MR JYRKI KATAINEN
VICE-PRESIDENT OF THE EUROPEAN COMMISSION
RUE DE LA LOI, 200
B-1049 BRUSSELS

Date 17 February 2016.

Dear Mr Katainen,

We acknowledge with thanks the public survey sent to the organisers of ECI Stop Vivisection, on behalf of the Joint Research Centre's European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM).

We agree that it is important to identify all types of knowledge sources that might be relevant to Replace, Reduce or Refine (the 3Rs) the use of animals for scientific purposes in order to understand how such knowledge is disseminated and to highlight what could be done to fill knowledge gaps.

However, we feel that there is a fundamental imbalance in the survey because it does not make any allowance to point out weaknesses in the 3Rs concept. None of the questions in the survey allow respondents to share knowledge about the following very important issues :

1. Ways in which to enforce the application of non animal methods that have already been validated by EURL ECVAM and approved by the OECD. There is little point in developing alternatives if there is no legal or other effective mechanism to apply them to replace animal experiments. An example is the availability of the Monocyte Activation Test (MAT) to replace the rabbit pyrogen test. Why are 170 000 rabbits still being used every year in Europe when a valid replacement method already exists ?

2. The majority of the public equate the term « alternatives » with « replacement » alternatives. The public does not realise that around 80% of the « alternatives » that have been validated by EURL ECVAM since 1992 still use live animals or animal cells and that only around 20% are actually animal free. EURL ECVAM must be transparent and make these facts easily accessible to the public on its website. The current website is not user-friendly.

3. The current validation process in use by EURL ECVAM cannot keep up with the pace of technological advance. If it takes 7 years on average to validate a new non animal method, that technology will already be surpassed by the time it achieves validation. Why is there no discussion in the survey about other validation paradigms (e.g. Weight-of-evidence) ?

4. There is widespread confusion among the public and even between scientists between the term « relative replacement » and the term « absolute replacement ». It is important to be clear about what we mean by these terms. Russell and Burch (1959) distinguished between relative replacement e.g. the humane killing of a vertebrate animal to provide cells, tissues, or organs for *in vitro* studies and absolute replacement in which animals would not need to be used at all, e.g. the culture of human cells and tissues.

5. Nowhere in the survey is the validity of the « animal model » mentioned or questioned. This is a huge omission considering the advances in scientific knowledge made since the publication of the 3Rs concept by Russell and Burch in 1959. Current scientific knowledge including the human genome, evolutionary biology and complexity theory all help to explain why one evolved complex system cannot predict the effect of drugs or disease in a different evolved complex system. Why does the survey not invite respondents to comment on these fundamental issues ? After all, paragraph 39 of Directive 2010/63/EU clearly states : *It is also essential, both on moral and scientific grounds, to ensure that each use of an animal is carefully evaluated as to the **scientific or educational validity, usefulness and relevance of the expected result of that use.***

Based on the above, we feel that the survey represents another missed opportunity to disseminate and to highlight what could be done to fill knowledge gaps.

Respectfully yours,

Dr Andre Menache (andre.menache@gmail.com)
Prof Gianni Tamino

On behalf of the ECI Stop Vivisection