 0  | 0   | 0                        | 0   | 0                                    | 2            |
| 6.p. Primates                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.q. New World Monkeys                | 0  | 11   | 0   | 0                        | 0   | 0                                    | 11           |
| 6.r. Old World Monkeys                | 51   | 0  | 0   | 0                        | 211   | 0                                    | 262          |
| 6.s. Apes                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.t. Other Mammals                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.u. Quail                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.v. Other birds                      | 0  | 4124   | 0   | 0                        | 0   | 0                                    | 4124         |
| 6.w. Reptiles                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.x. Amphibians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.y. Fish                             | 240  | 3476   | 0   | 0                        | 0   | 270                                  | 3986         |
| 6.z. TOTAL                            | 25686  | 25523  | 40  | 0                        | 9150  | 761                                  | 61160        |

**Examples:** 6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Norwegian requirement

6.5 – Poland is testing due to a US specific requirement

6.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

**Footnotes:**

- 1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus species**

| 7.1<br>Species                           | 7.2<br>Acute and sub-acute toxicity testing methods<br>(including limit test) |                                  |  | 7.3<br>Skin<br>irritation | 7.4<br>Skin<br>sensitisation | 7.5<br>Eye<br>irritation | 7.6<br>Sub-<br>chronic and<br>chronic<br>toxicity | 7.7<br>Carcino-<br>genicity | 7.8<br>Develop-<br>mental<br>toxicity | 7.9<br>Muta-<br>genic<br>ity | 7.10<br>Repro-<br>ductive<br>toxicity | 7.11<br>Toxicity<br>to aquatic<br>vertebra-<br>tes not<br>included<br>in other<br>columns | 7.12<br>Other | 7.13<br>Total |
|--|---|----------------------------------|--|---------------------------|------------------------------|--------------------------|---|-----------------------------|---------------------------------------|------------------------------|---------------------------------------|---|---------------|---------------|
|  | 7.2.1.<br>LD50,<br>LC50   | 7.2.2<br>Other lethal<br>methods | 7.2.3<br>Non lethal<br>clinical signs<br>methods |                           |                              |                          |   |                             |                                       |                              |                                       |   |               |               |
|  |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               |               |
| 7.a. Mice                                | 320   | 5089                             | 11864  | 0                         | 0                            | 0                        | 733   | 0                           | 0                                     | 182                          | 36                                    | 0   | 11002         | 29226         |
| 7.b. Rats                                | 24  | 405                              | 5618   | 6                         | 0                            | 0                        | 4390  | 0                           | 493                                   | 92                           | 2710                                  | 0   | 371           | 14109         |
| 7.c. Guinea-Pigs                         | 0   | 5                                | 116  | 0                         | 6410                         | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 6531          |
| 7.d. Hamsters                            | 0   | 0                                | 0  | 11                        | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 150           | 161           |
| 7.e. Other Rodents                       | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.f. Rabbits                             | 5   | 0                                | 234  | 351                       | 0                            | 117                      | 54  | 0                           | 34                                    | 0                            | 4                                     | 0   | 1119          | 1918          |
| 7.g. Cats                                | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.h. Dogs                                | 0   | 0                                | 249  | 0                         | 0                            | 0                        | 107   | 0                           | 0                                     | 0                            | 0                                     | 0   | 3             | 359           |
| 7.i. Ferrets                             | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.j. Other Carnivores                    | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.k. Horses, donkeys and cross<br>breeds | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.l. Pigs                                | 0   | 0                                | 187  | 3                         | 0                            | 0                        | 80  | 0                           | 0                                     | 0                            | 0                                     | 0   | 183           | 453           |
| 7.m. Goats                               | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.n. Sheep                               | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 18            | 18            |
| 7.o. Cattle                              | 0   | 0                                | 2  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 2             |
| 7.p. Primates                            | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.q. New World Monkeys                   | 0   | 0                                | 11   | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 11            |
| 7.r. Old World Monkeys                   | 0   | 0                                | 99   | 0                         | 0                            | 0                        | 145   | 0                           | 0                                     | 0                            | 0                                     | 0   | 18            | 262           |
| 7.s. Apes                                | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.t. Other Mammals                       | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.u. Quail                               | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.v. Other birds                         | 0   | 0                                | 3365   | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 759           | 4124          |
| 7.w. Reptiles                            | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.x. Amphibians                          | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                            | 0                                     | 0   | 0             | 0             |
| 7.y. Fish                                | 760   | 0                                | 2136   | 0                         | 0                            | 0                        | 1050  | 0                           | 0                                     | 274                          | 2750                                  | 0   | 40            | 3986          |
| 7.z. TOTAL                               | 1109  | 5499                             | 23881  | 371                       | 6410                         | 117                      | 6559  | 0                           | 527                                   | 274                          | 2750                                  | 0   | 13663         | 61160         |



**TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus products**

| 8.1<br>Products   | 8.2<br>Acute and sub-acute toxicity testing methods (including limit test) |                               |  | 8.3<br>Skin irritation | 8.4<br>Skin sensitisation | 8.5<br>Eye irritation | 8.6<br>Sub-chronic and chronic toxicity | 8.7<br>Carcinogenicity | 8.8<br>Developmental toxicity | 8.9<br>Mutagenicity | 8.10<br>Reproductive toxicity | 8.11<br>Toxicity to aquatic vertebrates not included in other columns | 8.12<br>Other | 8.13<br>Total |
|---|--|-------------------------------|--|------------------------|---------------------------|-----------------------|---|------------------------|-------------------------------|---------------------|-------------------------------|---|---------------|---------------|
|   | 8.2.1.<br>LD50, LC50   | 8.2.2<br>Other lethal methods | 8.2.3<br>Non lethal clinical signs methods |                        |                           |                       |   |                        |                               |                     |                               |   |               |               |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine        | 329  | 402                           | 12418                                      | 314                    | 5942                      | 78                    | 5248                                    | 0                      | 218                           | 152                 | 856                           | 0   | 2320          | 28277         |
| 8.b. Products/substances used or intended to be used mainly in agriculture                              | 0  | 90                            | 91   | 36                     | 468                       | 33                    | 0                                       | 0                      | 0                             | 0                   | 422                           | 0   | 0             | 1140          |
| 8.c. Products/substances used or intended to be used mainly in industry                                 | 0  | 82                            | 2149                                       | 21                     | 0                         | 6                     | 100                                     | 0                      | 289                           | 90                  | 1468                          | 0   | 0             | 4205          |
| 8.d. Products/substances used or intended to be used mainly in the household                            | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 8             | 8             |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries                  | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 0             |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption  | 0  | 36                            | 25   | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 32                  | 0                             | 0   | 218           | 311           |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption | 0  | 160                           | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 648           | 808           |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns   | 760  | 0                             | 0  | 0                      | 0                         | 0                     | 1050                                    | 0                      | 0                             | 0                   | 4                             | 0   | 0             | 1814          |
| 8.i. Other toxicological or safety evaluations  | 20   | 4729                          | 9198                                       | 0                      | 0                         | 0                     | 161                                     | 0                      | 20                            | 0                   | 0                             | 0   | 10469         | 24597         |
| 8.j. TOTAL  | 1109   | 5499                          | 23881                                      | 371                    | 6410                      | 117                   | 6559                                    | 0                      | 527                           | 274                 | 2750                          | 0   | 13663         | 61160         |

# **CYPRUS**

## **Statistical data submitted**

The statistical data were submitted by Veterinary Services of the Republic of Cyprus.

## **Comments of the Cypriot authorities**

None

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 1328         | 1301  | 10   |   | 17                                       |                        |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 0            |   |  |   |  |                        |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 0            |   |  |   |  |                        |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 0            |   |  |   |  |                        |
| 1.e. Other Rodents (other <i>Rodentia</i> )              | 0            |   |  |   |  |                        |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 0            |   |  |   |  |                        |
| 1.g. Cats ( <i>Felis catus</i> )                         | 0            |   |  |   |  |                        |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 0            |   |  |   |  |                        |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 0            |   |  |   |  |                        |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          |              |   |  |   |  |                        |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) |              |   |  |   |  |                        |
| 1.l. Pigs ( <i>Sus</i> )                                 |              |   |  |   |  |                        |
| 1.m. Goats ( <i>Capra</i> )                              |              |   |  |   |  |                        |
| 1.n. Sheep ( <i>Ovis</i> )                               |              |   |  |   |  |                        |
| 1.o. Cattle ( <i>Bos</i> )                               |              |   |  |   |  |                        |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 0            |   |  |   |  |                        |
| 1.q. New World Monkeys ( <i>Cebotidea</i> )              | 0            |   |  |   |  |                        |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 0            |   |  |   |  |                        |
| 1.s. Apes ( <i>Hominioidea</i> )                         | 0            |   |  |   |  |                        |
| 1.t. Other Mammals (other <i>Mammalia</i> )              |              |   |  |   |  |                        |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 0            |   |  |   |  |                        |
| 1.v. Other birds (other <i>Aves</i> )                    |              |   |  |   |  |                        |
| 1.w. Reptiles ( <i>Reptilia</i> )                        |              |   |  |   |  |                        |
| 1.x. Amphibians ( <i>Amphibia</i> )                      |              |   |  |   |  |                        |
| 1.y. Fish ( <i>Pisces</i> )                              |              |   |  |   |  |                        |
| 1.z. TOTAL   | 1328         |   |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 1139  | 108   |  |   |  |                             | 81                            |              | 1328          |
| 2.b. Rats                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.c. Guinea-Pigs                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.d. Hamsters                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.e. Other Rodents                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.f. Rabbits                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.g. Cats                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.h. Dogs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.i. Ferrets                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.j. Other Carnivores                 |   |   |  |   |  |                             |                               |              | 0             |
| 2.k. Horses, donkeys and cross breeds |   |   |  |   |  |                             |                               |              | 0             |
| 2.l. Pigs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.m. Goats                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.n. Sheep                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.o. Cattle                           |   |   |  |   |  |                             |                               |              | 0             |
| 2.p. Prosimians                       |   |   |  |   |  |                             |                               |              | 0             |
| 2.q. New World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.r. Old World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.s. Apes                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.t. Other Mammals                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.u. Quail                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.v. Other birds                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.w. Reptiles                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.x. Amphibians                       |   |   |  |   |  |                             |                               |              | 0             |
| 2.y. Fish                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.z. TOTAL                            | 1139  | 108   | 0  | 0   | 0  | 0                           | 81                            | 0            | 1328          |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             |   | 211  | 183  | 157                         |   | 551          |
| 4.b. Rats                             |   |  |  |                             |   | 0            |
| 4.c. Guinea-Pigs                      |   |  |  |                             |   | 0            |
| 4.d. Hamsters                         |   |  |  |                             |   | 0            |
| 4.e. Other Rodents                    |   |  |  |                             |   | 0            |
| 4.f. Rabbits                          |   |  |  |                             |   | 0            |
| 4.g. Cats                             |   |  |  |                             |   | 0            |
| 4.h. Dogs                             |   |  |  |                             |   | 0            |
| 4.i. Ferrets                          |   |  |  |                             |   | 0            |
| 4.j. Other Carnivores                 |   |  |  |                             |   | 0            |
| 4.k. Horses, donkeys and cross breeds |   |  |  |                             |   | 0            |
| 4.l. Pigs                             |   |  |  |                             |   | 0            |
| 4.m. Goats                            |   |  |  |                             |   | 0            |
| 4.n. Sheep                            |   |  |  |                             |   | 0            |
| 4.o. Cattle                           |   |  |  |                             |   | 0            |
| 4.p. Prosimians                       |   |  |  |                             |   | 0            |
| 4.q. New World Monkeys                |   |  |  |                             |   | 0            |
| 4.r. Old World Monkeys                |   |  |  |                             |   | 0            |
| 4.s. Apes                             |   |  |  |                             |   | 0            |
| 4.t. Other Mammals                    |   |  |  |                             |   | 0            |
| 4.u. Quail                            |   |  |  |                             |   | 0            |
| 4.v. Other birds                      |   |  |  |                             |   | 0            |
| 4.w. Reptiles                         |   |  |  |                             |   | 0            |
| 4.x. Amphibians                       |   |  |  |                             |   | 0            |
| 4.y. Fish                             |   |  |  |                             |   | 0            |
| 4.z. TOTAL                            | 0                                       | 211  | 183  | 157                         | 0   | 551          |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             |  |  |   |                          |   |                                      | 0            |
| 5.b. Rats                             |  |  |   |                          |   |                                      | 0            |
| 5.c. Guinea-Pigs                      |  |  |   |                          |   |                                      | 0            |
| 5.d. Hamsters                         |  |  |   |                          |   |                                      | 0            |
| 5.e. Other Rodents                    |  |  |   |                          |   |                                      | 0            |
| 5.f. Rabbits                          |  |  |   |                          |   |                                      | 0            |
| 5.g. Cats                             |  |  |   |                          |   |                                      | 0            |
| 5.h. Dogs                             |  |  |   |                          |   |                                      | 0            |
| 5.i. Ferrets                          |  |  |   |                          |   |                                      | 0            |
| 5.j. Other Carnivores                 |  |  |   |                          |   |                                      | 0            |
| 5.k. Horses, donkeys and cross breeds |  |  |   |                          |   |                                      | 0            |
| 5.l. Pigs                             |  |  |   |                          |   |                                      | 0            |
| 5.m. Goats                            |  |  |   |                          |   |                                      | 0            |
| 5.n. Sheep                            |  |  |   |                          |   |                                      | 0            |
| 5.o. Cattle                           |  |  |   |                          |   |                                      | 0            |
| 5.p. Primates                         |  |  |   |                          |   |                                      | 0            |
| 5.q. New World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.r. Old World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.s. Apes                             |  |  |   |                          |   |                                      | 0            |
| 5.t. Other Mammals                    |  |  |   |                          |   |                                      | 0            |
| 5.u. Quail                            |  |  |   |                          |   |                                      | 0            |
| 5.v. Other birds                      |  |  |   |                          |   |                                      | 0            |
| 5.w. Reptiles                         |  |  |   |                          |   |                                      | 0            |
| 5.x. Amphibians                       |  |  |   |                          |   |                                      | 0            |
| 5.y. Fish                             |  |  |   |                          |   |                                      | 0            |
| 5.z. TOTAL                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 - Spain is testing due to a Norwegian requirement

5.5 – Poland is testing due to a US specific requirement

5.6 – Germany is testing due to a Swiss requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslavia Rep. of Macedonia', Turkey, Ukraine

# **LATVIA**

## **Statistical data submitted**

The statistical data were submitted by the State Food and Veterinary Service.

## **Comments of Latvian authorities**

None

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 6300         | 6300  |  |   |  |                        |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 4020         | 4020  |  |   |  |                        |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 0            | 0   |  |   |  |                        |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 0            | 0   |  |   |  |                        |
| 1.e. Other Rodents (other <i>Rodentia</i> )              |              |   |  |   |  |                        |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 0            | 0   |  |   |  |                        |
| 1.g. Cats ( <i>Felis catus</i> )                         | 0            | 0   |  |   |  |                        |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 9            | 9   | 9  |   |  |                        |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 0            | 0   |  |   |  |                        |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          |              |   |  |   |  |                        |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) |              |   |  |   |  |                        |
| 1.l. Pigs ( <i>Sus</i> )                                 |              |   |  |   |  |                        |
| 1.m. Goats ( <i>Capra</i> )                              |              |   |  |   |  |                        |
| 1.n. Sheep ( <i>Ovis</i> )                               |              |   |  |   |  |                        |
| 1.o. Cattle ( <i>Bos</i> )                               |              |   |  |   |  |                        |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 0            | 0   |  |   |  |                        |
| 1.q. New World Monkeys ( <i>Ceboidae</i> )               | 0            | 0   |  |   |  |                        |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 0            | 0   |  |   |  |                        |
| 1.s. Apes ( <i>Hominioidea</i> )                         | 0            | 0   |  |   |  |                        |
| 1.t. Other Mammals (other <i>Mammalia</i> )              |              |   |  |   |  |                        |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 0            | 0   |  |   |  |                        |
| 1.v. Other birds (other <i>Aves</i> )                    |              |   |  |   |  |                        |
| 1.w. Reptiles ( <i>Reptilia</i> )                        |              |   |  |   |  |                        |
| 1.x. Amphibians ( <i>Amphibia</i> )                      |              |   |  |   |  |                        |
| 1.y. Fish ( <i>Pisces</i> )                              |              |   |  |   |  |                        |
| 1.z. TOTAL   | 10329        |   |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2



**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 1200  | 2111  | 2989   |   |  |                             |                               |              | 6300          |
| 2.b. Rats                             | 1370  | 527   | 2123   |   |  |                             |                               |              | 4020          |
| 2.c. Guinea-Pigs                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.d. Hamsters                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.e. Other Rodents                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.f. Rabbits                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.g. Cats                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.h. Dogs                             |   | 9   |  |   |  |                             |                               |              | 9             |
| 2.i. Ferrets                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.j. Other Carnivores                 |   |   |  |   |  |                             |                               |              | 0             |
| 2.k. Horses, donkeys and cross breeds |   |   |  |   |  |                             |                               |              | 0             |
| 2.l. Pigs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.m. Goats                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.n. Sheep                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.o. Cattle                           |   |   |  |   |  |                             |                               |              | 0             |
| 2.p. Primates                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.q. New World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.r. Old World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.s. Apes                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.t. Other Mammals                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.u. Quail                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.v. Other birds                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.w. Reptiles                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.x. Amphibians                       |   |   |  |   |  |                             |                               |              | 0             |
| 2.y. Fish                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.z. TOTAL                            | 2570  | 2647  | 5112   | 0   | 0  | 0                           | 0                             | 0            | 10329         |

**TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Products versus species**

| 3.1<br>Species                        | 3.2<br>Products/<br>substances or<br>devices for<br>human<br>medicine and<br>dentistry and<br>for veterinary<br>medicine | 3.3<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>agriculture | 3.4<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>industry | 3.5<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>the<br>household | 3.6<br>Products/<br>substances<br>intended to<br>be used<br>mainly as<br>cosmetics<br>or toiletries | 3.7<br>Products/<br>substances<br>intended to be<br>used mainly<br>as additives in<br>food for<br>human<br>consumption | 3.8<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>animal<br>consumption | 3.9<br>Potential or<br>actual contami-<br>nants in the<br>general envi-<br>ronment which<br>do not appear in<br>other columns | 3.10<br>Other toxico-<br>logical or<br>safety<br>evaluations | 3.11<br>Total |
|---------------------------------------|--|--|---|---|---|--|--|---|--|---------------|
| 3.a. Mice                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.b. Rats                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.c. Guinea-Pigs                      |  |  |   |   |   |  |  |   |  | 0             |
| 3.d. Hamsters                         |  |  |   |   |   |  |  |   |  | 0             |
| 3.e. Other Rodents                    |  |  |   |   |   |  |  |   |  | 0             |
| 3.f. Rabbits                          |  |  |   |   |   |  |  |   |  | 0             |
| 3.g. Cats                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.h. Dogs                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.i. Ferrets                          |  |  |   |   |   |  |  |   |  | 0             |
| 3.j. Other Carnivores                 |  |  |   |   |   |  |  |   |  | 0             |
| 3.k. Horses, donkeys and cross breeds |  |  |   |   |   |  |  |   |  | 0             |
| 3.l. Pigs                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.m. Goats                            |  |  |   |   |   |  |  |   |  | 0             |
| 3.n. Sheep                            |  |  |   |   |   |  |  |   |  | 0             |
| 3.o. Cattle                           |  |  |   |   |   |  |  |   |  | 0             |
| 3.p. Prosimians                       |  |  |   |   |   |  |  |   |  | 0             |
| 3.q. New World Monkeys                |  |  |   |   |   |  |  |   |  | 0             |
| 3.r. Old World Monkeys                |  |  |   |   |   |  |  |   |  | 0             |
| 3.s. Apes                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.t. Other Mammals                    |  |  |   |   |   |  |  |   |  | 0             |
| 3.u. Quail                            |  |  |   |   |   |  |  |   |  | 0             |
| 3.v. Other birds                      |  |  |   |   |   |  |  |   |  | 0             |
| 3.w. Reptiles                         |  |  |   |   |   |  |  |   |  | 0             |
| 3.x. Amphibians                       |  |  |   |   |   |  |  |   |  | 0             |
| 3.y. Fish                             |  |  |   |   |   |  |  |   |  | 0             |
| 3.z. TOTAL                            | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             | 854                                     | 1587   | 291  | 579                         |   | 3311         |
| 4.b. Rats                             | 605                                     | 1002   |  | 290                         |   | 1897         |
| 4.c. Guinea-Pigs                      |   |  |  |                             |   | 0            |
| 4.d. Hamsters                         |   |  |  |                             |   | 0            |
| 4.e. Other Rodents                    |   |  |  |                             |   | 0            |
| 4.f. Rabbits                          |   |  |  |                             |   | 0            |
| 4.g. Cats                             |   |  |  |                             |   | 0            |
| 4.h. Dogs                             |   |  |  | 9                           |   | 9            |
| 4.i. Ferrets                          |   |  |  |                             |   | 0            |
| 4.j. Other Carnivores                 |   |  |  |                             |   | 0            |
| 4.k. Horses, donkeys and cross breeds |   |  |  |                             |   | 0            |
| 4.l. Pigs                             |   |  |  |                             |   | 0            |
| 4.m. Goats                            |   |  |  |                             |   | 0            |
| 4.n. Sheep                            |   |  |  |                             |   | 0            |
| 4.o. Cattle                           |   |  |  |                             |   | 0            |
| 4.p. Prosimians                       |   |  |  |                             |   | 0            |
| 4.q. New World Monkeys                |   |  |  |                             |   | 0            |
| 4.r. Old World Monkeys                |   |  |  |                             |   | 0            |
| 4.s. Apes                             |   |  |  |                             |   | 0            |
| 4.t. Other Mammals                    |   |  |  |                             |   | 0            |
| 4.u. Quail                            |   |  |  |                             |   | 0            |
| 4.v. Other birds                      |   |  |  |                             |   | 0            |
| 4.w. Reptiles                         |   |  |  |                             |   | 0            |
| 4.x. Amphibians                       |   |  |  |                             |   | 0            |
| 4.y. Fish                             |   |  |  |                             |   | 0            |
| 4.z. TOTAL                            | 1459                                    | 2589   | 291  | 878                         | 0   | 5217         |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             |  | 2989   |   |                          |   |                                      | 2989         |
| 5.b. Rats                             |  | 2123   |   |                          |   |                                      | 2123         |
| 5.c. Guinea-Pigs                      |  |  |   |                          |   |                                      | 0            |
| 5.d. Hamsters                         |  |  |   |                          |   |                                      | 0            |
| 5.e. Other Rodents                    |  |  |   |                          |   |                                      | 0            |
| 5.f. Rabbits                          |  |  |   |                          |   |                                      | 0            |
| 5.g. Cats                             |  |  |   |                          |   |                                      | 0            |
| 5.h. Dogs                             |  |  |   |                          |   |                                      | 0            |
| 5.i. Ferrets                          |  |  |   |                          |   |                                      | 0            |
| 5.j. Other Carnivores                 |  |  |   |                          |   |                                      | 0            |
| 5.k. Horses, donkeys and cross breeds |  |  |   |                          |   |                                      | 0            |
| 5.l. Pigs                             |  |  |   |                          |   |                                      | 0            |
| 5.m. Goats                            |  |  |   |                          |   |                                      | 0            |
| 5.n. Sheep                            |  |  |   |                          |   |                                      | 0            |
| 5.o. Cattle                           |  |  |   |                          |   |                                      | 0            |
| 5.p. Primates                         |  |  |   |                          |   |                                      | 0            |
| 5.q. New World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.r. Old World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.s. Apes                             |  |  |   |                          |   |                                      | 0            |
| 5.t. Other Mammals                    |  |  |   |                          |   |                                      | 0            |
| 5.u. Quail                            |  |  |   |                          |   |                                      | 0            |
| 5.v. Other birds                      |  |  |   |                          |   |                                      | 0            |
| 5.w. Reptiles                         |  |  |   |                          |   |                                      | 0            |
| 5.x. Amphibians                       |  |  |   |                          |   |                                      | 0            |
| 5.y. Fish                             |  |  |   |                          |   |                                      | 0            |
| 5.z. TOTAL                            | 0  | 5112   | 0   | 0                        | 0   | 0                                    | 5112         |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Norwegian requirement

5.5 – Poland is testing due to a US specific requirement

5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

**Example:** a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine



# LITHUANIA

## Statistical data submitted

The statistical data have been submitted by the Animal Health and Welfare Department of the State Food and Veterinary Service of the Republic of Lithuania.

## Comments of Lithuanian authorities

The legal basis for the collection of statistics on the number and use of vertebrate animals for experimental and other scientific purposes in Lithuania is provided by:

The State Food and Veterinary Service Director Decree No B1-639 (Government Gazette 2009, No 8-287) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC and European Convention on the protection of animals used for experimental and other scientific purposes.

The total number of animals used in experiments in Lithuania in 2011 was 4,067.

Rodents accounted for 88,64% of all animals used – 3,605 animals (2,131 mice – accounting for 59,11 %, 1,297 rats - accounting for 35,98 %, 177 guinea pigs – accounting for 4,91 %).

Rabbits represent 6,74 % (274 animals).

Cold-blooded animals (amphibians) represented 3,66 % of the animals used – 149 animals, of which 100 % were used for education and training purposes.

Pigs accounted for 0,5 % of the animals used (19 animals), of which 52,63 % were used for research and development of products and devices for human medicine and dentistry and for veterinary medicine, 47,37 % for diagnosis of disease purposes.

Birds accounted for 0,5 % (20 animals), of which 100% were used for research and development of products and devices for human medicine and dentistry and for veterinary medicine.

No primates were used.

No animals have been used for cosmetics testing.

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 2131         | 2131  |  |   |  |                        |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 1297         | 1297  |  |   |  |                        |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 177          | 177   |  |   |  |                        |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 0            |   |  |   |  |                        |
| 1.e. Other Rodents (other <i>Rodentia</i> )              |              |   |  |   |  |                        |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 274          | 274   |  |   |  |                        |
| 1.g. Cats ( <i>Felis catus</i> )                         | 0            |   |  |   |  |                        |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 0            |   |  |   |  |                        |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 0            |   |  |   |  |                        |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          |              |   |  |   |  |                        |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) |              |   |  |   |  |                        |
| 1.l. Pigs ( <i>Sus</i> )                                 | 19           |   |  |   |  |                        |
| 1.m. Goats ( <i>Capra</i> )                              |              |   |  |   |  |                        |
| 1.n. Sheep ( <i>Ovis</i> )                               |              |   |  |   |  |                        |
| 1.o. Cattle ( <i>Bos</i> )                               |              |   |  |   |  |                        |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 0            |   |  |   |  |                        |
| 1.q. New World Monkeys ( <i>Cebioidea</i> )              | 0            |   |  |   |  |                        |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 0            |   |  |   |  |                        |
| 1.s. Apes ( <i>Hominidea</i> )                           | 0            |   |  |   |  |                        |
| 1.t. Other Mammals (other <i>Mammalia</i> )              |              |   |  |   |  |                        |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 0            |   |  |   |  |                        |
| 1.v. Other birds (other <i>Aves</i> )                    | 20           |   |  |   |  |                        |
| 1.w. Reptiles ( <i>Reptilia</i> )                        |              |   |  |   |  |                        |
| 1.x. Amphibians ( <i>Amphibia</i> )                      | 149          |   |  |   |  |                        |
| 1.y. Fish ( <i>Pisces</i> )                              |              |   |  |   |  |                        |
| 1.z. TOTAL   | 4067         |   |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|--|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 574   | 1014   | 25   |   | 200  | 309                         | 9                             |              | 2131          |
| 2.b. Rats                             | 670   | 506  |  |   | 26   | 90                          | 5                             |              | 1297          |
| 2.c. Guinea-Pigs                      | 55  | 110  |  |   | 7  |                             | 5                             |              | 177           |
| 2.d. Hamsters                         |   |  |  |   |  |                             |                               |              | 0             |
| 2.e. Other Rodents                    |   |  |  |   |  |                             |                               |              | 0             |
| 2.f. Rabbits                          | 53  | 206  |  |   | 7  | 2                           | 6                             |              | 274           |
| 2.g. Cats                             |   |  |  |   |  |                             |                               |              | 0             |
| 2.h. Dogs                             |   |  |  |   |  |                             |                               |              | 0             |
| 2.i. Ferrets                          |   |  |  |   |  |                             |                               |              | 0             |
| 2.j. Other Carnivores                 |   |  |  |   |  |                             |                               |              | 0             |
| 2.k. Horses, donkeys and cross breeds |   |  |  |   |  |                             |                               |              | 0             |
| 2.l. Pigs                             |   | 10   |  |   |  | 9                           |                               |              | 19            |
| 2.m. Goats                            |   |  |  |   |  |                             |                               |              | 0             |
| 2.n. Sheep                            |   |  |  |   |  |                             |                               |              | 0             |
| 2.o. Cattle                           |   |  |  |   |  |                             |                               |              | 0             |
| 2.p. Prosimians                       |   |  |  |   |  |                             |                               |              | 0             |
| 2.q. New World Monkeys                |   |  |  |   |  |                             |                               |              | 0             |
| 2.r. Old World Monkeys                |   |  |  |   |  |                             |                               |              | 0             |
| 2.s. Apes                             |   |  |  |   |  |                             |                               |              | 0             |
| 2.t. Other Mammals                    |   |  |  |   |  |                             |                               |              | 0             |
| 2.u. Quail                            |   |  |  |   |  |                             |                               |              | 0             |
| 2.v. Other birds                      |   | 20   |  |   |  |                             |                               |              | 20            |
| 2.w. Reptiles                         |   |  |  |   |  |                             |                               |              | 0             |
| 2.x. Amphibians                       |   |  |  |   |  |                             | 149                           |              | 149           |
| 2.y. Fish                             |   |  |  |   |  |                             |                               |              | 0             |
| 2.z. TOTAL                            | 1352  | 1866   | 25   | 0   | 240  | 410                         | 174                           | 0            | 4067          |



**TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Products versus species**

| 3.1<br>Species                        | 3.2<br>Products/<br>devices for<br>human<br>medicine and<br>dentistry and<br>for veterinary<br>medicine | 3.3<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>agriculture | 3.4<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>industry | 3.5<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>the<br>household | 3.6<br>Products/<br>substances<br>intended to<br>be used<br>mainly as<br>cosmetics<br>or toiletries | 3.7<br>Products/<br>substances<br>intended to be<br>used mainly<br>as additives in<br>food for<br>human<br>consumption | 3.8<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>animal<br>consumption | 3.9<br>Potential or<br>actual contami-<br>nants in the<br>general envi-<br>ronment which<br>do not appear in<br>other columns | 3.10<br>Other toxico-<br>logical or<br>safety<br>evaluations | 3.11<br>Total |
|---------------------------------------|---|--|---|---|---|--|--|---|--|---------------|
| 3.a. Mice                             |   |  |   |   |   |  | 200  |   |  | 200           |
| 3.b. Rats                             |   |  |   |   |   |  | 26   |   |  | 26            |
| 3.c. Guinea-Pigs                      |   |  |   |   |   |  | 7  |   |  | 7             |
| 3.d. Hamsters                         |   |  |   |   |   |  |  |   |  | 0             |
| 3.e. Other Rodents                    |   |  |   |   |   |  |  |   |  | 0             |
| 3.f. Rabbits                          |   |  |   |   |   |  | 7  |   |  | 7             |
| 3.g. Cats                             |   |  |   |   |   |  |  |   |  | 0             |
| 3.h. Dogs                             |   |  |   |   |   |  |  |   |  | 0             |
| 3.i. Ferrets                          |   |  |   |   |   |  |  |   |  | 0             |
| 3.j. Other Carnivores                 |   |  |   |   |   |  |  |   |  | 0             |
| 3.k. Horses, donkeys and cross breeds |   |  |   |   |   |  |  |   |  | 0             |
| 3.l. Pigs                             |   |  |   |   |   |  |  |   |  | 0             |
| 3.m. Goats                            |   |  |   |   |   |  |  |   |  | 0             |
| 3.n. Sheep                            |   |  |   |   |   |  |  |   |  | 0             |
| 3.o. Cattle                           |   |  |   |   |   |  |  |   |  | 0             |
| 3.p. Prosimians                       |   |  |   |   |   |  |  |   |  | 0             |
| 3.q. New World Monkeys                |   |  |   |   |   |  |  |   |  | 0             |
| 3.r. Old World Monkeys                |   |  |   |   |   |  |  |   |  | 0             |
| 3.s. Apes                             |   |  |   |   |   |  |  |   |  | 0             |
| 3.t. Other Mammals                    |   |  |   |   |   |  |  |   |  | 0             |
| 3.u. Quail                            |   |  |   |   |   |  |  |   |  | 0             |
| 3.v. Other birds                      |   |  |   |   |   |  |  |   |  | 0             |
| 3.w. Reptiles                         |   |  |   |   |   |  |  |   |  | 0             |
| 3.x. Amphibians                       |   |  |   |   |   |  |  |   |  | 0             |
| 3.y. Fish                             |   |  |   |   |   |  |  |   |  | 0             |
| 3.z. TOTAL                            | 0   | 0  | 0   | 0   | 0   | 0  | 240  | 0   | 0  | 240           |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             |   |  | 300  | 400                         |   | 700          |
| 4.b. Rats                             |   |  |  |                             |   | 0            |
| 4.c. Guinea-Pigs                      |   |  |  |                             |   | 0            |
| 4.d. Hamsters                         |   |  |  |                             |   | 0            |
| 4.e. Other Rodents                    |   |  |  |                             |   | 0            |
| 4.f. Rabbits                          |   |  |  |                             |   | 0            |
| 4.g. Cats                             |   |  |  |                             |   | 0            |
| 4.h. Dogs                             |   |  |  |                             |   | 0            |
| 4.i. Ferrets                          |   |  |  |                             |   | 0            |
| 4.j. Other Carnivores                 |   |  |  |                             |   | 0            |
| 4.k. Horses, donkeys and cross breeds |   |  |  |                             |   | 0            |
| 4.l. Pigs                             |   |  |  |                             |   | 0            |
| 4.m. Goats                            |   |  |  |                             |   | 0            |
| 4.n. Sheep                            |   |  |  |                             |   | 0            |
| 4.o. Cattle                           |   |  |  |                             |   | 0            |
| 4.p. Prosimians                       |   |  |  |                             |   | 0            |
| 4.q. New World Monkeys                |   |  |  |                             |   | 0            |
| 4.r. Old World Monkeys                |   |  |  |                             |   | 0            |
| 4.s. Apes                             |   |  |  |                             |   | 0            |
| 4.t. Other Mammals                    |   |  |  |                             |   | 0            |
| 4.u. Quail                            |   |  |  |                             |   | 0            |
| 4.v. Other birds                      |   |  |  |                             |   | 0            |
| 4.w. Reptiles                         |   |  |  |                             |   | 0            |
| 4.x. Amphibians                       |   |  |  | 43                          |   | 43           |
| 4.y. Fish                             |   |  |  |                             |   | 0            |
| 4.z. TOTAL                            | 0                                       | 0  | 300  | 443                         | 0   | 743          |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             | 25   |  |   |                          |   |                                      | 25           |
| 5.b. Rats                             |  |  |   |                          |   |                                      | 0            |
| 5.c. Guinea-Pigs                      |  |  |   |                          |   |                                      | 0            |
| 5.d. Hamsters                         |  |  |   |                          |   |                                      | 0            |
| 5.e. Other Rodents                    |  |  |   |                          |   |                                      | 0            |
| 5.f. Rabbits                          |  |  |   |                          |   |                                      | 0            |
| 5.g. Cats                             |  |  |   |                          |   |                                      | 0            |
| 5.h. Dogs                             |  |  |   |                          |   |                                      | 0            |
| 5.i. Ferrets                          |  |  |   |                          |   |                                      | 0            |
| 5.j. Other Carnivores                 |  |  |   |                          |   |                                      | 0            |
| 5.k. Horses, donkeys and cross breeds |  |  |   |                          |   |                                      | 0            |
| 5.l. Pigs                             |  |  |   |                          |   |                                      | 0            |
| 5.m. Goats                            |  |  |   |                          |   |                                      | 0            |
| 5.n. Sheep                            |  |  |   |                          |   |                                      | 0            |
| 5.o. Cattle                           |  |  |   |                          |   |                                      | 0            |
| 5.p. Prosimians                       |  |  |   |                          |   |                                      | 0            |
| 5.q. New World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.r. Old World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.s. Apes                             |  |  |   |                          |   |                                      | 0            |
| 5.t. Other Mammals                    |  |  |   |                          |   |                                      | 0            |
| 5.u. Quail                            |  |  |   |                          |   |                                      | 0            |
| 5.v. Other birds                      |  |  |   |                          |   |                                      | 0            |
| 5.w. Reptiles                         |  |  |   |                          |   |                                      | 0            |
| 5.x. Amphibians                       |  |  |   |                          |   |                                      | 0            |
| 5.y. Fish                             | 25   | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.z. TOTAL                            |  |  |   |                          |   |                                      | 25           |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 – Spain is testing due to a Norwegian requirement

5.5 – Poland is testing due to a US specific requirement

5.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

**Example:** a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be

entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Regulatory requirements versus species**

| 6.1<br>Species                        | 6.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 6.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 6.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 6.5<br>Other legislation | 6.6<br>Any combination of<br>6.2/ 6.3/ 6.4/ 6.5 | 6.7<br>No regulatory<br>requirements | 6.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 6.a. Mice                             |  |  | 200   |                          |   |                                      | 200          |
| 6.b. Rats                             |  |  | 26  |                          |   |                                      | 26           |
| 6.c. Guinea-Pigs                      |  |  | 7   |                          |   |                                      | 7            |
| 6.d. Hamsters                         |  |  |   |                          |   |                                      | 0            |
| 6.e. Other Rodents                    |  |  |   |                          |   |                                      | 0            |
| 6.f. Rabbits                          |  |  | 7   |                          |   |                                      | 7            |
| 6.g. Cats                             |  |  |   |                          |   |                                      | 0            |
| 6.h. Dogs                             |  |  |   |                          |   |                                      | 0            |
| 6.i. Ferrets                          |  |  |   |                          |   |                                      | 0            |
| 6.j. Other Carnivores                 |  |  |   |                          |   |                                      | 0            |
| 6.k. Horses, donkeys and cross breeds |  |  |   |                          |   |                                      | 0            |
| 6.l. Pigs                             |  |  |   |                          |   |                                      | 0            |
| 6.m. Goats                            |  |  |   |                          |   |                                      | 0            |
| 6.n. Sheep                            |  |  |   |                          |   |                                      | 0            |
| 6.o. Cattle                           |  |  |   |                          |   |                                      | 0            |
| 6.p. Prosimians                       |  |  |   |                          |   |                                      | 0            |
| 6.q. New World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 6.r. Old World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 6.s. Apes                             |  |  |   |                          |   |                                      | 0            |
| 6.t. Other Mammals                    |  |  |   |                          |   |                                      | 0            |
| 6.u. Quail                            |  |  |   |                          |   |                                      | 0            |
| 6.v. Other birds                      |  |  |   |                          |   |                                      | 0            |
| 6.w. Reptiles                         |  |  |   |                          |   |                                      | 0            |
| 6.x. Amphibians                       |  |  |   |                          |   |                                      | 0            |
| 6.y. Fish                             |  |  |   |                          |   |                                      | 0            |
| 6.z. TOTAL                            | 0  | 0  | 240   | 0                        | 0   | 0                                    | 240          |

**Examples:**

- 6.2 – France is testing due to a UK (or FR) specific requirement
- 6.3 - UK is testing according to EC legislation
- 6.4 – Spain is testing due to a Norwegian requirement
- 6.5 – Poland is testing due to a US specific requirement
- 6.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:**

- columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.
- Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

**Footnotes:**

- 1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus species**

| 7.1<br>Species                           | 7.2<br>Acute and sub-acute toxicity testing methods<br>(including limit test) |                                  |  | 7.3<br>Skin<br>irritation | 7.4<br>Skin<br>sensitisation | 7.5<br>Eye<br>irritation | 7.6<br>Sub-<br>chronic and<br>chronic<br>toxicity | 7.7<br>Carcino-<br>genicity | 7.8<br>Develop-<br>mental<br>toxicity | 7.9<br>Muta-<br>genicity | 7.10<br>Repro-<br>ductive<br>toxicity | 7.11<br>Toxicity<br>to aquatic<br>vertebra-<br>tes not<br>included<br>in other<br>columns | 7.12<br>Other | 7.13<br>Total |
|--|---|----------------------------------|--|---------------------------|------------------------------|--------------------------|---|-----------------------------|---------------------------------------|--------------------------|---------------------------------------|---|---------------|---------------|
|  | 7.2.1.<br>LD50,<br>LC50   | 7.2.2<br>Other lethal<br>methods | 7.2.3<br>Non lethal<br>clinical signs<br>methods |                           |                              |                          |   |                             |                                       |                          |                                       |   |               |               |
| 7.a. Mice                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   | 200           | 200           |
| 7.b. Rats                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   | 26            | 26            |
| 7.c. Guinea-Pigs                         |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   | 7             | 7             |
| 7.d. Hamsters                            |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.e. Other Rodents                       |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.f. Rabbits                             |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   | 7             | 7             |
| 7.g. Cats                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.h. Dogs                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.i. Ferrets                             |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.j. Other Carnivores                    |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.k. Horses, donkeys and cross<br>breeds |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.l. Pigs                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.m. Goats                               |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.n. Sheep                               |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.o. Cattle                              |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.p. Prosimians                          |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.q. New World Monkeys                   |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.r. Old World Monkeys                   |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.s. Apes                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.t. Other Mammals                       |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.u. Quail                               |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.v. Other birds                         |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.w. Reptiles                            |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.x. Amphibians                          |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.y. Fish                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               | 0             |
| 7.z. TOTAL                               | 0   | 0                                | 0  | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 240           | 240           |

**TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus products**

| 8.1<br>Products   | 8.2<br>Acute and sub-acute toxicity testing methods (including limit test) |                               |  | 8.3<br>Skin irritation | 8.4<br>Skin sensitisation | 8.5<br>Eye irritation | 8.6<br>Sub-chronic and chronic toxicity | 8.7<br>Carcinogenicity | 8.8<br>Developmental toxicity | 8.9<br>Mutagenicity | 8.10<br>Reproductive toxicity | 8.11<br>Toxicity to aquatic vertebrates not included in other columns | 8.12<br>Other | 8.13<br>Total |
|---|--|-------------------------------|--|------------------------|---------------------------|-----------------------|---|------------------------|-------------------------------|---------------------|-------------------------------|---|---------------|---------------|
|   | 8.2.1.<br>LD50, LC50   | 8.2.2<br>Other lethal methods | 8.2.3<br>Non lethal clinical signs methods |                        |                           |                       |   |                        |                               |                     |                               |   |               |               |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine        |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   | 200           | 200           |
| 8.b. Products/substances used or intended to be used mainly in agriculture                              |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   | 26            | 26            |
| 8.c. Products/substances used or intended to be used mainly in industry                                 |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   | 7             | 7             |
| 8.d. Products/substances used or intended to be used mainly in the household                            |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries                  |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption  |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   | 7             | 7             |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns   |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.i. Other toxicological or safety evaluations  |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.j. TOTAL  |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |

# LUXEMBOURG

## Statistical data submitted

The statistical data were submitted by the '*Ministère de l'Agriculture, de la viticulture et du développement rural. Administration des Services Vétérinaires*' (Ministry of Agriculture, viticulture and rural development. Administration of Veterinary Services).

## Comments of Luxembourg authorities

None

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 470          | 470   |  |   |  |                        |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 32           | 32  |  |   |  |                        |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 0            |   |  |   |  |                        |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 0            |   |  |   |  |                        |
| 1.e. Other Rodents (other <i>Rodentia</i> )              |              |   |  |   |  |                        |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 0            |   |  |   |  |                        |
| 1.g. Cats ( <i>Felis catus</i> )                         | 0            |   |  |   |  |                        |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 0            |   |  |   |  |                        |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 0            |   |  |   |  |                        |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          |              |   |  |   |  |                        |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) |              |   |  |   |  |                        |
| 1.l. Pigs ( <i>Sus</i> )                                 |              |   |  |   |  |                        |
| 1.m. Goats ( <i>Capra</i> )                              |              |   |  |   |  |                        |
| 1.n. Sheep ( <i>Ovis</i> )                               |              |   |  |   |  |                        |
| 1.o. Cattle ( <i>Bos</i> )                               |              |   |  |   |  |                        |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 0            |   |  |   |  |                        |
| 1.q. New World Monkeys ( <i>Cebioidea</i> )              | 0            |   |  |   |  |                        |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 0            |   |  |   |  |                        |
| 1.s. Apes ( <i>Hominioidea</i> )                         | 0            |   |  |   |  |                        |
| 1.t. Other Mammals (other <i>Mammalia</i> )              |              |   |  |   |  |                        |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 0            |   |  |   |  |                        |
| 1.v. Other birds (other <i>Aves</i> )                    |              |   |  |   |  |                        |
| 1.w. Reptiles ( <i>Reptilia</i> )                        |              |   |  |   |  |                        |
| 1.x. Amphibians ( <i>Amphibia</i> )                      |              |   |  |   |  |                        |
| 1.y. Fish ( <i>Pisces</i> )                              |              |   |  |   |  |                        |
| 1.z. TOTAL   | 502          |   |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2



**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 470   |   |  |   |  |                             |                               |              | 470           |
| 2.b. Rats                             | 32  |   |  |   |  |                             |                               |              | 32            |
| 2.c. Guinea-Pigs                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.d. Hamsters                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.e. Other Rodents                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.f. Rabbits                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.g. Cats                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.h. Dogs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.i. Ferrets                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.j. Other Carnivores                 |   |   |  |   |  |                             |                               |              | 0             |
| 2.k. Horses, donkeys and cross breeds |   |   |  |   |  |                             |                               |              | 0             |
| 2.l. Pigs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.m. Goats                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.n. Sheep                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.o. Cattle                           |   |   |  |   |  |                             |                               |              | 0             |
| 2.p. Prosimians                       |   |   |  |   |  |                             |                               |              | 0             |
| 2.q. New World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.r. Old World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.s. Apes                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.t. Other Mammals                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.u. Quail                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.v. Other birds                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.w. Reptiles                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.x. Amphibians                       |   |   |  |   |  |                             |                               |              | 0             |
| 2.y. Fish                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.z. TOTAL                            | 502   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 502           |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             | 100                                     | 50   | 280  | 40                          |   | 470          |
| 4.b. Rats                             | 20                                      | 12   |  |                             |   | 32           |
| 4.c. Guinea-Pigs                      |   |  |  |                             |   | 0            |
| 4.d. Hamsters                         |   |  |  |                             |   | 0            |
| 4.e. Other Rodents                    |   |  |  |                             |   | 0            |
| 4.f. Rabbits                          |   |  |  |                             |   | 0            |
| 4.g. Cats                             |   |  |  |                             |   | 0            |
| 4.h. Dogs                             |   |  |  |                             |   | 0            |
| 4.i. Ferrets                          |   |  |  |                             |   | 0            |
| 4.j. Other Carnivores                 |   |  |  |                             |   | 0            |
| 4.k. Horses, donkeys and cross breeds |   |  |  |                             |   | 0            |
| 4.l. Pigs                             |   |  |  |                             |   | 0            |
| 4.m. Goats                            |   |  |  |                             |   | 0            |
| 4.n. Sheep                            |   |  |  |                             |   | 0            |
| 4.o. Cattle                           |   |  |  |                             |   | 0            |
| 4.p. Prosimians                       |   |  |  |                             |   | 0            |
| 4.q. New World Monkeys                |   |  |  |                             |   | 0            |
| 4.r. Old World Monkeys                |   |  |  |                             |   | 0            |
| 4.s. Apes                             |   |  |  |                             |   | 0            |
| 4.t. Other Mammals                    |   |  |  |                             |   | 0            |
| 4.u. Quail                            |   |  |  |                             |   | 0            |
| 4.v. Other birds                      |   |  |  |                             |   | 0            |
| 4.w. Reptiles                         |   |  |  |                             |   | 0            |
| 4.x. Amphibians                       |   |  |  |                             |   | 0            |
| 4.y. Fish                             |   |  |  |                             |   | 0            |
| 4.z. TOTAL                            | 120                                     | 62   | 280  | 40                          | 0   | 502          |

# HUNGARY

## Statistical data submitted

The statistical data were submitted by the Ministry of Rural Development.

## Comments of the Hungarian authorities

The total number of animals used for experimental and other scientific purposes in 2011 was 276.179 which represents a 9,4% decrease compared to the same figure of 2008.

The use of other rodents, goats and reptiles fell to zero. The decrease was considerable in the number of cattle (94,6%), horses and donkeys (77,5%), hamsters (59%), amphibians (38,7%), rats (20,7%), and sheep (20%).

On the other hand the use of fish more than doubled and eighteen times as many quails were used than in 2008.

The trend of monkeys turned in the past few years: no new world monkey were used, but the number of old world monkeys grew.

Compared to 2008 no rabbits, but cats were re-used.

The amount of animals used for production and quality control of products and devices for veterinary medicine (more than doubled) and for toxicological and other safety evaluations (almost doubled) were increased , but a lot less (half) were used to education and training.

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| I.a. Mice ( <i>Mus musculus</i> )                        | 143755       | 104761  | 38678  | 316   | 0  | 0                      |
| I.b. Rats ( <i>Rattus norvegicus</i> )                   | 70873        | 56330   | 13520  | 1023  | 0  | 0                      |
| I.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 9228         | 9101  | 81   | 46  | 0  | 0                      |
| I.d. Hamsters ( <i>Mesocricetus</i> )                    | 88           | 88  | 0  | 0   | 0  | 0                      |
| I.e. Other Rodents (other <i>Rodentia</i> )              | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 7567         | 7233  | 13   | 321   | 0  | 0                      |
| I.g. Cats ( <i>Felis catus</i> )                         | 34           | 25  | 9  | 0   | 0  | 20                     |
| I.h. Dogs ( <i>Canis familiaris</i> )                    | 675          | 370   | 144  | 161   | 0  | 88                     |
| I.i. Ferrets ( <i>Mustela putorius furo</i> )            | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.j. Other Carnivores (other <i>Carnivora</i> )          | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) | 9            | 0   | 0  | 0   | 0  | 0                      |
| I.l. Pigs ( <i>Sus</i> )                                 | 1278         | 79  | 2  | 0   | 0  | 0                      |
| I.m. Goats ( <i>Capra</i> )                              | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.n. Sheep ( <i>Ovis</i> )                               | 160          | 0   | 0  | 0   | 0  | 0                      |
| I.o. Cattle ( <i>Bos</i> )                               | 5            | 0   | 0  | 0   | 0  | 0                      |
| I.p. Prosimians ( <i>Prosimia</i> )                      | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.q. New World Monkeys ( <i>Ceboidae</i> )               | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 7            | 7   | 0  | 0   | 0  | 0                      |
| I.s. Apes ( <i>Hominioidea</i> )                         | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.t. Other Mammals (other <i>Mammalia</i> )              | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.u. Quail ( <i>Coturnix coturnix</i> )                  | 235          | 235   | 0  | 0   | 0  | 0                      |
| I.v. Other birds (other <i>Aves</i> )                    | 36304        | 0   | 0  | 0   | 0  | 0                      |
| I.w. Reptiles ( <i>Reptilia</i> )                        | 0            | 0   | 0  | 0   | 0  | 0                      |
| I.x. Amphibians ( <i>Amphibia</i> )                      | 725          | 0   | 0  | 0   | 0  | 0                      |
| I.y. Fish ( <i>Pisces</i> )                              | 5236         | 2142  | 0  | 0   | 0  | 0                      |
| I.z. TOTAL   | 276179       | 26269   | 7891   | 1577  | 0  | 0                      |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 34512   | 69495   | 15833  | 2992  | 15649  | 3175                        | 829                           | 1270         | 143755        |
| 2.b. Rats                             | 22398   | 32540   | 111  | 0   | 12961  | 20                          | 2123                          | 720          | 70873         |
| 2.c. Guinea-Pigs                      | 436   | 781   | 858  | 1508  | 5398   | 0                           | 169                           | 78           | 9228          |
| 2.d. Hamsters                         | 88  | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 88            |
| 2.e. Other Rodents                    | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.f. Rabbits                          | 2128  | 772   | 221  | 1077  | 3052   | 110                         | 207                           | 0            | 7567          |
| 2.g. Cats                             | 14  | 20  | 0  | 0   | 0  | 0                           | 0                             | 0            | 34            |
| 2.h. Dogs                             | 228   | 89  | 0  | 0   | 340  | 0                           | 18                            | 0            | 675           |
| 2.i. Ferrets                          | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.j. Other Carnivores                 | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.k. Horses, donkeys and cross breeds | 0   | 8   | 0  | 0   | 1  | 0                           | 0                             | 0            | 9             |
| 2.l. Pigs                             | 885   | 101   | 0  | 252   | 39   | 0                           | 1                             | 0            | 1278          |
| 2.m. Goats                            | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.n. Sheep                            | 6   | 37  | 0  | 112   | 0  | 0                           | 0                             | 5            | 160           |
| 2.o. Cattle                           | 2   | 0   | 0  | 0   | 3  | 0                           | 0                             | 0            | 5             |
| 2.p. Primates                         | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.q. New World Monkeys                | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.r. Old World Monkeys                | 7   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 7             |
| 2.s. Apes                             | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.t. Other Mammals                    | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.u. Quail                            | 0   | 0   | 0  | 0   | 235  | 0                           | 0                             | 0            | 235           |
| 2.v. Other birds                      | 5177  | 1485  | 0  | 27725   | 30   | 15                          | 146                           | 1726         | 36304         |
| 2.w. Reptiles                         | 0   | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 0             |
| 2.x. Amphibians                       | 125   | 0   | 0  | 0   | 0  | 0                           | 600                           | 0            | 725           |
| 2.y. Fish                             | 374   | 0   | 0  | 0   | 4198   | 100                         | 564                           | 0            | 5236          |
| 2.z. TOTAL                            | 66380   | 105328  | 17023  | 33666   | 41906  | 3420                        | 4657                          | 3799         | 276179        |

**TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Products versus species**

| 3.1<br>Species                        | 3.2<br>Products/<br>substances or<br>devices for<br>human<br>medicine and<br>dentistry and<br>for veterinary<br>medicine | 3.3<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>agriculture | 3.4<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>industry | 3.5<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>the<br>household | 3.6<br>Products/<br>substances<br>intended to<br>be used<br>mainly as<br>cosmetics<br>or toiletries | 3.7<br>Products/<br>substances<br>intended to be<br>used mainly<br>as additives in<br>food for<br>human<br>consumption | 3.8<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>animal<br>consumption | 3.9<br>Potential or<br>actual contami-<br>nants in the<br>general envi-<br>ronment which<br>do not appear in<br>other columns | 3.10<br>Other toxico-<br>logical or<br>safety<br>evaluations | 3.11<br>Total |
|---------------------------------------|--|--|---|---|---|--|--|---|--|---------------|
| 3.a. Mice                             | 10608  | 560  | 921   | 0   | 0   | 0  | 0  | 139   | 3421   | 15649         |
| 3.b. Rats                             | 3909   | 958  | 269   | 0   | 0   | 0  | 0  | 219   | 7606   | 12961         |
| 3.c. Guinea-Pigs                      | 3854   | 20   | 0   | 0   | 0   | 0  | 0  | 0   | 1524   | 5398          |
| 3.d. Hamsters                         | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.e. Other Rodents                    | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.f. Rabbits                          | 1941   | 144  | 0   | 0   | 0   | 0  | 0  | 0   | 967  | 3052          |
| 3.g. Cats                             | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.h. Dogs                             | 196  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 144  | 340           |
| 3.i. Ferrets                          | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.j. Other Carnivores                 | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.k. Horses, donkeys and cross breeds | 1  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 1             |
| 3.l. Pigs                             | 37   | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 2  | 39            |
| 3.m. Goats                            | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.n. Sheep                            | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.o. Cattle                           | 3  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 3             |
| 3.p. Prosimians                       | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.q. New World Monkeys                | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.r. Old World Monkeys                | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.s. Apes                             | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.t. Other Mammals                    | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.u. Quail                            | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 235  | 235           |
| 3.v. Other birds                      | 30   | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 30            |
| 3.w. Reptiles                         | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.x. Amphibians                       | 0  | 0  | 0   | 0   | 0   | 0  | 0  | 0   | 0  | 0             |
| 3.y. Fish                             | 0  | 252  | 342   | 0   | 0   | 0  | 0  | 1720  | 1884   | 4198          |
| 3.z. TOTAL                            | 20579  | 1934   | 1532  | 0   | 0   | 0  | 0  | 2078  | 15783  | 41906         |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             | 993                                     | 61386  | 6711   | 15545                       | 2316  | 86951        |
| 4.b. Rats                             | 3537                                    | 33058  | 563  | 5954                        | 0   | 43112        |
| 4.c. Guinea-Pigs                      | 46                                      | 0  | 0  | 176                         | 68  | 290          |
| 4.d. Hamsters                         | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.e. Other Rodents                    | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.f. Rabbits                          | 518                                     | 13   | 0  | 174                         | 198   | 903          |
| 4.g. Cats                             | 0                                       | 0  | 0  | 9                           | 0   | 9            |
| 4.h. Dogs                             | 177                                     | 0  | 0  | 16                          | 0   | 193          |
| 4.i. Ferrets                          | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.j. Other Carnivores                 | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.k. Horses, donkeys and cross breeds | 0                                       | 0  | 0  | 0                           | 1   | 1            |
| 4.l. Pigs                             | 0                                       | 0  | 0  | 17                          | 58  | 75           |
| 4.m. Goats                            | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.n. Sheep                            | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.o. Cattle                           | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.p. Primates                         | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.q. New World Monkeys                | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.r. Old World Monkeys                | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.s. Apes                             | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.t. Other Mammals                    | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.u. Quail                            | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.v. Other birds                      | 0                                       | 0  | 0  | 15                          | 566   | 581          |
| 4.w. Reptiles                         | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.x. Amphibians                       | 0                                       | 0  | 0  | 100                         | 0   | 100          |
| 4.y. Fish                             | 0                                       | 0  | 0  | 0                           | 304   | 304          |
| 4.z. TOTAL                            | 5271                                    | 94457  | 7274   | 21997                       | 3520  | 132519       |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             | 14094  | 4471   | 0   | 210                      | 50  | 0                                    | 18825        |
| 5.b. Rats                             | 111  | 0  | 0   | 0                        | 0   | 0                                    | 111          |
| 5.c. Guinea-Pigs                      | 215  | 2151   | 0   | 0                        | 0   | 0                                    | 2366         |
| 5.d. Hamsters                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.e. Other Rodents                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.f. Rabbits                          | 13   | 1233   | 0   | 52                       | 0   | 0                                    | 1298         |
| 5.g. Cats                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.h. Dogs                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.i. Ferrets                          | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.j. Other Carnivores                 | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.k. Horses, donkeys and cross breeds | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.l. Pigs                             | 0  | 252  | 0   | 0                        | 0   | 0                                    | 252          |
| 5.m. Goats                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.n. Sheep                            | 0  | 112  | 0   | 0                        | 0   | 0                                    | 112          |
| 5.o. Cattle                           | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.p. Prosimians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.q. New World Monkeys                | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.r. Old World Monkeys                | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.s. Apes                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.t. Other Mammals                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.u. Quail                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.v. Other birds                      | 0  | 27355  | 0   | 370                      | 0   | 0                                    | 27725        |
| 5.w. Reptiles                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.x. Amphibians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.y. Fish                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 5.z. TOTAL                            | 14433  | 35574  | 0   | 632                      | 50  | 0                                    | 50689        |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement

5.3 - UK is testing according to EC legislation

5.4 - Spain is testing due to a Norwegian requirement

5.5 – Poland is testing due to a US specific requirement

5.6 – Germany is testing due to a Swiss requirement (also an EC requirement)

**Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

not to the body which has issued the actual test method, guideline or protocol.

**Example:** a test required by French legislation and carried out in Belgium according to an

ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine



**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Regulatory requirements versus species**

| 6.1<br>Species                        | 6.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 6.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 6.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 6.5<br>Other legislation | 6.6<br>Any combination of<br>6.2/ 6.3/ 6.4/ 6.5 | 6.7<br>No regulatory<br>requirements | 6.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 6.a. Mice                             | 1155   | 11809  | 0   | 90                       | 2112  | 483                                  | 15649        |
| 6.b. Rats                             | 466  | 5317   | 0   | 186                      | 6903  | 89                                   | 12961        |
| 6.c. Guinea-Pigs                      | 0  | 1308   | 0   | 531                      | 3559  | 0                                    | 5398         |
| 6.d. Hamsters                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.e. Other Rodents                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.f. Rabbits                          | 13   | 2154   | 0   | 0                        | 885   | 0                                    | 3052         |
| 6.g. Cats                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.h. Dogs                             | 16   | 99   | 0   | 81                       | 144   | 0                                    | 340          |
| 6.i. Ferrets                          | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.j. Other Carnivores                 | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.k. Horses, donkeys and cross breeds | 0  | 1  | 0   | 0                        | 0   | 0                                    | 1            |
| 6.l. Pigs                             | 0  | 20   | 0   | 0                        | 2   | 17                                   | 39           |
| 6.m. Goats                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.n. Sheep                            | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.o. Cattle                           | 0  | 3  | 0   | 0                        | 0   | 0                                    | 3            |
| 6.p. Primates                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.q. New World Monkeys                | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.r. Old World Monkeys                | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.s. Apes                             | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.t. Other Mammals                    | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.u. Quail                            | 0  | 0  | 0   | 0                        | 235   | 0                                    | 235          |
| 6.v. Other birds                      | 0  | 30   | 0   | 0                        | 0   | 0                                    | 30           |
| 6.w. Reptiles                         | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.x. Amphibians                       | 0  | 0  | 0   | 0                        | 0   | 0                                    | 0            |
| 6.y. Fish                             | 1284   | 1094   | 0   | 20                       | 1800  | 0                                    | 4198         |
| 6.z. TOTAL                            | 2934   | 21835  | 0   | 908                      | 15640   | 589                                  | 41906        |

**Examples:**

6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Norwegian requirement

6.5 – Poland is testing due to a US specific requirement

6.6 – Germany is testing due to a Swiss requirement (also an EC requirement)

Note: columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.

Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

**Footnotes:**

- 1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus species**

| 7.1<br>Species                           | 7.2<br>Acute and sub-acute toxicity testing methods<br>(including limit test) |                 |                                  | 7.3<br>Skin<br>irritation | 7.4<br>Skin<br>sensitisation | 7.5<br>Eye<br>irritation | 7.6<br>Sub-<br>chronic and<br>chronic<br>toxicity | 7.7<br>Carcino-<br>genicity | 7.8<br>Develop-<br>mental<br>toxicity | 7.9<br>Muta-<br>genicity | 7.10<br>Repro-<br>ductive<br>toxicity | 7.11<br>Toxicity<br>to aquatic<br>vertebra-<br>tes not<br>included<br>in other<br>columns | 7.12<br>Other | 7.13<br>Total |  |
|--|---|-----------------|----------------------------------|---------------------------|------------------------------|--------------------------|---|-----------------------------|---------------------------------------|--------------------------|---------------------------------------|---|---------------|---------------|--|
|  | 7.2.1<br>LD50,<br>LC50  |                 | 7.2.2<br>Other lethal<br>methods |                           |                              |                          |   |                             |                                       |                          |                                       |   |               |               | 7.2.3<br>Non lethal<br>clinical signs<br>methods |
|  | 7.2.1.1<br>LD50   | 7.2.1.2<br>LC50 |                                  |                           |                              |                          |   |                             |                                       |                          |                                       |   |               |               |  |
| 7.a. Mice                                | 8746  | 0               | 2189                             | 0                         | 2574                         | 0                        | 0   | 0                           | 0                                     | 269                      | 0                                     | 0   | 1871          | 15649         |  |
| 7.b. Rats                                | 3915  | 0               | 3008                             | 0                         | 0                            | 0                        | 2606  | 0                           | 96                                    | 364                      | 2008                                  | 0   | 964           | 12889         |  |
| 7.c. Guinea-Pigs                         | 631   | 0               | 1291                             | 0                         | 1822                         | 0                        | 1582  | 0                           | 0                                     | 0                        | 0                                     | 0   | 72            | 5398          |  |
| 7.d. Hamsters                            | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.e. Other Rodents                       | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.f. Rabbits                             | 0   | 0               | 1866                             | 377                       | 0                            | 328                      | 0   | 0                           | 0                                     | 0                        | 362                                   | 0   | 119           | 3052          |  |
| 7.g. Cats                                | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.h. Dogs                                | 0   | 0               | 148                              | 0                         | 0                            | 0                        | 176   | 0                           | 0                                     | 0                        | 0                                     | 0   | 16            | 340           |  |
| 7.i. Ferrets                             | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.j. Other Carnivores                    | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.k. Horses, donkeys and cross<br>breeds | 0   | 0               | 1                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 1             |  |
| 7.l. Pigs                                | 0   | 0               | 37                               | 0                         | 0                            | 0                        | 2   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 39            |  |
| 7.m. Goats                               | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.n. Sheep                               | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.o. Cattle                              | 0   | 0               | 3                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 3             |  |
| 7.p. Primates                            | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.q. New World Monkeys                   | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.r. Old World Monkeys                   | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.s. Apes                                | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.t. Other Mammals                       | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.u. Quail                               | 155   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 80            | 235           |  |
| 7.v. Other birds                         | 0   | 0               | 30                               | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 30            |  |
| 7.w. Reptiles                            | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.x. Amphibians                          | 0   | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 0             | 0             |  |
| 7.y. Fish                                | 2327  | 0               | 0                                | 0                         | 0                            | 0                        | 0   | 0                           | 0                                     | 0                        | 0                                     | 0   | 1159          | 4198          |  |
| 7.z. TOTAL                               | 15774   | 0               | 8573                             | 377                       | 4396                         | 328                      | 4366  | 0                           | 96                                    | 633                      | 2370                                  | 712   | 4281          | 41906         |  |

**TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus products**

| 8.1<br>Products   | 8.2<br>Acute and sub-acute toxicity testing methods (including limit test) |                               |  | 8.3<br>Skin irritation | 8.4<br>Skin sensitisation | 8.5<br>Eye irritation | 8.6<br>Sub-chronic and chronic toxicity | 8.7<br>Carcinogenicity | 8.8<br>Developmental toxicity | 8.9<br>Mutagenicity | 8.10<br>Reproductive toxicity | 8.11<br>Toxicity to aquatic vertebrates not included in other columns | 8.12<br>Other | 8.13<br>Total |
|---|--|-------------------------------|--|------------------------|---------------------------|-----------------------|---|------------------------|-------------------------------|---------------------|-------------------------------|---|---------------|---------------|
|   | 8.2.1.<br>LD50, LC50   | 8.2.2<br>Other lethal methods | 8.2.3<br>Non lethal clinical signs methods |                        |                           |                       |   |                        |                               |                     |                               |   |               |               |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine        | 9377   | 0                             | 6655                                       | 19                     | 395                       | 0                     | 2630                                    | 0                      | 96                            | 0                   | 488                           | 0   | 919           | 20579         |
| 8.b. Products/substances used or intended to be used mainly in agriculture                              | 1043   | 0                             | 388  | 97                     | 95                        | 97                    | 0                                       | 0                      | 0                             | 0                   | 124                           | 0   | 90            | 1934          |
| 8.c. Products/substances used or intended to be used mainly in industry                                 | 0  | 0                             | 0  | 0                      | 772                       | 0                     | 0                                       | 0                      | 0                             | 418                 | 0                             | 342   | 0             | 1532          |
| 8.d. Products/substances used or intended to be used mainly in the household                            | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 0             |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries                  | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 0             |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption  | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 0             |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption | 0  | 0                             | 0  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 0   | 0             | 0             |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns   | 1220   | 0                             | 130  | 0                      | 0                         | 0                     | 0                                       | 0                      | 0                             | 0                   | 0                             | 370   | 358           | 2078          |
| 8.i. Other toxicological or safety evaluations  | 4134   | 0                             | 1400                                       | 261                    | 3134                      | 231                   | 1736                                    | 0                      | 0                             | 215                 | 1758                          | 0   | 2914          | 15783         |
| 8.j. TOTAL  | 15774  | 0                             | 8673                                       | 377                    | 4396                      | 328                   | 4366                                    | 0                      | 96                            | 633                 | 2370                          | 712   | 4281          | 41906         |

## **MALTA**

### **Statistical data submitted**

The data were submitted by the Ministry for Resources and Rural Affairs, Veterinary and Phytosanitary Regulation Department.

### **Comments of Malta authorities**

None

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 0            |   |  |   |  |                        |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 0            |   |  |   |  |                        |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 0            |   |  |   |  |                        |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 0            |   |  |   |  |                        |
| 1.e. Other Rodents (other <i>Rodentia</i> )              | 0            |   |  |   |  |                        |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 0            |   |  |   |  |                        |
| 1.g. Cats ( <i>Felis catus</i> )                         | 0            |   |  |   |  |                        |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 0            |   |  |   |  |                        |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 0            |   |  |   |  |                        |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          | 0            |   |  |   |  |                        |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) | 0            |   |  |   |  |                        |
| 1.l. Pigs ( <i>Sus</i> )                                 | 0            |   |  |   |  |                        |
| 1.m. Goats ( <i>Capra</i> )                              | 0            |   |  |   |  |                        |
| 1.n. Sheep ( <i>Ovis</i> )                               | 0            |   |  |   |  |                        |
| 1.o. Cattle ( <i>Bos</i> )                               | 0            |   |  |   |  |                        |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 0            |   |  |   |  |                        |
| 1.q. New World Monkeys ( <i>Cebioidea</i> )              | 0            |   |  |   |  |                        |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 0            |   |  |   |  |                        |
| 1.s. Apes ( <i>Hominioidea</i> )                         | 0            |   |  |   |  |                        |
| 1.t. Other Mammals (other <i>Mammalia</i> )              | 10           |   |  |   |  |                        |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 0            |   |  |   |  |                        |
| 1.v. Other birds (other <i>Aves</i> )                    | 0            |   |  |   |  |                        |
| 1.w. Reptiles ( <i>Reptilia</i> )                        | 0            |   |  |   |  |                        |
| 1.x. Amphibians ( <i>Amphibia</i> )                      | 0            |   |  |   |  |                        |
| 1.y. Fish ( <i>Pisces</i> )                              | 0            |   |  |   |  |                        |
| 1.z. TOTAL   | 10           |   |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.b. Rats                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.c. Guinea-Pigs                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.d. Hamsters                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.e. Other Rodents                    |   |   |  |   |  |                             |                               |              | 0             |
| 2.f. Rabbits                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.g. Cats                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.h. Dogs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.i. Ferrets                          |   |   |  |   |  |                             |                               |              | 0             |
| 2.j. Other Carnivores                 |   |   |  |   |  |                             |                               |              | 0             |
| 2.k. Horses, donkeys and cross breeds |   |   |  |   |  |                             |                               |              | 0             |
| 2.l. Pigs                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.m. Goats                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.n. Sheep                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.o. Cattle                           |   |   |  |   |  |                             |                               |              | 0             |
| 2.p. Primates                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.q. New World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.r. Old World Monkeys                |   |   |  |   |  |                             |                               |              | 0             |
| 2.s. Apes                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.t. Other Mammals                    | 10  |   |  |   |  |                             |                               |              | 10            |
| 2.u. Quail                            |   |   |  |   |  |                             |                               |              | 0             |
| 2.v. Other birds                      |   |   |  |   |  |                             |                               |              | 0             |
| 2.w. Reptiles                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.x. Amphibians                       |   |   |  |   |  |                             |                               |              | 0             |
| 2.y. Fish                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.z. TOTAL                            | 10  | 0   | 0  | 0   | 0  | 0                           | 0                             | 0            | 10            |

# THE NETHERLANDS

## Statistical data submitted

The statistical data were prepared, quality assured and submitted by the '*Nederlandse Voedsel en Waren Autoriteit*' (Netherlands Food and Consumer Product Safety Authority).

## Comments of the Dutch authorities

On 5 February 1997, the revised version of the Experiments on Animals Act (1977) entered into force.

The provisions of the European Directive on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC) have been implemented.

In addition, among others the following provisions have been issued:

- Animal experiments using LD<sub>50</sub>/LC<sub>50</sub> methods are prohibited. However, for acute dermal and acute respiratory toxicity tests a general exemption is granted, due to the lack of validated alternative methods.
- Animal experiments for new or existing cosmetics are prohibited.
- Since 2003 animal experiments on great apes are prohibited.
- Every animal experiment to be performed has to be recommended by a recognised ethical review committee. Such a committee comprises at least seven members, one of whom is the chairperson. In addition, such a committee comprises in equal numbers experts in the fields of animal experiments, experts in the field of alternative methods, experts in the field of animal welfare and protection and experts in the field of ethical assessment. At least two of these experts are not involved in the conduct of experiments on animals. The chairperson and at least two members are not in the employ of any licence holder applying to the committee. The animal welfare officer is involved already at an early stage in the review of experiments and acts as a permanent advisor for the ethical review committee. At this moment 23 ethical review committees are recognized.

**Licenses** to perform animal experiments are issued by the Minister of Public Health, Welfare and Sport to a natural or legal person who is a mandated representative of an establishment for animal use. So licensed, those people are responsible for assuring that the legal requirements are complied with. The welfare of the experimental animals is supervised by a qualified veterinarian or another competent person in charge of the licensee.

**A Standing Committee** advises the Minister on the administration of the Act and other related issues. The Committee consists of experts in the field of animal experimentation, laboratory animal science and animal welfare.

The **enforcement** of the Act has been commissioned to the Netherlands Food and Consumer Product Safety Authority.

## The creation of transgenic animals

In 2011, for the creation of transgenic animals, 12,251 animals (11,494 mice, 546 rats, 48 other birds and 163 fish) were used.

## **Breeding of animals which had a phenotype with harmful effect**

In 2011 there were 11,890 animals used for breeding which had a phenotype with harmful effects. Concerning 11,015 genetically altered mice, 172 genetically altered rats and 703 mice without a genetical modification

### **Collection of data**

72 establishments completed the 2011 registration form.

These establishments can be categorized as follows:

|  |    |
|--|----|
| a) Universities and university hospitals           | 15 |
| b) Public health research institutes               | 4  |
| c) Agricultural and veterinary research institutes | 3  |
| d) Other research institutes                       | 4  |
| e) Industries and companies                        | 38 |
| f) Schools for vocational training                 | 6  |
| g) Breeders  | 2  |

## **The killing of an animal without any previous intervention**

In the Netherlands, the killing of an animal without any previous intervention in the framework of research or testing, e.g. for organ/blood collection, is considered to be an experiment. The rationale of this is that the Inspectorate must have the power to supervise the killing of laboratory animals.

This is in contrast to the Council of Europe Convention ETS 123 and Directive 86/609/EEC, where the use of an animal for an experimental or other scientific purpose is not considered an experiment if the least painful method of killing accepted in modern practice ('humane' methods') is used.

In 2011, 67,196 animals were killed without previous intervention.

Re-use of the animals (in 2011, 8,077 animals) is included as well in the Dutch statistics

### **Total number of animals used**

In 2011, according to the EU Tables, the total number of animals used was 514,617.

This is 3,2% (16,314) more than the number of animals used in 2010 (498,303).

The total number of genetically modified animals that was used was 93,349. When split up into species, the numbers of genetically modified animals used are: 89,704 mice, 419 rats, 200 rabbits and 3,026 fish.

### **Discomfort**



## General

Data has to be registered after an experiment has been performed. This includes data on the degree of discomfort; i.e. experienced discomfort.

As a consequence of the animal experiments performed in 2008:

- 36,35% of the animals experienced minor discomfort;
- 29,30% of the animals experienced minor/moderate discomfort;
- 21,67% of the animals experienced moderate discomfort;
- 8,98% of the animals experienced moderate/severe discomfort;
- 3,68% of the animals experienced severe discomfort; and
- 0.02% of the animals experienced very severe discomfort.

**TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN**

**Origin versus species**

| 1.1<br>Species   | 1.2<br>Total | 1.3<br>Animals coming from registered breeding or supplying establishments within the reporting country | 1.4<br>Animals coming from elsewhere in the EC | 1.5<br>Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6<br>Animals coming from other origins | 1.7<br>Re-used animals |
|--|--------------|---|--|---|--|------------------------|
| 1.a. Mice ( <i>Mus musculus</i> )                        | 237 784      | 202 725   | 31 817   |   | 3 242                                    |                        |
| 1.b. Rats ( <i>Rattus norvegicus</i> )                   | 98 881       | 57 765  | 41 029   |   | 87                                       |                        |
| 1.c. Guinea-Pigs ( <i>Cavia porcellus</i> )              | 5 493        | 3 191   | 2 287  |   | 15                                       |                        |
| 1.d. Hamsters ( <i>Mesocricetus</i> )                    | 3 632        | 3 476   | 156  |   | 0  |                        |
| 1.e. Other Rodents (other <i>Rodentia</i> )              | 979          |   |  |   |  |                        |
| 1.f. Rabbits ( <i>Oryctolagus cuniculus</i> )            | 6 293        | 1 614   | 4 651  |   | 28                                       | 138                    |
| 1.g. Cats ( <i>Felis catus</i> )                         | 174          | 103   | 0  |   | 71                                       | 22                     |
| 1.h. Dogs ( <i>Canis familiaris</i> )                    | 692          | 415   | 149  |   | 128                                      | 289                    |
| 1.i. Ferrets ( <i>Mustela putorius furo</i> )            | 852          | 0   | 666  |   | 186                                      | 14                     |
| 1.j. Other Carnivores (other <i>Carnivora</i> )          | 430          |   |  |   |  |                        |
| 1.k. Horses, donkeys and cross breeds ( <i>Equidae</i> ) | 2 371        |   |  |   |  |                        |
| 1.l. Pigs ( <i>Sus</i> )                                 | 14 686       |   |  |   |  |                        |
| 1.m. Goats ( <i>Capra</i> )                              | 284          |   |  |   |  |                        |
| 1.n. Sheep ( <i>Ovis</i> )                               | 2 600        |   |  |   |  |                        |
| 1.o. Cattle ( <i>Bos</i> )                               | 2 383        |   |  |   |  |                        |
| 1.p. Prosimians ( <i>Prosimia</i> )                      | 0            | 0   | 0  |   | 0  | 0                      |
| 1.q. New World Monkeys ( <i>Cebioidea</i> )              | 22           | 0   | 0  |   | 22                                       | 1                      |
| 1.r. Old World Monkeys ( <i>Cercopithecoidea</i> )       | 184          | 73  | 20   |   | 91                                       | 111                    |
| 1.s. Apes ( <i>Hominioidea</i> )                         | 0            | 0   | 0  |   | 0  | 0                      |
| 1.t. Other Mammals (other <i>Mammalia</i> )              | 41           |   |  |   |  |                        |
| 1.u. Quail ( <i>Coturnix coturnix</i> )                  | 68           | 68  | 0  |   | 0  |                        |
| 1.v. Other birds (other <i>Aves</i> )                    | 99 354       |   |  |   |  |                        |
| 1.w. Reptiles ( <i>Reptilia</i> )                        | 133          |   |  |   |  |                        |
| 1.x. Amphibians ( <i>Amphibia</i> )                      | 1 247        |   |  |   |  |                        |
| 1.y. Fish ( <i>Pisces</i> )                              | 36 034       |   |  |   |  |                        |
| 1.z. TOTAL   | 514 617      |   |  |   |  |                        |

**Note 1:** Column 1.5 concerns only those Member Countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column.

**Note 2:** Only the white boxes need to be completed.

**Note 3:** The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

**TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES**

**Purpose versus species**

| 2.1<br>Species                        | 2.2<br>Biological studies of a fundamental nature | 2.3<br>Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4<br>Production and quality control of products and devices for human medicine and dentistry | 2.5<br>Production and quality control of products and devices for veterinary medicine | 2.6<br>Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7<br>Diagnosis of disease | 2.8<br>Education and training | 2.9<br>Other | 2.10<br>Total |
|---------------------------------------|---|---|--|---|--|-----------------------------|-------------------------------|--------------|---------------|
| 2.a. Mice                             | 166 354   | 30 471  | 4 930  | 14 372  | 5 229  | 9 380                       | 7 048                         |              | 237 784       |
| 2.b. Rats                             | 28 621  | 4 886   | 28 937   | 5 802   | 27 619   |                             | 3 016                         |              | 98 881        |
| 2.c. Guinea-Pigs                      | 505   | 524   | 829  | 3 465   | 116  |                             | 54                            |              | 5 493         |
| 2.d. Hamsters                         | 432   | 245   |  | 2 916   |  |                             | 39                            |              | 3 632         |
| 2.e. Other Rodents                    | 699   | 280   |  |   |  |                             |                               |              | 979           |
| 2.f. Rabbits                          | 498   | 402   | 366  | 1 973   | 2 872  | 28                          | 154                           |              | 6 293         |
| 2.g. Cats                             | 49  |   |  | 38  |  |                             | 87                            |              | 174           |
| 2.h. Dogs                             | 164   | 101   |  | 183   | 152  |                             | 92                            |              | 692           |
| 2.i. Ferrets                          | 282   | 497   | 58   |   |  |                             | 15                            |              | 852           |
| 2.j. Other Carnivores                 | 121   |   |  | 309   |  |                             |                               |              | 430           |
| 2.k. Horses, donkeys and cross breeds | 24  | 194   | 101  | 2 030   |  |                             | 22                            |              | 2 371         |
| 2.l. Pigs                             | 8 925   | 3 387   | 6  | 1 671   | 43   |                             | 654                           |              | 14 686        |
| 2.m. Goats                            | 139   | 137   |  | 1   |  |                             | 7                             |              | 284           |
| 2.n. Sheep                            | 274   | 273   | 1 900  | 26  |  |                             | 127                           |              | 2 600         |
| 2.o. Cattle                           | 586   | 883   | 237  | 307   |  |                             | 370                           |              | 2 383         |
| 2.p. Primates                         |   |   |  |   |  |                             |                               |              | 0             |
| 2.q. New World Monkeys                | 5   | 17  |  |   |  |                             |                               |              | 22            |
| 2.r. Old World Monkeys                | 39  | 145   |  |   |  |                             |                               |              | 184           |
| 2.s. Apes                             |   |   |  |   |  |                             |                               |              | 0             |
| 2.t. Other Mammals                    | 39  | 2   |  |   |  |                             |                               |              | 41            |
| 2.u. Quail                            | 68  |   |  |   |  |                             |                               |              | 68            |
| 2.v. Other birds                      | 65 293  | 11 532  | 22   | 21 180  |  | 281                         | 1 046                         |              | 99 354        |
| 2.w. Reptiles                         | 133   |   |  |   |  |                             |                               |              | 133           |
| 2.x. Amphibians                       | 127   |   |  |   | 1 120  |                             |                               |              | 1 247         |
| 2.y. Fish                             | 31 967  |   |  |   | 3 580  |                             | 487                           |              | 36 034        |
| 2.z. TOTAL                            | 305 344   | 53 976  | 37 386   | 54 273  | 40 731   | 9 689                       | 13 218                        | 0            | 514 617       |

**TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Products versus species**

| 3.1<br>Species                        | 3.2<br>Products/<br>substances or<br>devices for<br>human<br>medicine and<br>dentistry and<br>for veterinary<br>medicine | 3.3<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>agriculture | 3.4<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>industry | 3.5<br>Products/<br>substances<br>intended to<br>be used<br>mainly in<br>the<br>household | 3.6<br>Products/<br>substances<br>used or<br>intended to<br>be used<br>mainly as<br>cosmetics<br>or toiletries | 3.7<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>human<br>consumption | 3.8<br>Products/<br>substances<br>used or<br>intended to be<br>used mainly<br>as additives in<br>food for<br>animal<br>consumption | 3.9<br>Potential or<br>actual contami-<br>nants in the<br>general envi-<br>ronment which<br>do not appear in<br>other columns | 3.10<br>Other toxico-<br>logical or<br>safety<br>evaluations | 3.11<br>Total |
|---------------------------------------|--|--|---|---|--|---|--|---|--|---------------|
| 3.a. Mice                             | 3 020  | 80   | 1 985   |   |  | 144   |  |   |  | 5 229         |
| 3.b. Rats                             | 7 127  | 6 150  | 14 093  | 28  |  | 200   |  |   | 21   | 27 619        |
| 3.c. Guinea-Pigs                      | 67   |  | 49  |   |  |   |  |   |  | 116           |
| 3.d. Hamsters                         |  |  |   |   |  |   |  |   |  | 0             |
| 3.e. Other Rodents                    |  |  |   |   |  |   |  |   |  | 0             |
| 3.f. Rabbits                          | 1 783  |  | 1 089   |   |  |   |  |   |  | 2 872         |
| 3.g. Cats                             |  |  |   |   |  |   |  |   |  | 0             |
| 3.h. Dogs                             | 152  |  |   |   |  |   |  |   |  | 152           |
| 3.i. Ferrets                          |  |  |   |   |  |   |  |   |  | 0             |
| 3.j. Other Carnivores                 |  |  |   |   |  |   |  |   |  | 0             |
| 3.k. Horses, donkeys and cross breeds |  |  |   |   |  |   |  |   |  | 0             |
| 3.l. Pigs                             | 43   |  |   |   |  |   |  |   |  | 43            |
| 3.m. Goats                            |  |  |   |   |  |   |  |   |  | 0             |
| 3.n. Sheep                            |  |  |   |   |  |   |  |   |  | 0             |
| 3.o. Cattle                           |  |  |   |   |  |   |  |   |  | 0             |
| 3.p. Primates                         |  |  |   |   |  |   |  |   |  | 0             |
| 3.q. New World Monkeys                |  |  |   |   |  |   |  |   |  | 0             |
| 3.r. Old World Monkeys                |  |  |   |   |  |   |  |   |  | 0             |
| 3.s. Apes                             |  |  |   |   |  |   |  |   |  | 0             |
| 3.t. Other Mammals                    |  |  |   |   |  |   |  |   |  | 0             |
| 3.u. Quail                            |  |  |   |   |  |   |  |   |  | 0             |
| 3.v. Other birds                      |  |  |   |   |  |   |  |   |  | 0             |
| 3.w. Reptiles                         |  |  |   |   |  |   |  |   |  | 0             |
| 3.x. Amphibians                       |  |  |   |   |  |   |  |   |  | 0             |
| 3.y. Fish                             |  |  |   |   |  |   |  |   |  | 0             |
| 3.z. TOTAL                            | 12 192   | 6 230  | 17 216  | 28  | 0  | 344   | 0  | 4 492   | 208  | 40 731        |

**TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES**

**Main categories versus species**

| 4.1<br>Species                        | 4.2<br>Human cardiovascular<br>diseases | 4.3<br>Human nervous and<br>mental disorders | 4.4<br>Human cancer (excluding<br>evaluations of carcinogenic<br>hazards or risks) | 4.5<br>Other human diseases | 4.6<br>Studies specific to animal<br>diseases | 4.7<br>Total |
|---------------------------------------|---|--|--|-----------------------------|---|--------------|
| 4.a. Mice                             | 18 898                                  | 17 365                                       | 52 091   | 71 800                      | 11 253  | 171 407      |
| 4.b. Rats                             | 3 625                                   | 11 731                                       | 1 350  | 9 474                       | 139   | 26 319       |
| 4.c. Guinea-Pigs                      | 0                                       | 55   | 0  | 391                         | 430   | 876          |
| 4.d. Hamsters                         | 0                                       | 0  | 0  | 168                         | 245   | 413          |
| 4.e. Other Rodents                    | 0                                       | 0  | 0  | 288                         | 0   | 288          |
| 4.f. Rabbits                          | 230                                     | 0  | 164  | 411                         | 54  | 859          |
| 4.g. Cats                             | 0                                       | 0  | 0  | 0                           | 42  | 42           |
| 4.h. Dogs                             | 68                                      | 0  | 0  | 43                          | 154   | 265          |
| 4.i. Ferrets                          | 0                                       | 0  | 0  | 779                         | 0   | 779          |
| 4.j. Other Carnivores                 | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.k. Horses, donkeys and cross breeds | 0                                       | 0  | 0  | 10                          | 184   | 194          |
| 4.l. Pigs                             | 421                                     | 0  | 32   | 188                         | 3 737   | 4 378        |
| 4.m. Goats                            | 33                                      | 0  | 0  | 147                         | 34  | 214          |
| 4.n. Sheep                            | 10                                      | 0  | 0  | 271                         | 266   | 547          |
| 4.o. Cattle                           | 0                                       | 0  | 0  | 19                          | 969   | 988          |
| 4.p. Primates                         | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.q. New World Monkeys                | 0                                       | 1  | 0  | 17                          | 0   | 18           |
| 4.r. Old World Monkeys                | 0                                       | 0  | 0  | 169                         | 0   | 169          |
| 4.s. Apes                             | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.t. Other Mammals                    | 0                                       | 0  | 0  | 10                          | 0   | 10           |
| 4.u. Quail                            | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.v. Other birds                      | 0                                       | 0  | 100  | 373                         | 26 516  | 26 989       |
| 4.w. Reptiles                         | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.x. Amphibians                       | 0                                       | 0  | 0  | 0                           | 0   | 0            |
| 4.y. Fish                             | 0                                       | 4 162  | 119  | 936                         | 184   | 5 401        |
| 4.z. TOTAL                            | 23 285                                  | 33 314                                       | 53 856   | 85 494                      | 44 207  | 240 156      |

**TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE**

**Regulatory requirements versus species**

| 5.1<br>Species                        | 5.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 5.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 5.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 5.5<br>Other legislation | 5.6<br>Any combination of<br>5.2/ 5.3/ 5.4/ 5.5 | 5.7<br>No regulatory<br>requirements | 5.8<br>Total |
|---------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 5.a. Mice                             |  | 1 320  |   | 1 864                    | 11 596  | 4 522                                | 19 302       |
| 5.b. Rats                             |  | 4 354  |   | 684                      | 29 053  | 648                                  | 34 739       |
| 5.c. Guinea-Pigs                      |  | 190  |   | 250                      | 2 034   | 1 820                                | 4 294        |
| 5.d. Hamsters                         |  |  |   |                          | 2 916   |                                      | 2 916        |
| 5.e. Other Rodents                    |  |  |   |                          |   |                                      | 0            |
| 5.f. Rabbits                          |  | 1  |   | 70                       | 1 892   | 376                                  | 2 339        |
| 5.g. Cats                             |  |  |   |                          | 38  |                                      | 38           |
| 5.h. Dogs                             |  |  |   |                          | 168   | 15                                   | 183          |
| 5.i. Ferrets                          |  |  |   |                          |   | 58                                   | 58           |
| 5.j. Other Carnivores                 |  |  |   |                          |   | 309                                  | 309          |
| 5.k. Horses, donkeys and cross breeds |  |  |   |                          | 82  | 2 049                                | 2 131        |
| 5.l. Pigs                             |  |  |   |                          | 1 290   | 387                                  | 1 677        |
| 5.m. Goats                            |  |  |   |                          |   | 1                                    | 1            |
| 5.n. Sheep                            |  |  |   |                          |   | 1 924                                | 1 926        |
| 5.o. Cattle                           | 25   |  |   | 4                        | 104   | 411                                  | 544          |
| 5.p. Prosimians                       |  |  |   |                          |   |                                      | 0            |
| 5.q. New World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.r. Old World Monkeys                |  |  |   |                          |   |                                      | 0            |
| 5.s. Apes                             |  |  |   |                          |   |                                      | 0            |
| 5.t. Other Mammals                    |  |  |   |                          |   |                                      | 0            |
| 5.u. Quail                            |  |  |   |                          |   |                                      | 0            |
| 5.v. Other birds                      |  |  |   |                          | 18 381  | 2 821                                | 21 202       |
| 5.w. Reptiles                         |  |  |   |                          |   |                                      | 0            |
| 5.x. Amphibians                       |  |  |   |                          |   |                                      | 0            |
| 5.y. Fish                             |  |  |   |                          |   |                                      | 0            |
| 5.z. TOTAL                            | 25   | 5 865  | 0   | 2 872                    | 67 556  | 15 341                               | 91 659       |

**Examples:** 5.2 – France is testing due to a UK (or FR) specific requirement **Note:** columns 5.2 - 5.5 refer to the legislation imposing that the test be carried out and

5.3 - UK is testing according to EC legislation **Example:** not to the body which has issued the actual test method, guideline or protocol.

5.4 – Spain is testing due to a Norwegian requirement **Example:** a test required by French legislation and carried out in Belgium according to an

5.5 – Poland is testing due to a US specific requirement **Example:** ISO protocol must be coded as a national (FR) legislative requirement and be

5.6 – Germany is testing due to a Czech requirement (also an EC requirement) entered into column 5.2 in the tables submitted by Belgium.

**Footnotes:**

1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Regulatory requirements versus species**

| 6.1<br>Species                      | 6.2<br>National legislation<br>specific to a single EC<br>Member State<br>1) | 6.3<br>EC legislation<br>including European<br>Pharmacopoeia<br>(requirements) | 6.4<br>Member Country of Council<br>of Europe (but not EC)<br>legislation<br>2) | 6.5<br>Other legislation | 6.6<br>Any combination of<br>6.2/ 6.3/ 6.4/ 6.5 | 6.7<br>No regulatory<br>requirements | 6.8<br>Total |
|-------------------------------------|--|--|---|--------------------------|---|--------------------------------------|--------------|
| 6.a. Mice                           |  |  |   | 5                        | 3 598   | 1 626                                | 5 229        |
| 6.b. Rats                           |  |  |   | 80                       | 27 346  | 193                                  | 27 619       |
| 6.c. Guinea-Pigs                    |  |  |   |                          | 114   | 2                                    | 116          |
| 6.d. Hamsters                       |  |  |   |                          |   |                                      | 0            |
| 6.e. Other Rodents                  |  |  |   |                          |   |                                      | 0            |
| 6.f. Rabbits                        |  |  |   |                          | 2 863   | 9                                    | 2 872        |
| 6.g. Cats                           |  |  |   |                          |   |                                      | 0            |
| 6.h. Dogs                           |  |  |   |                          | 152   |                                      | 152          |
| 6.i. Ferrets                        |  |  |   |                          |   |                                      | 0            |
| 6.j. Other Carnivores               |  |  |   |                          |   |                                      | 0            |
| 6.k. Horses, donkeys and cross bred |  |  |   |                          |   |                                      | 0            |
| 6.l. Pigs                           |  |  |   |                          | 33  | 10                                   | 43           |
| 6.m. Goats                          |  |  |   |                          |   |                                      | 0            |
| 6.n. Sheep                          |  |  |   |                          |   |                                      | 0            |
| 6.o. Cattle                         |  |  |   |                          |   |                                      | 0            |
| 6.p. Primates                       |  |  |   |                          |   |                                      | 0            |
| 6.q. New World Monkeys              |  |  |   |                          |   |                                      | 0            |
| 6.r. Old World Monkeys              |  |  |   |                          |   |                                      | 0            |
| 6.s. Apes                           |  |  |   |                          |   |                                      | 0            |
| 6.t. Other Mammals                  |  |  |   |                          |   |                                      | 0            |
| 6.u. Quail                          |  |  |   |                          |   |                                      | 0            |
| 6.v. Other birds                    |  |  |   |                          |   |                                      | 0            |
| 6.w. Reptiles                       |  |  |   |                          |   |                                      | 0            |
| 6.x. Amphibians                     |  |  |   |                          | 1 120   |                                      | 1 120        |
| 6.y. Fish                           |  |  |   |                          | 3 072   | 508                                  | 3 580        |
| 6.z. TOTAL                          | 0  | 0  | 0   | 85                       | 38 298  | 2 348                                | 40 731       |

**Examples:** 6.2 – France is testing due to a UK (or FR) specific requirement

6.3 - UK is testing according to EC legislation

6.4 – Spain is testing due to a Norwegian requirement

6.5 – Poland is testing due to a US specific requirement

6.6 – Germany is testing due to a Czech requirement (also an EC requirement)

**Note:** columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.  
**Example:** a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

**Footnotes:**

- 1) EC Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Rep, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom
- 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Armenia, Azerbaijan, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Norway, Russia, San Marino, Serbia and Montenegro, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

**TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus species**

| 7.1<br>Species                           | 7.2<br>Acute and sub-acute toxicity testing methods<br>(including limit test) |                                  |  | 7.3<br>Skin<br>irritation | 7.4<br>Skin<br>sensitisation | 7.5<br>Eye<br>irritation | 7.6<br>Sub-<br>chronic and<br>chronic<br>toxicity | 7.7<br>Carcino-<br>genicity | 7.8<br>Develop-<br>mental<br>toxicity | 7.9<br>Muta-<br>genic<br>ity | 7.10<br>Repro-<br>ductive<br>toxicity | 7.11<br>Toxicity<br>to aquatic<br>vertebra-<br>tes not<br>included<br>in other<br>columns | 7.12<br>Other | 7.13<br>Total |
|--|---|----------------------------------|--|---------------------------|------------------------------|--------------------------|---|-----------------------------|---------------------------------------|------------------------------|---------------------------------------|---|---------------|---------------|
|  | 7.2.1.<br>LD50,<br>LC50   | 7.2.2<br>Other lethal<br>methods | 7.2.3<br>Non lethal<br>clinical signs<br>methods |                           |                              |                          |   |                             |                                       |                              |                                       |   |               |               |
| 7.a. Mice                                |   | 1 525                            | 210  |                           | 2 577                        |                          |   |                             |                                       | 877                          |                                       |   | 40            | 5 229         |
| 7.b. Rats                                |   | 617                              | 5 173  | 179                       |                              |                          | 968   | 610                         | 10 211                                | 83                           | 9 479                                 |   | 299           | 27 619        |
| 7.c. Guinea-Pigs                         |   |                                  | 63   |                           | 49                           |                          |   |                             |                                       |                              |                                       |   | 4             | 116           |
| 7.d. Hamsters                            |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.e. Other Rodents                       |   |                                  | 109  | 162                       |                              | 136                      | 170   |                             |                                       |                              | 1 177                                 |   | 1 118         | 2 872         |
| 7.g. Cats                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.h. Dogs                                |   |                                  | 99   |                           |                              |                          | 40  |                             |                                       |                              |                                       |   | 13            | 152           |
| 7.i. Ferrets                             |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.j. Other Carnivores                    |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.k. Horses, donkeys and cross<br>breeds |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.l. Pigs                                |   |                                  | 29   |                           |                              |                          |   |                             |                                       |                              |                                       |   | 14            | 43            |
| 7.m. Goats                               |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.n. Sheep                               |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.o. Cattle                              |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.p. Primates                            |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.q. New World Monkeys                   |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.r. Old World Monkeys                   |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.s. Apes                                |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.t. Other Mammals                       |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.u. Quail                               |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.v. Other birds                         |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.w. Reptiles                            |   |                                  |  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 0             |
| 7.x. Amphibians                          |   |                                  | 1 120  |                           |                              |                          |   |                             |                                       |                              |                                       |   |               | 1 120         |
| 7.y. Fish                                | 570   | 288                              | 605  |                           |                              |                          | 2 117   |                             |                                       |                              |                                       |   |               | 3 580         |
| 7.z. TOTAL                               | 570   | 2 430                            | 7 408  | 341                       | 2 626                        | 136                      | 3 295   | 610                         | 10 211                                | 960                          | 10 656                                | 0   | 1 488         | 40 731        |



**TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS**

**Types of tests versus products**

| 8.1<br>Products   | 8.2<br>Acute and sub-acute toxicity testing methods (including limit test) |                               |  | 8.3<br>Skin irritation | 8.4<br>Skin sensitisation | 8.5<br>Eye irritation | 8.6<br>Sub-chronic and chronic toxicity | 8.7<br>Carcinogenicity | 8.8<br>Developmental toxicity | 8.9<br>Mutagenicity | 8.10<br>Reproductive toxicity | 8.11<br>Toxicity to aquatic vertebrates not included in other columns | 8.12<br>Other | 8.13<br>Total |
|---|--|-------------------------------|--|------------------------|---------------------------|-----------------------|---|------------------------|-------------------------------|---------------------|-------------------------------|---|---------------|---------------|
|   | 8.2.1.<br>LD50, LC50   | 8.2.2<br>Other lethal methods | 8.2.3<br>Non lethal clinical signs methods |                        |                           |                       |   |                        |                               |                     |                               |   |               |               |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine        |  | 1 657                         | 2 789                                      | 100                    | 1 255                     | 48                    | 610                                     |                        | 783                           | 103                 | 3 447                         |   | 1 400         | 12 192        |
| 8.b. Products/substances used or intended to be used mainly in agriculture                              |  | 16                            | 455  |                        |                           |                       | 200                                     | 610                    |                               |                     | 4 913                         |   | 36            | 6 230         |
| 8.c. Products/substances used or intended to be used mainly in industry                                 |  | 465                           | 2 383                                      | 241                    | 1 347                     | 88                    | 200                                     |                        | 9 428                         | 716                 | 2 296                         |   | 52            | 17 216        |
| 8.d. Products/substances used or intended to be used mainly in the household                            |  | 4                             | 24   |                        |                           |                       |   |                        |                               |                     |                               |   |               | 28            |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries                  |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption  |  |                               | 32   |                        | 24                        |                       | 168                                     |                        |                               | 120                 |                               |   |               | 344           |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption |  |                               |  |                        |                           |                       |   |                        |                               |                     |                               |   |               | 0             |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns   | 570  | 288                           | 1 725                                      |                        |                           |                       | 1 909                                   |                        |                               |                     |                               |   |               | 4 492         |
| 8.i. Other toxicological or safety evaluations  |  |                               |  |                        |                           |                       | 208                                     |                        |                               | 21                  |                               |   |               | 229           |
| 8.j. TOTAL  | 570  | 2 430                         | 7 408                                      | 341                    | 2 626                     | 136                   | 3 295                                   | 610                    | 10 211                        | 960                 | 10 656                        | 0   | 1 488         | 40 731        |