Petizione al Parlamento europeo

Petition to the European Parliament

TUTELA DEGLI ANIMALI, DELLA SALUTE E DELLA LIBERTA' DI COSCIENZA

PROTECTION OF ANIMALS, HEALTH AND FREEDOM OF CONSCIENCE

(original version in Italian)

Note: any further adhesion (European associations only) please write to the Coordinator of the 'Commettee for Petitions to the E.P:': terrilemassimo@gmail.com stating: the official name of the association, the name and surname of the legal representative, the full address of the association including the European State, and the related official e-mail. New adhesions will be routed to the E.P. Portal monthly by the Promoter, as well as to all subscribers. Thankyou

May 24th, 2025.

The undersigned, with reference to the right to Petition pursuant to Article 227 of the Treaty on the Functioning of the Union, to Article 44 of the Charter of Fundamental Rights of the Union and to Articles 226-229 of the Rules of Procedure of the European Parliament, taking into account that:

1. The 'Charter of Fundamental Rights of the European Union' establishes in article 10 the right of European citizens to freedom of thought, conscience and religion […] also in practice. In art. 35, the right to health protection. In art. 38, the right to consumer protection, and in art. 42 the right of access to documents of the institutions.

2. The Treaty on the Functioning of the Union (TFEU) provides:

- In Article 13: "In formulating and implementing the Union's policies in the areas of agriculture, fisheries, transport, the internal market, research and technological development and space, the Union and the Member States *shall pay full regard to the welfare requirements of animals, since animals are sentient beings*, while respecting the legislative or administrative provisions and customs of the Member States relating, in particular, to religious rites, *cultural traditions* and regional heritage";

- In Article 114: "The Commission shall base its approach to *health, safety, environmental protection and consumer protection on a high level of protection,* taking into account, in particular, any new developments based on scientific evidence";

- In Article 168: " […] *a high level of human health protection shall be ensured* in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving *public health, preventing human illness and diseases, and obviating sources of danger to physical and mental health*' […] The European Parliament and the Council […] shall contribute to the achievement of the objectives set out in this Article by adopting, in order to address common safety concerns: […] measures setting *high standards of quality and safety for medicinal products and devices for medical use.'*

- In Article 169: 'In order to promote the interests of consumers and to ensure a *high level of consumer protection*, the Union shall contribute to protecting the *health, safety* and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their interests'[…].

3. EU Directive 2010/63 on the protection of animals used for scientific purposes, EC Regulation 1907/2006 (REACH) on the Registration, Evaluation, Authorization and Restriction of Chemicals, EC Regulation 1223/2009 on cosmetic products, the Guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the OECD Guidelines on the Testing of

Chemicals, promote changes in the way in which toxicity, efficacy and safety tests on such substances and products are carried out in favor of the transition from *in vivo* tests to non-animal methods.

4. Regulation (EU) 2019/6 on veterinary medicinal products notes in point 28 of the considerations: " […] The design and conduct of clinical trials, which provide essential information on the safety and efficacy of a veterinary medicinal product, *should* take into account the principles of replacement, reduction and refinement with regard to the treatment and use of live animals for scientific purposes, and *should* be optimized so as to provide the most satisfactory results using the smallest possible number of animals. The procedures relating to such clinical trials *should* be designed to avoid causing pain, suffering or distress to the animals and take into account the principles laid down in Directive 2010/63/EU, including the use, *whenever possible*, of alternative test methods, and the guidelines of the International Cooperation for Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products ('VICH')".

5. Regulations EC 1907/2006 (REACH) and EC 440/2008 on toxicological testing of chemical substances, as well as Directive EC 2001/83 on toxicological testing of medicinal products for human use (referred to in Regulation EC 726/2004 on testing of medicinal products for human and veterinary use), *do not, however, provide for the mandatory use* of the alternative *in vitro* or *non-human animal methods* indicated therein. In these regulations, the choice of method is often left to the experimenter without the obligation of documentary proof, the instructions being limited, a priori, to considering the use of available alternative methods as 'possible', 'appropriate', 'preferable', or 'desirable'. Therefore, the choices made by experimenters are not under the direct control of the authorities responsible for authorizing the experimental procedures provided for by the regulations (see Directive 2010/63), encouraging the tendency to use routine methodologies and the non-human animals already available in the animal facilities (1).

See, for example:

a) EC Regulation 1907/2006, in Article 13, paragraph 1, which states: "Information on the intrinsic properties of substances *may be* acquired by means other than testing provided that the conditions set out in Annex XI are met", which states in point 1: "Testing *does not appear* to be scientifically necessary even in the case in which: (1.3) "the results are derived from a QSAR model whose scientific validity has been established"; (1.4) "the results are derived from an *in vitro* method whose scientific validity has been established by a validation study, according to internationally recognized validation principles".

c) EU Regulation 2016/1688 (new test methods for skin sensitization) where in point 6 of the considerations it is stated that alternative methods are considered to be used not singly but *'in combination*', as well as points 8.3 and 8.3.1. of the Annex itself, where it is stated that *it is not necessary* to carry out the studies provided for in points 8.3.1. and 8.3.2. if certain conditions are met.

d) Directive 2001/83 EC, where in point 4.2.1. Pharmacology, it is stated: "The pharmacology study must be conducted following two distinct approaches. In the first, the actions related to the proposed therapeutic use must be investigated and adequately described. *Where possible,* recognized and validated determinations must be used, both *in vivo* and *in vitro* ..", and in Point 4.2.3. Toxicology, f) Local tolerance: "Animal studies *may be* replaced by validated *in vitro* tests, provided that the test results are of equivalent quality and usefulness for the safety assessment".

6. Transition to non-animal methods would eliminate the suffering to which non-human animals are subjected for toxicological tests and avoid the known variability (2) of their responses due to biological differences towards humans, ensuring real protection of citizens' health. In particular, for chemical substances, taking into account that EC Regulation 1272/2008, on the classification, labelling and packaging of chemical substances and mixtures, provides in Article 7 paragraph 3: "For the purposes of this Regulation, *tests on human beings shall not be carried out*. However, data obtained from other sources, such as clinical studies, *may be used* for the purposes of this Regulation". The performance of toxicity tests for these substances only on non-human animals and the omission of clinical tests, which are mandatory for drugs because preclinical tests for human purposes, as is known (3) are not at all reliable, therefore represents a serious violation of the right to health

protection of European citizens enshrined in the Union Treaties and causes an enormous slaughter of non-human animals, who are also subjected to terrible suffering (4).

7. Making scientifically validated alternative *in vitro* or *non-human animal methods* mandatory in the Union is therefore the most effective way to ensure that they enter into common use by experimenters and are not discarded out for pure convenience or distrust, thus ensuring minimal recourse to *in vivo* procedures. Therefore, in order to allow the elimination as much as possible of the use of non-human animals and the related risks to human health, it appears essential to include in EU Regulation 2019/6 on veterinary medicinal products, in Directive 2001/83 EC for toxicological tests on medicinal products for human use, in EC Regulation 726/2004 on testing of medicinal products for human and veterinary use, and in EC Regulation 440/2008 on toxicity tests for chemical substances and in those complementary to these, *the obligation to use* the aforementioned alternative *in vitro or non-human animal methods* validated at Community level (EURL ECVAM) and/or internationally (OECD), or which the experts of the European Commission consider scientifically valid.

8. The 'roadmap' indicated in the 2nd Conference of the European Commission and NGOs, held on 25 October 2024, to be defined at the beginning of 2026, for the abandonment of tests on non-human animals to the purpose of assessing the safety of chemical substances through *non-animal-methods (NAMs)* in the EU, highlighted the opinion of the participants on the criticality of being able to have a *flexible* regulatory structure, in order to facilitate the integration of such methodologies into the regulatory provisions. As well as the difficulty of discussing this matter with international bodies, such as the OECD, requiring the related procedure to take a very long time and the approval of all the countries adhering to them.

It is to be considered as well that alternative *in vitro* or *non-human animal* methods validated in the EU by EURL ECVAM and sent to the OECD for acceptance *are not included in EU legislation* – due to a European Commissions' choice - until they have been accepted, even though they are available. This choice prevents Member States from using such methods for the purposes of evaluating and authorizing regulatory testing procedures, also because Directive 2010/63 on the protection of animals used for scientific purposes states in article 13 (Choice of methods): "[…] Member States shall ensure that a procedure is not carried out where Union *legislation* recognizes other testing methods or strategies to obtain the desired result that do not involve the use of live animals".

However, since the of the OECD alternative methods validation parameters are known and published in the appropriate International Guidelines, such an omission may represent both a disavowal of the reliability of the validations carried out by EURL ECVAM and a violation of the provisions of Regulation 1907/2006 (see Article 13) which does not provide for the approval of bodies outside the Union for the authorization to use scientifically valid alternative methods. The reasons why the European Commission believes it must wait for the OECD acceptance therefore appear not to be related to strictly scientific aspects, but to commercial ones, to the detriment of the suffering of non-human animals, health and rights of European citizens.

9. The EURL ECVAM Status Report 2024 reports that over 1.1 million non-human animals were used for regulatory purposes only in 2022. The delay with which the aforementioned alternative methods validated by EURL ECVAM are included in Union legislation currently varies from 3 to over 5 years, and is partly due to the slowness of the OECD acceptance procedure (1 or 2 years), but also to the failure of the European Commission to update regulations, as acknowledged by the Commission itself in the considerations included in Regulation 2023/464 (5). Therefore, tens of thousands of non-human animals are 'sacrificed' every year due to delays caused by bureaucratic and commercial reasons. It is therefore necessary and *urgent* that the aforementioned alternative methods, once validated by EURL ECVAM, are promptly included in the respective EU regulations and their use is recognized for the purposes of the toxicity tests required for the marketing of the relevant products in the Union.

Moreover, this authorization could represent, for the European pharmaceutical and chemical industries, a significant strategic advantage compared to other countries, both in economic terms (*in vitro* tests or tests without the use of non-human animals are shorter), scientific (absence of variability connected to *in vivo* tests),

and cultural (adoption of appropriate instruments and researchers training). For European citizens, it would represent a guarantee of protection of their health and respect for their ethical beliefs.

10. EU regulations on pharmaceutical products, cosmetics, or products containing chemicals for household use labelling do not prescribe to report information on the use of non-human animals carried out during the relevant toxicity tests for regulatory purposes, in order to allow European citizens to make appropriate choices, in practices, regarding their own thoughts, conscience or religion. Nor do they prescribe to report information concerning risks to their health due to the omission of clinical tests on the used chemical components (see Article 7, paragraph 3 of the above-mentioned EC regulation 1272/2008, where it states: "Tests on humans shall not be performed for the purposes of this Regulation. Data obtained from other sources, such as clinical studies, *can however* be used for the purposes of this Regulation". Furthermore, many cosmetic products carry the wording 'product not tested on animals', deceiving the consumer about the true meaning of this statement since no toxicity test has ever been required by the Community legislator on 'finished products', but only on the components.

It is well known, however, that under the aforementioned 'REACH' regulation, all chemical substances considered dangerous, including those used for cosmetics, must be subjected to toxicity tests in relation to the quantities produced, with the exception of those in use for a long time and used only in cosmetic products.

It is therefore necessary and urgent that the labelling of the aforementioned products reports this information, allowing citizens to acquire a true awareness of both the risks to their health and the possibility of exercising their own ethical choices, in compliance with what is established by the Treaties of the Union and the Charter of Fundamental Rights of the Union.

11. The precautionary principle, which guides the international validation process of *in vitro* preclinical testing methodologies using parts of non-human or human animals to the purpose of assessing the safety of pharmaceutical products and chemical substances, cannot, by analogy, fail to be considered satisfied even when using internationally validated non-animal methodologies,

they ask

the European Parliament, on the basis of the above considerations, for the purposes of the effective application of the Treaties of the Union and of the Charter of Fundamental Rights of the Union, with regard to the protection and safeguarding of their own health and that of all European citizens as well as consumers, and with regard to the right to information, in order to be able to exercise their right to freedom of conscience in 'practices' as far as the choice of pharmaceutical and veterinary products, biosimilars, medical devices, cosmetics and chemical substances marketed in the European Union is concerned, and in relation to their feelings for the suffering of non-human animals used for scientific purposes, to express their opinion on the following requests and to issue a Resolution, or equivalent act, to ask the European Commission to submit any appropriate proposal pursuant to Article 225 of the Treaty on the Functioning of the Union, for the purposes of:

a) Include, in the regulations concerning the preclinical toxicity and efficacy testing for drugs for human or veterinary use, biosimilar products, medical devices, cosmetics and chemical substances produced in the EU, the obligation to use alternative *in vitro* or *non-animal methods* accepted by the OECD or considered scientifically valid by the EU.

b) Include, in the regulations concerning the preclinical toxicity and efficacy testing for drugs for human or veterinary use, biosimilar products, medical devices, cosmetics and chemical substances produced in the EU, the alternative *in vitro* or *non-animal* methods validated in the Union and transmitted to the OECD for acceptance, allowing their use as an alternative to *in vivo* methods for marketing purposes in the Union.

c) Strongly promote at all levels research into new methodological approaches *in vitro* and/or without the use of animals, aiming at the qualification and standardization of computational methods, 'organ-on-chip' technologies, organoids and similar based on the specific biological species and promote the use for these purposes of materials coming from the donation of human bodies.

d) Include, in the regulations regarding the labelling of the products referred to in the previous points, when marketed in the EU, the obligation to report on the packaging the words: 'substance tested on animals / not tested on animals' and 'substance clinically tested / not clinically tested', for each component, depending on the tests carried out.

Notes

(1) EU Directive 2010/63, in Article 13 (Choice of methods), point 1, establishes: "Without prejudice to the prohibition of certain methods under national legislation, Member States shall ensure that a procedure is not carried out where Union legislation recognizes other methods or testing strategies to obtain the desired result which do not involve the use of live animals". Furthermore, in Article 38 (Evaluation of the project) point 2 letter b, it indicates among the evaluation criteria the "compliance" with the requirements of the '3Rs'. In the above-mentioned regulations, on the other hand, it has been shown that the indication of the method to be followed is sometimes expressed in an ambiguous manner or the choice of the method is left to the experimenter. Therefore, Union legislation, in such cases, is contradictory and could potentially lead to its incorrect application in Member States if , for the authorization of procedures, regulated by Directive 2010/63, national legislation complies with the provisions of the same, contravening those regulations, and vice versa."

(2) See: A framework for establishing scientific confidence in new approach methodologies
https://publications.jrc.ec.europa.eu/repository/handle/JRC129264

(3) See: Journal of the American College of Cardiology; JACC: dalla scienza di base a quella traslazionale Volume 4, numero 7 ,novembre 2019, pagine 845-854

(4) See: (PDF) REACH out-numbered! The future of REACH and animal numbers
10.14573/altex.2307121

(5) See: EU Regulation 2023/464 amending Regulation (EC) No 440/2008, Considerations (5):

"This situation has created uncertainty for registrants under Regulation (EC) No 1907/2006, as well as for duty holders under other Union legislation, as to which methods should be used for the generation of data for the purposes of that Regulation and other legislation. Article 13(2) of Regulation (EC) No 1907/2006 provides that methods are to be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved, and that the Commission is to, if appropriate, make a proposal as soon as possible to amend Regulation (EC) No 440/2008, so as to replace, reduce or refine animal testing. Furthermore, Article 13 of Directive 2010/63/EU of the European Parliament and of the Council ([3]) on the protection of animals used for scientific purposes, makes it a legal obligation in the Union to use an alternative method that does not entail the use of a live animal, instead of an animal method, once such method is recognised under the legislation of the Union. Any delays to the process of introducing new alternative methods into Regulation (EC) No 440/2008 therefore could hinder a timely uptake of such methods once they are adopted at international level.

Pursuant to Article 232, point 13, of the Rules of Procedure of the European Parliament 2024-2029, in derogation from the provisions of point 12, the signatories of this petition, with the sole exception of the presenter and the substitutes, request that their names not be disclosed, in order to protect their privacy.

We wish to authorise other persons to support the Petition.

Attachments:

Attachment 1 : Signatories from association SOS GAIA

Attachment 2 : Petition (PDF)

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Other signatories

Persons

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