

A MISSED OPPORTUNITY

By Mojca Drcar Murko, former Member of the European Parliament

The debate on the Commission draft directive covering the protection of animals used for scientific purposes in the European Parliament's committees in 2009 revealed to full extent the traditional legal and ethical conflict that surrounds animal experimentation. It also signalled the powerful position of the pharmaceutical industry as well as of the part of the academia that resisted to any meaningful change of the status quo. The harshness of vocabulary used by the animal research industry ("violation of the freedom of science") and almost ridiculous emotional pressure towards the deputies ("children will die if this directive is going to be approved") created an atmosphere in which arguments of the supporters of the proposal were easily overheard, and later outnumbered by perfectly organized voting machine claiming for "science-friendliness".

This was the state of affairs at the end of the legislative mandate of the 6th parliament. Considering the compromise reached between representatives of the European Commission, the European Parliament and the Council on 7 April 2010, nothing much has changed since then. The text of the compromise still must be ratified by the parliament and Council, but it is likely to happen without further debate.

If this is a final version of the directive after a decade of debates the compromise is a missed opportunity. It fails to inspire the science and move it forward for ethical treatment of animals across the whole EU, which was one of the main goals of the revision of the old directive (1986). It brings some improvements (such as minimum cage size for research animals), but allows so many exemptions that it seriously hampers the attempts for advances in lab-animal protection, which were designed in the previous drafts of the directive.

As the supporters of a meaningful progress we did not demand stopping all animal experiments, but we welcomed more stringent regulations along the lines of the internationally accepted principles of humane experimental techniques and good science. Good progress has been made in animal protection since 1986, particularly with regard to the introduction of 3Rs principles (reduction, replacement and refinement of the testing methods) and new applications of

animals in the area of genetic engineering made the revision of the directive from 1986 an urgent matter.

The attempts of modernizing the old directive were based on the tighter controlled experimentation and on phasing out of unnecessary experiments. We might sooner combine currently irreplaceable animal experiments with a range of multidisciplinary, sophisticated techniques that already allow the safe and accurate examination of potential medicines on humans (particularly on the brain). The results could be then quicker, cheaper and scientifically superior. The molecular-, computing- and imaging revolutions have already rendered many hitherto essential testing and manufacturing techniques obsolete. It is common knowledge that the primates, our closest relatives, are inaccurate predictor of human responses to medicines.

The quest for replacing the lab-animal tests with existing validated non-animal testing methods is based on both humane and scientific grounds. Not just animal defenders, a part of the academia too, researching into development of alternatives, supports tighter controls which would eventually phase out pointless models using lab-animals (mostly in basic science) or ban outdated tests (in applied science).

Many European states lack any proper system of authorization of animal use or ethical review, stricter authorization procedure for the use of animals is therefore reasonable attempt in the process of harmonizing European legislation. It is quite possible that in absence of the ethical urge for balancing of the experiments with the aims of the experimentation, people are developing certain models, which have nothing to do with finding cures for diseases, just because they can.

The difference between supporters of a meaningful progress and defenders of the status quo can be seen in the ways of thinking. Whilst the supporters acknowledged the efforts made by the industry since 1986 they also knew from experience that the legislator can accelerate the efforts for replacement with non-animal alternatives. Good legal drafting is essential for moving forward.

Lack of substance of the compromise reached on April 7 can easily be covered by the rhetoric, which is evidenced in many hitherto published opinions.

Whilst a written declaration claiming for legislative framework for replacement for the use of apes and wild-caught monkeys in scientific experiments with

alternatives has been signed in 2009 by more than the half of the European deputies, this has not been properly transposed into the directive. In this respect biomedical scientists now say that the new directive 'averts feared disaster for research'. Why? 'Planned significant restrictions on invasive studies using primates were abandoned. There are almost no restrictions on the use of non-human primates.' (Nature 464/2010) 'Basic research using primates will be allowed'.

The biomedical scientific community is also pleased that the new legislation will not impose destruction of the animals after research procedures that cause 'moderate' pain as previous drafts of the directive had decreed. Ban on the duplicated use of animals, which the supporters considered as problem of decency in a civilized society, proved extremely controversial in the debate. The resulting compromise abandoned it. 'The animals can be used in other procedures' sounds economically sane, yet it means the right to cause repeated 'moderate' suffering to the same animal inclusive invasive surgery.

The directive does ban some forms of research – those involving great apes or causing extreme and prolonged pain – but researchers can appeal for an exemption, on grounds of clinical urgency. Numbers of unnecessary exemptions limit the scope of the revision. How 'long-lasting, severe pain' will be interpreted is not certain at all, given the big discrepancies between national legislations of the Member States.

If this is a final version of the directive experiments on endangered species will be allowed and researchers will continue to be able to use cats and dogs. Mandatory sharing of animal-research data, which has been proposed in order to restrict the number of animal experiments, has been dropped and the emphasis on the use of alternative methods is far from being strong enough to move industry or academia towards non-animal replacements.

The defenders of the status quo described the stricter authorization procedure as bureaucratic burden. The current interpretation of the compromise such as 'procedures for project applications and evaluations are more streamlined' and 'bureaucratic burden should not increase' mean that they have successfully resisted any meaningful transparency.

Some proposals for higher protection of animals in scientific experiments were result of changing testing methods and improved knowledge. Some are simply a question of human decency in a civilised society. Not every means used in

scientific research, even those causing great pain to the animals, is good science.
There is no higher goal that excuses the vivisection Albert Einstein put it quite
some time ago.