

[...]

Parte 2 - Qual è l'istituzione o l'organo dell'Unione europea che intende denunciare?

Commissione europea

Parte 3 - Qual è la decisione all'origine della denuncia? Quando è stata presa tale decisione o quando Le è stata notificata? Corredare di allegati se necessario.

La decisione all'origine della denuncia è la risposta della Commissione Europea all'ICE Stop Vivisection, rilasciata il 3 giugno 2015 e qui allegata, insieme alla lettera in cui si spiegano le ragioni della denuncia.

Parte 4 - Che cosa considera che l'istituzione od organo comunitario abbia fatto di sbagliato?

Le ragioni della denuncia sono contenute nel secondo allegato al passo precedente.

Parte 5 - Secondo Lei, cosa dovrebbe fare l'istituzione o l'organo europeo per risolvere il suo problema?

Per le ragioni spiegate diffusamente nel "Complaint to the European Ombudsman", sopra allegato, la Commissione Europea dovrebbe

- 1) accogliere le richieste dell'ICE Stop Vivisection;
- 2) applicare il principio di precauzione (Trattato istitutivo dell'Unione Europea, 1992-1998, art. 174, par. 2) in relazione all'accertamento dei rischi e dell'efficacia di sostanze chimiche e medicinali, e in particolare emanare una /moratoria/ sull'uso della sperimentazione su animali a tali scopi;
- 3) redigere una nuova direttiva che
 - 3.1 riconosca il carattere /scientificamente controverso/ dell'uso di metodi fondati sulla nozione di "modello animale", metodi che non sono mai stati validati e che non possono quindi fungere da "golden standard" per nuovi metodi;
 - 3.2 renda /obbligatorio/ l'uso dei metodi senza animali fin qui approvati;
 - 3.3 promuova lo sviluppo e la rapida approvazione, /sulla base di dati direttamente rilevanti agli esseri umani/, di metodi realmente scientifici;
 - 3.4 risolva, in tutti gli altri casi, la /grave contraddizione/ tra l'affermazione che «the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals» (art. 13 del Trattato sul Funzionamento dell'Unione Europea) e il permesso, previsto dall'attuale direttiva 2010/63/EU del 22 settembre 2010, di eseguire esperimenti dolorosi su animali, anche selvatici e randagi (artt. 9 e 11), a discrezione dello sperimentatore (art. 14, "Anestesia": l'anestesia può non essere applicata «se l'anestesia è incompatibile con lo scopo della procedura»), in un contesto, quello degli stabulari dei laboratori, che è di per sé la negazione della esigenza di «full regard to the welfare requirements of animals» (le condizioni poste dall'art. 33 sono in generale insoddisfacibili, e del resto derogabili ai sensi del comma 3).

Parte 6 - Ha già contattato tale istituzione od organo al fine di ottenerne la risoluzione?

Sì (specificare e inviare copia della corrispondenza pertinente)

La mia denuncia nasce dalla inadeguata risposta della CE alla lettera del Comitato Stop Vivisection, inoltrata nel settembre 2015 e che qui riproduco:

«Dear Members of the European Commission,

Your written "Communication on the European Citizens' Initiative Stop Vivisection" dated 3 June 2015 (1) is yet another demonstration of the fact that we, the citizens of Europe, are considered in Brussels to be an amorphous mass of individuals unable to discern between propaganda and true facts, incapable of understanding the difference between a number of generic, undemanding declarations and the crude dynamics of vested interests underlying animal experimentation.

Your official response to three years of democratically motivated campaigning involving tens of thousands of tireless activists across Europe and nearly 1,200,000 signatories, came as a shocking revelation of the inability by the European Commission to analyse or appropriately address the fundamental *raison d'être* of Stop Vivisection, namely to expose and to challenge the very unscientific assumption that the animal model is a valid modality for human drug development and disease research, and that the current use of animals as human surrogates is therefore unsound and invalid.

Your text completely misses the point from the very beginning, when it states that "The EU shares the Citizens' Initiative's conviction that animal testing should be phased out" (pages 2 and 7). You failed to notice that the main focus of Stop Vivisection is not about the phasing out of animal experimentation *per sé*, an objective which is widely shared by the great majority of people both in Europe and elsewhere (with the obvious exception of those who earn a living and billionaire budgets from it).

We did not need to mobilise 1,200,000 people across 28 European countries had our aim been to gradually phase out animal experiments. No: our goal was and is to end animal experiments without delay by making it patent how many false obstacles - both political and scientific - stand in the way of achieving this aim.

To that end, we asked for an independent scientific inquiry involving international experts to discuss the historical, legal and predictive aspects of animal research and testing. All we were presented with was a ritualistic reaffirmation of your reliance upon the current laws addressing animal experiments: directive 2010/63/EU and Cosmetics regulation 1223/2009. A very poor response indeed.

Directive 2010/63/UE, which is the formal object of our Initiative as well as the crude materialisation of countless vested interests, neither protects animals nor is it a legal text paving the way to a world free of animal testing. Quite the contrary, under a thin layer of winsome, would-be reassuring enunciations about animal welfare, it reveals the backward and cunning nature of the *in vivo* business.

°° Do we need to remind you that no animal experiment has ever been validated and that an ever increasing number of internationally renowned scientists question its validity with irrefutable arguments pertaining both its theoretical basis and its practical results?

°° Do we need to remind you that the 3Rs principle on which Directive 2010/63 is founded has stood in the way for several decades of implementation, to achieve any meaningful reduction in the numbers of animals used for experiments, and all statistical data concerning animal experimentation at a national level show an alarming increase in the number of animals used in EU laboratories?

°° Do we need to remind you that compared with the previous law dated 1986, Directive 2010/63 is more backward on such extremely sensitive issues as the levels of suffering and stress that can be legally inflicted on animals? And namely:

- that directive 86/609/EEC prohibited experiments on stray cats and dogs whilst the one passed in 2010 allows them?

- that directive 86/609/EEC prohibited the use of neuromuscular blocking agents without general anaesthesia whilst the one passed in 2010 allows it?

- that in response to the pressures of the professionals in the field the law was supplied with two additional clauses, the first of which permits experimenters to surpass "the upper limit of pain that the animal can be subjected to", whilst the second allows the use of nonhuman primates in applied research in areas that are not linked with debilitating and lifethreatening conditions in humans?

°° Do we need to remind you that contrary to all claims of transparency and accountability, under articles 40/42 member states may allow the authorisation of multiple generic projects for a period up to five years and introduce simplified administrative procedures (if the projects contain procedures classified as "non-recovery", "mild" or "moderate", and are held to satisfy regulatory requirements) waiving the requirement for a non technical summary accessible to the public?

°° Do we need to remind you that alternative methods are mostly recommended but never made compulsory?

°° Do we need to remind you that Cosmetics Regulation EC 1223/2009 imposes "a complete marketing ban on cosmetics products and ingredients tested on animals" but only in theory, only to dazzle the more optimistic and credulous opponents of vivisection? Worse than ever, in fact, nobody in Europe can possibly ascertain whether the solar filter or lipstick or make up she/he is using has been totally or partially tested on animals (or not) given the intricacy of derogations the law has been abundantly furnished with.³

To sum up:

the focal point explaining why Stop Vivisection was set up three years ago is that whilst conceived and finalised to satisfy relevant economic and financial needs, Directive 2010/63 proves to be thoroughly out of step with modern scientific knowledge. This is particularly evident at recital n. 10 which summarizes the spirit of the law by stating that "the use of lives animals continues to be necessary to protect human and animal health", a principle repeatedly echoed in your response to Stop Vivisection. But no explanation, no written references, no scientific in-depth examinations are provided, alas, to support such an egregious declaration while countless scientific studies underpin the contrary.

To discuss and overcome these scientific loopholes, and to promote Europe as a preminent scientific economic force worldwide we presented a Dossier supported by 1,173,131 signatures with 10 requests, none of which was taken into account.

We didn't want to know how much you like Directive 2010/63. We didn't want to know how much you appreciate the false premises of cosmetic regulation 1223/2009. We didn't want to know that you will go on spending money on conferences about the pitiful 3Rs principle nor funding morally degrading, counter productive and wasteful enterprises where millions of animals and millions of euros are being sacrificed on the altar of a perversion of science (2).

We want Europe to strive unequivocally for a leading role both on scientific and ethical grounds. We want Brussels authorities to take seriously the problems posed by an increased, uncontrolled rise in all acute and chronic illnesses, and unequivocally embrace a new vision and new modern strategies that rely upon evidence-based medical and toxicological research. We want the leading

international scientists of both sides to enter publicly the arena and discuss the principles of a truly modern science.

Pursuant to the all the above we therefore respectfully ask you to reconsider and provide real answers to our proposals. Here attached you will find them again so that you can give us and millions of european citizens the 10 answers they deserve (3).

Please note that in the absence of a reply within 30 days following the sending of this letter, we reserve the right to pursue all possible legal means to enforce compliance with the spirit of the European treaties.

Andre Menache and Gianni Tamino,
representatives for Stop Vivisection Initiative

(1) <http://ec.europa.eu/transparency/regdoc/rep/3/2015/EN/3-2015-3773-EN-F1-1.PDF>

(2) to name but two, the Xenome Project, and the European Conditional Mouse

Mutagenesis Program: <http://www.mousephenotype.org/about-ikmc/eucomm>

(3) http://www.stopvivisection.eu/sites/default/files/dossier_-11_may_2015.pdf

Parte 7 - Sono state esaurite le possibilità interne di domanda o ricorso amministrativo previste dello statuto del personale? In tal caso, sono scaduti i termini fissati per la risposta da parte dell'autorità interessata? (Rispondere solo se la denuncia è inerente ai rapporti di lavoro con le istituzioni ed organi comunitari)

Nono applicabile

Parte 8 - L'oggetto della Sua denuncia è stato già trattato da un tribunale o è ancora in stato di pendenza?

No

Parte 9 - Sei pregato di confermare di aver letto le informazioni seguenti.

You have read the information note on data processing and confidentiality

Parte 10 - Autorizza il trasferimento della Sua denuncia ad un'altra istituzione od organo (europeo o nazionale), qualora il Mediatore europeo ritenga di non essere abilitato a trattarla?

Sì