EUROPEAN
COMMISSION

Brussels, 3.6.2015
C(2015) 3773 final

COMMUNICATION FROM THE COMMISSION

on the European Citizens' Initiative "Stop Vivisection"

1. INTRODUCTION

"**Stop Vivisection**" is the third European Citizens' Initiative submitted to the European Commission on 3 March 2015. It was signed by 1.17 million citizens. The Initiative asks the Commission

> *to abrogate Directive 2010/63/EU[1] on the protection of animals used for scientific purposes and put forward a new proposal aimed at phasing out the practice of animal experimentation, making compulsory the use - in biomedical and toxicological research - of data directly relevant for the human species*[2].

The Commission received the organisers on 11 May 2015 and, on the same day, the organisers presented their initiative at a public hearing at the European Parliament, on both occasions providing the Commission with clarifications on their request[3].

This Communication sets out the Commission's legal and political conclusions, the actions it intends to take and the reasons for taking these in line with Article 10(1)(c) of Regulation (EU) No 211/2011 on the Citizens' Initiative ("the Regulation")[4].

2. ANIMAL WELFARE AND THE PROTECTION OF HEALTH AND THE ENVIRONMENT

The EU is committed to animal welfare and it aims to meet this objective while striving to also protect human health and the environment. The EU shares the Citizens' Initiative's conviction that animal testing should be phased out. This is the ultimate goal of EU legislation.

Animal welfare is embedded in the Treaty on the Functioning of the European Union ("the Treaty") and covered by EU legislation. Article 13 of the Treaty[5] requires that the welfare of animals must be taken into account in the Union's policy on internal market, research, and agriculture among others. Directive 2010/63/EU and the Cosmetics Regulation EC No 1223/2009[6] are among the world's most advanced pieces of legislation concerning animal welfare. Directive 2010/63/EU mandates the application of scientifically valid alternative approaches and establishes mechanisms to speed up their development, validation and uptake. For cosmetics, the EU imposed a complete marketing ban on cosmetics products and ingredients tested on animals. The Cosmetics Regulation acts as an accelerator for the development of alternatives, with effects beyond the cosmetics sector. Furthermore, the European Commission supports research into alternatives and promotes these approaches for meeting regulatory requirements.

Despite significant progress in the development of alternative approaches, considerable scientific challenges remain for the more complex endpoints in basic and applied research, pharmaceutical product development and safety testing of substances. Where the toxicological or physiological processes and mechanisms are not sufficiently understood or are very complex, alternative solutions are often not available. Thus, the complete replacement of animal studies is currently not possible while needing to ensure a high level of protection of human and animal health and the environment.

The Citizens' Initiative "Stop Vivisection" comes at a time of transition. Technological advances enable the processing of increasingly complex information coming from animal and non-animal

---

[1] Directive 2010/63/EU OJ L276, 20.10.2010, p.33-79 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063
[2] For the full text of the initiative please see: http://ec.europa.eu/citizens-initiative/public/initiatives/finalised/details/2012/000007
[3] Annex I provides further information on the procedural aspects of this initiative.
[4] Regulation (EU) No 211/2011 on the Citizens' Initiative;
O.J. L 65, 11.3.2011, p. 1. Official Register : http://ec.europa.eu/citizens-initiative/public/welcome
[5] Article 13 of the Treaty http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT
[6] Regulation (EC) No 1223/2009 on cosmetic products http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R1223

research, which will allow to gradually fill the knowledge gaps currently hindering the full replacement of animals. However, a premature ban of research using animals in the EU would likely export the biomedical research and testing outside the EU to countries where welfare standards may be lower and more animals may be needed to achieve the same scientific result.

Protecting human health and the environment

An important objective enshrined in the Treaty is for the EU to protect human health and the environment[7]. The EU strives to improve health and prevent diseases, e.g. by promoting research into causes and diagnoses of disease as well as prevention measures such as vaccines and therapies. The regulatory framework for *inter alia* health products (pharmaceuticals), chemicals (including pesticides, biocides), and food and feed requires testing of products prior to marketing them to prove that they are safe for humans, animals or the environment.

The EU Health Strategy 2020[8] and the 7th Environmental Action Programme (EAP)[9] set out actions needed to reach the Union's health and environment objectives. Whilst some of these actions imply the use of animals, the 7th EAP also encourages the development of methods predicting toxicity without, or with reduced or refined use of animals. Whenever animal testing is performed it must follow the stringent high standards of the EU[10].

The role of animal studies

Animal studies have historically been key to developing ways to prevent and reduce human and animal diseases. They have contributed to improved health and quality of life as well as longer life expectancy. Today, there are effective treatments for many infectious diseases, some forms of cancer, and several chronic diseases such as diabetes. These advancements would have been impossible without the insights gained in animal studies. Such studies are required by legislation to authorise human clinical trials, and to protect health and the environment. The same holds true for the prediction of medicine efficacy. In such cases, after generating as much information as possible from alternative methods, animal studies are used to fill the knowledge gaps to safeguard human, animal and environmental health.

Furthermore, animal studies have provided invaluable insight into basic biological processes that underpin health and disease of humans and animals. Animal models[11] have also been used for their predictive value for pharmacology and toxicology[12].

Animal models have their strengths and limitations, depending on the question to be addressed. For instance, zebra fish have been an excellent model to study developmental processes of higher organisms. Mice are a highly informative model for many human genetic diseases, e.g. for hearing, vision or bone disorders. However, the mouse is of limited use for studying Ebola or AIDS, for which more appropriate models exist.

In the last decade, technological advances have revolutionised biomedical research bringing new possibilities to improve our knowledge, such as the capacity to sequence the genome of organisms, computational tools to analyse biological processes and to simulate the complex mechanisms involved

[7] Articles 168 and 191 of the Treaty http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT
[8] http://ec.europa.eu/health/strategy/policy/index_en.htm
[9] http://ec.europa.eu/environment/newprg/
[10] Directive 2010/63/EU, OJ L276, 20.10.2010, p.33-79. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063
[11] Model to study the biology, behaviour, spontaneous or induced diseases having common aspects with a phenomenon equivalent in humans or other animal species.
[12] Special issue - 34 publications on the translational value of animal models in the European Journal of Pharmacology; http://www.sciencedirect.com/science/article/pii/S0014299915002678).

in health and disease. Innovative tools currently in development include human 3D-tissues and reconstituted mini organs. These major breakthroughs allow the development of alternatives based mainly on cell or tissue cultures, as well as computational methods, thus reducing animal use.

Concerning the safety testing of chemicals, which accounts for less than 10% of animals used in the EU, alternatives are being implemented where the underlying biological mechanisms are well understood – e.g. testing for local harmful effects on skin and eyes. However, more complex toxicological effects cannot yet be adequately assessed by alternatives.

Phasing out animal testing

Directive 2010/63/EU

The Directive states that the final goal is a full phasing out of animal testing, but acknowledges that animal use is still necessary on the way to reaching this goal. Directive 2010/63/EU modernised and further harmonised rules on animal use across the EU in line with the most ambitious global standards and hence greatly increased the welfare of animals in scientific research and testing.

The new rules firmly anchor in EU legislation the "**Three Rs**"[13], the requirement to **R**eplace, **R**educe and **R**efine the use of animals wherever possible. This means that animal studies should be either replaced by methods not involving animals, or adapted to reduce the number of animals needed, or refined so as to minimise pain, suffering or distress experienced by the animal, or to increase their welfare. If an alternative approach to achieve a research objective is available, the Directive makes its use mandatory.

The Directive implements the Three Rs via a number of principles[14] such as:

- *Systematic project evaluation* by a competent authority of any proposed use of live animals that must take ethical considerations into account when weighing up potential harm to animals against expected benefits of the project to humans, animals or environment.
- Specific requirements on *education, training and competence of personnel* were improved. All staff dealing with animals must demonstrate a requisite competence.
- More *detailed and comprehensive reporting* [15] on animals used for scientific purposes.
- More robust and faster mechanisms for *development, validation*[16] *and uptake of alternative approaches*.

All Member States have fully completed the transposition into national law, and are now responsible for enforcement. The Directive's effectiveness is scheduled to be evaluated in 2017.

The Directive legally established and broadened the mandate of the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)[17] which is to coordinate and promote the development and use of alternatives. Member States contribute to this crucial activity by law. A network of national regulators was established to guide the validation of methods with the highest

[13] Information on the Three Rs concept: http://ec.europa.eu/environment/chemicals/lab_animals/3r/alternative_en.htm
[14] Information on the Directive 2010/63 and its provisions: http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm
[15] Common format for submission of information pursuant to Directive 2010/63/EU http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012D0707-20140115
[16] **Alternative methods' validation process:** New test methods replacing an animal method need to be validated before they can be accepted as meeting legal requirements for safety or efficacy testing of a chemical or a new medicine. This is to ensure that (1) the method can correctly predict relevant effects of concern, (2) results can be reproduced across laboratories and (3) the method is suitable for all types of substances that should be tested with it. The validation process respects the principles established at international level by the Organisation of Economic Cooperation and Development (OECD).
[17] EURL-ECVAM is part of the Joint Research Centre, Institute for Health and Consumer Protection (IHCP) of the European Commission, located in Ispra, Italy.

regulatory relevance (PARERE-Network)[18]. Finally, Member States must nominate qualified laboratories to support the validation work (EU-NETVAL)[19], and must promote alternatives at national level.

EU Research into alternative approaches

The EU Framework Programmes for Research and Innovation (FPs) aim to provide leading edge science, removal of barriers to innovation and to make it easier for the public and private sectors to deliver innovation together. The EU FPs address major societal challenges and have greatly advanced the development of alternatives.

More than €250 million was dedicated during FP7 (2007-2013) to research into alternatives. As part of this, six large projects for a total of €140 million have been co-financed as public-private partnerships with either the cosmetics industry (through Cosmetics Europe) or the Innovative Medicines Initiative (IMI). IMI is the public-private partnership between the EC and the European Federation of Pharmaceutical Industries and Associations working to improve health by developing innovative medicines, particularly in areas where there is an unmet medical or social need.

Horizon 2020 (H2020), the current EU research and innovation programme (2014-2020), builds on FP7 and provides funding to enhance human safety. Several H2020 research projects aiming at developing and validating animal-free methods for safety assessment of chemicals, food contaminants or nanomaterials have been or are in the process of being granted. The first calls for IMI2 proposals include topics relevant to alternative testing, such as "the consistency approach to quality control in vaccine manufacture", calling for a new approach to improve quality control of established human and veterinary vaccines using non-animal methods[20].

Validation and practical support for promotion of alternatives to animal use

EURL-ECVAM publishes a series of strategies[21] outlining holistic solutions to achieving replacement, reduction and refinement of animal use while maintaining or improving human and environmental protection. Such strategies exist for skin sensitisation, genotoxicity, acute systemic toxicity, aquatic toxicity and bio-concentration / bioaccumulation testing, and one on toxico-kinetics soon to be published. ECVAM also issues recommendations on validated test methods summarising their performance and possible use for regulatory and non-regulatory purposes. Prior to finalising these, EURL ECVAM consults with regulators via PARERE, its stakeholder community via the EURL ECVAM Stakeholder Forum (ESTAF) as well as validation bodies under the International Collaboration on Alternative Test Methods (ICATM).

Since its establishment, EURL ECVAM has validated around 50 test methods in various toxicological areas for the testing of chemicals, biological products and vaccines. Most of these approaches achieved regulatory acceptance (e.g. incorporated into the EU Test Method Regulation[22]) and have been adopted internationally (e.g. as OECD test guidelines). See also recent reports by EURL ECVAM[23] .

[18]PARERE Network (*P*reliminary *A*ssessment of *RE*gulatory *RE*levance) under Article 47(5) of Directive 2010/63/EU http://ec.europa.eu/environment/chemicals/lab_animals/parere_en.htm

[19] EU NETVAL: https://eurl-ecvam.jrc.ec.europa.eu/eu-netval

[20] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2Call3/IMI2Call3_TopicTextWebFINAL.pdf

[21] https://eurl-ecvam.jrc.ec.europa.eu/eurl-ecvam-strategy-papers

[22] Regulation (EC) No 440/2008 laying down test methods pursuant to regulation (EC) no 1907/2006 (REACH). OJ L142:1-739.

[23] EURL ECVAM status report on the development, validation and regulatory acceptance of alternative methods and approaches (2013-April 2014). JRC report EUR 26702 EN. http://publications.jrc.ec.europa.eu/repository/handle/JRC90989
Alternative methods for regulatory toxicology – a state-of-the-art review. JRC report EUR 26797 EN. http://publications.jrc.ec.europa.eu/repository/handle/JRC91361

The Commission and sector regulatory agencies do complementary work to facilitate the process from the development of alternative methods to their validation and implementation. Some examples:

- *The European Chemicals Agency (ECHA)* plays a key role in ensuring that data requirements in EU chemicals regulations REACH and Biocides are met by alternatives where possible. ECHA publishes materials (e.g. webinars, fact sheets, practical guides) promoting the use of alternatives[24]. ECHA is also active on (1) the OECD QSAR (Quantitative Structure-Activity Relationship) Toolbox, which is the most comprehensive, widely recognised platform for filling data gaps in regulatory hazard assessment without animal testing; it now holds 1.5 million information items for 90 000 substances; (2) making publicly available data from REACH registration dossiers.
- *The European Medicines Agency (EMA)* contributes to the elimination of animal testing through its role in developing harmonised regulatory requirements for the testing of human and veterinary medicinal products, applicable at EU level and, through collaboration with multinational organisations such as ICH[25] and VICH[26], at global level. To promote best practice in the implementation of the 3Rs, EMA set up an expert group to advise its committees and working parties on the use of animals in regulatory testing of medicinal products and actively cooperates with other groups working in the 3Rs area.
- *The European Food Safety Authority (EFSA[27])* through its Scientific Committee and Scientific Panels is continuously reviewing new scientific approaches to contribute to the Three Rs within EFSA's activities[28].

Moreover, the voluntary collaboration platform *European Partnership for Alternative Approaches to Animal Testing (EPAA)* [29], launched in 2005, grouping the European Commission, European trade associations, and currently 36 companies from 7 industry sectors, aims for the replacement, reduction and refinement of animal use for meeting regulatory requirements through better, more predictive science. EPAA works towards identifying scientific gaps and facilitating regulatory acceptance of alternative methods.

International cooperation

As industry works globally, Europe cannot act in isolation, but must find solutions at global level through internationally harmonised approaches.

The Commission and EPAA are working together with OECD and other international organisations to achieve globally harmonised results. Alternatives to animal testing have been the focus of the International Collaboration on Cosmetics Regulation (ICCR), a cooperation forum between regulatory authorities of the USA, Brazil, Canada, Japan and the EU[30]. The International Cooperation on Alternative Test Methods (ICATM) including EURL ECVAM and the respective agencies of Japan, US, South Korea, Canada, and Brazil, works together on the validation process, the development of international guidance and guidelines, and the dissemination and promotion of alternative methods worldwide.

---

[24] http://echa.europa.eu/support/information-toolkit

[25] ICH - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use http://www.ich.org/home.html

[26] VICH - International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. http://www.vichsec.org/

[27] http://www.efsa.europa.eu/en/topics/topic/animalwelfare.htm

[28] EFSA Opinions:
EFSA Journal 2012;10(6):2767. http://www.efsa.europa.eu/it/efsajournal/doc/2767.pdf;
EFSA Journal (2009) 1052, 1-77. http://www.efsa.europa.eu/en/efsajournal/pub/2760.htm;
EFSA Journal (2005) 292, 1-46. http://www.efsa.europa.eu/en/efsajournal/doc/292.pdf;
EFSA Journal 2014;12(4):36384 http://www.efsa.europa.eu/it/efsajournal/pub/3638.htm.

[29] http://ec.europa.eu/enterprise/epaa/index_en.htm

[30] http://www.iccrnet.org/

3. ASSESSMENT OF AND ACTIONS ON THE CITIZENS' INITIATIVE

Assessment

The Citizens' Initiative asks for the abrogation of Directive 2010/63/EU and for the adoption of a new legislative framework that fully phases out animal experiments by 2020.

The organisers underline that *"there are clear ethical objections of EU citizens to animal experiments"*[31] and claim that *"the animal model is not suitable to predict human responses and that animal testing hinders the development of new and more efficient methods in research […]".*

The Commission 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[32]. 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.

The Commission is of the opinion that animal experimentation does not pose an obstacle to developing alternative research tools. The use of animals in research actually provides a mechanistic understanding of the biology of animals and humans, which enables the development of more ethical, cost-effective, predictive and faster alternative methods. The Commission recognises the limitations of both animal models and alternatives, and constantly follows up and supports new developments for improved predictive methods. Today, the development processes for new medicines, basic research and predictive safety testing of substances no longer rely exclusively on animal models. In all areas, a weight of evidence approach is followed that takes into account existing knowledge, resulting from alternatives, animal tests and human exposures together. Most relevant pieces of EU legislation in the field of testing make the use of reliable alternatives mandatory once they have been validated.

The continued need for Directive 2010/63/EU

The Directive is needed to ensure a high level of protection of the animals in accordance with Article 13 of the Treaty. Abrogating the Directive would not prevent the use of animals in experiments. It would instead deregulate the way in which such experiments are carried out, make the animals concerned more vulnerable and hinder the perspectives of developing alternatives.

A full implementation of Directive 2010/63/EU is paramount to increasing the welfare of animals still used today. The Commission rigorously examines the correct and complete transposition of the Directive into national legislation and will follow up through infringement procedures[33] where appropriate.

---

[31] The organisers refer to a 2006 survey. The Commission notes that the 2006 report did not address ethical views on animal experiments. It addressed whether more needs to be done to enhance welfare of animals still in use, which animals should be used, or which type of research should be allowed. In that survey a large majority of respondents supported additional measures to be taken at EU level to increase the welfare of animals. The EU responded by improving the existing EU standards through the adoption of the 2010/63/EU Directive.

[32] Examples of treatments developed thanks to animal research include anaesthetics, vaccines, penicillin, insulin, scanning techniques like CT and MRI, asthma medication, organ transplants and various treatments to increase cancer and AIDS survival rates. More information at http://eara.eu/home/.

[33] http://ec.europa.eu/atwork/applying-eu-law/infringements-proceedings/index_en.htm

The Directive has not been in force long enough to draw conclusions on its effectiveness. The Commission plans to review it in 2017 and will emphasize the availability of alternative approaches. In addition, the Directive requires an implementation report in 2019. These reports will be the first assessments of the extent to which the Directive is reaching its objectives.

Actions in relation to the ECI

The Commission will take the following actions to accelerate the development and uptake of non-animal approaches in research and testing.

1. Accelerating progress in the Three Rs through knowledge sharing

Translating knowledge across disciplines and sectors accelerates progress in the Three Rs. Relevant knowledge is wide-ranging and can include scientific understanding of fundamental biological processes, how to refine animal experiments to minimise potential pain and suffering, how to optimally design non-animal approaches to tackle research questions or assess the safety of a substance, or how to characterise and standardise novel models to ensure that they are fit-for-purpose. A number of platforms and networks exist that contribute greatly to the advancement of the Three Rs, some of which are facilitated by the Commission. However, the systematic sharing of information and knowledge could likely be further enhanced.

Action 1 - Building on existing activities of the Commission, relevant EU agencies and OECD, the Commission will analyse technologies, information sources and networks from all relevant sectors with potential impact on the advancement of the Three Rs, and will present by end 2016 an assessment of options to enhance knowledge sharing among all relevant parties. The assessment will consider how to systematically accelerate knowledge exchange through communication, dissemination, education and training.

2. Development, validation and implementation of new alternative approaches

Action 2 - The Commission will continue to support the development, validation and implementation of alternative approaches for regulatory and research use. This will include close cooperation between the Commission, Member States and international organisations and be supported, as appropriate, by EU programmes.

3. Enforcement of compliance with the Three Rs principle and alignment of relevant sector legislation

In line with Directive 2010/63/EU, sector legislation and related guidance should reflect the requirement to use non-animal approaches as soon as they are validated and accepted for regulatory purposes.

Action 3 – The Commission will actively monitor compliance with the Directive, in particular the Three Rs principle, and with the relevant obligations in sector legislation to use available alternatives. The Commission will also actively monitor the correct enforcement by all Member States.

By end 2016, the Commission will examine regulatory requirements in the relevant sector legislation mandating animal testing to assess if the legislative text enables an efficient up-take of available alternative approaches and the Commission will ensure that future proposals for relevant sector legislation will reflect the rules on the protection of animals used for scientific purposes.

4. Engaging in a dialogue with the scientific community

Action 4 – To facilitate an efficient dialogue, by end 2016 the Commission will organise a conference engaging the scientific community and relevant stakeholders in a debate on how to exploit the advances in science for the development of scientifically valid non-animal approaches and advance towards the goal of phasing out animal testing.

On that occasion, the Commission will also report progress on actions 1, 2 and 3.

4. CONCLUSIONS

In reply to the European Citizens' Initiative "**Stop Vivisection**", the Commission concludes as follows:

The Commission welcomes the mobilisation of citizens in support of animal welfare. The Citizens' Initiative has provided an opportunity to critically examine how the EU can reinforce its efforts in moving from animal to non-animal based research and testing.

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.

Fully recognising the need to further advance the scientific understanding before alternatives can be developed for all areas where testing still occurs, the Commission will continue to promote the development and implementation of alternative approaches, encourage cooperation and knowledge sharing across sectors, validate new methods and facilitate their regulatory approval. In addition, the Commission will actively monitor compliance with Directive 2010/63/EU in particular the Three Rs principle. The Commission will stay in close dialogue with the scientific community at EU and international level to identify alternative test methods, and will organise a conference by end 2016 on how to advance towards the goal of phasing out animal testing.

Finally, the Commission urges the Member States, acting within their competences, to take account of the concerns raised in this initiative and to step up their efforts to fully implement and enforce Directive 2010/63/EU, and to actively participate in the development of alternative approaches.

In accordance with article 10(2) of the Regulation, the Communication will be notified to the organisers of the initiative as well as to the European Parliament and the Council and it will be made public.

EUROPEAN
COMMISSION

Brussels, 3.6.2015
C(2015) 3773 final

ANNEX 1

ANNEX

to the

COMMUNICATION FROM THE COMMISSION

on the European Citizen's Initiative 'Stop Vivisection'

ANNEX 1

PROCEDURAL ASPECTS OF THE STOP VIVISECTION CITIZENS' INITIATIVE

In accordance with Article 4(2) of Regulation (EU) No 211/2011 the present initiative was registered on 22 June 2012 and published in the Commission's online register.

The members of the citizens' committee registered with the Commission are residents of the following Member States: the United Kingdom, Italy, Belgium, France, the Netherlands, Spain and Sweden.

The initiative was registered in English. Then the organisers provided translations of the title, subject-matter, and objectives of the initiative in all official EU languages.

In accordance with the Regulation on the Citizens' Initiative, the forms used by citizens to give their support to the initiative contained the title, subject-matter and objectives of the initiative. The link to the Commission's online register (see above) was also available on the forms, allowing citizens who wished so to find more detailed information on the initiative, as provided by the organisers in an Annex as part of their registration request. The organisers provided the translation of this Annex in Italian. This Annex may not have been consulted by all citizens who supported the initiative.

The formal 12-month collection period for the initiative ended on 22 June 2013. However, the Commission has accepted statements in support of the initiative up until 1 November 2013, due to the difficulties that most organisers experienced as regards the setting-up of their online collection systems during the start-up phase of the European Citizens' Initiative[1]. After the verification of the collected statements of support by the relevant competent Member States' authorities, the organisers submitted their initiative to the Commission on 3 March 2015, together with certificates issued by the 26 Member States' competent authorities and information on their sources of funding and support, in accordance with Article 9 of the Regulation.

The number of valid statements of support indicated in the certificates and information provided by the Member States' competent authorities are reflected in the table below. These figures take into account the additional collection period until 1 November 2013.

Member State	Number of signatories	Threshold to be counted among the minimum number of seven Member States
Austria	9 208	14 250
Bulgaria	12 598	13 500
Cyprus	533	4 500

[1] Press release of 18/07/2012: http://ec.europa.eu/archives/commission_2010-2014/sefcovic/headlines/press-releases/2012/07/2012_07_18_eci_en.htm

Czech Republic	4 075	16 500
Denmark	4 610	9 750
Estonia	2 502	4 500
Finland	12 495	9 750
France	61 818	55 500
Germany	164 304	74 250
Greece	1 952	16 500
Hungary	26 948	16 500
Ireland	3 333	9 000
Italy	690 325	54 750
Latvia	3 167	6 750
Lithuania	4 737	9 000
Luxembourg	1 291	4 500
Malta	1 662	4 500
Netherlands	9 909	19 500
Poland	38 824	38 250
Portugal	11 305	16 500
Romania	1 645	24 750
Slovakia	12 055	9 750
Slovenia	19 507	6 000
Spain	47 194	40 500
Sweden	7 661	15 000
United Kingdom	19 472	54 750
Total	**1 173 130**	**Threshold reached in 9 Member States**

In accordance with Article 10 of the Regulation, the Commission:

- published on 3 March 2015 the relevant information in the register at: http://ec.europa.eu/citizens-initiative/public/initiatives/finalised/details/2012/000007

- received the organisers on 11 May 2015.

During the meeting at the Commission, the Commission was represented by Vice-President Katainen and senior officials from the various services concerned.

On the same day in the afternoon, in accordance with Article 11 of the Regulation, organisers were given the opportunity to present their initiative in a public hearing organised at the European Parliament. On this occasion, for the first time, external experts have also been invited to take the floor. The Commission was represented by Vice-President Katainen.