Moving away from regulatory animal experiments?

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The authorisation of substances is subject to various regulatory and legal requirements, which fall outside of the legislation on animal welfare. Examples in Switzerland are the Therapeutic Products Licensing Requirements Ordinance (TPLRO; SR 812.212.22) and the Plant Protection Products Ordinance (PlantPPO; SR 916.161). In isolated cases, regulatory requirements take account of animal welfare. For example, Art. 7 PlantPPO states that for every experiment or trial that involves vertebrate animals, evidence of the measures taken to avoid animal experiments and duplicated experiments on vertebrate animals must be supplied. According to REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), experiments on vertebrate animals should only be conducted as a last resort to meet the information requirements for the registration.

Under Art. 3 Animal Welfare Act (AniWA; SR 455) an animal experiment is any procedure in which a live animal is used for a number of purposes, including testing a substance. Regulatory animal experiments are therefore subject to the authorisation requirement set out in the AniWA. In the animal experimentation statistics compiled by the Federal Food Safety and Veterinary Office (SFVO), regulatory animal experiments are understood to be all animal experiments that relate to procedures required by law. Regulatory toxicological tests (protection of humans, animals and the environment through toxicological or other safety tests for substances; field of application 5 in the SFVO's explanatory notes to form A) constitute a sub-category of experiments relating to procedures required by law.

How is regulatory animal testing evolving in Switzerland?

The number of animals used in regulatory animal experiments (Figure 1) has decreased by over 50% in the last ten years, and by around 40% since 1997. Toxicological tests (in the strict sense; area of application 5 in the SFVO's explanatory notes to form A) have used around 80% fewer animals since 2010. The number of animals used in regulatory animal experiments has therefore declined more sharply than for total animal experiments.

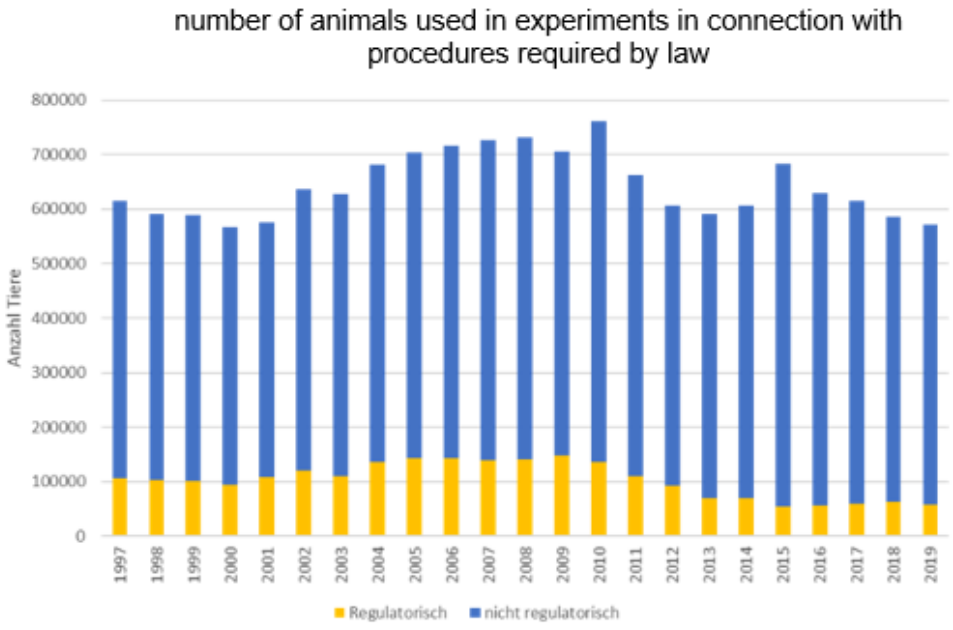

Figure 1: Evolution of all animal experiments that relate to procedures required by law

The most frequently used animals in regulatory experiments are rats (approx. 30,000 animals/year), followed by mice (approx. 20,000 animals/year). The number of fishes used (approx. 5,000 animals per year) has risen in recent years. Animal species that were previously used more frequently – such as guinea pigs, rabbits and dogs – saw a sharp decline up to 2019. For example, certain safety tests, such as the pyrogen test and the dermal irritation and corrosion test on rabbits were no longer conducted in the most recent animal experimentation statistics in 2019.

The percentage of animals used in regulatory animal experiments with moderate constraint (SG2) to severe constraint (SG3) has fallen in both absolute and relative terms in the last twenty years. In the last ten years, the percentage of animals used in SG2 and SG3 combined was between 10% and 15%. In other words, in animal experiments related to procedures required by law, the trend runs counter to that of all animal experiments, which have seen an increase in SG2 and SG3 experiments in recent years (2019: around +30%).

What next for regulatory animal experiments? All 3Rs is the goal!

Under the applicable legislation on animal welfare, the indispensable minimum must be considered in the authorisation procedure and when conducting animal experiments. Accordingly, applicants must demonstrate that there is no alternative to the animal experiment (Art. 137 para. 2 Animal Welfare Ordinance; AniWO, SR 455.1). In addition, efforts must be made to keep the number of animals used to the necessary minimum and to minimise the distress they experience (Art. 137 para. 4 AniWO). From this follows a legal mandate to implement the 3Rs – replace, reduce and refine – and this also applies to regulatory testing.

3R development is primarily influenced by legal and regulatory principles, which depend, among other things, on risk management in relation to ‘dangerous’ substances in Switzerland and worldwide. The public interest also plays a role here, as political initiatives can change the framework conditions, including legislation on animal welfare. The adjustment of test guidelines shows through the REACH example that alternative methods (e.g. in vivo skin sensitisation) can be promoted and are effective. To promote alternatives, 3R research also has to be supported. Alternatives and adjustments have also emerged in recent years through read across, data waiving, weight of evidence and QSAR. It is clear that methods that have to draw on existing data are heavily dependent on the availability and quality of the data. A great deal of impact could be achieved in this area and corresponding efforts must continue. If nothing else, the impact of the 3Rs also depends on how they are implemented in the authorisation and approval procedures, and in animal experiments (e.g. endpoint criteria).

There has been a decline in the number of animals used in regulatory testing in Switzerland in recent years. How the situation evolves will depend heavily on the above developments in the field of the 3Rs.