European Animal
Research Association

Public Hearing on the European Citizens' Initiative "Stop Vivisection"

Monday, 11th of May 2015 from 15h00 to 18h30

European Parliament Brussels, Room JAN 4Q2

Organised by the Committee on Agriculture and Rural Development (AGRI) in association with the Committee on Petitions, the Committee on the Environment, Public Health and Food Safety and the Committee on Industry, Research and Energy

Summary:

1. The main points of the petitioners concerned the validity of animal experiments and their extrapolation to humans.
2. The petitioners' aim was to challenge the communications on animal research in order to move away from predetermined conventions (that animal models are necessary) and to prompt an open debate.
3. Expert Panel Speaker Emily McIvor (HSI) acknowledged this was the first time that biomedical animal research had been challenged. She welcomed the challenge since 90% of animal use happens in this field.
4. Majority of MEP´s opinions were supportive of the Directive.
5. There was a consensus on the need to encourage and support the development of alternative methods from all speakers and MEPs so that the number of animals used is reduced.
6. MEPs and petitioners agreed that the Commission should ensure that alternative methods are developed, facilitate the validation process and ensure these methods become mandatory.
7. The Commission agreed to the suggestion of the petitioners to organise a scientific conference in 2017 to evaluate the validity of animal research.

Transcript of the Hearing

Opening

Welcome and opening by Mr Czeslaw Siekierski, AGRI Chair

Mr Siekierski invited the audience to think about why animals are used in research and also whether the Directive is blocking the implementation of alternative methods in the research area in Europe.

Introductory remarks by Ms Rosa Estaras Ferragut, PETI Vice-Chair

Ms Estaras highlighted the existence of public misunderstanding between ECI (petitions) and the petitions procedures at the European Parliament (EP).

Stop Vivisection (SV) petitioners request the abolition of 'vivisection' and Directive 2010/63/EU.

PETI Committee will report in due course on the outcome of this petition.

Statement by the Vice-President of the European Commission Mr Jyrki Katainen

Mr Katainen confirmed that the Commission will provide an answer to the petitioners before 3rd June.

General presentation of the initiative by ECI organisers

Mr Gianni Tamino – "Stop vivisection" Organiser

- Results of animal research are not transferable from animal to animal and therefore not to the humans!
- Animal research is not a guarantee of EU citizens' health.
- There are more valid methods, more valid "real" scientific methods.
- There will be more security and safety for citizens by abolishing animal testing.

Mr Claude Reiss - "Stop vivisection" Organiser

- An animal species is defined by its reproductive capacity and the pathogens that affect them. These two features are not the same for every species.
- The prevalence and incidence of diseases is increasing in humans (diabetes incidence in France has double from 2000 to 2009). According to the current prognosis rate, all men will be diagnosed with prostate cancer by 2050.
- There are methods to circumvent the use of animals like stem cells to model cell processes, perfusion assays to model tissues and clinical tests to study processes at the whole body level.

Debate

Presentation on the current regulatory framework (Directive 2010/63/EU) by the Director-General of DG Environment, Mr Karl Falkenberg

The need to introduce safer methods into the market prompted the review in 1993 of the previous 1986 Directive. Article 4 of the current Directive states that Member States shall ensure that alternative methods to animal models shall be used wherever possible.

This Directive is still rather new and a full review will take place after five years of implementation in 2018/2019.

The real challenge of the Directive is to rapidly validate alternative methods so that they become mandatory. Nevertheless, the EU is well ahead of the rest of the world with this Directive. This ECI can contribute to the Directive's challenge. .

Round 1 of presentations

Mr Ray Greek, President of Americans for Medical Advancement (AFMA)

- There are vested interests in those who support animal research and opinion polls indicating wide scientific support for this cause are misleading.
- Referred to the lack of a HIV vaccine to demonstrate the absence of the validity of the animal model.
- Animals cannot be used to predict human outcome on the basis of evolution, complexity and results from empirical models (scatter plot showing that the absolute bioavailability of a compound in three different animal models does not follow a linear regression when compared to humans).
- Genetic differences outweigh the similarities between animal models and humans.
- Since animal models show no predictive value, they are not a necessary evil.

Q&A session with Mr Greek

Clara Aguilera (S&D) - AGRI (supportive)

She visited a research lab at Granada University biomedical centre (organised by EARA in collaboration with SECAL).

- The petitioners pursue replacing all animal research on the basis that one animal cannot predict outcomes in another animal. However, scientists state that animal experiments are absolutely necessary for the time being. How can this be?
- The Directive aims to phase out animal research when alternative methods are developed and validated, hence Ms. Aguilera asked the petitioners whether it is possible to replace all animal experiments at this moment.

Mr. Häusling Martin (Bündniss90/ Die Grünen) (semi- supportive)

- We must decrease the number of animals used for scientific procedures.
- 92% failure rate of testing compounds on animals. What are the alternatives? Are they enough?
- Directive 2010/63 cannot be completely replaced. Are there other options that allow not using animals at all at this point?

Anja HAZEKAMP (GUE/NGL) - AGRI (Not supportive)

- There has been a massive increase in animal testing.
- Many experiments are useless, as the predictive value is questioned.
- We should welcome newer rules that avoid the use of animals, and we should aim to implement them as soon as possible.
- On top of the 3Rs we should encourage rehoming of those animals used in experiments.

Marco ZULLO (EFDD) – AGRI (Not supportive but reasonable)

- We should aim to support new predictive alternative methods, which are possible thanks to scientific progress.
- Validation procedure is rigid and long, up to ten years.
- Animal research does not have to undergo validation procedures, which is an unfair competition.
- Asked the Commission to reasses the validation procedures in order to speed up the availability of alternative animal-free procedures.

Françoise GROSSETÊTE (EPP) - ENVI/ITRE (Supportive)

- Article 4 of the Directive states that Member States should ensure the Directive is implemented properly and checked.
- Ethical hurdles have to be overcome.
- The Directive includes the 3R principles which enable the balance between animal welfare and scientific progress so that Europe remains a trailblazer in the biomedical field.
- Better to carry out these procedures in Europe with high standards rather than in other continents without such animal welfare rules.
- She questioned the petitioners' statement that animal testing jeopardizes human health. Current therapies such as mitochondrial donation have been possible thanks to experiments on rodents and primates.
- The patient's voice has not been represented today and they are the ones who are benefiting from the therapies and treatments developed through animal research.
- Developing alternatives is enshrined in the Directive, hence we still need to support this Directive.

Soledad CABEZÓN RUIZ (S&D) - ENVI/ITRE (Supportive)

- Alternative methods cannot provide information on many of the current health threats. We still need animal research to gain knowledge about drugs and treatments.

- It is necessary and vital to continue animal research in an ethical and stringent manner. One example is the thalidomide case which would have benefited if tested appropriately on animals.
- Lack of complete genetic identity is not an argument for questioning the predictive value of animal models.
- Increase in disease incidence is not the result of animal research as the petitioners stated.
- The Directive protects animals, we cannot dismiss the advances made to date.
- We need to revise critically the Directive in due course and use alternatives methods when possible.
- What would the petitioners replace animal experiments with at the moment?

Philippe DE BACKER (ALDE) – ITRE (Supportive)

- The Directive pursues the aim of avoiding the use of animals in research where possible.
- Questioned the lack of predictive value of animal research indicated by Greek. We have made progress, we need these models to develop alternative methods.
- The revision of the Directive is important to ensure that all Member States implement the Directive to the same level.
-

UK Labour MP (Supportive)

- Supportive of the Directive since it encourages the development of alternative methods at the national level.
- What alternatives exist to find cures for neurological problems in humans (MS)?
- What measures should we be pursuing at the national level to push the 3Rs?

Answers

Mr Ray Greek

- Society is being harmed because of the use of animal models.
- Both sides of the debate should be given two to three days debate to explain their arguments, and allow their arguments to be scrutinised by a competent scientific panel.
- Past successes of animal research are questioned since their role was minimal or none and even misleading.
-

Andre Menache, “Stop vivisection” organiser

- We not test a horse drug on parrots, likewise not one for humans on rats.
- The Directive does not allow challenges to the validity of animal research.
- We should invest in improving methods resulting from available human data.
- Basic research is applicable and produces clinical results in only 0.004% of cases, is this an efficient way of using our resources and to progress?

- The Directive has betrayed public trust in terms of the composition of ethical committees which are staffed with those in favour of animal research.
- There is no legal definition of alternative methods. To ensure the use of an available alternative method requires disproportionate investments.

Round 2

Statement by Ms Francoise Barré-Sinoussi, 2008 Nobel Laureate of Medicine or Physiology

- Animal models are required to translate the results produced in the laboratories into new therapies and treatments (bench to bedside development).
- The differences between animals and humans must be carefully considered, but they are outweighed by the similarities: same tissues, organs, physiology, diseases, 90% genetic identity between mice and humans.
- 90% of veterinary medicine is the same as used to treat humans.
- There are non-invasive methods that are being use to avoid harm to the animal, such as imaging technologies.
- Diversity in any animal species is responsible for different responses to treatments (even within the same species).
- Many treatments have been shown to be successful when tested in animal models.
- Failure in predicting human outcomes is the result of using the wrong conditions when experimenting in animals (type of model, doses, experimental design etc).
- We need animal models even with their limitations.
- Alternative methods are widely used by researchers before animal models but they are not sufficient by themselves because they do not represent the interactions between tissues and organs present in the whole body.
- Clinical trials in humans aid the development of better animal models.
- The Directive is very similar to the existing regulation of clinical trials in humans.
- The Directive protects animals to make progress for animal and human health, so it would be a disaster to stop it.
- Encourage the European scientific community to develop more alternative methods.

Q&A session with Ms Francoise Barré-Sinoussi

Marc TARABELLA (S&D) - AGRI (Supportive)

- We should listen to the scientists.

Maria HEUBUCH (Greens) - AGRI (Not supportive)

- Greens voted against this Directive in 2010 because animal-free experimentation had not gone far enough and still hasn't.
- AIDS still has no vaccine despite the huge amount of animals used for it.
- There are economic interests that want to promote rather than to avoid animal testing.
- Need for better scientists, better scientific procedures and better extrapolation to human conditions.
- We allowed cosmetic testing in the past, the banning of which contributed to decreasing the number of animals suffering in scientific procedures.

Lidia SENRA RODRIGUEZ (GUE/NGL) – AGRI (Not supportive)

- Is animal based research actually useful for humans?
- Requested a wider debate to discuss this topic.
- Is there any link between animal research and the fact that the pharma industry is the third cause of death in the world?

Christian Bursoi (EPP) (Supportive)

- Need for less emotional debate.
- Full abolition of animal research will result in knowledge/scientists leaving Europe.
- Scientists support the Directive as indicated by the joint statement undersigned by more than 160 scientific organisations.
- Alternative methods cannot fully replace the use of animals since they cannot model whole body itneractions and therefore animal research remains essential.

Stefan ECK (GUE/NGL) - ENVI (Not supportive)

- People signed this petition because they do not see the promises of politicians becoming a reality, if the Commission does not take this petition seriously then any remaining faith in European institutions will disappear together with the value of politics and democracy.
- The Directive helps the pharma industry but not the animals.
- Switch to alternative methods.

Keith TAYLOR (Greens) - ENVI (Not supportive)

- He signed the petition but does not believe that the abrogation of the Directive is the best or only way to replace the use of animals.
- NIH study indicates that 95% of medicines that are safe and effective in animals fail in clinical trials and have a lack of efficacy.
-

- Urged the Commission to accept the principle of a complete phase out of animal experimentation and to set up a working party with the European Coalition to End Animal Experimentation (ECEAE) and the HSI to identify a concrete revision of relevant EU law which will advance the process.

Anne SANDER (EPP) – ITRE (Supportive)

- Following the discovery of AIDS in 1983, would it have been possible to do your research on finding a vaccine for HIV if there were no experiments on animals?
- Requested more info regarding the translation of the research of Nobel laureates into humans.
- Asked Nobel laureate what would be the impact of abolishing the Directive for her research and the development of vaccines such as AIDS and Ebola.
- Is it possible to use the EU funding scheme Horizon 2020 to find alternatives to animal research?

Philippe de BACKER (ALDE) – ITRE (Supportive)

- Although there are shortcomings in animal research and we have made progress in reducing the number of animals in research, animal research remains necessary.
- Asked the petitioners whether they think that we will be better off with or without the Directive that is in place now in Europe.
- How can we ensure that the right models and conditions are used to improve the value of animal research?
-

Danish MEP

- Denmark has stricter laws. It is forbidden to inflict pain on animals which sometimes leads to the use of more animals.
- Urged the Commission to impose stricter laws such as the Danish one in Europe.

Italian MEP

- Does the expert think that the main subjects of experimentation should be humans?
- The pharma industry and European agencies such as the EMA need to work to be more transparent.

French MEP

- Research allows the development of alternatives, generates jobs. Relocation would be a problem.
- We need to reform this Directive.

Polish MEP

- We have to make sure that the provisions of the Directive are implemented.
- Need for specific European or national bodies that ensure this process.
- Need to scrutinise animal welfare beyond vested interests.

Answers

Ms Francoise Barré-Sinoussi

- There is progress in toxicogenetics but it cannot yet replace the use of animals.
- We need to support and encourage more research on alternative methods.
- H2020 is one option to make a call for research into alternative methods and to improve animal methods.
- Despite not having yet a vaccine for HIV, we have learnt a lot from experiments on animals that are allowing us today to make progress in this field (scientific studies on neutralizing antibodies confirm the results obtained in monkey models).
- There is no way to develop therapies for patients without animal research.
- Translation of experiments in animals is possible as shown by the current 43% efficacy in humans of the current cocktail antibody Ebola therapy.
- Alternatives are necessary and complementary to animal research. We work so that in the future there will be better alternatives available to continue reducing and even replacing the use of animals in research.
- We need innovation to find better models.

Mr. Claude Reiss - “Stop vivisection” Organiser

- 275 publications by Ms Soniussi on transfer of HIV from mother to baby. If we had a cure for AIDS we would not need to research into this.
- Scientific hypotheses are constantly adapted to the need so that animal research can continue under one reasoning or another.
- SIV is not the same as HIV.
- There is an existing patent on HIV treatment that completely cleans the virus from the body, but it is not profitable to develop.

Ms Francoise Barré-Sinoussi

- No longer working in mother-to-child transmission nor in HIV vaccine. Currently studying those individuals who naturally control HIV infection.
- There are treatments for HIV that allow it to become a chronic disease rather than deadly like in the past. It also stops transmission from mother to child.
- Only 40% of HIV-infected people have access to this treatment.

Statement by Ms. Emily McIvor, Human Society International

- Actions that can be taken now and in the future: improve implementation of the Directive, regulatory testing represents only 10% of animal research and it is important to challenge assumptions in other fields such as biomedical research.
- This is the first time that biomedical animal research has been discussed here.
- Development of drugs is in crisis, 95% of drugs fail in preclinical trial since human diseases might not naturally occur in the animal model used, hence toxicology test are unreliable. 99% of drugs fail in clinical trials
- Article 13 of the treaty states that animal welfare is a value of the EU, article 10 of the Directive 2010/63 states the same.
- 2% of procedures are severe.
- Final goal of the Directive is full replacement of procedures on live animals. Project evaluation and retrospective evaluation should be well done.
- Funding bodies, journals and publishers should move away from conservationism.
- UK delivery plan: cross agency plan which creates a consensus based on business and welfare opportunities that highlights the need for exploring and promoting non-animal technologies.

Nicola CAPUTO (S&D) - AGRI/ENVI (Supportive)

- The number of signatories demonstrates the topic is of interest to European citizens.
- Objectives: more transparency, development of more alternatives, use of alternative methods should be mandatory and validation should be made easier.
- We need to prioritise investment to develop alternatives.

Fredrick FEDERLEY (ALDE) – AGRI (Not supportive)

- Administrative procedures should anonymously provide vital information, number of species and objectives to evaluate the projects and achievements. This information should be made available by all Member States.
- The current problems seen in many European countries indicate we must revise the Directive and listen to the citizens.

Mark DEMESMAEKER European Conservatives and Reformists Group (Supportive)

- TTIP will have far-reaching consequences for animal research. The consequences may be positive. TTIP could contribute to the application of the 3Rs principle.

E. EVI, Europe of Freedom and Direct Democracy Group (Not supportive)

- Annex 8 Directive, gravity of a procedure: why did we go backwards and allow the use of force and fear in procedures?
- Does the Directive really protect the animals?

Claude TURMES (Greens/EFA)

- ECI brings political pressure to make further progress.
- Where are animals being used? 90% in biomedical research, where we should direct our interests.
- The Commission should take the petition seriously and give specific answers on the Directive: how to improve it; more investment into alternatives; address the lack of correct implementation of the ban on cosmetic testing.

Marco ZULLO (EFDD) (Not supportive)

- Article 13 Treaty EU (animal welfare).
- Set up a general set of regulations on animal welfare.

Answers

Ms. Emily McIvor

- Unjustified flaws of the Directive: simplified procedures; project evaluation; a procedure cannot be carried on if an alternative exists.
- TTIP: Pushes the reduction of animal research since it decreases costs, yet does not address animal welfare.
- Cosmetics Directive: Less autonomous democratic processes due to TTIP will have an effect in implementing EU laws.
- Industry lobbying pursues a clause that allows all procedures (even severe ones).
- Getting away from conservatism: animal research community has to present a coherent message to the Commission on how we should proceed to improve the field.
- Implementation: Member States should ensure that a critical evaluation of the animal research project should be made.

Reaction by ECI organiser Mr Andre Menache

- Communications is the biggest challenge of animal research.
- Asked Commission to organise a scientific debate of three to five days with experts from both sides, otherwise we will let down petitioners, animals and patients.
- Botox safety testing in animals was questioned by cosmetic testing regulation and stopped. We need to challenge the communications on this complex debate.

Concluding remarks

Wrap-up by ECI organiser Mr Gianni Tamino

Animal experimentation will not predict or guarantee citizens' health. It is a flawed method.

We need to set up the right conditions to ensure the health of citizens without the use of animals. We have to set our goals and deadlines. By 2020 we should aim to stop using animals in scientific procedures. Remove references to the need for animal experimentation from narratives. We need to be more efficient and keep on investing in developing alternatives. Called for the organising of a conference on the scientific and economic path to animal free experimentation within two years. Ensure that validation is done properly and that the European organisations pursue it effectively.

END

European Animal
Research Association

www.eara.eu

Hodgkin Huxley House
30 Farringdon Lane
London, EC1R 3AW

T +44 (0) 20 3675 1230
F +44 (0) 20 3411 7808

Registered as European Animal
Research Association
Company no. 8924697
VAT no. 184 1486 91
Registered company at the above address