Paris, the 5th of October 2019

To the attention of the Members of the European Parliament

Subject: **Evaluation of the implementation of the Directive 2010/63/EU on the protection of animals used for scientific purposes, and request for review**

Madam MEP, Mr. MEP,

The European Commission will present you next November **a report on the implementation by the Member States of the European Union of Directive 2010/63 / EU on the protection of animals used for scientific purposes ("the Directive"), pursuant to Article 57 thereof.**

We do not prejudge the content of this report, but we know that it will be based on the analysis of experts appointed by the Member States and on various information provided by them.

It would be suitable to have the MEPs ensuring that the outcome of the Directive's implementation are actually measured on the basis of **the most objective data**, namely **the evolution of the number of animals used for scientific and educational purposes** and not on the basis of purely subjective data.

Indeed, it turns out that the number of animals used is not decreasing in "biggest consumers" countries, namely Great Britain, Germany and France. Although some Member States seem to be more virtuous (Spain, Italy, Netherlands), the reduction in the number of animals used remains very small. Moreover, this reduction was initiated before the publication of the Directive and its transposition by the Member States, and is therefore not attributable to the implementation of the Directive.

Furthermore, we could underline that in France the number of severe procedures (the most painful) and the number of non-human primates used, including in education and training (even though this last use is not allowed), are increasing.

In its current wording, the Directive does not allow neither **an effective protection of animals** used for scientific and educational purposes nor a **significant reduction in their number**. Nor does it provide the means to support the development and implementation of alternative (non-animal) methods.

An in-depth revision seems necessary and urgent to ensure that the Directive actually becomes the tool towards a non-animal research, as required in recital 10: "[…] *this Directive represents an important step towards achieving the* ***final goal of full replacement of procedures on live animals for scientific and educational purposes*** *as soon as it is scientifically possible to do so […]"* and **it guarantees the best as possible protection of the animals still used in the procedures** pursuant to the principle mentioned in recital 12: "[…] *Animals have an intrinsic value which must be respected [...]" and "[…] Therefore, animals should always be treated as sentient creatures […] "*

In that perspective, here are the loopholes and breaches that we have identified **in the text of the Directive:**

- Many provisions of the Directive are too lax and many exceptions to the rule are possible, which considerably limits its scope;

- The 3R principle (Replacement, Reduction, Refinement) - developed in 1959 by two British scientists - is widely considered to be tantamount to applying alternative methods. But this fact undermines seriously the development of Replacement methods (which do not use live animals), because researchers focus mainly on Refinement or Reduction methods which are still based on animal testing;

- Some categories of vertebrate animals - yet subject to procedures - are not protected by the Directive (or are not until they are killed);

- The criteria for assessing pain, suffering and stress experienced by animals are approximate and often irrelevant, resulting in systematic underestimation and inadequate management;

- The methods of killing "recognised" by the Directive are ethically unacceptable;

- The standards set for accommodation conditions do not take into account the actual needs of animals, nor the specific needs of animals subjected to painful and / or stressful procedures;

- The supply of animal-using institutions from breeders and suppliers is not regulated and many animals used in the procedures come from non-authorised breeders or suppliers (European or non-European);

- The use of non-human primates is increasing (particularly in France, the first European user) even though the European legislator wanted to restrict it to specific areas of research; furthermore, public opinion is very largely opposed to their use;

- The transparent, impartial and informed evaluation of projects using animals is not guaranteed by the authorities in charge because the required competences are not defined in the Directive, and the interpretations are likely to vary from one Member State to another;

- The development, enhancement and implementation of alternative methods that do not use animals are not supported by the Directive: they are just mentioned in a few articles.

Each of the above points is developed in the annex attached to this letter.

More generally, the Directive should be revised to ensure:

1) **Transparency**

The Directive must impose transparency on Member States: publication of figures and non-technical project summaries (which must be provided by the designer at the time of the request for administrative authorisation) within one year of first use of the animals, description of the methodology for data collection and control procedures, readability of documents published for the benefit of non-specialized public, mandatory publication of retrospective project assessments, publication of activity reports by national authorities responsible for the protection of animals used for scientific purposes, etc. This concern for transparency should also be reflected in the presence of NGOs and independent experts within authorities responsible for evaluating projects using animals (see item 9 of the Annex).

2) **The independence and expertise of the evaluation authorities members**

The current Directive does not specify what means the term "competent authorities" responsible for assessing projects using animals before obtaining an administrative authorisation. Paragraph 4 of Article 38 only states that the assessment must be carried out in an "impartial and transparent" manner. In fact, in France, the Ministry of Research delegates this evaluation mission to local "ethics committees" which – due to their composition (see item 9 of the Annex) - do not guarantee that the recommendations of the Directive are strictly applied. Being involved in animal-using institutions, they could often be both judges and interested parties.
One can also wonder about the choice of experts mandated by the European Commission to assess the effects of the Directive implementation by the Member States and decide whether it is necessary to revise it.
How are they selected? What are their jobs, their skills?

3) **The controls and sanctions effectiveness**

The Directive must lay down the control procedures applied by the European Commission to the Member States to ensure that all Directive provisions are rigorously applied, including penalties in case of non-compliance. The latter should be effective and dissuasive. Each Member State has today considerable freedom in implementing the Directive provisions. In absence of real political will in most States, shortcomings are observed in transposition into national law, as well as a lack of rigorous application. These breaches do not give rise to any sanction from the European Commission (infringement proceedings). Likewise, realising that the objectives announced in the recitals are not achieved because Member States do not mobilise the adequate resources, the European Commission should apply the principle of subsidiarity (Article 5 of the TEU) in order to achieve these objectives.

4) **Visibility of the Directive's dual objective**

Today, the title of the Directive only takes into account "*the protection of animals used for scientific purposes*". However, if the European legislator has considered that the Directive should be reviewed in the light of progress made in alternative methods (see Article 58), it must be clearly indicated in the title.
Furthermore, the notion of non-animal methods needs to be revisited to include - beyond the simple replacement of existing methods using animals – completely new research methods (ex-novo).
The term "New Approach Methodologies" (NAMs) is increasingly used because it covers all approaches that allow us to understand life complexity without using animal model.
The title of the Directive would then become: "***Directive on the protection of animals used for scientific purposes and development of new approach methodologies".***

In the sake of European Union law consistency, a thorough revision of the Directive is needed and it is essential that the **non-regression principle** is mentioned so that the achieved progress cannot subsequently be questioned.

Therefore, the signatories of this letter ask you to intercede with the European Commission in order to obtain a **reassessment by the European Parliament of Directive 2010/63/EU** as soon as possible. The choice of experts and other stakeholders should be transparent, involve transdisciplinary skills and ensure that the animals' interests are represented.

Remaining at your disposal, we ask you to accept, Madam MEP, Mr. MEP, the assurance of our highest consideration.

Florence BURGAT – Philosopher, Research director - INRA (National Institute of Agriculture Research – France)
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Dr Colette GOUJON – MD, Hospital practitioner, Expert neurologist in pain assessment and treatment - Henri Mondor Hospital (Créteil, France)
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Jean-Pierre MARGUENAUD – Associate professor in private law, Expert in animal law, Researcher at the European Institute of Human Rights
Muriel OBRIET – Member of animal rights commission (The Greens – France), referent on animal experimentation and New Approach Methodologies (NAM's)
Dr veterinary Charly PIGNON – Algologist veterinary, graduated from the European college of zoological medicine (small mammals)

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ANNEX

1) A Directive with low binding objectives and leaving too much room for discretion to the Member States

- The current drafting of the Directive considers multiple exceptions to the recommendations; it also presents breaches that allow Member States a very flexible application and its scope is therefore limited. Exceptions should be limited to very rare cases and a clear and deliberate drafting should be adopted which does not leave room for interpretation by the Member States.

- No specific targets are set in terms of reducing the use of animals, nor is there any time limit for implementing the means necessary for the transition yet advocated in the recitals. In order to ensure that the ultimate goal of total replacement of animals in procedures is not an ever-widening horizon, a timetable with quantified targets should be set. The deadlines may be differentiated according to the purpose of the projects (basic research, applied research, toxicology, education and training) and the scientific prospects of replacement in the short and medium term. A progress report will be completed every 5 years.

- In order to ensure that the achievements contained in the Directive cannot be questioned, it is necessary to include **the principle of non-regression in one of the articles of the revised Directive**.

2) Confusion between the 3Rs rule and the notion of alternative method

• What is it about?

The 3Rs rule was first enunciated in 1959 by two British scientists who wanted to improve the fate of animals used in scientific procedures: "Replacement, Reduction, Refinement". The aim was to replace the animals in procedures where possible, to reduce the number if it was not possible to replace them and finally to limit the suffering and stress of those which were used. This principle is still used as a reference in regulatory texts and its application is considered to correspond to the application of the so-called "alternative" methods.

• So-called "alternative" methods that use animals

Only "replacement" methods do not use live animals.

It is therefore important not to confuse the 3Rs rule (which corresponds to a hierarchy of methods) with the implementation of alternative methods.

The terminology used in the Directive and in national transpositions should clearly differentiate between 3 categories: non-animal approaches and methods (or "New approach methodologies"), reduction methods (which are not alternative methods but which can reduce the number of animals used), refinement methods (which are not alternatives but which can reduce the stresses and pains inflicted on animals).

- **A change in terminology that has become essential**

  The current terminology used in the Directive does not distinguish between new approach methodologies (NAM's) that do not use animals, and methods of reduction and refinement. It is therefore imperative to modify the terminology in order to be able to differentiate the resources allocated to the development of methods without animals from those that are allocated to the other methods. Indeed, only the development of the former will guarantee a decrease in the number of animals used.

3) Some animals forgotten by the Directive

- **Animals killed for removal of their organs and tissues**

  The animals - more and more numerous - used for removal of their organs and tissues are not specifically protected by the Directive (no article contains specific provisions concerning them) and their killing is explicitly outside its scope (art 3 §1 – 2nd paragraph).

- **Animals used to produce biological substances (blood, hormones, antibodies, etc.)**

  These animals are not even mentioned in the Directive while they are subject to long and painful procedures.

- **An overly restrictive definition of « procedure »**

  The explanation of the lack of consideration (or partial consideration) of these animals by the Directive is that they do not participate in what is defined in the Directive as a "procedure" (art 1 §1). This also means that they are not counted and do not appear in the statistical data (only Germany shows in its annual data the number of animals used for tissue or organ sampling).

  A broader definition of the concept of “procedure” should be provided, which would allow these animals to be also under the protection of the Directive, including for their killing, and to be counted by all Member States as having been “used for scientific or educational purposes”.

4) Undervalued and poorly managed pain and suffering

- **Classification of severity of procedures**

  The Directive requires that a severity category be assigned to each procedure using animals (knowing that a project may include several procedures) (see art. 15). This classification is based on the level of pain, suffering, stress "estimated" by the project designers (mild, moderate, severe, non-recovery). Animals used in so-called mild or moderate procedures may be "reused". Only projects involving procedures classified as severe or using non-human primates will give rise to a retrospective assessment, i.e. an ex-post evaluation of the project, its progress and its results.

- **What evaluation criteria for project designers?**
  Annex VIII of the Directive is intended to provide evaluation criteria to "classify" procedures, with some examples. Not only are these examples inaccurate and incomplete, but the classification itself underestimates grossly the level of pain, suffering and stress experienced by animals undergoing procedures. This point is illustrated by the fact that serious surgical procedures (thoracotomy, craniotomy, orthopedic surgery) or the induction of tumors are classified as "moderate" procedures. While surgical interventions are obviously performed under anesthesia, the post-operative consequences or tumor proliferation are extremely painful (human patients could attest) and are not taken into account. As pain is not properly assessed, the classification of procedures is not relevant and pain management cannot be appropriate.
  Too much room is left in the current drafting of the Directive for a subjective assessment of the level of pain, suffering and stress experienced by animals.

- **The need of objective evaluation for effective management**
  An objective evaluation requires:
  - to establish a comprehensive typology of procedures (themselves broken down into technical acts) applied to animals,
  - to produce detailed grids for assessing pain, suffering and stress,
  - to define the management modalities according to the species and type of procedure (acupuncture and other approaches will be considered when analgesics could distort the experiment results),
  - to require the recruitment of a veterinarian expert in algology in all animal-using institutions (must be present at the time of killing),
  - to gradually introduce in accommodation facilities a visual capture of animals to ensure permanent monitoring and rapid management of pain, suffering and stress,
  - to end the reuse of animals in several procedures except in the cases of procedures objectively assessed as light (limitation to two reuses).

- **Human pain and animal pain**
  The same care must be given to the management of the pain and suffering of "animal patients" - including during experimental procedures - as those of human patients, because these pains and sufferings are of the same nature, even if modes of expression differ.

  In particular, it should be noted:
  1) That barely 50 years ago, human infants were not considered to be suffering (or only slightly) because medical staff was not trained to interpret the signs by which they manifested their pain and **these manifestations were interpreted as reflexes that did not include consciousness,**
  2) **That human pain is studied using animal models**, and these studies are based precisely on the anatomical and physiological similarities between vertebrate species that allow **analogies to be drawn between animal pain and human pain.**

5) Methods of killing that are ethically unacceptable

- **What are the methods of killing recognized by the Directive?**
  Annex IV of the Directive lists the killing methods that may be used at the end of a procedure: anaesthetic overdose, captive bolt, carbon dioxide, cervical dislocation, concussion / percussive blow to the head, decapitation, electrical stunning *(note: this is not a lethal method*), use of inert gases, shooting with a bullet.
  And it is mentioned that *"methods other than those listed in the table may be used"* - without any more precision - on animals that are unconscious or used in agronomic research.

- **Methods incompatible with taking into account the sensitivity and consciousness of animals**
  Excluding anaesthetic overdose, none of these methods are acceptable and some of them - in another context - would be prosecuted as acts of cruelty. For example, "cervical dislocation" is considered unethical in the United States. And in most Member States, the crushing of the skull of a newborn kitten or puppy by any "citizen" would lead to criminal proceedings.

- **The necessary establishment of « human » killing conditions**
  For the sake of consistency of European Union law, if animals are considered to be sentient beings and have an "intrinsic value" (*see recital 12*), it should be stated in the Directive that the only authorized method of killing - ethically acceptable - is the overdose of anaesthetic preceded by sedation. The use of carbon dioxide could be allowed for some species provided the animals are previously unconscious.

- **The presence of a veterinarian should be mandatory at the time of killing** (which is the case in Anglo-Saxon countries).
  This should be done in a quiet room away from the presence of congeners. There is no justification for the fact that the killing of these animals is not carried out under the same conditions as those applied in veterinary clinic.

6) Accommodation conditions that do not respect the real needs of animals

- **A reductive approach of animal welfare**
  In Annex II of the Directive, the choice was made to limit the definition of animal "welfare" to a purely quantitative and material approach: measurements, quantities, number of animals per m^2, nature of the flooring, etc. on 18 pages.
  These are minimum standards that are supposed to enable animals to endure the condition they are under until they are killed while avoiding excessive investment by institutions supplying and using animals.

- **The need to take into account the physiological, social and cognitive needs of each species and their health status**
  Regardless of sufficient space to move freely (the concept of territory is also to be taken into account), every animal needs natural air and light, exchanges with its congeners and various activities.
  It is not possible to claim to take animal welfare into account without integrating all these parameters into the regulatory standards. Moreover, animals can be subjected to experiments for months or even years.
  It would also appear that the Directive sets standards for accommodation and care only for healthy animals. What happens when they are subjected to painful and / or stressful procedures? Standards should be different in order to take into account their physical and mental state.

- **Integration of the latest scientific knowledge into standards**
  In order to be consistent with the principles set out in the Directive recitals, accommodation and care conditions should be considered in the light of the most recent ethological knowledge, species by species. **Species used in agronomic research must be able to enjoy the same level of protection as other animals**.

7) Lack of regulation for the supply of animals used for scientific purposes

- **A major omission of the European legislator**
  The Directive requires Member States to ensure that all breeders, suppliers and users of animals are authorised by the competent authority designated by them (Art. 20). But the European legislator has forgotten the most important: **there is nothing in the Directive to indicate that the user is obliged to buy from a breeder in the European Union, authorised or not.**

- **A mandatory supply from authorised suppliers and breeders in the European Union**

  In order to ensure that the legislator's desire to protect animals before they are subjected to a procedure is not circumvented, it is necessary to make it compulsory for users in the European Union to purchase animals from authorised breeders and suppliers in the European Union.

8) Increasing use of non-human primates

- **An increase in the number of non-human primates used in procedures that conflicts with the objectives of the Directive and societal expectations**
  Not only the number of animals used for scientific and educational purposes is not decreasing in the European Union, but there is also an increase in the number of non-human primates. In France, for example, this increase has been continuous since 2010 (the number of non-human primates used has more than doubled between 2010 and 2017). They are not only used in research but also in the assessment of health and environmental risks.

However, recital 17 of the Directive states that: *"Their use should be permitted only for basic research, the preservation of the respective non-human primate species or when the work […] is carried out in relation to potentially life-threatening conditions in humans or in relation to cases having a substantial impact on a person's day-to-day functioning, i.e. debilitating conditions."*

- In addition, recent surveys of European citizens show the public's desire to take non-human primates out of scientific procedures.

  56% of them **do not consider experiments on dogs and non-human primates acceptable,** according to the 2010 Eurobarometer (pages 64 to 67):

  http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_340_fr.pdf

- **Genetic manipulations that should alert**

  The use of non-human primates is raising more and more ethical issues.

  For several years, Japanese and Chinese teams have been creating genetically modified primate lines, "models" of human diseases. In early 2019, Chinese researchers were delighted to have cloned genetically modified macaques so that they had a disrupted circadian rhythm, leading to mental disorders. Regardless of any doubts that may be raised about the relevance of such "models" for human mental illnesses, there is a need to question more broadly the increasing use of genetically modified animals in research.

  "Humanized" mice have long been manipulated, but for non-human primates - who share 98% of their genetic code with the human species - the question is taking on a new dimension with the risk of producing "human / non-human" hybrids. The European legislator should react against this issue as soon as possible.

9) A project evaluation procedure that does not guarantee the implementation of non-animal methods

- **Pre-project evaluation**

  Any project using animals must obtain an authorisation from the competent administrative authority after having been evaluated on the basis of two criteria: 1- Could this project be carried out without using animals? 2- Are the expected benefits higher than the (estimated) "cost" suffered by the animals?

  The Directive is not sufficiently explicit on the project evaluation process, on the functioning and composition of the evaluation bodies, leaving too much room for interpretation of the text by the Member States.

  In France for example, 4/5 of the ethics committees that carry out this evaluation are people with a link with animal experimentation. There is no obligation for these committees to include scientists who are experts in alternative methods (methods that do not use animals) and / or non-biologists, ethicists, NGOs.

  In fact, ethics committees do not provide the necessary guarantees for the objectively impartial, informed and transparent evaluation of projects using animals, yet legitimately expected.

- **Retrospective assessment**
  In the Directive, only projects using non-human primates and those including procedures considered as severe (see point 4) are subject to retrospective assessment. This ex-post evaluation of the project must answer the following questions: did the project proceed under the conditions initially planned? Have the expected results been achieved? However, Member States have no obligation to publish these retrospective assessments.

  In the name of the consistency of European Union law, if animals have - as stated in the Directive - an "intrinsic value" and therefore the life of each of them must be respected, **any project using animals should give rise to a retrospective assessment.** All these ex-post evaluations will be published on websites of the Member States' research ministries, in order to ensure transparency for citizens.

10) Development, enhancement and implementation of alternative methods that do not use animals

- **The Directive does not go far enough in the direction of alternative methods for replacing animals in procedures.**
  Whereas the ultimate objective of the Directive, expressed in recital 10, is the *"full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so",* the Directive devotes only one article to the development of alternative methods (Article 47) - out of 64 - which deals as much with replacement methods as with methods of reduction or refinement. Why set a goal if you do not give yourself the means to achieve it?

- **Therefore, a substantial part of the Directive must be devoted to new approach methodologies (NAMs)** and the various measures to be implemented both at Member State and European level.

  In particular, the new provisions of the Directive should make it possible:

  - To focus research efforts on **alternative methods** - more broadly on the new approach methodologies that deviate from the animal model - and ensure the strict application of **the hierarchy of methods** when designing projects (1 - replacement, 2 - reduction, 3 - refinement) in accordance with the 3R deontological rule,

  - **To stop referring to the 3R rule (see above) when discussing about alternative methods** because the scope of these should be limited to methods that do not use animals (i.e. NAMs),

  - To allocate **sufficient and sustainable human and financial resources to ECVAM** (European Centre for the Validation of Alternative Methods) in order to accelerate the validation of alternative regulatory tests and the performance of the other tasks provided for in Annex VII,

- To create a **European data bank** to avoid duplication of experiments and support any initiative to share data,

- To **mandate the use of non-animal method**s when they exist and have been validated within the European Union,

- To actively encourage the implementation of alternatives to the use of animals in education and vocational training as **simulation methods exist and are very unevenly used in the Member States**. For example, in 2016, France used 34 280 animals for this purpose (and even 35 512 in 2017) whereas the United Kingdom used only 1 438 (2017 figure not yet available),

- To support projects for the **creation of graduate training courses** devoted to non-animal methods in all Member States so that future researchers in life sciences gradually abstain from the animal model,

- To **set up a European Info Centre on the new approach methodologies** for researchers.