



Decision

in case 1609/2016/JAS on the European Commission's response and follow-up to the European Citizens' Initiative "Stop Vivisection"

The complaint concerned the European Commission's response to the European Citizens' Initiative "Stop Vivisection", which called for the phasing out of animal testing. The complainants, the organisers of the initiative, considered that the Commission had given an inadequate response to the initiative and the detailed proposals put forward in the context of the initiative.

The Ombudsman inquired into the issue and found that the Commission had explained, in a clear, comprehensible and detailed manner, its position and the political choices it had made regarding the objectives of the initiative. The Commission had also started to implement a number of concrete actions in response to the initiative. While the complainants are understandably disappointed, as they wished the Commission to go further in its actions, the Ombudsman concluded that there was no maladministration by the Commission.

The background to the complaint

1. The complaint concerns the European Commission's response and follow-up to the European Citizens' Initiative¹ (ECI) "Stop Vivisection"². The aim of the ECI "Stop Vivisection" was "to abrogate Directive 2010/63/EU on the protection of animals used for scientific purposes³ and put forward a new **proposal aimed at phasing out the practice of animal experimentation, making compulsory the use -**

¹ A European Citizens' Initiative is a request to the European Commission to propose legislation on matters where the EU can legislate. An initiative has to be backed by at least one million EU citizens, coming from at least 7 out of the 28 member states. A minimum number of signatories is required in each of those 7 member states. More information on the ECI as available at: <http://ec.europa.eu/citizens-initiative/public/welcome> and <http://www.europarl.europa.eu/atyourservice/en/20150201PVL00039/Citizen-s-initiative>

² More information on the ECI "Stop Vivisection" is available at: <http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2012/000007>

³ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ 2010 L 276, p. 33.



in biomedical and toxicological research - of data directly relevant for the human species"⁴ (emphasis added).

2. Between June 2012 and November 2013, the ECI "Stop Vivisection" collected more than one million signatures⁵, which allowed the organisers to submit the initiative to the Commission for its examination and answer. In May 2015, the Commission met with the organisers of the ECI "Stop Vivisection" and the organisers also presented their initiative during a public hearing organised at the European Parliament⁶. At the same time, the organisers provided the Commission with a dossier⁷, in which they put forward ten requests to the Commission:

1. EU Legislation to phase out animal experiments should be introduced;
2. The statement "*the use of live animals continues to be necessary to protect human health*" should be removed from EU legislation;
3. Every two years, a conference should be organised on this topic;
4. Available alternative methods should be mandatory by law;
5. Research into alternative methods should be a priority;
6. Alternative methods should be validated as soon as possible;
7. Alternative methods should not be validated by comparison with animal data;
8. Internationally, the EU should take a leading role in promoting the need to phase out animal testing;
9. The costs for validating alternative methods should be borne by the EU, not by researchers;
10. Annual reports listing methods of animal testing and the main alternatives to them should be produced. Where alternatives to a particular technique are available, these should be mandatory.

3. As provided for in the rules on ECIs⁸, the Commission replied to the ECI "Stop Vivisection" in June 2015⁹.

4. Not satisfied with the Commission's response and follow-up, the ECI's organisers complained to the Ombudsman in October 2016.

The inquiry

5. The Ombudsman opened an inquiry into the complainants' concerns that the Commission's response to the ECI "Stop Vivisection" was inadequate and not in accordance with the rules on ECIs¹⁰.

⁴ <http://ec.europa.eu/citizens-initiative/public/documents/43>

⁵ More information on the procedure available at: <http://ec.europa.eu/transparency/regdoc/rep/3/2015/EN/3-2015-3773-EN-F1-1-ANNEX-1.PDF>

⁶ A video of the public hearing is available at: <http://www.europarl.europa.eu/committees/en/envi/events-citizint.html?id=20150424CHE00301>

⁷ Available at: http://www.stopvivisection.eu/sites/default/files/dossier_-11_may_2015.pdf

⁸ Article 10(1)(c) of Regulation (EU) No 211/2011 of the European Parliament and of the Council of 16 February 2011 on the citizens' initiative, OJ 2011 L 65, p. 1.

⁹ The Commission's response is available at: <http://ec.europa.eu/transparency/regdoc/rep/3/2015/EN/3-2015-3773-EN-F1-1.PDF>

¹⁰ Regulation 211/2011.



6. In the course of the inquiry, the Ombudsman duly considered the information provided in the complaint. In particular, the Ombudsman carried out a thorough analysis of the correspondence that had taken place between the Commission and the complainants before the complainants turned to the Ombudsman.

Adequacy of the Commission's response

Arguments made by the complainants

7. The complainants argued that the Commission, in its reply to the ECI in June 2015, had failed to explain clearly the reasons for not pursuing the ten proposals put forward in the complainants' dossier. According to the complainants, this was against the spirit of the ECI legislation.

8. The complainants also argued that the Commission's position was incoherent: while the Commission appeared to agree with the aim of the ECI, it did not propose any changes to the Directive 2010/63/EU, on the protection of animals used for scientific purposes, with a view to achieving this aim.

9. Finally, the complainants argued that there was no significant difference between the Commission's answer to a parliamentary question, its observations on a petition made to the European Parliament and its response to the ECI "Stop Vivisection".

The Ombudsman's assessment

10. The European Citizens' Initiative, available since 2012, allows a group of at least one million EU citizens to call on the Commission to propose new EU legislation¹¹. While the Commission is not *obliged* to make the a corresponding legislative proposal, it must, among other things, "*set out in a communication its legal and political conclusions on the citizens' initiative, the action it intends to take, if any, and its reasons for taking or not taking that action*"¹² (emphasis added).

11. On this point, the Ombudsman has already drawn the Commission's attention to the need to explain to the public, in a **detailed and transparent manner**, the political choices it makes in responding to an ECI that has obtained the necessary signatures¹³. While political choices are sometimes difficult and cannot satisfy everyone, the Ombudsman is nevertheless convinced that citizens deserve to be told the truth¹⁴.

¹¹ The right to launch an ECI is set out in Article 11(4) of the Treaty on European Union.

¹² Article 10(1)(c) of Regulation 211/2011.

¹³ Decision of the European Ombudsman closing her own-initiative inquiry OI/9/2013/TN concerning the European Commission, paragraph 23, available at: <https://www.ombudsman.europa.eu/en/cases/decision.faces/en/59205/html.bookmark>

¹⁴ Follow-up to the guidelines for further improvement issued to the European Commission when closing own-initiative inquiry OI/9/2013/TN into the functioning of the European citizens' initiative (ECI), page 2, available at:

https://www.ombudsman.europa.eu/showResource?resourceId=1460365434547_FOLLOW_UP_CFR_REPLY_201302371_20160308_102940.pdf&type=pdf&download=true&lang=en



12. It must thus be determined whether the Commission, in its response to the ECI “Stop Vivisection”, failed to explain its political choices in a clear, comprehensible and detailed manner. Failure to do so would indeed make the Commission’s response inadequate.

13. The Commission’s response to the ECI “Stop Vivisection” contains a detailed assessment of the ECI’s aim which is, essentially, for the Commission to put forward legislation phasing out animal testing.

14. In the response, the Commission stated that it “shares the Citizens’ Initiative’s conviction that animal testing should be phased out. This is the ultimate goal of EU legislation.”

“However, the Commission does not share the view that scientific principles invalidate the ‘animal model’. Indeed, despite differences with humans, animal models have been the key scientific drivers to develop almost all existing effective and safe medical treatments and prevention measures for human and animal diseases. In medicine development, animal models have been very effective in removing candidate medicines that could have been dangerous to humans when tested in later clinical phases. In areas of great biological complexity where existing alternatives do not yet provide sufficient predictive power, animal models are still needed to decipher the complex biological mechanisms leading to an observed effect or to provide the information needed to ensure that a product is safe.”¹⁵

“The Commission underlines that, for the time being, animal experimentation remains important for protecting human and animal health, and for maintaining an intact environment. While working towards the ultimate goal of full replacement of animals, Directive 2010/63/EU is an indispensable tool at the EU level to protect those animals still required.

The Directive implements the Three Rs - to replace, reduce and refine animal use in Europe - and the Commission underlines the importance of continued efforts by all players, from Member States to the research community, to reach these goals.

At the same time, Directive 2010/63/EU is the catalyst for the development and uptake of alternative approaches, which is in line with the request of this Initiative.

The Commission therefore does not intend to submit a proposal to repeal Directive 2010/63/EU and is not intending to propose the adoption of a new legislative framework”¹⁶ (emphasis added).

15. It is clear from its response that the Commission does not agree with the view of the ECI “Stop Vivisection” that Directive 2010/63/EU, on the protection of animals used for scientific purposes, should be repealed and replaced. The Commission supports its position by arguing that animal testing remains necessary in certain areas. Contrary to what the complainants argue, the Commission’s position – that animal testing should ultimately be phased out but is, during a time of transition, still necessary – is not incoherent.

16. Furthermore, the Commission outlined a number of actions it intended to take in response to the ECI: (i) accelerating progress in applying the “Three

¹⁵ Commission’s response, page 7.

¹⁶ Commission’s response, page 10.



Rs” through knowledge sharing; (ii) development, validation and implementation of alternative approaches; (iii) enforcement of compliance with the Three Rs principle and alignment of relevant sector legislation; and (iv) engaging in a dialogue with the scientific community and relevant stakeholders by organising a conference on how to exploit the advances in science for the development of scientifically valid non-animal approaches.

17. The Ombudsman notes that the Commission has started to implement the actions outlined in its response to the ECI “Stop Vivisection”. The Commission’s Joint Research Centre has published a Science for Policy report¹⁷ on the first action—knowledge sharing—which includes a public survey that has also been shared with the complainants¹⁸. Efforts are ongoing in relation to the second action—development, validation and implementation of alternative approaches—for example through EU funded projects such as EU-ToxRisk¹⁹ and VAC2VAC²⁰. The fourth action—a conference—took place on 6-7 December 2016²¹, and included a session on the progress of the other three actions²².

18. While falling short of achieving an immediate end to animal testing, which is what the organisers of the ECI “Stop Vivisection” would have wanted, it does indeed seem that the ECI “Stop Vivisection” has had an impact on the Commission’s actions in this area. The Ombudsman would expect that the outcome of the actions taken in response to the ECI will also feed into the review of Directive 2010/63/EU, on the protection of animals used for scientific purposes, which is due by November 2017²³.

19. Taking this into account, the Ombudsman does not agree with the complainants’ argument that there is no significant difference between the Commission’s response to the ECI and its replies to a parliamentary question²⁴ or its observations on a petition submitted to the European Parliament²⁵. In particular, it was not until its response to the ECI “Stop Vivisection” that the Commission announced concrete actions.

20. The Commission is obliged to outline its legal and political conclusions on a successful citizens’ initiative in a detailed and transparent manner. However, the Commission was not required to explain in detail its position on each of the ten proposals submitted to it by the organisers after the ECI had been registered and after it had succeeded in being supported by at least one million EU citizens. Nevertheless, the Commission’s response does contain information on its positions on the ten proposals. The response shows that the Commission does not consider it possible, at the moment, to outlaw animal testing (proposals 1 and 2). As noted above, the Commission has organised a

¹⁷ Available at: <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/accelerating-progress-replacement-reduction-and-refinement-animal-testing-through-better>

¹⁸ <https://ec.europa.eu/jrc/en/news/public-survey-alternatives-animal-testing-launched>

¹⁹ http://cordis.europa.eu/project/rcn/198787_en.html

²⁰ <https://ec.europa.eu/jrc/en/news/launch-research-project-vac2va-develop-animal-free-methods-quality-control-vaccines>

²¹ <https://ec.europa.eu/jrc/en/news/european-commission-scientific-conference-non-animal-approaches-way-forward>

²² Not satisfied with the organisation and set-up of the conference, the organisers of the ECI “Stop Vivisection” decided not to attend.

²³ Article 58 of Directive 2010/63/EU.

²⁴ Available at: <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2014-006155&language=EN>

²⁵ Petition 1833/2013.



conference, although the organisers did not agree with its scope and set-up (proposal 3). According to the Commission, there already exists a legal obligation to use validated alternative methods instead of animal tests²⁶, an obligation which must be enforced by the Member States (proposal 4). Finally, the Commission's response outlines the efforts in the area of researching, validating and promoting alternative methods to animal testing, including through the use of EU funds (proposals 5-10).

21. The complainants appear to be dissatisfied with the speed of progress by the Commission in phasing out animal testing. The complainants might even disagree, from a scientific or ethical point of view, with the reasoning upon which the Commission relied when arriving at its position (the complainants challenge the assumption that animal tests can be used to assess effects on humans). It is of course regrettable that the organisers of the ECI "Stop Vivisection" are dissatisfied with the outcome, given that the ECI was supported by a significant number of European citizens.

22. However, in view of the above, **the Ombudsman finds that the Commission has complied with its duty to explain, in a clear, comprehensible and detailed manner, its position and political choices regarding the objectives of the ECI "Stop Vivisection"**. The Ombudsman does not consider that the Commission has failed to comply with the spirit and logic of the ECI rules. There was thus no maladministration by the Commission.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion²⁷:

There was no maladministration by the European Commission.

The complainants and the Commission will be informed of this decision.

Emily O'Reilly
European Ombudsman

Strasbourg, 18/04/2017

²⁶ Article 13 of Directive 2010/63/EU.

²⁷ Information on the review procedure can be found on the Ombudsman's website:
<http://www.ombudsman.europa.eu/en/resources/otherdocument.faces/en/70669/html.bookmark>