

## 1. Animals used by species

Table 1: In total animals used by species<sup>1</sup>

| Animal Species                 | Number of Animals | %           |
|--------------------------------|-------------------|-------------|
| Mice                           | 1.877.552         | 56.65%      |
| Rats                           | 357.124           | 10.78%      |
| Guinea-Pigs                    | 20.037            | 0.60%       |
| Hamsters (Syrian)              | 1.628             | 0.05%       |
| Hamsters (Chinese)             | 24                | 0.00%       |
| Mongolian gerbil               | 3.960             | 0.12%       |
| Other Rodents                  | 22.781            | 0.69%       |
| Rabbits                        | 102.523           | 3.09%       |
| Cats                           | 581               | 0.02%       |
| Dogs                           | 2.202             | 0.07%       |
| Ferrets                        | 141               | 0.00%       |
| Other carnivores               | 414               | 0.01%       |
| Horses, donkeys & cross-breeds | 635               | 0.02%       |
| Pigs                           | 13.768            | 0.42%       |
| Goats                          | 724               | 0.02%       |
| Sheep                          | 1.373             | 0.04%       |
| Cattle                         | 3.817             | 0.12%       |
| Prosimians                     | 85                | 0.00%       |
| Marmoset and tamarins          | 234               | 0.01%       |
| Cynomolgus monkey              | 1.475             | 0.04%       |
| Rhesus monkey                  | 111               | 0.00%       |
| Baboons                        | 2                 | 0.00%       |
| Other Mammals                  | 1.607             | 0.05%       |
| Domestic fowl                  | 34.806            | 1.05%       |
| Other birds                    | 20.503            | 0.62%       |
| Reptiles                       | 707               | 0.02%       |
| Rana                           | 31                | 0.00%       |
| Xenopus                        | 7.929             | 0.24%       |
| Other Amphibians               | 5.363             | 0.16%       |
| Zebra fish                     | 123.336           | 3.72%       |
| Other Fish                     | 708.462           | 21.38%      |
| Cephalopods                    | 63                | 0.00%       |
| <b>Total</b>                   | <b>3.314.098</b>  | <b>100%</b> |

<sup>1</sup> Excludes re-use

Figure 1: Animals used by species groups

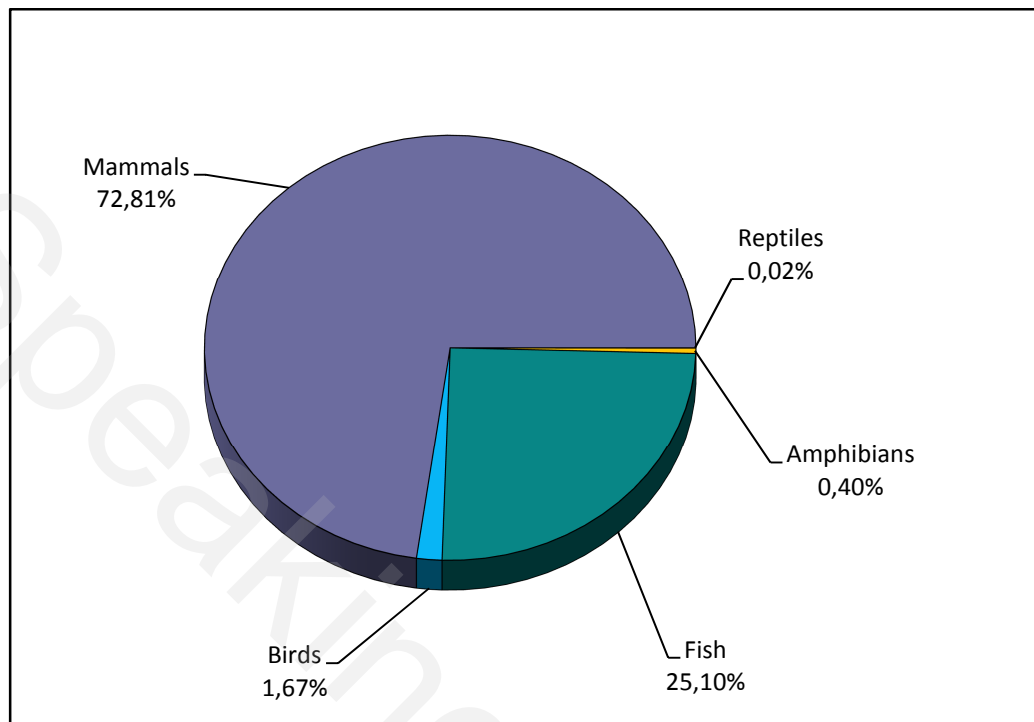


Table 2: Animals used by species groups

| Species grouping Level 1 | Number of Animals |
|--------------------------|-------------------|
| Warm-blooded vertebrates | 2.468.207         |
| Cold-blooded vertebrates | 845.828           |
| Invertebrates            | 63                |
| <b>Total</b>             | <b>3.314.098</b>  |

| Species grouping Level 2 | Number of Animals |
|--------------------------|-------------------|
| Mammals                  | 2.412.898         |
| Birds                    | 55.309            |
| Fish                     | 831.798           |
| Amphibians               | 13.323            |
| Reptiles                 | 707               |
| Cephalopods              | 63                |
| <b>Total</b>             | <b>3.314.098</b>  |

| Mammals            | Number of Animals |
|--------------------|-------------------|
| Rodents            | 2.283.206         |
| Rabbits            | 102.523           |
| Carnivores         | 3.338             |
| Equidae            | 635               |
| Artiodactyla       | 19.682            |
| Non-human primates | 1.907             |
| Other mammals      | 1.607             |
| <b>Total</b>       | <b>2.412.898</b>  |

| Non-human primates | Number of Animals |
|--------------------|-------------------|
| Prosimians         | 85                |
| New World Monkeys  | 234               |
| Old World Monkeys  | 1.588             |
| <b>Total</b>       | <b>1.907</b>      |

## 2. Origin of used Animals<sup>2</sup>

Table 3: Origin of used animals in total

|                                | Animals born in                |                                        |                |                   | Total     |
|--------------------------------|--------------------------------|----------------------------------------|----------------|-------------------|-----------|
|                                | the EU at a registered breeder | the EU but not at a registered breeder | rest of Europe | rest of the world |           |
| Mice                           | 1.817.726                      | 53.797                                 | 313            | 5.716             | 1.877.552 |
| Rats                           | 349.368                        | 6.095                                  | 1              | 1.660             | 357.124   |
| Guinea-Pigs                    | 19.949                         | 88                                     |                |                   | 20.037    |
| Hamsters (Syrian)              | 1.628                          |                                        |                |                   | 1.628     |
| Hamsters (Chinese)             | 24                             |                                        |                |                   | 24        |
| Mongolian gerbil               | 3.921                          | 39                                     |                |                   | 3.960     |
| Other Rodents                  | 1.448                          | 21.433                                 |                |                   | 22.881    |
| Rabbits                        | 101.859                        | 402                                    |                | 262               | 102.523   |
| Cats                           | 147                            | 220                                    |                | 214               | 581       |
| Dogs                           | 324                            | 678                                    |                | 1.200             | 2.202     |
| Ferrets                        | 129                            | 12                                     |                |                   | 141       |
| Other carnivores               | 368                            | 43                                     | 3              |                   | 414       |
| Horses, donkeys & cross-breeds | 181                            | 454                                    |                |                   | 635       |
| Pigs                           | 10.129                         | 3.639                                  |                |                   | 13.768    |
| Goats                          | 78                             | 646                                    |                |                   | 724       |
| Sheep                          | 706                            | 667                                    |                |                   | 1.373     |
| Cattle                         | 2.791                          | 1.026                                  |                |                   | 3.817     |
| Prosimians                     | 85                             |                                        |                |                   | 85        |
| Marmoset and tamarins          | 230                            |                                        |                | 4                 | 234       |

<sup>2</sup> Excludes re-use

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|                   |                  |                |               |               |                  |
|-------------------|------------------|----------------|---------------|---------------|------------------|
| Cynomolgus monkey | 14               |                |               | 1.461         | 1.475            |
| Rhesus monkey     | 22               |                |               | 89            | 111              |
| Baboons           | 2                |                |               |               | 2                |
| Other Mammals     | 170              | 1.391          | 34            | 12            | 1.607            |
| Domestic fowl     | 27.033           | 7.769          | 4             |               | 34.806           |
| Other birds       | 13.617           | 6.735          | 42            | 109           | 20.503           |
| Reptiles          | 25               | 368            |               | 231           | 624              |
| Rana              | 13               | 18             |               |               | 31               |
| Xenopus           | 5.668            | 107            | 13            | 2.141         | 7.929            |
| Other Amphibians  | 1.513            | 3.510          |               | 340           | 5.363            |
| Zebra fish        | 112.290          | 10.816         | 15            | 215           | 123.336          |
| Other Fish        | 643.661          | 30.743         | 29674         | 4.384         | 708.462          |
| Cephalopods       |                  | 63             |               |               | 63               |
| <b>Total</b>      | <b>3.115.119</b> | <b>150.742</b> | <b>30.099</b> | <b>18.038</b> | <b>3.314.098</b> |

Table 4 – 6: Origin of used animals by species groups

|                          | Animals born in the EU at a registered breeder | Animals born in the EU but not at a registered breeder | Animals born in rest of Europe | Animals born in rest of the world | Total            |
|--------------------------|------------------------------------------------|--------------------------------------------------------|--------------------------------|-----------------------------------|------------------|
| Warm-blooded vertebrates | 2.351.949                                      | 105.134                                                | 397                            | 10.727                            | 2.468.207        |
| Cold-blooded vertebrates | 763.170                                        | 45.645                                                 | 29.702                         | 7.311                             | 845.828          |
| Invertebrates            |                                                | 63                                                     |                                |                                   | 63               |
| <b>Total</b>             | <b>3.115.119</b>                               | <b>150.842</b>                                         | <b>30.099</b>                  | <b>18.038</b>                     | <b>3.314.098</b> |

|              | Animals born in the EU at a registered breeder | Animals born in the EU but not at a registered breeder | Animals born in rest of Europe | Animals born in rest of the world | Total            |
|--------------|------------------------------------------------|--------------------------------------------------------|--------------------------------|-----------------------------------|------------------|
| Mammals      | 2.311.299                                      | 90.630                                                 | 351                            | 10.618                            | 2.412.898        |
| Birds        | 40.650                                         | 14.504                                                 | 46                             | 109                               | 55.309           |
| Fish         | 755.951                                        | 41.559                                                 | 29.689                         | 4.599                             | 831.798          |
| Amphibians   | 7.194                                          | 3.718                                                  | 13                             | 2.481                             | 13.406           |
| Reptiles     | 25                                             | 368                                                    |                                | 231                               | 624              |
| Cephalopods  |                                                | 63                                                     |                                |                                   | 63               |
| <b>Total</b> | <b>3.115.119</b>                               | <b>150.842</b>                                         | <b>30.099</b>                  | <b>18.038</b>                     | <b>3.314.098</b> |

|                    | Animals born in the EU at a registered breeder | Animals born in the EU but not at a registered breeder | Animals born in rest of Europe | Animals born in rest of the world | Total            |
|--------------------|------------------------------------------------|--------------------------------------------------------|--------------------------------|-----------------------------------|------------------|
| Rodents            | 2.194.064                                      | 81.452                                                 | 314                            | 7.376                             | 2.283.206        |
| Rabbits            | 101.529                                        | 402                                                    |                                | 262                               | 102.523          |
| Carnivores         | 968                                            | 953                                                    | 3                              | 1.414                             | 3.338            |
| Equidae            | 181                                            | 454                                                    |                                |                                   | 635              |
| Artiodactyla       | 13.704                                         | 5.978                                                  |                                |                                   | 19.682           |
| Non-human primates | 353                                            |                                                        |                                | 1.554                             | 1.907            |
| Other mammals      | 170                                            | 1.391                                                  | 34                             | 12                                | 1.607            |
| <b>Total</b>       | <b>2.311.299</b>                               | <b>90.630</b>                                          | <b>351</b>                     | <b>10.618</b>                     | <b>2.412.898</b> |

### 3. Non-Human Primates by source and generation<sup>3</sup>

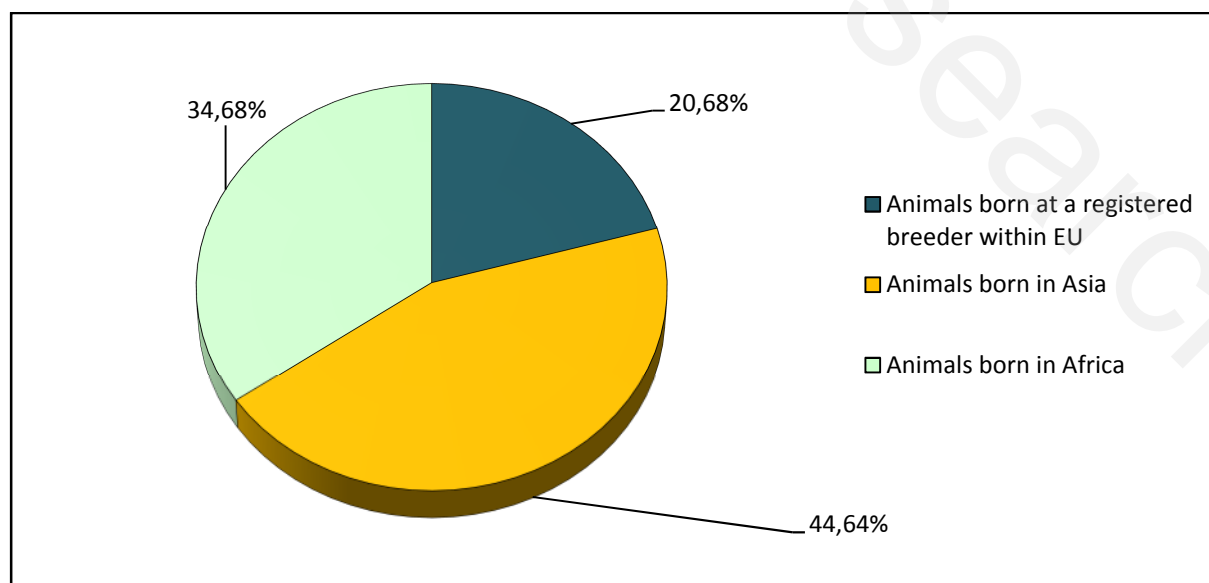
Table 7: Generation of non-human primates

| NHP Generation         | Number of Animals |
|------------------------|-------------------|
| F0                     | 6                 |
| F1                     | 563               |
| F2 or greater          | 904               |
| Self-sustaining colony | 434               |
| <b>Total</b>           | <b>1.907</b>      |

Table 8: Origin of non-human primates

| NHP Source (origin)                            | Number of Animals |
|------------------------------------------------|-------------------|
| Animals born at a registered breeder within EU | 353               |
| Animals born in rest of Europe                 | 0                 |
| Animals born in Asia                           | 762               |
| Animals born in America                        | 0                 |
| Animals born in Africa                         | 592               |
| Animals born elsewhere                         | 0                 |
| <b>Total</b>                                   | <b>1.907</b>      |

Figure 2: Origin of non-human primates (%)



<sup>3</sup> Excludes re-use

Speaking of Research

#### 4. Use of species in procedures by purposes

Table 9: Use of species in procedures by purposes

|                                | Basic Research | Translational and applied research | Regulatory use and Routine production | Protection of the natural environment in the interests of the health or welfare of human beings or animals | Preservation of species | Higher education or training for the acquisition, maintenance or improvement of vocational skills | Forensic enquiries | Maintenance of colonies of established genetically altered animals, not used in other procedures | Total     |
|--------------------------------|----------------|------------------------------------|---------------------------------------|------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------|-----------|
| Mice                           | 1.233.400      | 271.931                            | 329.145                               |                                                                                                            | 7.318                   | 32.857                                                                                            |                    | 80.603                                                                                           | 1.901.985 |
| Rats                           | 107.522        | 53.406                             | 134.411                               |                                                                                                            | 247                     | 13.433                                                                                            | 30                 | 1.117                                                                                            | 362.530   |
| Guinea-Pigs                    | 773            | 2.747                              | 16.433                                |                                                                                                            |                         | 366                                                                                               | 1                  |                                                                                                  | 20.576    |
| Hamsters (Syrian)              | 67             | 605                                | 777                                   |                                                                                                            |                         | 83                                                                                                |                    |                                                                                                  | 1.632     |
| Hamsters (Chinese)             | 12             |                                    | 10                                    |                                                                                                            |                         | 2                                                                                                 |                    |                                                                                                  | 24        |
| Mongolian gerbil               | 1.498          | 1.320                              | 1.773                                 |                                                                                                            |                         | 229                                                                                               |                    |                                                                                                  | 4.820     |
| Other Rodents                  | 3.731          | 1.689                              | 17.089                                | 186                                                                                                        |                         | 256                                                                                               |                    |                                                                                                  | 23.051    |
| Rabbits                        | 1.349          | 1.174                              | 102.703                               |                                                                                                            |                         | 337                                                                                               |                    |                                                                                                  | 105.784   |
| Cats                           | 152            | 267                                | 519                                   |                                                                                                            | 2                       | 57                                                                                                |                    |                                                                                                  | 997       |
| Dogs                           | 317            | 1.022                              | 3.178                                 |                                                                                                            | 7                       | 112                                                                                               |                    |                                                                                                  | 4.636     |
| Ferrets                        | 20             | 131                                | 0                                     |                                                                                                            |                         | 8                                                                                                 |                    |                                                                                                  | 159       |
| Other carnivores               | 9              |                                    | 368                                   | 37                                                                                                         |                         |                                                                                                   |                    |                                                                                                  | 414       |
| Horses, donkeys & cross-breeds | 569            | 74                                 | 84                                    |                                                                                                            |                         | 54                                                                                                |                    |                                                                                                  | 781       |
| Pigs                           | 3.213          | 4.177                              | 4.488                                 | 265                                                                                                        |                         | 2.231                                                                                             |                    |                                                                                                  | 14.374    |
| Goats                          | 73             | 572                                | 27                                    |                                                                                                            |                         | 77                                                                                                |                    |                                                                                                  | 749       |
| Sheep                          | 308            | 767                                | 648                                   |                                                                                                            |                         | 214                                                                                               |                    |                                                                                                  | 1.937     |

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|                                    |                  |                |                |              |               |               |           |               |                  |
|------------------------------------|------------------|----------------|----------------|--------------|---------------|---------------|-----------|---------------|------------------|
| Cattle                             | 2.360            | 1.057          | 631            | 144          |               | 214           |           |               | 4.408            |
| Prosimians                         | 148              |                |                |              |               |               |           |               | 148              |
| Marmoset and tamarins              | 189              |                | 134            |              |               | 2             |           |               | 325              |
| Cynomolgus monkey                  | 27               | 90             | 1.678          |              |               | 10            |           |               | 2.231            |
| Rhesus monkey                      | 39               | 5              | 82             |              |               | 2             |           |               | 128              |
| Vervets Chlorocebus spp.           |                  | 5              |                |              |               |               |           |               | 5                |
| Baboons                            | 2                |                |                |              |               |               |           |               | 2                |
| Other species of Old World Monkeys |                  | 3              |                |              |               |               |           |               | 3                |
| Other Mammals                      | 1.324            | 129            | 64             | 82           | 87            | 2             |           |               | 1.688            |
| Domestic fowl                      | 14.834           | 5.757          | 13.661         |              |               | 750           |           |               | 35.002           |
| Other birds                        | 10.977           | 4.331          | 5.129          | 2            |               | 256           |           |               | 20.695           |
| Reptiles                           | 460              | 24             | 280            |              | 159           | 14            |           |               | 1.020            |
| Rana                               | 9                | 6              | 5              |              |               | 11            |           |               | 31               |
| Xenopus                            | 9.398            | 48             | 89             |              |               | 525           |           |               | 9.977            |
| Other Amphibians                   | 4.972            | 245            | 104            |              |               | 42            |           |               | 5.363            |
| Zebra fish                         | 103.996          | 515            | 19.859         | 184          |               | 1.444         |           | 800           | 126.798          |
| Other Fish                         | 610.441          | 74.869         | 11.959         | 6.078        | 3.778         | 2.602         |           |               | 709.727          |
| Cephalopods                        |                  |                |                |              | 18            | 45            |           |               | 63               |
| <b>Total</b>                       | <b>2.112.189</b> | <b>426.966</b> | <b>665.328</b> | <b>6.978</b> | <b>11.616</b> | <b>56.235</b> | <b>31</b> | <b>82.520</b> | <b>3.362.063</b> |

Figure 3: Use of animals in procedures by purposes

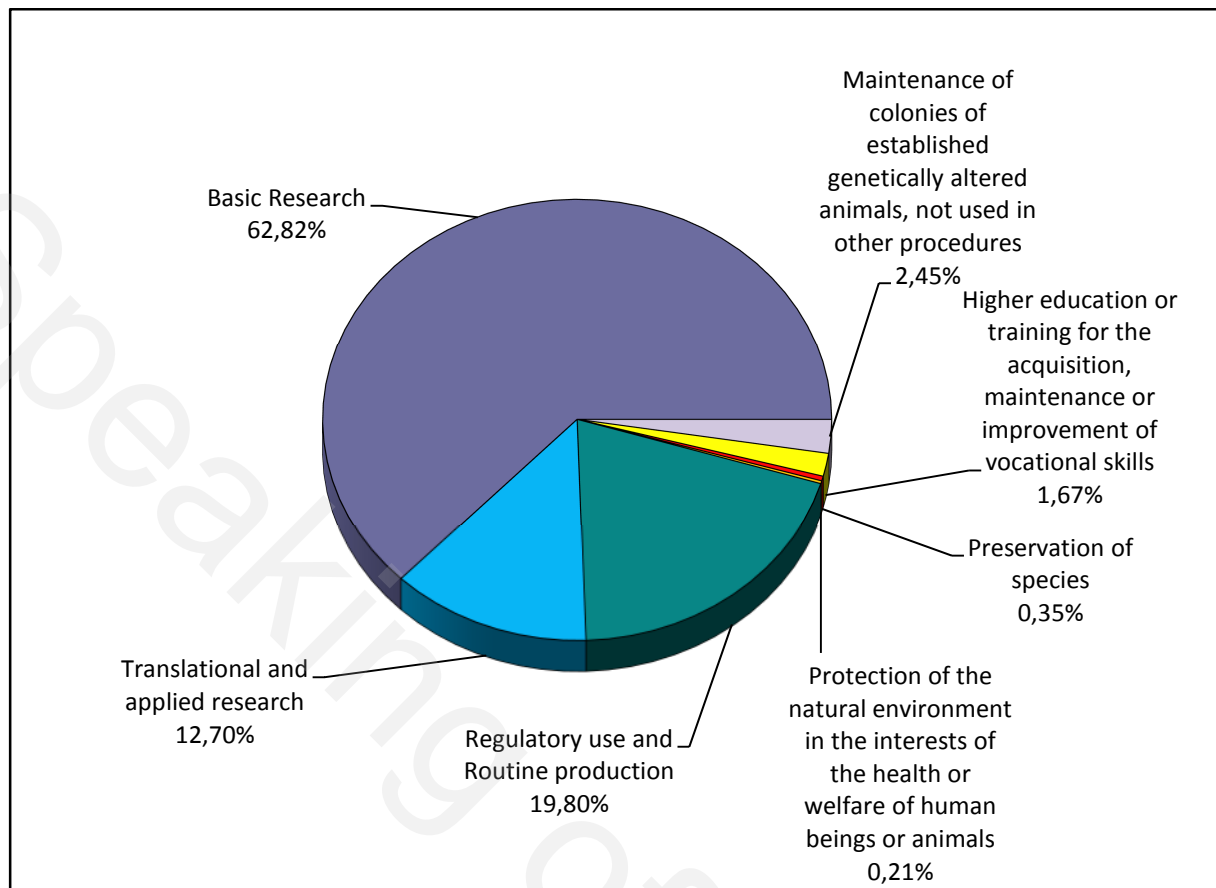


Table 10: Use of species in basic research purposes

|                                | Oncology | Cardio-vascular Blood and Lymphatic System | Nervous System | Respiratory System | Gastrointestinal System including Liver | Musculoskeletal System | Immune System | Urogenital/ Reproductive System | Sensory Organs (skin, eyes and ears) | Endocrine System/ Metabolism | Multisystemic | Ethology / Animal Behaviour / Animal Biology | Other basic research | Total     |
|--------------------------------|----------|--------------------------------------------|----------------|--------------------|-----------------------------------------|------------------------|---------------|---------------------------------|--------------------------------------|------------------------------|---------------|----------------------------------------------|----------------------|-----------|
| Mice                           | 95.578   | 121.555                                    | 250.934        | 62.047             | 45.043                                  | 15.477                 | 332.266       | 20.358                          | 32.602                               | 51.571                       | 71.377        | 4.495                                        | 130.097              | 1.233.400 |
| Rats                           | 2.192    | 27.968                                     | 48.697         | 2.512              | 4.088                                   | 1.240                  | 5.524         | 1.554                           | 1.592                                | 2.238                        | 2.450         | 421                                          | 7.046                | 107.522   |
| Guinea-Pigs                    | 50       | 52                                         | 24             | 85                 | 116                                     |                        | 40            | 6                               | 272                                  |                              | 20            | 73                                           | 35                   | 773       |
| Hamsters (Syrian)              |          |                                            | 67             |                    |                                         |                        |               |                                 |                                      |                              |               |                                              |                      | 67        |
| Hamsters (Chinese)             |          |                                            |                |                    |                                         |                        |               |                                 |                                      | 12                           |               |                                              |                      | 12        |
| Mongolian gerbil               |          |                                            | 1.293          |                    | 125                                     |                        |               |                                 | 61                                   |                              |               |                                              | 19                   | 1.498     |
| Other Rodents                  | 92       |                                            | 311            |                    |                                         |                        | 262           |                                 | 60                                   | 403                          | 30            | 2.006                                        | 567                  | 3.731     |
| Rabbits                        | 39       | 388                                        | 10             | 11                 |                                         | 128                    | 77            | 36                              | 47                                   | 140                          | 46            |                                              | 427                  | 1.349     |
| Cats                           |          |                                            | 17             |                    | 28                                      |                        |               |                                 | 96                                   |                              |               |                                              | 11                   | 152       |
| Dogs                           |          | 20                                         | 104            |                    | 22                                      | 120                    | 18            | 3                               |                                      | 6                            | 22            |                                              | 2                    | 317       |
| Ferrets                        |          |                                            | 20             |                    |                                         |                        |               |                                 |                                      |                              |               |                                              |                      | 20        |
| Other carnivores               |          |                                            |                |                    |                                         |                        |               |                                 |                                      |                              |               | 6                                            | 3                    | 9         |
| Horses, donkeys & cross-breeds |          |                                            |                | 51                 | 114                                     | 46                     | 2             | 50                              |                                      | 36                           |               | 4                                            | 266                  | 569       |
| Pigs                           | 10       | 483                                        | 48             | 186                | 337                                     | 50                     | 512           | 39                              |                                      | 390                          | 154           | 290                                          | 714                  | 3.213     |
| Goats                          |          |                                            |                |                    |                                         |                        | 1             |                                 |                                      |                              |               | 72                                           |                      | 73        |
| Sheep                          |          | 45                                         | 12             | 4                  | 32                                      | 110                    | 35            |                                 | 12                                   |                              | 5             | 28                                           | 25                   | 308       |

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|                       |                |                |                |               |               |               |                |               |               |               |               |               |                |                  |
|-----------------------|----------------|----------------|----------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|----------------|------------------|
| Cattle                |                | 1              | 22             |               | 18            |               | 42             | 1.086         |               | 307           |               | 235           | 649            | <b>2.360</b>     |
| Prosimians            |                |                | 12             |               |               |               |                |               | 75            |               |               | 61            |                | <b>148</b>       |
| Marmoset and tamarins |                |                | 47             | 34            |               |               | 28             | 23            | 2             | 55            |               |               |                | <b>189</b>       |
| Cynomolgus monkey     |                |                | 21             |               |               |               |                | 6             |               |               |               |               |                | <b>27</b>        |
| Rhesus monkey         |                |                | 28             |               |               |               | 10             |               |               | 1             |               |               |                | <b>39</b>        |
| Baboons               |                |                |                |               |               |               | 2              |               |               |               |               |               |                | <b>2</b>         |
| Other Mammals         |                |                | 36             |               |               |               | 187            |               | 7             |               |               | 953           | 141            | <b>1.324</b>     |
| Domestic fowl         |                |                | 4              |               | 1.730         |               | 9.927          | 8             | 290           | 412           | 174           | 1.055         | 1.234          | <b>14.834</b>    |
| Other birds           |                | 154            | 341            |               | 61            | 10            | 30             | 30            | 52            |               | 29            | 7.492         | 2.778          | <b>10.977</b>    |
| Reptiles              |                |                | 237            | 72            | 30            |               |                | 70            | 44            |               |               | 7             |                | <b>460</b>       |
| Rana                  |                | 2              |                |               |               |               |                |               |               |               |               | 7             |                | <b>9</b>         |
| Xenopus               |                | 62             | 3.314          | 66            | 12            |               | 4              | 277           |               | 916           | 335           | 556           | 3.856          | <b>9.398</b>     |
| Other Amphibians      |                | 65             | 560            | 2             |               | 477           |                | 3             |               |               |               | 2.031         | 1.834          | <b>4.972</b>     |
| Zebra fish            | 1.145          | 19.854         | 35.035         |               |               | 6.522         | 8.454          | 5.310         | 2.807         | 7.459         | 4.685         | 3.670         | 9.055          | <b>103.996</b>   |
| Other Fish            | 3.520          |                | 1.958          | 2             | 10            | 147           | 2.871          | 1.431         | 574           | 1.736         | 3.119         | 35.957        | 559.116        | <b>610.441</b>   |
| <b>Total</b>          | <b>102.626</b> | <b>170.649</b> | <b>343.152</b> | <b>65.072</b> | <b>51.766</b> | <b>24.327</b> | <b>360.292</b> | <b>30.290</b> | <b>38.593</b> | <b>65.682</b> | <b>82.446</b> | <b>59.419</b> | <b>717.875</b> | <b>2.112.189</b> |
| <b>%</b>              | <b>4.86%</b>   | <b>8.08%</b>   | <b>16.25%</b>  | <b>3.08%</b>  | <b>2.45%</b>  | <b>1.15%</b>  | <b>17.06%</b>  | <b>1.43%</b>  | <b>1.83%</b>  | <b>3.11%</b>  | <b>3.90%</b>  | <b>2.81%</b>  | <b>33.99%</b>  | <b>100%</b>      |

Table 11: Use of species in translational and applied research purposes

|                                | Human Cancer | Human Infectious Disorders | Human Cardiovascular Disorders | Human Nervous and Mental Disorders | Human Respiratory Disorders | Human Gastrointestinal Disorders including Liver | Human Musculoskeletal Disorders | Human Immune Disorders | Human Urogenital/Reproductive Disorders | Human Sensory Organ Disorders (skin, eyes and ears) | Human Endocrine/Metabolism Disorders | Other Human Disorders | Animal Welfare | Diagnosis of diseases | Plant diseases | Non-regulatory toxicology and ecotoxicology | Total   |
|--------------------------------|--------------|----------------------------|--------------------------------|------------------------------------|-----------------------------|--------------------------------------------------|---------------------------------|------------------------|-----------------------------------------|-----------------------------------------------------|--------------------------------------|-----------------------|----------------|-----------------------|----------------|---------------------------------------------|---------|
| Mice                           | 112.029      | 28.005                     | 14.326                         | 42.449                             | 14.495                      | 3.988                                            | 5.403                           | 18.352                 | 3.680                                   | 2.956                                               | 9.728                                | 3.463                 | 743            | 5.865                 |                | 3.393                                       | 271.931 |
| Rats                           | 1.266        | 242                        | 7.351                          | 17.761                             | 6.800                       | 1.209                                            | 2.566                           | 990                    | 850                                     | 466                                                 | 8.603                                | 1.906                 | 14             | 133                   | 20             | 2.227                                       | 53.406  |
| Guinea-Pigs                    | 26           | 262                        | 75                             | 6                                  | 1.559                       | 53                                               | 186                             | 60                     |                                         | 147                                                 | 20                                   | 84                    |                | 6                     |                | 160                                         | 2.747   |
| Hamsters (Syrian)              |              | 434                        |                                | 54                                 | 82                          | 3                                                |                                 |                        | 13                                      | 1                                                   |                                      |                       | 18             |                       |                |                                             | 605     |
| Mongolian gerbil               |              | 621                        |                                |                                    |                             |                                                  |                                 |                        |                                         | 46                                                  |                                      |                       |                |                       |                |                                             | 1.320   |
| Other Rodents                  |              | 1.633                      |                                |                                    |                             |                                                  |                                 |                        |                                         |                                                     |                                      |                       |                |                       |                |                                             | 1.689   |
| Rabbits                        | 201          | 109                        | 170                            |                                    |                             |                                                  | 191                             |                        |                                         | 139                                                 | 11                                   | 19                    |                | 22                    |                | 36                                          | 1.174   |
| Cats                           |              |                            |                                |                                    |                             |                                                  |                                 |                        |                                         |                                                     |                                      |                       |                |                       |                |                                             | 267     |
| Dogs                           | 29           |                            | 9                              | 141                                | 108                         |                                                  |                                 |                        | 11                                      |                                                     | 46                                   | 2                     |                | 3                     |                | 41                                          | 1.022   |
| Ferrets                        |              | 119                        |                                |                                    |                             |                                                  |                                 |                        |                                         |                                                     |                                      |                       |                |                       |                |                                             | 131     |
| Horses, donkeys & cross-breeds |              |                            |                                |                                    |                             |                                                  | 7                               | 3                      |                                         |                                                     |                                      |                       |                |                       |                |                                             | 74      |
| Pigs                           | 174          | 67                         | 376                            | 19                                 | 220                         | 213                                              | 28                              | 3                      |                                         | 1                                                   | 162                                  | 164                   | 429            | 29                    |                | 6                                           | 4.177   |
| Goats                          |              | 4                          |                                |                                    |                             |                                                  |                                 |                        |                                         |                                                     |                                      |                       |                | 2                     |                |                                             | 572     |
| Sheep                          | 5            | 7                          | 204                            | 2                                  | 30                          |                                                  | 206                             |                        |                                         |                                                     | 1                                    |                       |                | 2                     |                |                                             | 767     |

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|                                                       |         |        |        |        |        |       |       |        |       |       |        |       |        |       |       |       |         |
|-------------------------------------------------------|---------|--------|--------|--------|--------|-------|-------|--------|-------|-------|--------|-------|--------|-------|-------|-------|---------|
| Cattle                                                |         |        | 3      |        |        |       |       |        |       |       |        |       | 102    | 209   |       |       | 1.057   |
| Cynomolgus monkey                                     |         |        | 45     | 6      | 12     |       |       |        |       |       | 3      | 11    |        |       |       | 13    | 90      |
| Rhesus monkey                                         |         |        | 5      |        |        |       |       |        |       |       |        |       |        |       |       |       | 5       |
| Vervets Chlorocebus spp.                              |         |        | 5      |        |        |       |       |        |       |       |        |       |        |       |       |       | 5       |
| Other species of Old World Monkeys (Cercopithecoidea) |         |        | 3      |        |        |       |       |        |       |       |        |       |        |       |       |       | 3       |
| Other Mammals                                         |         |        | 63     |        |        |       |       |        | 32    |       |        |       | 20     |       |       |       | 129     |
| Domestic fowl                                         |         |        | 6      |        |        |       | 20    |        |       |       |        |       | 3.524  | 8     |       |       | 5.757   |
| Other birds                                           |         |        | 10     |        |        |       |       |        |       |       |        |       |        |       |       |       | 4.331   |
| Reptiles                                              |         |        |        |        |        |       |       |        |       |       |        |       |        |       |       |       | 24      |
| Rana                                                  |         |        |        |        |        |       |       |        |       |       |        |       |        |       |       |       | 6       |
| Xenopus                                               |         |        |        | 36     |        |       |       |        |       | 12    |        |       |        |       |       |       | 48      |
| Other Amphibians                                      |         |        |        |        |        |       |       |        |       |       |        |       |        |       |       |       | 245     |
| Zebra fish                                            |         |        |        | 515    |        |       |       |        |       |       |        |       |        |       |       |       | 515     |
| Other Fish                                            |         |        |        |        |        |       |       |        |       |       |        |       | 26.869 |       | 5     | 2215  | 74.869  |
| Total                                                 | 113.730 | 31.595 | 22.559 | 60.989 | 23.306 | 5.486 | 8.587 | 19.408 | 4.586 | 3.768 | 18.574 | 5.649 | 31.719 | 6.279 | 25    | 8.091 | 426.966 |
| %                                                     | 26.64%  | 7.40%  | 5.28%  | 14.28% | 5.46%  | 1.28% | 2.01% | 4.55%  | 1.07% | 0.88% | 4.35%  | 1.32% | 7.43%  | 1.47% | 0.01% | 1.89% | 100%    |

**Table 12: Regulatory use of animals and routine production purposes**

|                                | Quality control<br>(incl batch safety and potency testing) | Other efficacy and tolerance testing | Toxicity and other safety testing including pharmacology | Routine production | Total          |
|--------------------------------|------------------------------------------------------------|--------------------------------------|----------------------------------------------------------|--------------------|----------------|
| Mice                           | 118.641                                                    | 53.053                               | 99.778                                                   | 4.404              | <b>275.876</b> |
| Rats                           | 76.934                                                     | 5.445                                | 103.651                                                  | 745                | <b>186.775</b> |
| Guinea-Pigs                    | 11.808                                                     | 189                                  | 4.475                                                    | 217                | <b>16.689</b>  |
| Hamsters (Syrian)              | 378                                                        |                                      | 421                                                      | 78                 | <b>877</b>     |
| Hamsters (Chinese)             |                                                            |                                      | 10                                                       |                    | <b>10</b>      |
| Mongolian gerbil               |                                                            |                                      | 1.499                                                    | 274                | <b>1.773</b>   |
| Other Rodents                  |                                                            |                                      | 17.189                                                   |                    | <b>17.189</b>  |
| Rabbits                        | 15.069                                                     | 225                                  | 7.107                                                    | 80.523             | <b>102.294</b> |
| Cats                           | 91                                                         | 112                                  | 306                                                      | 10                 | <b>519</b>     |
| Dogs                           |                                                            | 434                                  | 2.742                                                    | 2                  | <b>3.178</b>   |
| Other carnivores               | 253                                                        | 115                                  |                                                          |                    | <b>368</b>     |
| Horses, donkeys & cross-breeds |                                                            | 43                                   | 3                                                        | 38                 | <b>84</b>      |
| Pigs                           | 708                                                        | 2.820                                | 906                                                      | 54                 | <b>4.488</b>   |
| Goats                          |                                                            |                                      | 2                                                        | 25                 | <b>27</b>      |
| Sheep                          | 20                                                         |                                      | 116                                                      | 512                | <b>648</b>     |
| Cattle                         | 47                                                         | 143                                  | 345                                                      | 98                 | <b>633</b>     |
| Marmoset and tamarins          |                                                            |                                      | 134                                                      |                    | <b>134</b>     |
| Cynomolgus monkey              |                                                            |                                      | 2.104                                                    |                    | <b>2.104</b>   |
| Rhesus monkey                  |                                                            |                                      | 82                                                       |                    | <b>82</b>      |
| Other Mammals                  |                                                            | 27                                   | 3                                                        |                    | <b>64</b>      |
| Domestic fowl                  | 2.600                                                      | 10.773                               | 145                                                      |                    | <b>13.661</b>  |
| Other birds                    |                                                            | 32                                   | 5.026                                                    |                    | <b>5.129</b>   |
| Reptiles                       |                                                            |                                      | 83                                                       | 280                | <b>363</b>     |
| Rana                           |                                                            |                                      | 5                                                        |                    | <b>5</b>       |
| Xenopus                        |                                                            |                                      | 6                                                        |                    | <b>6</b>       |
| Other Amphibians               |                                                            |                                      | 104                                                      |                    | <b>104</b>     |
| Zebra fish                     |                                                            |                                      | 19.959                                                   |                    | <b>19.959</b>  |
| Other Fish                     |                                                            | 200                                  | 11.759                                                   |                    | <b>11.959</b>  |
| Cephalopods                    |                                                            |                                      |                                                          |                    |                |
| <b>Total</b>                   | <b>226.908</b>                                             | <b>73.611</b>                        | <b>277.301</b>                                           | <b>87.508</b>      | <b>665.528</b> |
| <b>%</b>                       | <b>34.40%</b>                                              | <b>11.06%</b>                        | <b>41.75%</b>                                            | <b>13.51%</b>      | <b>100%</b>    |

Table 13: Use of animals in quality control purposes

|                   | Batch safety testing | Pyrogenicity testing | Batch potency testing | Other quality controls | Total          |
|-------------------|----------------------|----------------------|-----------------------|------------------------|----------------|
| Mice              | 21.295               |                      | 97.346                |                        | 118.861        |
| Rats              | 657                  |                      | 76.277                |                        | 76.934         |
| Guinea-Pigs       | 3.147                |                      | 8.652                 | 9                      | 11.808         |
| Hamsters (Syrian) | 8                    |                      | 370                   |                        | 378            |
| Rabbits           | 108                  | 7.259                | 7.702                 |                        | 15.069         |
| Cats              | 91                   |                      |                       |                        | 91             |
| Other carnivores  | 14                   |                      | 239                   |                        | 253            |
| Pigs              | 343                  |                      | 323                   | 42                     | 708            |
| Sheep             |                      |                      |                       | 20                     | 20             |
| Cattle            | 32                   |                      | 15                    |                        | 47             |
| Domestic fowl     | 2.259                |                      | 341                   |                        | 2.600          |
| <b>Total</b>      | <b>27.954</b>        | <b>7.259</b>         | <b>191.265</b>        | <b>71</b>              | <b>226.549</b> |
| <b>%</b>          | <b>12.34%</b>        | <b>3.20%</b>         | <b>84.43%</b>         | <b>0.03%</b>           | <b>100%</b>    |

Table 14: Use of animals in routine production purposes

|                                | Blood based products | Monoclonal antibodies | Other product types | Total         |
|--------------------------------|----------------------|-----------------------|---------------------|---------------|
| Mice                           | 425                  | 1.370                 | 2.609               | 4.404         |
| Rats                           | 14                   | 331                   | 400                 | 745           |
| Guinea-Pigs                    | 210                  |                       | 7                   | 217           |
| Hamsters (Syrian)              |                      |                       | 78                  | 78            |
| Mongolian gerbil               |                      |                       | 274                 | 274           |
| Rabbits                        | 79.347               | 15                    | 1.161               | 80.523        |
| Cats                           |                      |                       | 10                  | 10            |
| Dogs                           |                      |                       | 2                   | 2             |
| Horses, donkeys & cross-breeds | 38                   |                       |                     | 38            |
| Pigs                           |                      |                       | 54                  | 54            |
| Goats                          | 25                   |                       |                     | 25            |
| Sheep                          | 489                  |                       | 23                  | 512           |
| Cattle                         | 73                   |                       | 25                  | 98            |
| Other Mammals                  | 24                   |                       | 10                  | 34            |
| Domestic fowl                  | 77                   |                       | 66                  | 143           |
| Other birds                    | 31                   |                       | 40                  | 71            |
| Reptiles                       |                      |                       | 280                 | 280           |
| <b>Total</b>                   | <b>80.753</b>        | <b>1.716</b>          | <b>5.039</b>        | <b>87.508</b> |
| <b>%</b>                       | <b>92.28%</b>        | <b>1.96%</b>          | <b>5.76%</b>        | <b>100%</b>   |

**Table 15: Use of animals in toxicity and other safety testing by test type purposes**

[illegible]

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|                       |        |       |       |        |       |       |        |        |       |        |         |       |        |        |       |       |         |
|-----------------------|--------|-------|-------|--------|-------|-------|--------|--------|-------|--------|---------|-------|--------|--------|-------|-------|---------|
| Marmoset and tamarins |        |       |       | 58     |       |       |        |        |       | 4      | 24      |       |        |        |       | 48    | 134     |
| Cynomolgus monkey     | 2      |       |       | 1.242  |       |       | 62     | 13     |       | 451    | 82      |       |        |        |       | 252   | 2.104   |
| Rhesus monkey         |        |       |       | 70     |       |       |        |        |       | 12     |         |       |        |        |       |       | 82      |
| Other Mammals         |        |       |       |        |       |       |        |        |       |        |         |       |        |        |       | 3     | 3       |
| Domestic fowl         | 48     |       |       |        |       |       |        |        |       | 12     |         |       |        | 85     |       |       | 145     |
| Other birds           | 381    |       |       |        |       |       |        |        |       |        |         |       | 4.547  |        |       | 98    | 5.026   |
| Reptiles              |        |       |       |        |       |       |        |        |       |        |         |       | 83     |        |       |       | 86      |
| Rana                  |        |       |       |        |       |       |        |        |       |        |         |       |        |        |       | 5     | 5       |
| Xenopus               |        |       |       |        |       |       |        |        |       |        |         |       | 89     |        |       |       | 86      |
| Other Amphibians      |        |       |       |        |       |       |        |        |       |        |         |       |        |        |       | 104   | 104     |
| Zebra fish            | 21     |       |       |        |       |       |        | 2.020  |       |        |         |       | 17.818 |        |       |       | 19.859  |
| Other Fish            | 2.961  |       |       |        |       |       |        |        |       |        |         |       | 8523   | 275    |       |       | 11.759  |
| Total                 | 14.375 | 703   | 9.326 | 19.111 | 688   | 5.024 | 17.280 | 20.264 | 469   | 34.245 | 103.448 | 84    | 37.329 | 10.051 | 221   | 5.242 | 277.860 |
| %                     | 5.17%  | 0.25% | 3.36% | 6.88%  | 0.25% | 1.81% | 6.22%  | 7.29%  | 0.17% | 12.32% | 37.23%  | 0.03% | 13.43% | 3.62%  | 0.08% | 1.89% | 100%    |

Table 16: Use of animals in repeated dose toxicity testing methods

|                       | up to 28 days | 29 - 90 days  | > 90 days    | Total         |
|-----------------------|---------------|---------------|--------------|---------------|
| Mice                  | 2.801         | 745           | 240          | 3.786         |
| Rats                  | 9.228         | 3.012         | 1.006        | 13.246        |
| Guinea-Pigs           | 60            |               |              | 60            |
| Rabbits               | 109           |               |              | 109           |
| Dogs                  | 444           | 270           | 120          | 834           |
| Pigs                  | 17            |               | 4            | 21            |
| Marmoset and tamarins |               | 54            | 4            | 58            |
| Cynomolgus monkey     | 284           | 304           | 339          | 927           |
| Rhesus monkey         |               | 70            |              | 70            |
| <b>Total</b>          | <b>12.943</b> | <b>4.455</b>  | <b>1.713</b> | <b>19.111</b> |
| <b>%</b>              | <b>67.73%</b> | <b>23.31%</b> | <b>8.96%</b> | <b>100%</b>   |

Table 17: Use of animals in acute and subacute toxicity testing methods

|                   | LD50, LC50    | Other lethal methods | Non lethal methods | Total         |
|-------------------|---------------|----------------------|--------------------|---------------|
| Mice              | 2.127         | 63                   | 3.593              | 5.783         |
| Rats              | 1981          | 489                  | 2.692              | 5.162         |
| Guinea-Pigs       | 20            |                      | 46                 | 66            |
| Rabbits           |               |                      | 56                 | 56            |
| Dogs              |               |                      | 30                 | 30            |
| Cynomolgus monkey | 2             |                      |                    | 2             |
| Domestic fowl     |               | 48                   |                    | 48            |
| Other birds       | 49            |                      | 332                | 381           |
| Zebra fish        | 21            |                      |                    | 21            |
| Other Fish        | 2.961         |                      |                    | 2.961         |
| <b>Total</b>      | <b>7.161</b>  | <b>600</b>           | <b>6.749</b>       | <b>14.510</b> |
| <b>%</b>          | <b>49.35%</b> | <b>4.14%</b>         | <b>46.51%</b>      | <b>100%</b>   |

Table 18: Use of animals in ecotoxicity testing methods

|               | Acute toxicity | Chronic toxicity | Reproductive ecotoxicity | Endocrine activity | Bioaccumulation | Other ecotoxicity | Total         |
|---------------|----------------|------------------|--------------------------|--------------------|-----------------|-------------------|---------------|
| Mice          |                |                  |                          |                    |                 | 135               | 135           |
| Other Rodents |                |                  |                          |                    |                 | 6.217             | 6.217         |
| Other birds   | 757            |                  | 3.790                    |                    |                 |                   | 4.547         |
| Reptiles      | 83             |                  |                          |                    |                 |                   | 86            |
| Xenopus       | 6              |                  |                          |                    |                 |                   | 6             |
| Zebra fish    | 2.021          | 5.075            |                          | 9.550              | 732             | 440               | 17.818        |
| Other Fish    | 3.925          | 2.323            | 96                       | 1.152              | 991             | 36                | 8.523         |
| <b>Total</b>  | <b>6.792</b>   | <b>7.398</b>     | <b>3.886</b>             | <b>10.702</b>      | <b>1.723</b>    | <b>6.826</b>      | <b>37.329</b> |
| <b>%</b>      | <b>21.93%</b>  | <b>23.88%</b>    | <b>12.54%</b>            | <b>34.55%</b>      | <b>5.56%</b>    | <b>18.29%</b>     | <b>100%</b>   |

## 5. Use of species and severity

Table 19: Use of species and severity in total

|                                | Non-recovery | %      | Mild<br>[up to and including] | %       | Moderate | %      | Severe  | %      | Total     |
|--------------------------------|--------------|--------|-------------------------------|---------|----------|--------|---------|--------|-----------|
| Mice                           | 778.455      | 40,93% | 692.919                       | 36,43%  | 327.864  | 17,24% | 102.747 | 5,40%  | 1.901.985 |
| Rats                           | 87.786       | 24,21% | 198.745                       | 54,82%  | 70.849   | 19,54% | 5.150   | 1,42%  | 362.530   |
| Guinea-Pigs                    | 1.641        | 7,98%  | 11.100                        | 53,95%  | 2.638    | 12,82% | 5.197   | 25,26% | 20.576    |
| Hamsters (Syrian)              | 153          | 9,38%  | 1.133                         | 69,42%  | 338      | 20,71% | 8       | 0,49%  | 1.632     |
| Hamsters (Chinese)             | 14           | 58,33% | 10                            | 41,67%  |          |        |         |        | 24        |
| Mongolian gerbil               | 1.090        | 22,61% | 2.585                         | 53,63%  | 1.108    | 22,99% | 37      | 0,77%  | 4.820     |
| Other Rodents                  | 819          | 3,55%  | 21.586                        | 93,64%  | 646      | 2,80%  |         |        | 23.051    |
| Rabbits                        | 41.096       | 38,85% | 62.998                        | 59,55%  | 1.609    | 1,52%  | 81      | 0,08%  | 105.784   |
| Cats                           | 98           | 9,83%  | 718                           | 72,02%  | 181      | 18,15% |         |        | 997       |
| Dogs                           | 100          | 2,16%  | 3.832                         | 82,66%  | 680      | 14,67% | 24      | 0,52%  | 4.636     |
| Ferrets                        | 10           | 6,29%  | 60                            | 37,74%  | 89       | 55,97% |         |        | 159       |
| Other carnivores               | 51           | 12,32% | 202                           | 48,79%  | 161      | 38,89% |         |        | 414       |
| Horses, donkeys & cross-breeds | 66           | 8,45%  | 706                           | 90,40%  | 9        | 1,15%  |         |        | 781       |
| Pigs                           | 4.163        | 28,96% | 8.102                         | 56,37%  | 1.704    | 11,85% | 405     | 2,82%  | 14.374    |
| Goats                          | 49           | 6,54%  | 680                           | 90,79%  | 20       | 2,67%  |         |        | 749       |
| Sheep                          | 200          | 10,33% | 1.142                         | 58,96%  | 563      | 29,07% | 32      | 1,65%  | 1.937     |
| Cattle                         | 10           | 0,23%  | 4.083                         | 92,63%  | 307      | 6,96%  | 8       | 0,18%  | 4.408     |
| Prosimians                     |              |        | 148                           | 100,00% |          |        |         |        | 148       |

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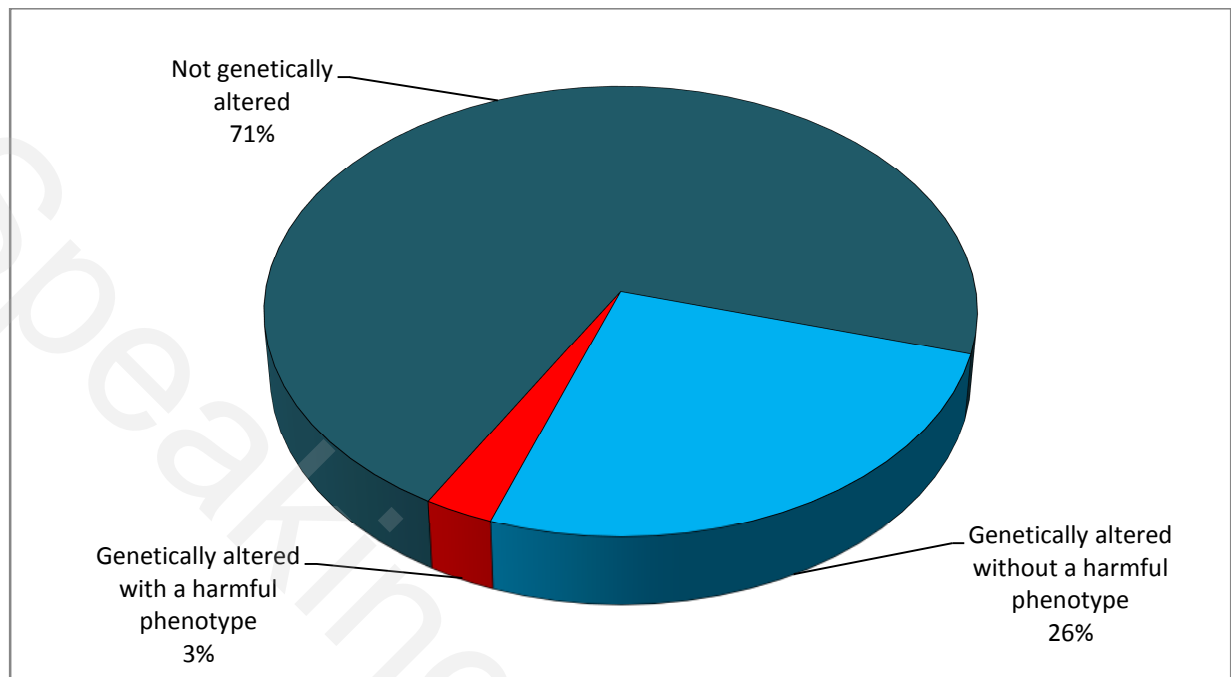
|                                    |                  |               |                  |               |                |               |                |              |                  |
|------------------------------------|------------------|---------------|------------------|---------------|----------------|---------------|----------------|--------------|------------------|
| Marmoset and tamarins              | 35               | 10,77%        | 272              | 83,69%        | 18             | 5,54%         |                |              | 325              |
| Cynomolgus monkey                  | 12               | 0,54%         | 1.713            | 76,78%        | 485            | 21,74%        | 21             | 0,94%        | 2.231            |
| Rhesus monkey                      |                  |               | 99               | 77,34%        | 29             | 22,66%        |                |              | 128              |
| Vervets Chlorocebus spp.           |                  |               | 5                | 100,00%       |                |               |                |              | 5                |
| Baboons                            |                  |               |                  |               |                |               | 2              | 100,00%      | 2                |
| Other species of Old World Monkeys |                  |               | 3                | 100,00%       |                |               |                |              | 3                |
| Other Mammals                      | 162              | 9,60%         | 1.382            | 81,87%        | 140            | 8,29%         | 4              | 0,24%        | 1.688            |
| Domestic fowl                      | 15.382           | 43,95%        | 14.731           | 42,09%        | 2.257          | 6,45%         | 2.632          | 7,52%        | 35.002           |
| Other birds                        | 1.448            | 7,00%         | 17.767           | 85,85%        | 1.420          | 6,86%         | 60             | 0,29%        | 20.695           |
| Reptiles                           | 137              | 13,43%        | 656              | 64,31%        | 227            | 22,25%        |                |              | 1.020            |
| Rana                               | 19               | 61,29%        | 12               | 38,71%        |                |               |                |              | 31               |
| Xenopus                            | 4.471            | 44,81%        | 5.337            | 53,49%        | 169            | 1,69%         |                |              | 9.977            |
| Other Amphibians                   | 1.128            | 21,03%        | 4.037            | 75,28%        | 198            | 3,69%         |                |              | 5.363            |
| Zebra fish                         | 47.833           | 37,72%        | 66.533           | 52,47%        | 9.894          | 7,80%         | 2.538          | 2,00%        | 126.798          |
| Other Fish                         | 22.179           | 3,13%         | 678.355          | 95,58%        | 2.921          | 0,41%         | 6.272          | 0,88%        | 709.727          |
| Cephalopods                        | 45               | 71,43%        | 18               | 28,57%        |                |               |                |              | 63               |
| <b>Total</b>                       | <b>1.008.652</b> | <b>30.00%</b> | <b>1.801.669</b> | <b>53.59%</b> | <b>426.524</b> | <b>12.69%</b> | <b>125.218</b> | <b>3.72%</b> | <b>3.362.063</b> |

## 6. Use of species and genetic status

Table 20: Use of species and genetic status in total

|                                                       | Not genetically altered | Genetically altered without a harmful phenotype | Genetically altered with a harmful phenotype | Total            |
|-------------------------------------------------------|-------------------------|-------------------------------------------------|----------------------------------------------|------------------|
| Mice                                                  | 1.012.965               | 798.135                                         | 90.885                                       | 1.901.985        |
| Rats                                                  | 351.266                 | 7.445                                           | 3.819                                        | 362.530          |
| Guinea-Pigs                                           | 20.575                  | 1                                               |                                              | 20.576           |
| Hamsters (Syrian)                                     | 1.532                   |                                                 |                                              | 1.532            |
| Hamsters (Chinese)                                    | 24                      |                                                 |                                              | 24               |
| Mongolian gerbil                                      | 4.820                   |                                                 |                                              | 4.820            |
| Other Rodents                                         | 23.051                  |                                                 |                                              | 23.051           |
| Rabbits                                               | 105.784                 |                                                 |                                              | 105.784          |
| Cats                                                  | 997                     |                                                 |                                              | 997              |
| Dogs                                                  | 4.636                   |                                                 |                                              | 4.636            |
| Ferrets                                               | 159                     |                                                 |                                              | 159              |
| Other carnivores                                      | 414                     |                                                 |                                              | 414              |
| Horses, donkeys & cross-breeds                        | 781                     |                                                 |                                              | 781              |
| Pigs                                                  | 14.060                  | 110                                             | 204                                          | 14.374           |
| Goats                                                 | 749                     |                                                 |                                              | 749              |
| Sheep                                                 | 1.937                   |                                                 |                                              | 1.937            |
| Cattle                                                | 4.406                   |                                                 |                                              | 4.406            |
| Prosimians                                            | 148                     |                                                 |                                              | 148              |
| Marmoset and tamarins                                 | 325                     |                                                 |                                              | 325              |
| Cynomolgus monkey                                     | 2.231                   |                                                 |                                              | 2.231            |
| Rhesus monkey                                         | 128                     |                                                 |                                              | 128              |
| Vervets Chlorocebus spp.                              | 5                       |                                                 |                                              | 5                |
| Baboons                                               | 2                       |                                                 |                                              | 2                |
| Other species of Old World Monkeys (Cercopithecoidea) | 3                       |                                                 |                                              | 3                |
| Other Mammals                                         | 1.688                   |                                                 |                                              | 1.688            |
| Domestic fowl                                         | 35.002                  |                                                 |                                              | 35.002           |
| Other birds                                           | 20.695                  |                                                 |                                              | 20.695           |
| Reptiles                                              | 1.020                   |                                                 |                                              | 1.020            |
| Rana                                                  | 31                      |                                                 |                                              | 31               |
| Xenopus                                               | 9.977                   |                                                 |                                              | 9.977            |
| Other Amphibians                                      | 5.363                   |                                                 |                                              | 5.363            |
| Zebra fish                                            | 58.975                  | 66.322                                          | 1.501                                        | 126.798          |
| Other Fish                                            | 706.781                 | 2.404                                           | 542                                          | 709.727          |
| Cephalopods                                           | 63                      |                                                 |                                              | 63               |
| <b>Total</b>                                          | <b>2.390.695</b>        | <b>874.417</b>                                  | <b>96.951</b>                                | <b>3.362.063</b> |

Figure 4: Use of animals: genetic status



## 7. Use of Species and re-use

Table 21: Use of species and re-use in total

|                                    | (Naive) First use | Re-uses       | Total            |
|------------------------------------|-------------------|---------------|------------------|
| Mice                               | 1.877.552         | 24.433        | 1.901.985        |
| Rats                               | 357.124           | 5.406         | 362.530          |
| Guinea-Pigs                        | 20.037            | 539           | 20.576           |
| Hamsters (Syrian)                  | 1.628             | 4             | 1.632            |
| Hamsters (Chinese)                 | 24                |               | 24               |
| Mongolian gerbil                   | 3.960             | 860           | 4.820            |
| Other Rodents                      | 22.881            | 170           | 23.051           |
| Rabbits                            | 102.523           | 3.261         | 105.784          |
| Cats                               | 581               | 416           | 997              |
| Dogs                               | 2.202             | 2.434         | 4.636            |
| Ferrets                            | 141               | 18            | 159              |
| Other carnivores                   | 414               |               | 414              |
| Horses, donkeys & cross-breeds     | 635               | 146           | 781              |
| Pigs                               | 13.768            | 606           | 14.374           |
| Goats                              | 724               | 25            | 749              |
| Sheep                              | 1.373             | 564           | 1.937            |
| Cattle                             | 3.817             | 591           | 4.408            |
| Prosimians                         | 85                | 63            | 148              |
| Marmoset and tamarins              | 234               | 91            | 325              |
| Cynomolgus monkey                  | 1.475             | 756           | 2.231            |
| Rhesus monkey                      | 111               | 17            | 128              |
| Vervets Chlorocebus spp.           |                   | 5             | 5                |
| Baboons                            | 2                 |               | 2                |
| Other species of Old World Monkeys |                   | 3             | 3                |
| Other Mammals                      | 1.607             | 81            | 1.688            |
| Domestic fowl                      | 34.806            | 196           | 35.002           |
| Other birds                        | 20.503            | 192           | 20.695           |
| Reptiles                           | 707               | 313           | 1.020            |
| Rana                               | 31                |               | 31               |
| Xenopus                            | 7.929             | 2.048         | 9.977            |
| Other Amphibians                   | 5.363             |               | 5363             |
| Zebra fish                         | 123.336           | 3.462         | 126.798          |
| Other Fish                         | 708.462           | 1.265         | 709.727          |
| Cephalopods                        | 63                |               | 63               |
| <b>Total</b>                       | <b>3.314.098</b>  | <b>47.965</b> | <b>3.362.063</b> |

Figure 5: Use of species groups and re-use

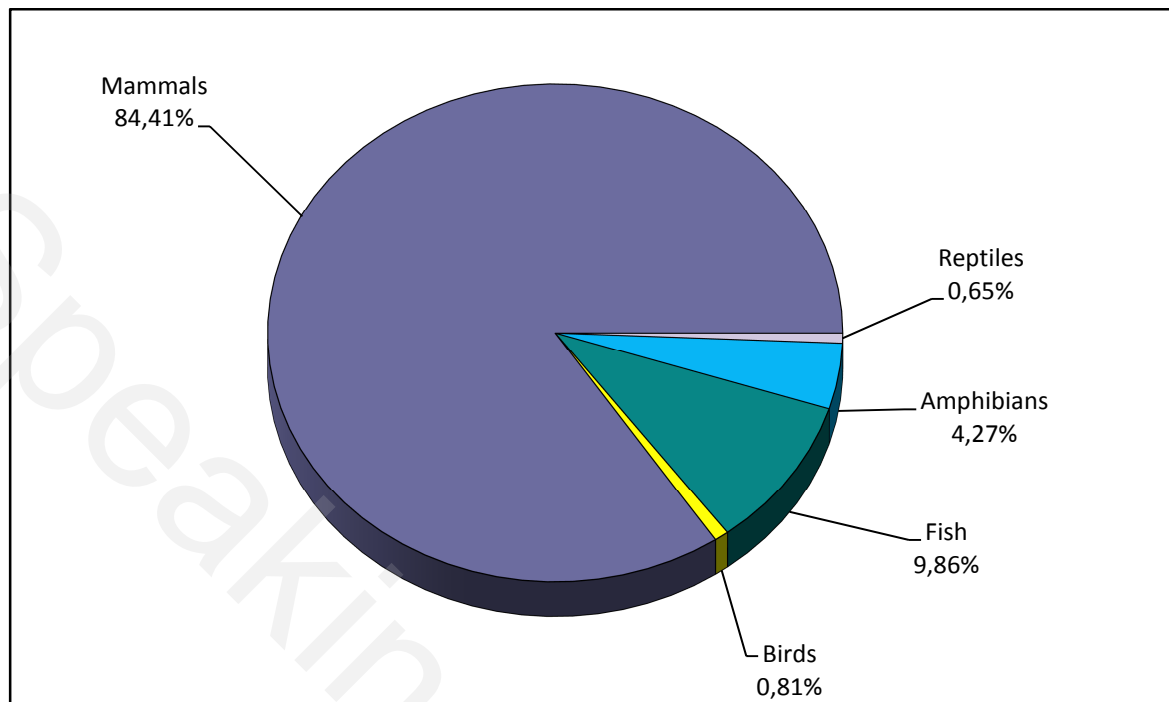
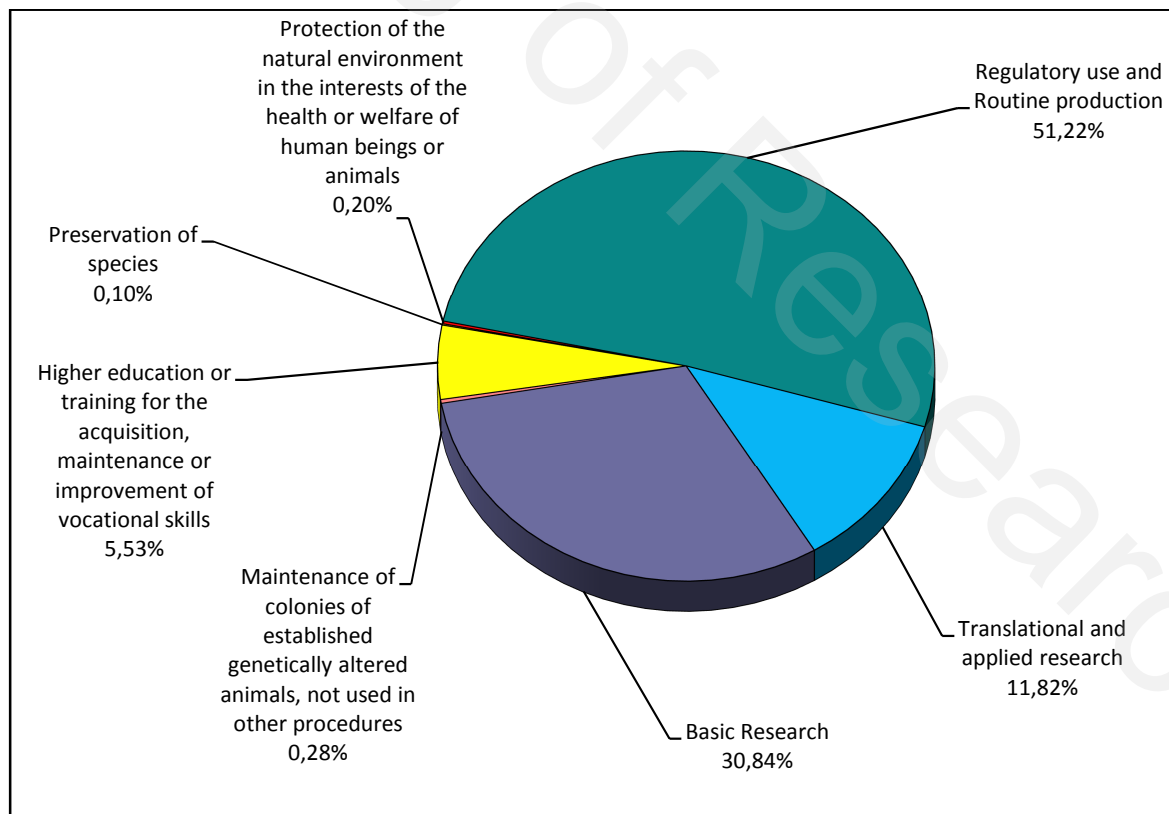


Figure 6: Primary purpose and re-use



## 8. Purposes and severity

Table 22: Purpose and severity

|                                                                                                            | Non-recovery     | Mild [up to and including] | Moderate       | Severe         | Total            |
|------------------------------------------------------------------------------------------------------------|------------------|----------------------------|----------------|----------------|------------------|
| Basic Research                                                                                             | 798.727          | 1.090.145                  | 204.062        | 19.255         | <b>2.112.189</b> |
| Translational and applied research                                                                         | 78.747           | 241.547                    | 94.851         | 11.821         | <b>426.966</b>   |
| Regulatory use and Routine production                                                                      | 58.204           | 405.350                    | 109.363        | 92.611         | <b>665.528</b>   |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 394              | 5.522                      | 712            | 350            | <b>6.978</b>     |
| Preservation of species                                                                                    | 3.127            | 7.504                      | 385            | 600            | <b>11.616</b>    |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 18.702           | 26.278                     | 10.994         | 260            | <b>56.234</b>    |
| Forensic enquiries                                                                                         | 31               |                            |                |                | <b>31</b>        |
| Maintenance of colonies of established genetically altered animals, not used in other procedures           | 50.720           | 25.323                     | 6.157          | 321            | <b>82.521</b>    |
| <b>Total</b>                                                                                               | <b>1.008.652</b> | <b>1.801.669</b>           | <b>426.524</b> | <b>125.218</b> | <b>3.362.063</b> |
| <b>%</b>                                                                                                   | <b>30.00%</b>    | <b>53.59%</b>              | <b>12.69%</b>  | <b>3.72%</b>   | <b>100%</b>      |

Table 23: Basic research purposes and severity

|                                              | Non-recovery   | Mild [up to and including] | Moderate       | Severe        | Total            |
|----------------------------------------------|----------------|----------------------------|----------------|---------------|------------------|
| Oncology                                     | 33.039         | 38.866                     | 27.356         | 3.365         | <b>102.626</b>   |
| Cardiovascular Blood and Lymphatic System    | 111.272        | 39.394                     | 18.736         | 1.247         | <b>170.649</b>   |
| Nervous System                               | 202.075        | 83.195                     | 54.613         | 3.269         | <b>343.152</b>   |
| Respiratory System                           | 46.459         | 12.350                     | 5.971          | 292           | <b>65.072</b>    |
| Gastrointestinal System including Liver      | 29.715         | 12.297                     | 9.237          | 517           | <b>51.766</b>    |
| Musculoskeletal System                       | 12.611         | 8.344                      | 3.283          | 89            | <b>24.327</b>    |
| Immune System                                | 146.786        | 149.073                    | 56.484         | 7.947         | <b>360.292</b>   |
| Urogenital/ Reproductive System              | 16.823         | 10.204                     | 2.859          | 404           | <b>30.290</b>    |
| Sensory Organs (skin, eyes and ears)         | 26.719         | 9.568                      | 2.179          | 127           | <b>38.593</b>    |
| Endocrine System/ Metabolism                 | 28.736         | 30.049                     | 6.892          | 5             | <b>65.682</b>    |
| Multisystemic                                | 52.755         | 25.538                     | 3.308          | 845           | <b>82.446</b>    |
| Ethology / Animal Behaviour / Animal Biology | 6.316          | 49.835                     | 3.111          | 157           | <b>59.419</b>    |
| Other basic research                         | 85.421         | 621.432                    | 10.033         | 989           | <b>717.875</b>   |
| <b>Total</b>                                 | <b>798.727</b> | <b>1.101.134</b>           | <b>204.062</b> | <b>19.253</b> | <b>2.112.189</b> |
| <b>%</b>                                     | <b>37.82%</b>  | <b>52.13%</b>              | <b>9.66%</b>   | <b>0.91%</b>  | <b>100%</b>      |

Table 24: Basic research: species and severity

|                                | Non-recovery   | Mild [up to and including] | Moderate       | Severe        |
|--------------------------------|----------------|----------------------------|----------------|---------------|
| Mice                           | 652.237        | 392.277                    | 171.966        | 16.920        |
| Rats                           | 63.079         | 17.591                     | 24.697         | 2.155         |
| Guinea-Pigs                    | 418            | 234                        | 121            |               |
| Hamsters (Syrian)              | 29             | 38                         |                |               |
| Hamsters (Chinese)             | 12             |                            |                |               |
| Mongolian gerbil               | 805            | 291                        | 402            |               |
| Other Rodents                  | 461            | 2.664                      | 606            |               |
| Rabbits                        | 573            | 534                        | 231            | 11            |
| Cats                           | 7              | 133                        | 12             |               |
| Dogs                           | 8              | 309                        |                |               |
| Ferrets                        | 10             | 7                          | 3              |               |
| Horses, donkeys & cross-breeds | 20             | 547                        | 2              |               |
| Pigs                           | 1.263          | 1.438                      | 508            | 4             |
| Goats                          |                | 72                         | 1              |               |
| Sheep                          | 60             | 118                        | 121            | 9             |
| Cattle                         | 4              | 2.283                      | 73             |               |
| Prosimians                     |                | 148                        |                |               |
| Marmoset and tamarins          | 34             | 143                        | 12             |               |
| Cynomolgus monkey              |                | 6                          | 21             |               |
| Rhesus monkey                  |                | 10                         | 29             |               |
| Baboons                        |                |                            |                | 2             |
| Other Mammals                  | 110            | 1.074                      | 140            |               |
| Domestic fowl                  | 10.919         | 2.907                      | 1.008          |               |
| Other birds                    | 925            | 8.944                      | 1.054          | 54            |
| Reptiles                       | 137            | 179                        | 144            |               |
| Rana                           | 2              | 7                          |                |               |
| Xenopus                        | 3.972          | 5.275                      | 151            |               |
| Other Amphibians               | 842            | 3.932                      | 198            |               |
| Zebra fish                     | 44.021         | 58.741                     | 1.234          |               |
| Other Fish                     | 18.779         | 590.234                    | 1.328          | 100           |
| <b>Total</b>                   | <b>798.727</b> | <b>1.090.145</b>           | <b>204.062</b> | <b>19.255</b> |

Table 25: Translational and applied research: purposes and severity

|                                                     | Non-recovery  | Mild [up to and including] | Moderate      | Severe        | Total          |
|-----------------------------------------------------|---------------|----------------------------|---------------|---------------|----------------|
| Human Cancer                                        | 12.608        | 58.979                     | 41.429        | 714           | <b>113.730</b> |
| Human Infectious Disorders                          | 5.459         | 17.207                     | 6.783         | 2.146         | <b>31.595</b>  |
| Human Cardiovascular Disorders                      | 8.043         | 8.522                      | 4.330         | 1.664         | <b>22.559</b>  |
| Human Nervous and Mental Disorders                  | 16.173        | 29.927                     | 14.235        | 654           | <b>60.989</b>  |
| Human Respiratory Disorders                         | 3.808         | 11.208                     | 7.107         | 1.183         | <b>23.306</b>  |
| Human Gastrointestinal Disorders including Liver    | 1.965         | 1.512                      | 1.535         | 474           | <b>5.486</b>   |
| Human Musculoskeletal Disorders                     | 4.446         | 1.532                      | 2.478         | 131           | <b>8.587</b>   |
| Human Immune Disorders                              | 9.359         | 5.364                      | 4.552         | 133           | <b>19.408</b>  |
| Human Urogenital/Reproductive Disorders             | 1.478         | 1.392                      | 868           | 848           | <b>4.586</b>   |
| Human Sensory Organ Disorders (skin, eyes and ears) | 1.337         | 1.608                      | 822           | 1             | <b>3.768</b>   |
| Human Endocrine/Metabolism Disorders                | 3.650         | 12.343                     | 2.560         | 21            | <b>18.574</b>  |
| Other Human Disorders                               | 1.335         | 2.731                      | 1.532         | 51            | <b>5.649</b>   |
| Animal Diseases and Disorders                       | 1.523         | 57.245                     | 3.248         | 599           | <b>62.615</b>  |
| Animal Welfare                                      | 3.481         | 27.612                     | 56            | 570           | <b>31.719</b>  |
| Diagnosis of diseases                               | 2.039         | 590                        | 1.030         | 2.620         | <b>6.279</b>   |
| Plant diseases                                      | 25            |                            |               |               | <b>25</b>      |
| Non-regulatory toxicology and ecotoxicology         | 2.018         | 3.775                      | 2.286         | 12            | <b>8.091</b>   |
| <b>Total</b>                                        | <b>78.747</b> | <b>241.547</b>             | <b>94.851</b> | <b>11.821</b> | <b>426.966</b> |
| <b>%</b>                                            | <b>18.44%</b> | <b>56.57%</b>              | <b>22.22%</b> | <b>2.77%</b>  | <b>100%</b>    |

Table 26: Translational and applied research: species and severity

|                                | Non-recovery  | Mild [up to and including] | Moderate      | Severe        |
|--------------------------------|---------------|----------------------------|---------------|---------------|
| Mice                           | 59.734        | 122.800                    | 79.439        | 9.958         |
| Rats                           | 12.525        | 28.733                     | 11.289        | 859           |
| Guinea-Pigs                    | 348           | 1.184                      | 1.049         | 166           |
| Hamsters (Syrian)              | 4             | 488                        | 113           |               |
| Mongolian gerbil               |               | 1.087                      | 207           | 26            |
| Other Rodents                  | 59            | 1.590                      | 40            |               |
| Rabbits                        | 205           | 595                        | 347           | 27            |
| Cats                           |               | 185                        | 82            |               |
| Dogs                           | 1             | 912                        | 108           | 1             |
| Ferrets                        |               | 45                         | 86            |               |
| Horses, donkeys & cross-breeds | 12            | 55                         | 7             |               |
| Pigs                           | 511           | 2.801                      | 498           | 367           |
| Goats                          |               | 562                        | 10            |               |
| Sheep                          | 87            | 402                        | 256           | 22            |
| Cattle                         | 6             | 956                        | 87            | 8             |
| Cynomolgus monkey              | 8             | 81                         | 1             |               |
| Other Mammals                  | 32            | 97                         |               |               |
| Domestic fowl                  | 3.534         | 983                        | 1.103         | 137           |
| Other birds                    | 380           | 3.942                      | 9             |               |
| Reptiles                       |               | 24                         |               |               |
| Rana                           | 6             |                            |               |               |
| Xenopus                        |               | 36                         | 12            |               |
| Other Amphibians               | 245           |                            |               |               |
| Zebra fish                     | 170           | 345                        |               |               |
| Other Fish                     | 880           | 73.631                     | 108           | 250           |
| <b>Total</b>                   | <b>78.747</b> | <b>241.547</b>             | <b>94.851</b> | <b>11.821</b> |

Table 27: Regulatory use/routine production purposes and severity

|                                                          | Non-recovery  | Mild [up to and including] | Moderate       | Severe        | Total          |
|----------------------------------------------------------|---------------|----------------------------|----------------|---------------|----------------|
| Routine production                                       | 39.742        | 44.868                     | 2.869          | 29            | <b>87.508</b>  |
| Quality control (incl batch safety and potency testing)  | 587           | 149.461                    | 2.294          | 74.566        | <b>226.549</b> |
| Other efficacy and tolerance testing                     | 3.428         | 33.789                     | 34.676         | 1.718         | <b>73.611</b>  |
| Toxicity and other safety testing including pharmacology | 14.447        | 177.591                    | 69.524         | 16.298        | <b>277.860</b> |
| <b>Total</b>                                             | <b>58.204</b> | <b>405.350</b>             | <b>109.363</b> | <b>92.611</b> | <b>665.528</b> |
| <b>%</b>                                                 | <b>8.75%</b>  | <b>60.91%</b>              | <b>16.43%</b>  | <b>13.92%</b> | <b>100%</b>    |

Table 28: Regulatory use/routine production: species and severity

|                                | Non-recovery  | Mild [up to and including] | Moderate       | Severe        |
|--------------------------------|---------------|----------------------------|----------------|---------------|
| Mice                           | 5.298         | 132.789                    | 62.477         | 75.312        |
| Rats                           | 7.034         | 145.692                    | 31.937         | 2.112         |
| Guinea-Pigs                    | 807           | 9.479                      | 1.372          | 5.031         |
| Hamsters (Syrian)              | 80            | 564                        | 225            | 8             |
| Hamsters (Chinese)             |               | 10                         |                |               |
| Mongolian gerbil               | 134           | 1.130                      | 498            | 11            |
| Other Rodents                  | 290           | 16.899                     |                |               |
| Rabbits                        | 40.226        | 61.684                     | 971            | 43            |
| Cats                           | 91            | 341                        | 87             |               |
| Dogs                           | 91            | 2.492                      | 572            | 23            |
| Other carnivores               | 36            | 171                        | 161            |               |
| Horses, donkeys & cross-breeds | 12            | 72                         |                |               |
| Pigs                           | 933           | 2.880                      | 641            | 34            |
| Goats                          |               | 25                         | 2              |               |
| Sheep                          |               | 503                        | 144            | 1             |
| Cattle                         |               | 486                        | 147            |               |
| Marmoset and tamarins          | 1             | 127                        | 6              |               |
| Cynomolgus monkey              | 4             | 1.623                      | 456            | 21            |
| Rhesus monkey                  |               | 82                         |                |               |
| Other Mammals                  |               | 60                         |                | 4             |
| Domestic fowl                  | 281           | 10.739                     | 146            | 2.495         |
| Other birds                    | 32            | 4.744                      | 347            | 6             |
| Reptiles                       |               | 280                        | 83             |               |
| Rana                           |               | 5                          |                |               |
| Xenopus                        |               |                            | 6              |               |
| Other Amphibians               |               | 104                        |                |               |
| Zebra fish                     | 2.490         | 6.177                      | 8.654          | 2.538         |
| Other Fish                     | 364           | 6.192                      | 431            | 4.972         |
| <b>Total</b>                   | <b>58.204</b> | <b>405.350</b>             | <b>109.363</b> | <b>92.611</b> |

Table 29: Quality control purposes and severity

|                        | Non-recovery | Mild [up to and including] | Moderate     | Severe        | Total          |
|------------------------|--------------|----------------------------|--------------|---------------|----------------|
| Batch safety testing   | 428          | 24.760                     | 310          | 2.456         | 27.954         |
| Pyrogenicity testing   |              | 7.055                      | 204          |               | 7.259          |
| Batch potency testing  | 159          | 117.243                    | 1.762        | 72.101        | 191.265        |
| Other quality controls |              | 44                         | 18           | 9             | 71             |
| <b>Total</b>           | <b>587</b>   | <b>149.102</b>             | <b>2.294</b> | <b>74.566</b> | <b>226.549</b> |
| <b>%</b>               | <b>0.26%</b> | <b>65.81%</b>              | <b>1.01%</b> | <b>32.91%</b> | <b>100%</b>    |

Table 30: Routine production purposes and severity

|                       | Non-recovery  | Mild [up to and including] | Moderate     | Severe       | Total         |
|-----------------------|---------------|----------------------------|--------------|--------------|---------------|
| Blood based products  | 38.869        | 41.699                     | 168          | 17           | 80.753        |
| Monoclonal antibodies | 621           | 1.027                      | 68           |              | 1.716         |
| Other product types   | 252           | 2.142                      | 2.633        | 12           | 5.039         |
| <b>Total</b>          | <b>39.742</b> | <b>44.868</b>              | <b>2.869</b> | <b>29</b>    | <b>87.508</b> |
| <b>%</b>              | <b>45.42%</b> | <b>51.27%</b>              | <b>3.28%</b> | <b>0.03%</b> | <b>100%</b>   |

Table 31: Toxicity and other safer testing by test type purposes and severity

|                                              | Non-recovery  | Mild [up to and including] | Moderate      | Severe        | Total          |
|----------------------------------------------|---------------|----------------------------|---------------|---------------|----------------|
| Acute and sub-acute                          | 1             | 6.714                      | 3.351         | 5.309         | 14.375         |
| Skin irritation/corrosion                    |               | 661                        | 42            |               | 703            |
| Skin sensitisation                           |               | 8.574                      | 745           | 7             | 9.326          |
| Eye irritation/corrosion                     |               | 73                         | 148           |               | 221            |
| Repeated dose toxicity                       | 41            | 11.769                     | 6.929         | 372           | 19.111         |
| Carcinogenicity                              |               | 472                        | 206           | 10            | 688            |
| Genotoxicity                                 | 22            | 4.725                      | 194           | 83            | 5.024          |
| Reproductive toxicity                        | 54            | 15.565                     | 1.627         | 34            | 17.280         |
| Developmental toxicity                       |               | 17.969                     | 255           | 2.040         | 20.264         |
| Neurotoxicity                                |               | 401                        | 68            |               | 469            |
| Kinetics                                     | 1.454         | 26.258                     | 6.187         | 346           | 34.245         |
| Pharmaco-dynamics (incl safety pharmacology) | 7.775         | 48.528                     | 41.559        | 5.586         | 103.448        |
| Phototoxicity                                |               | 6.217                      | 84            |               | 84             |
| Ecotoxicity                                  | 2.989         | 22.763                     | 9.066         | 2.511         | 37.329         |
| Target animal safety                         | 85            | 9.937                      | 29            |               | 10.051         |
| Other toxicity/safety testing                | 2.026         | 3.182                      | 34            |               | 5.242          |
| <b>Total</b>                                 | <b>14.447</b> | <b>177.591</b>             | <b>69.524</b> | <b>16.298</b> | <b>277.860</b> |
| <b>%</b>                                     | <b>5.20%</b>  | <b>63.91%</b>              | <b>25.02%</b> | <b>5.87%</b>  | <b>100%</b>    |

Table 32: Repeated dose toxicity testing methods and severity

|               | Non-recovery | Mild [up to and including] | Moderate      | Severe       | Total         |
|---------------|--------------|----------------------------|---------------|--------------|---------------|
| up to 28 days | 41           | 8.125                      | 4.449         | 328          | 12.943        |
| 29 - 90 days  |              | 2.681                      | 1.733         | 41           | 4.455         |
| > 90 days     |              | 963                        | 747           | 3            | 1.713         |
| <b>Total</b>  | <b>41</b>    | <b>11.769</b>              | <b>6.929</b>  | <b>372</b>   | <b>19.111</b> |
| <b>%</b>      | <b>0.21%</b> | <b>61.58%</b>              | <b>36.26%</b> | <b>1.95%</b> | <b>100%</b>   |

Table 33: Acute and subacute toxicity testing methods and severity

|                      | Non-recovery | Mild [up to and including] | Moderate      | Severe        | Total         |
|----------------------|--------------|----------------------------|---------------|---------------|---------------|
| LD50, LC50           |              | 911                        | 1270          | 4.980         | 7.161         |
| Other lethal methods |              | 369                        |               | 231           | 600           |
| Non lethal methods   | 1            | 5434                       | 1.081         | 98            | 6.614         |
| <b>Total</b>         | <b>1</b>     | <b>6.714</b>               | <b>2.351</b>  | <b>5.309</b>  | <b>14.375</b> |
| <b>%</b>             | <b>0.01%</b> | <b>46.27%</b>              | <b>16.35%</b> | <b>36.93%</b> | <b>100%</b>   |

Table 34: Ecotoxicity testing methods and severity

|                          | Non-recovery | Mild [up to and including] | Moderate      | Severe       | Total         |
|--------------------------|--------------|----------------------------|---------------|--------------|---------------|
| Acute toxicity           | 854          | 3.536                      | 381           | 2.021        | 6.792         |
| Chronic toxicity         | 1.460        | 5.384                      | 84            | 470          | 7.398         |
| Reproductive ecotoxicity |              | 3.886                      |               |              | 3.886         |
| Endocrine activity       |              | 2.206                      | 8.496         |              | 10.702        |
| Bioaccumulation          | 100          | 1.498                      | 105           | 20           | 1.723         |
| Other ecotoxicity        | 575          | 6.253                      |               |              | 6.828         |
| <b>Total</b>             | <b>2.989</b> | <b>22.763</b>              | <b>9.066</b>  | <b>2.511</b> | <b>37.329</b> |
| <b>%</b>                 | <b>8.01%</b> | <b>60.98%</b>              | <b>24.29%</b> | <b>6.73%</b> | <b>100%</b>   |

## 9. Purposes and testing by type of legislation

Table 35: Regulatory use and routine production purposes: type of legislation

|                                                                                                                     | Quality control<br>(incl batch safety<br>and potency<br>testing) | Other efficacy<br>and tolerance<br>testing | Toxicity and<br>other safety<br>testing includ-<br>ing pharma-<br>cology | Routine pro-<br>duction | Total          | %           |
|---------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------------------------------|--------------------------------------------------------------------------|-------------------------|----------------|-------------|
| Legislation on<br>medicinal prod-<br>ucts for human<br>use                                                          | 203.652                                                          | 57.134                                     | 167.288                                                                  | 38.755                  | 466.829        | 70.14%      |
| Legislation on<br>medicinal prod-<br>ucts for veterinary<br>use and their resi-<br>dues                             | 20.667                                                           | 12.377                                     | 9.277                                                                    | 86                      | 42.407         | 6.37%       |
| Medical devices<br>legislation                                                                                      | 1.722                                                            | 245                                        | 8.345                                                                    | 43.716                  | 54.028         | 8.12%       |
| Industrial chemi-<br>cals legislation                                                                               |                                                                  |                                            | 35.293                                                                   |                         | 35.293         | 5.30%       |
| Plant protection<br>product legislation                                                                             |                                                                  |                                            | 54.713                                                                   | 478                     | 55.191         | 8.29%       |
| Biocides legislati-<br>on                                                                                           |                                                                  | 553                                        | 166                                                                      | 141                     | 860            | 0.13%       |
| Food legislation<br>including food<br>contact material                                                              |                                                                  |                                            | 48                                                                       | 16                      | 64             | 0.01%       |
| Feed legislation<br>including legisla-<br>tion for the safety<br>of target animals,<br>workers and envi-<br>ronment | 20                                                               | 2.465                                      | 281                                                                      |                         | 2.766          | 0.42%       |
| Other legislation                                                                                                   | 488                                                              | 837                                        | 2.449                                                                    | 4.316                   | 8.090          | 1.22%       |
| <b>Total</b>                                                                                                        | <b>226.549</b>                                                   | <b>73.611</b>                              | <b>277.860</b>                                                           | <b>87.508</b>           | <b>665.528</b> | <b>100%</b> |

Table 36: Quality control purposes: type of legislation

|                                                                                                  | Batch potency testing | Batch safety testing | Other quality controls | Pyrogenicity testing | Total          |
|--------------------------------------------------------------------------------------------------|-----------------------|----------------------|------------------------|----------------------|----------------|
| Legislation on medicinal products for human use                                                  | 175.824               | 22.561               | 9                      | 5.258                | 203.652        |
| Legislation on medicinal products for veterinary use and their residues                          | 15.441                | 4.917                |                        | 309                  | 20.667         |
| Medical devices legislation                                                                      |                       |                      | 30                     | 1.692                | 1.722          |
| Plant protection product legislation                                                             |                       |                      |                        |                      |                |
| Feed legislation including legislation for the safety of target animals, workers and environment |                       |                      | 20                     |                      | 20             |
| Other legislation                                                                                |                       | 476                  | 12                     |                      | 488            |
| <b>Total</b>                                                                                     | <b>191.265</b>        | <b>27.954</b>        | <b>71</b>              | <b>7.259</b>         | <b>226.549</b> |

Table 37: Routine production purposes: type of legislation

|                                                                         | Blood based products | Monoclonal antibodies | Other product types | Total         |
|-------------------------------------------------------------------------|----------------------|-----------------------|---------------------|---------------|
| Legislation on medicinal products for human use                         | 38.475               |                       | 280                 | 38.755        |
| Legislation on medicinal products for veterinary use and their residues |                      | 3                     | 83                  | 86            |
| Medical devices legislation                                             | 40.880               | 110                   | 2.726               | 43.716        |
| Plant protection product legislation                                    |                      |                       | 478                 | 478           |
| Biocides legislation                                                    |                      |                       | 141                 | 141           |
| Food legislation including food contact material                        | 16                   |                       |                     | 16            |
| Other legislation                                                       | 1.382                | 1.603                 | 1.331               | 4.316         |
| <b>Total</b>                                                            | <b>80.753</b>        | <b>1.716</b>          | <b>5.039</b>        | <b>87.508</b> |

Table 38: Toxicity and other safety testing by test type purposes: type of legislation

|                                              | Legislation on medicinal products for human use | Legislation on medicinal products for veterinary use and their residues | Medical devices legislation | Industrial chemicals legislation | Plant protection product legislation | Biocides legislation | Food legislation including food contact material | Feed legislation including legislation for the safety of target animals, workers and environment | Other legislation | Total          |
|----------------------------------------------|-------------------------------------------------|-------------------------------------------------------------------------|-----------------------------|----------------------------------|--------------------------------------|----------------------|--------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------|----------------|
| Acute and sub-acute                          | 2.262                                           | 1.911                                                                   | 3.175                       | 2.741                            | 3.954                                |                      | 48                                               |                                                                                                  | 284               | 14.375         |
| Skin irritation/corrosion                    |                                                 |                                                                         | 462                         | 205                              | 36                                   |                      |                                                  |                                                                                                  |                   | 703            |
| Skin sensitisation                           | 383                                             | 6                                                                       | 3.859                       | 4.588                            | 480                                  |                      |                                                  |                                                                                                  | 10                | 9.326          |
| Eye irritation/corrosion                     | 1                                               |                                                                         | 30                          | 151                              | 39                                   |                      |                                                  |                                                                                                  |                   | 221            |
| Repeated dose toxicity                       | 13.806                                          | 173                                                                     | 111                         | 2.489                            | 2.532                                |                      |                                                  |                                                                                                  |                   | 19.111         |
| Carcinogenicity                              | 93                                              |                                                                         | 195                         |                                  | 400                                  |                      |                                                  |                                                                                                  |                   | 688            |
| Genotoxicity                                 | 1.485                                           |                                                                         | 365                         | 1.522                            | 1.632                                |                      |                                                  |                                                                                                  | 20                | 5.024          |
| Reproductive toxicity                        | 2.413                                           | 684                                                                     |                             | 8.843                            | 5.340                                |                      |                                                  |                                                                                                  |                   | 17.280         |
| Developmental toxicity                       | 268                                             | 560                                                                     |                             | 9.729                            | 9.707                                |                      |                                                  |                                                                                                  |                   | 20.264         |
| Neurotoxicity                                | 126                                             |                                                                         |                             | 95                               | 248                                  |                      |                                                  |                                                                                                  |                   | 469            |
| Kinetics                                     | 31.453                                          | 2.123                                                                   |                             | 8                                | 661                                  |                      |                                                  |                                                                                                  |                   | 34.245         |
| Pharmaco-dynamics (incl safety pharmacology) | 101.924                                         | 1.395                                                                   |                             |                                  |                                      |                      |                                                  |                                                                                                  | 129               | 103.448        |
| Phototoxicity                                | 84                                              |                                                                         |                             |                                  |                                      |                      |                                                  |                                                                                                  |                   | 84             |
| Ecotoxicity                                  | 10.608                                          | 2.200                                                                   |                             | 4.922                            | 18.450                               | 166                  |                                                  | 196                                                                                              | 787               | 37.329         |
| Target animal safety                         |                                                 | 201                                                                     |                             |                                  | 9.510                                |                      |                                                  | 85                                                                                               | 255               | 10.051         |
| Other toxicity/safety testing                | 2.382                                           | 24                                                                      | 148                         |                                  | 1.724                                |                      |                                                  |                                                                                                  | 964               | 5.242          |
| <b>Total</b>                                 | <b>168.288</b>                                  | <b>9.277</b>                                                            | <b>8.345</b>                | <b>35.293</b>                    | <b>54.713</b>                        | <b>166</b>           | <b>48</b>                                        | <b>281</b>                                                                                       | <b>2.449</b>      | <b>277.860</b> |

**Table 39: Repeated dose toxicity purposes: type of legislation**

|                                                                         | up to 28 days | 29 - 90 days | > 90 days    | Total         |
|-------------------------------------------------------------------------|---------------|--------------|--------------|---------------|
| Legislation on medicinal products for human use                         | 9.106         | 3.124        | 1.576        | <b>13.806</b> |
| Legislation on medicinal products for veterinary use and their residues | 173           |              |              | <b>173</b>    |
| Medical devices legislation                                             | 54            | 57           |              | <b>111</b>    |
| Industrial chemicals legislation                                        | 1.668         | 724          | 97           | <b>2.489</b>  |
| Plant protection product legislation                                    | 1.942         | 550          | 40           | <b>2.532</b>  |
| <b>Total</b>                                                            | <b>12.943</b> | <b>4.455</b> | <b>1.713</b> | <b>19.111</b> |

**Table 40: Acute and subacute toxicity testing methods: type of legislation**

|                                                                         | LD50, LC50   | Other lethal methods | Non lethal methods | Total         |
|-------------------------------------------------------------------------|--------------|----------------------|--------------------|---------------|
| Legislation on medicinal products for human use                         | 193          | 15                   | 2.054              | <b>2.262</b>  |
| Legislation on medicinal products for veterinary use and their residues | 1.843        | 48                   | 20                 | <b>1.911</b>  |
| Medical devices legislation                                             |              |                      | 3.175              | <b>3.175</b>  |
| Industrial chemicals legislation                                        | 1.878        |                      | 863                | <b>2.741</b>  |
| Plant protection product legislation                                    | 3.055        | 489                  | 410                | <b>3.954</b>  |
| Food legislation including food contact material                        |              | 48                   |                    | <b>48</b>     |
| Other legislation                                                       | 192          |                      | 92                 | <b>284</b>    |
| <b>Total</b>                                                            | <b>7.161</b> | <b>600</b>           | <b>6.614</b>       | <b>14.375</b> |

**Table 41: Ecotoxicity purposes: type of legislation**

|                                                                                                  | Acute toxicity | Chronic toxicity | Reproductive ecotoxicity | Endocrine activity | Bioaccumulation | Other ecotoxicity | Total         |
|--------------------------------------------------------------------------------------------------|----------------|------------------|--------------------------|--------------------|-----------------|-------------------|---------------|
| Legislation on medicinal products for human use                                                  | 72             | 1.829            |                          | 8.400              | 172             | 135               | <b>10.473</b> |
| Legislation on medicinal products for veterinary use and their residues                          | 110            | 1.610            |                          |                    | 480             |                   | <b>2.200</b>  |
| Industrial chemicals legislation                                                                 | 1.274          | 1.819            | 509                      | 800                | 80              | 440               | <b>4.922</b>  |
| Plant protection product legislation                                                             | 4.218          | 2.140            | 3.377                    | 1.502              | 971             | 6.242             | <b>18.450</b> |
| Biocides legislation                                                                             | 166            |                  |                          |                    |                 |                   | <b>166</b>    |
| Feed legislation including legislation for the safety of target animals, workers and environment | 196            |                  |                          |                    |                 |                   | <b>196</b>    |
| Other legislation                                                                                | 756            |                  |                          |                    | 20              | 11                | <b>787</b>    |
| <b>Total</b>                                                                                     | <b>6.792</b>   | <b>7.398</b>     | <b>3.886</b>             | <b>10.702</b>      | <b>1.723</b>    | <b>6.828</b>      | <b>37.329</b> |

## 10. Purposes and origin of legislative requirement

Table 42: Regulatory use and routine production: origin of legislative requirement

|                                                                                  | Quality control<br>(incl batch safety<br>and potency test-<br>ing) | Other efficacy<br>and tolerance<br>testing | Toxicity and<br>other safety<br>testing<br>including phar-<br>macology | Routine<br>production | Total          |
|----------------------------------------------------------------------------------|--------------------------------------------------------------------|--------------------------------------------|------------------------------------------------------------------------|-----------------------|----------------|
| Legislation<br>satisfying EU<br>requirements                                     | 212.912                                                            | 54.447                                     | 276.399                                                                | 85.979                | 629.737        |
| Legislation<br>satisfying na-<br>tional re-<br>quirements<br>only<br>[within EU] | 75                                                                 | 19.138                                     | 1.180                                                                  | 1.529                 | 21.922         |
| Legislation<br>satisfying Non-<br>EU require-<br>ments only                      | 13.562                                                             | 26                                         | 281                                                                    |                       | 13.869         |
| <b>Total</b>                                                                     | <b>226.549</b>                                                     | <b>73.611</b>                              | <b>277.860</b>                                                         | <b>87.508</b>         | <b>665.528</b> |

Table 43: Toxicity and other safety testing: origin of legislative requirement

|                                                      | Legislation satisfying<br>EU requirements | Legislation satisfying<br>national requirements<br>only [within EU] | Legislation satisfying<br>Non-EU requirements<br>only | Total          |
|------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------|----------------|
| Acute and sub-acute                                  | 14.219                                    | 150                                                                 | 6                                                     | 14.375         |
| Skin irritation/corrosion                            | 703                                       |                                                                     |                                                       | 703            |
| Skin sensitisation                                   | 9.316                                     | 10                                                                  |                                                       | 9.326          |
| Eye irritation/corrosion                             | 219                                       |                                                                     | 2                                                     | 221            |
| Repeated dose toxicity                               | 19.111                                    |                                                                     |                                                       | 19.111         |
| Carcinogenicity                                      | 688                                       |                                                                     |                                                       | 688            |
| Genotoxicity                                         | 5.024                                     |                                                                     |                                                       | 5.024          |
| Reproductive toxicity                                | 17.280                                    |                                                                     |                                                       | 17.280         |
| Developmental toxicity                               | 20.264                                    |                                                                     |                                                       | 20.264         |
| Neurotoxicity                                        | 469                                       |                                                                     |                                                       | 469            |
| Kinetics                                             | 34.220                                    | 25                                                                  |                                                       | 34.245         |
| Pharmaco-dynamics<br>(incl safety pharmacol-<br>ogy) | 103.448                                   |                                                                     |                                                       | 103.448        |
| Phototoxicity                                        | 84                                        |                                                                     |                                                       | 84             |
| Ecotoxicity                                          | 36.346                                    | 710                                                                 | 273                                                   | 37.326         |
| Target animal safety                                 | 9.776                                     | 275                                                                 |                                                       | 10.051         |
| Other toxicity/safety<br>testing                     | 5.232                                     | 10                                                                  |                                                       | 5.242          |
| <b>Total</b>                                         | <b>276.399</b>                            | <b>1.180</b>                                                        | <b>281</b>                                            | <b>277.860</b> |

Table 44: Repeated dose toxicity: origin of legislative requirement

|                                                               | up to 28 days | 29 - 90 days | > 90 days    | Total         |
|---------------------------------------------------------------|---------------|--------------|--------------|---------------|
| Legislation satisfying EU requirements                        | 12.943        | 4.455        | 1.713        | <b>19.111</b> |
| Legislation satisfying national requirements only [within EU] |               |              |              |               |
| Legislation satisfying Non-EU requirements only               |               |              |              |               |
| <b>Total</b>                                                  | <b>12.943</b> | <b>4.455</b> | <b>1.713</b> | <b>19.111</b> |

Table 45: Acute and subacute toxicity testing: origin of legislative requirement

|                                                               | LD50, LC50   | Other lethal methods | Non lethal methods | Total         |
|---------------------------------------------------------------|--------------|----------------------|--------------------|---------------|
| Legislation satisfying EU requirements                        | 7.161        | 552                  | 6.506              | <b>14.219</b> |
| Legislation satisfying national requirements only [within EU] |              | 48                   | 102                | <b>150</b>    |
| Legislation satisfying Non-EU requirements only               |              |                      | 6                  | <b>6</b>      |
| <b>Total</b>                                                  | <b>7.161</b> | <b>600</b>           | <b>6.614</b>       | <b>14.375</b> |

Table 46: Ecotoxicity testing: origin of legislative requirement

|                                                               | Acute toxicity | Chronic toxicity | Endocrine activity | Bioaccumulation | Other ecotoxicity | Total         |
|---------------------------------------------------------------|----------------|------------------|--------------------|-----------------|-------------------|---------------|
| Legislation satisfying EU requirements                        | 5.840          | 7.398            | 10.702             | 1.703           | 6.817             | <b>32.460</b> |
| Legislation satisfying national requirements only [within EU] | 679            |                  |                    | 20              | 11                | <b>710</b>    |
| Legislation satisfying Non-EU requirements only               | 273            |                  |                    |                 |                   | <b>273</b>    |
| <b>Total</b>                                                  | <b>6.792</b>   | <b>7.398</b>     | <b>10.702</b>      | <b>1.723</b>    | <b>6.828</b>      | <b>33.443</b> |

Table 47: Animals used under § 7 (2) and § 4 (3) of the Animal Protection Act by species

|                                                       | Animals used under § 7 (2)<br>Animal Protection Act | Animals used under § 4 (3)<br>Animal Protection Act | Total            |
|-------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|------------------|
| Mice                                                  | 1.263.519                                           | 638.466                                             | 1.901.985        |
| Rats                                                  | 296.662                                             | 65.868                                              | 362.530          |
| Guinea-Pigs                                           | 19.612                                              | 964                                                 | 20.576           |
| Hamsters (Syrian)                                     | 1.521                                               | 111                                                 | 1.632            |
| Hamsters (Chinese)                                    | 24                                                  |                                                     | 24               |
| Mongolian gerbil                                      | 4.187                                               | 633                                                 | 4.820            |
| Other Rodents                                         | 22.525                                              | 526                                                 | 23.051           |
| Rabbits                                               | 105.336                                             | 448                                                 | 105.784          |
| Cats                                                  | 997                                                 |                                                     | 997              |
| Dogs                                                  | 4.627                                               | 9                                                   | 4.636            |
| Ferrets                                               | 155                                                 | 4                                                   | 159              |
| Other carnivores                                      | 414                                                 |                                                     | 414              |
| Horses, donkeys & cross-breeds                        | 732                                                 | 49                                                  | 781              |
| Pigs                                                  | 13.070                                              | 1.304                                               | 14.374           |
| Goats                                                 | 700                                                 | 49                                                  | 749              |
| Sheep                                                 | 1.899                                               | 38                                                  | 1.937            |
| Cattle                                                | 4.398                                               | 10                                                  | 4.408            |
| Prosimians                                            | 148                                                 |                                                     | 148              |
| Marmoset and tamarins                                 | 318                                                 | 7                                                   | 325              |
| Cynomolgus monkey                                     | 2.219                                               | 12                                                  | 2.231            |
| Rhesus monkey                                         | 128                                                 |                                                     | 128              |
| Vervets Chlorocebus spp.                              | 5                                                   |                                                     | 5                |
| Baboons                                               | 2                                                   |                                                     | 2                |
| Other species of Old World Monkeys (Cercopithecoidea) | 3                                                   |                                                     | 3                |
| Other Mammals                                         | 1.572                                               | 116                                                 | 1.688            |
| Domestic fowl                                         | 20.463                                              | 14.539                                              | 35.002           |
| Other birds                                           | 19.969                                              | 726                                                 | 20.695           |
| Reptiles                                              | 883                                                 | 137                                                 | 1.020            |
| Rana                                                  | 12                                                  | 19                                                  | 31               |
| Xenopus                                               | 5.918                                               | 4.059                                               | 9.977            |
| Other Amphibians                                      | 4.263                                               | 1.100                                               | 5.363            |
| Zebra fish                                            | 87.789                                              | 39.009                                              | 126.798          |
| Other Fish                                            | 688.022                                             | 21.705                                              | 709.727          |
| Cephalopods                                           | 45                                                  | 18                                                  | 63               |
| <b>Total</b>                                          | <b>2.572.137</b>                                    | <b>789.926</b>                                      | <b>3.362.063</b> |

Table 48: Animals used under § 7 (2) and § 4 (3) of the Animal Protection Act by purpose

|                                                                                                            | Animals used under § 7 (2) | %           | Animals used under § 4 (3) | %           | Total           |             |
|------------------------------------------------------------------------------------------------------------|----------------------------|-------------|----------------------------|-------------|-----------------|-------------|
| Basic Research                                                                                             | 1.408.358                  | 54.57%      | 703.831                    | 89.10%      | 2.112.189       | 62.82%      |
| Translational and applied research                                                                         | 357.180                    | 13.89%      | 69.786                     | 8.83%       | 426.966         | 12.70%      |
| Regulatory use and Routine production                                                                      | 663.274                    | 25.79%      | 2.254                      | 0.29%       | 665.528         | 19.80%      |
| Protection of the natural environment in the interests of the health or welfare of human beings or animals | 6.958                      | 0.27%       | 20                         | 0.01%       | 6.978           | 0.21%       |
| Preservation of species                                                                                    | 8.861                      | 0.34%       | 2.755                      | 0.34%       | 11.616          | 0.35%       |
| Higher education or training for the acquisition, maintenance or improvement of vocational skills          | 50.288                     | 1.96%       | 5.946                      | 0.74%       | 56.234          | 1.66%       |
| Forensic enquiries                                                                                         |                            |             | 31                         | 0.01%       | 31              | 0.01%       |
| Maintenance of colonies of established genetically altered animals, not used in other procedures           | 77.218                     | 3.00%       | 5.303                      | 0.68%       | 82.521          | 2.45%       |
| <b>Total</b>                                                                                               | <b>2.572.137</b>           | <b>100%</b> | <b>789.926</b>             | <b>100%</b> | <b>3.362.63</b> | <b>100%</b> |

Table 49: Animals used under § 7 (2) and § 4 (3) of the Animal Protection Act by genetic status

|                                                 | Animals used under § 7 (2)<br>Animal Protection Act | Animals used under § 4 (3)<br>Animal Protection Act | Total            |             |
|-------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|------------------|-------------|
| Not genetically altered                         | 1.407.557 <sup>4</sup>                              | 419.538                                             | 1.827.095        | 65%         |
| Genetically altered without a harmful phenotype | 537.581                                             | 336.836                                             | 874.417          | 31%         |
| Genetically altered with a harmful phenotype    | 63.399                                              | 33.552                                              | 96.951           | 3%          |
| <b>Total</b>                                    | <b>2.008.537</b>                                    | <b>789.926</b>                                      | <b>2.798.463</b> | <b>100%</b> |

<sup>4</sup> Excludes 563.300 fish larvae

Table 50: Animals used under § 7 (2) and § 4 (3) of the Animal Protection Act by severity

|                            | Animals used under § 7 (2)<br>Animal Protection Act | Animals used under § 4 (3)<br>Animal Protection Act | Total            |             |
|----------------------------|-----------------------------------------------------|-----------------------------------------------------|------------------|-------------|
| Non-recovery               | 271.881                                             | 789.926                                             | <b>1.061.807</b> | <b>32%</b>  |
| Mild [up to and including] | 1.759.160                                           |                                                     | <b>1.759.160</b> | <b>52%</b>  |
| Moderate                   | 416.499                                             |                                                     | <b>416.499</b>   | <b>12%</b>  |
| Severe                     | 124.597                                             |                                                     | <b>124.597</b>   | <b>4%</b>   |
| <b>Total</b>               | <b>2.572.137</b>                                    | <b>789.926</b>                                      | <b>3.362.063</b> | <b>100%</b> |