

MEMBER STATE NARRATIVE

Member State: Slovak republic

Year:2018

1. General information on any changes in trends observed since the previous reporting period. 1.

Increased number of animals used in the projects was also caused by the fact that more approved establishments of the users have merged into larger law organizations, e.g. to the Biomedical Center SAS Bratislava, the Centre of Bioscience SAS or Centre of Experimental Science SAS Bratislava. Therefore, the possibilities of performance of the projects have raised. In 2018, more establishments started to use more actively 2 large new establishments serving as complexes for the users, e.g. Central Animal establishment of the Pavilion of Medical Science Bratislava and Establishment for Immunodeficient Mice. By merging more approved user establishments into one organization several originally approved user establishments have lost their legal subjectivity and became only organizational units of the given subject. This is also the reason of decreased number of approved user establishments in comparison to the previous years. The number of approved projects for 2018 has decreased due to the legislative requirements regarding length of approval of the project, which has raised up to 5 years, since 2013. This has caused decrease of the number of new applications because the users already had projects approved for quite a long time of 5 years. Nevertheless, increased number of animals used in the projects has been recorded of approved user establishments approved since 2017 could fully perform the projects. These establishments have been undergone reconstruction changes, they were in a transitional period to reach 1 January 2017 for harmonization of Annex III of the Directive No.: 2010/63/EU./

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

The number of animals used in regulated project performed for the purpose of control of effectiveness and safety of chemical substances, medical products has increased significantly up to 27,44% of the total number of used animals in comparison to 2017. Multiple orders for performance of these projects were from the foreign sponsors. In 2018, the number of user establishments, performing also regulated projects, related to orders from the foreign sponsors, increased. In the Slovak Republic, the most of animals are used in the area of basic research (up to 64,60% of the total number of animals).

3. Information on any changes in trends in actual severities and analysis of the reasons thereof. 3.

In comparison to 2017, the number of projects classified as "mild" decreased to 21,46 % of the overall number from 2017, when the projects with mild severity used 33,21% of overall

number of used animals. At the same time, the percentage of animals used in projects classified as “moderate” represented 68,02% of the overall number compared to 2017. That year, the number of animals used in projects classified as moderate was 57,47% of overall number of used animals. The reason is , that several projects in 2018 have got the purpose of the project in the area of nervous system research and urogenital system research. In several cases, the animals are subject to pathological changes in health, paying maximum attention to 3R, analgesia and human endpoint. The percentage of animals used in projects classified as “severe” increased to 7,82 % from the total number. In 2017, in severe projects only 2,27 % of the total number of animals was used. Based on the retrospective assessments and mainly regulated projects it was found that some regulated projects after their performance were classified as severe, what increased the percentage of animals used in the severe projects.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

In SK, high efforts are being made to the submission of applications for approval of the project, where the applicant must describe in details steps 3R, human end point and used analgesia and anaesthesia, apart from the other requirements. High attention is paid to 3R principles, human endpoint and searching of alternative methods at each training of the users, breeders and suppliers.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

The common animal species for performance of the projects are used in SK; only in “other birds” category one approved user establishment is using species *Taeniopygia guttata* and *Lonchura striata domestica*.

6. Details on cases where the 'severe' classification is exceeded, whether pre-authorized or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

In SK no cases of exceeding the “severe” classification in projects was reported in 2018. This is not even possible that such a case would occurs. Rather the contrary, several projects classified as “severe”, after retrospective assessment have got the actual severity “moderate” or “mild”. All projects are authorized by the Decision, where the exact process of execution of the project is described in details and classification of severity of each procedure performed on the animal and its consequences. In case of execution of the project wilfully outside the

approved methodology, the user would be punished by a financial fine, cancellation of the project or by other repressive means according to the type of violation of the law