Brussels, 16 February 2015

Dear Member of the European Parliament, dear friend,

STOP VIVISECTION, a European Ctizens' Initiative (ECI), was born in 2012 out of a strong desire of EU citizens to reach a common ideal: the protection of life on our planet, now compromised by an ever more critical situation.

1) Rich but increasingly sick societies

In industrialized countries, with Europe and the US in the lead, the most serious diseases are rapidly increasing in incidence. Following are some examples, according to official sources (WHO, Eurostat, OECD, IARC, etc.).
The incidence of cancer in the EU population - in particular breast (**1**) and prostate (**2**) cancer - appears to have doubled, for some countries, in the last decades. A doubling is also seen in diabetes (**3**), as well as in autism (**4**). And while male fertility is getting closer to the threshold of infertility (**5**) (Eurostat), a major increase is also observed in the diagnosis of Alzheimer's (**6**). We do not currently possess effective treatments for these diseases, and if these trends should continue, the future of our species could be threatened in the coming decades.

2) Chemical substances pose a major risk

The "Paris Appeal", launched by oncologist Dominique Belpomme and two Nobel prize for medicine winners, Luc Montagnier and François Jacob, (plus nearly one hundred more international scientists), entitled "International Declaration on the Dangers of Chemical Pollution", begins with the statement "the human species is in danger". It was presented to UNESCO in 2004 (**7**) and urged the EU to start a preventive health policy and put an end to 50 years of legislative Wild West, in order to reduce the growing incidence of most serious diseases. These were attributed, by the scientists as well as by extensive scientific documentation (**8**), to the release of more than 100.000 potentially toxic chemicals, in common use, with which we come into daily contact, and for which no adequate safety requirements had ever been applied. Three years later, in 2007, the REACH regulation (Registration, Evaluation, Authorization and restriction of Chemicals) was launched after a long battle with the lobbies of the chemical industry, which succeeded in weakening nearly every article in the regulation. It was consequently decided to evaluate each new substance and 30.000 of those already on the market. An extraordinary investment in terms of financial and human resources, which still continues. Too bad that REACH, from its birth, was doomed to fail: all toxicity assessments were and still are, in 2015, almost exclusively based on animal toxicity tests.

3) The animal model has no value for the human species

It is well demonstrated that no animal species can be a biological model for another species. This is supported by peer reviewed scientific articles (**9**) and numerous relevant statistics. Following are just a few examples:

- the British Medical Journal stated that "if research conducted on animals continues to be unable to reasonably predict what can be expected in humans, the public's continuing endorsement and funding of preclinical animal research seems to be misplaced" (P. Pound, 30.5.2014) (**10**).
- Nature, the most famous scientific journal in the world, referred to animal testing as "simply bad science" (T. Hartung, 10.11. 2005) (**11**) and "nearly useless" (T. Hartung, 7.8.2008) (**12**).
- 92% of drugs that pass animal tests do not pass clinical trials on humans (**13**).
- Of the remainder, 51% resulted in severe adverse drug reactions previously not reported (**14**).
- 81% of serious adverse drug reactions are not revealed by animal testing (**15**).
- 75% of basic research is on animals (**16**) and leads to a clinically useful result in around 0,004% of the time (**17**).

It should also be noted that animal testing has never formally undergone the process of "validation", while strict validation protocols are rightly requested today for the approval of new toxicity testing methods. Despite this lack of validation, animal test data are still used as the "gold standard" for regulatory approvals of all these new methods.

4) Our request is: the replacement in the EU of animal research with modern scientific methods, based on data directly relevant for the human species

The current alarming state of human health has, as explained above, the burden of chemical substances as its main cause (around 300 industrial chemicals are present in the human body) and, in addition, the extensive use of an erroneous research method - animal experimentation - which makes it impossibile to reliably assess their toxicity.
Animal experimentation diverts research resources not only from curing human diseases, but also from preventing them, by slowing down the development of toxicity tests that could better inform on risks for humans. It therefore greatly increases the harm of chemical pollution. The "animal model" used in any research purported to provide knowledge about man should be banned and promptly replaced by evidence-based technologies, both for medical and toxicological research.
Many innovative methods are already available. These include, for example: organs-on-a-chip, multi-compartmental modular bioreactors [Quasi-Vivo®], integrated discrete multiple organ co-cultures [IdMOC], pharmacogenomics, toxicogenomics, advanced 3D in vitro and in silico methodologies, microarray, neuroimaging. microdosing, bioartificial organs, virtual organs, stem cells, mathematical models, and organoid culture systems (**18**). In the US, robotic systems provide huge savings in terms of time and cost, as well as far more reliable and relevant data, and are able to evaluate the combined effects of various toxic substances (**19**).

5) A paradigm shift has already begun in the USA

The National Academy of Sciences of the USA published, in 2007, a report entitled "Toxicity Testing in the 21st Century: a Vision and a Strategy" (**20**), announcing a revolution in toxicity assessment, that will abandon the animal model - long criticised for the unreliability and the unpredictability for humans - and instead use the potential of a modern research paradigm (especially in genetics and biology). The advent of this new paradigm has been referred to as "a scientific pivot point that opens the door to a new era". The report adds that "pivotal events in science include the discovery of penicillin, the elucidation of the DNA double helix, the development of computers. etc.".
A few months later, at the annual meeting of the AAAS (the renowned American Association for the Advancement of Science), the major control agencies of the USA (EPA, NIEHS, NHGRI) signed a Memorandum of Understanding for a series of cellular toxicology five-year projects that are still ongoing and that are providing results which previously were thought to be unattainable.

6) The new scientific paradigm should be applied in Europe, or else we will be left dangerously behind

For progress to happen in the EU and in order to keep up with the new scientific developments, the outdated and misleading practice of animal testing has to give way to modern methods, which utilize the outstanding achievements of science in the fields of genetics, molecular engineering, biochemistry, etc … As stated by Herman Koeter, former director EFSA (European Agency for Food Safety) in the press release issued at the closure of the "7th World Congress on animal experiments and alternative methods" (Rome, 2009), attended by hundreds of scientists around the world: "New technologies are able to collect an unprecedented amount of information on the possibile adverse effects caused by a substance to biological systems. They are also able to generate an amount of knowledge far greater than that to date we have been able to identify and understand. In the very near future we will consider the use of animals for experimental purposes very obsolete".

7) Dear Member of the European Parliament, it is essential that you participate in the "pivotal change" advocated by so many scientists

The European Citizens'Initiative "STOP VIVISECTION" calls for the EU to protect human health and the environment by following the scientific renewal initiated by the USA in research. It asks for a progressive but rapid change in all relevant laws and regulations that until now have relied on the use of animals as a "model " for the human species, As a Member of the European Parliament you have a say, and therefore a responsibility, in matters concerning human health. Please see to it that our initiative be quickly accepted within the European Parliament.
We also encourage you strongly to attend the next Public Hearing - that will soon be held in the European Parliament - at which the proposal made by STOP VIVISECTION will be discussed.
We will give prompt notice as soon as the date is set.

Yours sincerely, **The Promoting Committee of STOP VIVISECTION**

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