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For greater transparency in animal experimentation

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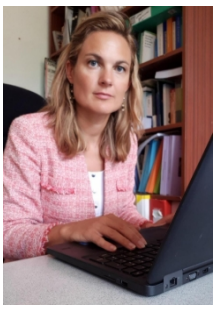

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IN BRIEF: THE ISSUES

Despite increasingly stringent European regulations, **the conditions under which animal experimentation carried out in France remain opaque.** This may be the result of legislation that still too lax, or it may be the result of poor enforcement, which is a priority area for attention. While access to slaughterhouses is highly secure, the doors to animal testing laboratories are simply impenetrable. By comparison, nuclear sites and classified facilities are much more transparent, in terms of their number, location and inspection conditions. At a time when transparency is becoming widespread, how can we justify the continuing secrecy surrounding the conditions under which animals are used for scientific purposes?

In particular, administrative documents relating to animal experimentation are rarely published, or only very selectively. Despite the provisions guaranteeing the public's right of access to these documents, **it is particularly difficult to obtain them**: lists of establishments carrying out animal experiments; authorisation decisions for experimentation projects; approvals of the ethics committees responsible for evaluating projects; annual activity report of the Committee, etc.

national de réflexion éthique sur l'expérimentation animale (CNREEA); activity reports from ethics committees submitted to CNREEA each year; annual audits carried out by the Ministry, timetable and lists of inspections of establishments using animals for scientific purposes; inspection reports themselves, produced by the veterinary services. Faced with the reluctance of the administrative departments concerned, more and more cases were referred to the CADA and then to the administrative courts.

The context has changed: protecting the welfare of animals is becoming a societal concern, in line with the recognition of their sentience or, more broadly, because of greater consideration for the environment and living beings. European regulations on animal experimentation have become stricter since 2010, and Member States are being urged to change their practices, under the watchful eye increasingly vigilant associations. This is upsetting some in the research community, who are sceptical about the alternative solutions on offer, worried about the opening up of the debate on the subject and also about the effects of the newly recommended transparency. It should be recognised that, in some cases, the use of animals for scientific purposes may be protected by industrial or military secrecy. It often takes place in a competitive environment, where the economic stakes weigh heavily on scientific progress. Both the operation and the image of the research organisations, universities and public or private establishments concerned are at stake.

While laboratories that use animals shy away from publicity, transparency is necessary, and it is precisely transparency that makes it possible to accommodate mediation. It is not a question of systematically publishing all data in open data, but at least of "letting see" the information needed monitor and evaluate practices. **Opacity in this area is counter-productive.** If practices comply with the regulations, of which there are now many, then there is nothing to hide. And if they are not, then we need to make that known. It is easy to see the value of a process that is already under way, one that would lift the omerta, **ensure full compliance with the rules** and lift the veil of suspicion that is generally cast over all things secret, and more particularly over a practice that is the subject of many questions, and no doubt of a few fantasies.

In addition to the transparency of data relating to the use of animals for scientific purposes, two issues raise particular difficulties. The concerns the operation of

local ethics committees responsible for evaluating projects, whose legal status appears fragile, and within which the rules of independence and the fight against conflicts of interest are difficult to comply with; and, secondly, the conditions of inspection in experimental establishments, the procedures and results of which are still too difficult to access.

1. For greater transparency of data and statistics on animals used for scientific purposes

Every year, almost **2 million animals are used in experiments in France**, and almost **10 million in the European Union**. Rodents (mice, rats) and rabbits account for 70%, but birds, fish and all kinds of mammals (llamas, cattle, horses, pigs, etc.) are also used, including cats, dogs, monkeys and other non-human primates (NHPs). Fundamental research accounts for 45% of experiments, followed by applied or translational research (30%) and use for regulatory purposes (25%). The figures can be doubled[1] if we take into account breeding animals that are too old, animals killed to supply organs and tissues, animals eliminated because there are too many to meet market demand, or genetically modified animals that have not developed the expected characteristics.

A European regulations prescriptive and incentive, still room for improvement

For the past decade, European regulations have been encouraging transparency in this area, by providing for relatively detailed statistical reports, compiled from data

[1] Report of 5 February 2020 from the Commission to the European Parliament and the Council (2019 report on the statistics on the use of animals for scientific purposes in the Member States of the European Union in 2015-2017).

which Member States are now obliged to collect and forward to the Commission, annually or every five years, depending on the nature of the data, pursuant to Article 54 of **Directive 2010/63/EU1 of 22 September 2010** on the protection of animals used for scientific purposes, transposed in France by Decree 2013-118 of 1 February 2013. Statistics must be compiled on an annual basis on the number of animals used, their species, purpose of the project in which they are used, and the severity of the damage inflicted on them (from "light" to "severe" or even "no revival"). **Data publicity is strengthened thanks to European Regulation 10/1010 of 5 June 2019**, which stipulates that Member States' data, accompanied by a summary, must now be sent to the Commission by electronic transfer in a non-synthetic format. They have been made available online on the European Commission's ALURES platform by all EU states since 1st January 2022, along with "*non-technical summaries of projects and any related updates".*

Despite these advances, **transparency remains inadequate**. Some of the data submitted by the Member States is incomplete, underestimated or unreliable. For example, the latest summaries submitted to the platform by the French Ministry of Research, in April 2022, do not specify the dates on which the corresponding projects were authorised. But above all, a whole series of data remains legally excluded from the annual statistical reports, under terms of article 54 §1 of the 2010 directive. Either because they concern animals that are **not protected by the directive** (most invertebrates, larval or foetal forms, animals used as 'sentinelsin experiments that they have not undergone directly), or because they are **only** counted **every five years**, taking into account only the past year. These are animals eliminated even though they were not the subject of a "procedure(because they were supernumerary, from unusable batches or lines, no longer useful after being used for reproduction in approved farms, or eliminated for their organs or tissues). They were counted for 2017, and will be counted again for 2022[2].

[2] The only data available to date, for 2017 (pending publication of data for 2023), show that the number of animals killed "in experiments" is at least equivalent to the number killed "after experiments", which doubles the statistics.

As a result, it is not possible to compile complete and reliable statistics to provide food for thought on the subject. It should be noted that the 2010 directive is presented as

This is "*an important step towards the ultimate goal of total replacement of procedures on live animals for scientific and educational purposes, as soon as scientifically possible".*

In France, minimal *investment in transparency*

On 16 September 2021, the European Parliament adopted a resolution calling for innovation without the use of animals in research, regulatory testing and education (2021/2784 RSP). It states that "*some Member States have adopted national implementing measures which ensure a high level of protection for animals used for scientific purposes, while others merely apply the minimum requirements set out in Directive 2010/63/EU*". The resolution calls on the Commission to activate an ambitious and feasible plan to implement and finance alternatives to animal experimentation [3] . One of the requirements is to speed up training, education and awareness-raising on these subjects. The European Union is therefore exerting pressure on the Member States, which are showing varying degrees of receptiveness. France is not one of the countries singled out for its efforts to promote transparency and new practices with conclusive results (Sweden, United Kingdom, Germany). **France is rather the exception:** the number animals used is not falling. This is particularly true of cats, dogs and monkeys. What's more, the proportion of 'severe procedures is higher in France than the European average. The reasons for this include a lack of political will, relatively low levels of funding for "replacement projects, and the influence of pro-experimentation lobbies in consultative bodies.

Advertising remains exception when it comes to animal testing

[3] Stem cells, 3D printing, organoids, modelling software, etc.

In terms of transparency of processes and practices, efforts in France remain limited for the time being. **The low level of investment in this area can be seen firstly in the decree of 1 February 2013**, which transposed the 2010 European directive, and which **contains virtually no provisions for the publication of the documents** (or notices) that it requires to be drawn up.

Publication is not expressly provided for:

- the opinions issued by the Commission nationale de l'expérimentation animale (CNEA, which became CNPAfis on 20 March 2020) to the Minister for Agriculture,

- the annual activity reports of the animal experimentation ethics committees (CEEA) sent to CNREEA and the annual audit reports of the same CEEAs produced by the Ministry of Research (art. 3 of the Order of 1 February 2013),

- the annual activity reports of the Comité national de réflexion éthique sur l'expérimentation animale (CNREEA) sent to the President of the CNPAfis (R. 214-136 and R 214-130 of the CRPM),

- the annual national report CEEA activity produced by the CNREEA (art. R 214-134 and R 214-136 CRPM),

- minutes of EAEC meetings.

Secondly, transparency is not ensured **in practice by the three ministries that share responsibility for animal experimentation**: The Ministry of Research (MESRI - Directorate General for Research and Innovation - Department of Regulated Research Practices), which authorises experimentation projects (APAFis platform); the Ministry Agriculture (Directorate-General for Food, and the decentralised services of the Departmental Directorates for the Protection of the Population -DDPP), which are responsible for inspections and controls; and the Ministry of Defence and the Armed Forces (Directorate-General of the Armed Forces) for projects relating to defence and armament (Armed Forces Biomedical Research Institute - IRBA).

The websites of the relevant ministries provide a certain amount of information, but it patchy. For example

1- **Project authorisation** notifications issued by the MESRI are not published.

2- Until 2022, only part of the non-technical summaries of experimentation projects (**RNT**) was published on the MESRI website, with considerable delay, and in a format that was not very user-friendly.

It is not always clear what species are used, or why live animals are required. The 2019 European regulation has made it possible to publish them in open data and in a standard format, on the European ALURES database, finally bringing practice into line with the requirements of the 2010 directive.

3- The **list of 115 animal experimentation ethics committees** (CEEA), responsible the ethical assessment of projects using animals, has been published. However, neither their location (commune or at least department), nor the names or even the number of experimentation establishments under their jurisdiction are specified, which does not provide any information on the effectiveness of practices. 4- Even **the list of establishments** (around 640 according to unofficial figures) **involved in experimentation is not public**, for reasons linked to the - relative - risk of intrusion, or more obviously of counter-publicity for institutions or teams. The right to access this administrative document is proving very difficult to enforce (see, for example, CADA notice no. 20184054 of 28 February 2019, which will not be implemented until 2022, after legal action has been taken). While it is understandable that the list of establishments should not be published online, with precise details of the institutions, locations and addresses, it should be accessible under certain conditions, for example on reasoned request to the Préfecture, as is the case for declarations.

of the assets of certain elected representatives and public officials.

5- Furthermore, **the retrospective evaluations** carried out by the designers at end of the projects (mandatory when the experimental procedures are "severeor when the projects include the use of non-human primates) are not published, contrary to the practices of other Member States.

Finally, in general, we can also regret the delay and lack of resources invested in **updating the statistical data available online,** which is sometimes found to be lacking in rigour, with certain omissions, errors or inconsistencies casting doubt on its reliability.

No effective right of access to administrative documents

Publication of documents relating to animal experimentation is not compulsory, but is, depending on the case, ad hoc, late, partial, deficient or absent, when it is not the documents themselves that do not exist... If the administration's regulations and practices are not conducive to transparency, this reluctance turns into illegality when the administration even refuses to disclose documents that it has chosen not to publish. It is in fact very difficult obtain access to these documents, despite appeals to the CADA and sometimes to the administrative courts. However, **these administrative documents fall under the rules guaranteeing the public's right of access to administrative documents** (Act of 17 July 1978, articles L 311-1 et seq. CRPA), as confirmed by the succession of CADA opinions issued in their regard[4] .

In particular, **data on experiments in the defence sector (IRBA)**, which are subject to a specific circuit, remain opaque. They should normally be included in the annual statistics, especially as until a few years ago they involved non-human primates, for which the regulations are stricter. However, this is still not the case in practice, despite favourable opinions from the CADA (opinion no. 20202630 of 24 September 2020), which has also called for the disclosure of documents relating to the ethics dedicated to IRBA projects and its minutes of meetings (opinion 20202358 of 29/10/2020). The CADA considers that it "*does not have any information concerning the existence of a decision to classify the statistical data requested as part of national defence, nor any information that would make it possible to consider that their disclosure would be likely to infringe one of the protected secrets*". Consequently, these documents may be disclosed to any person who so requests, pursuant to article L311-1 of the CPRA, after removal of any information covered by one of the secrets protected by article L311- 6 of the same code. This favourable opinion was not acted upon, as is often the case in this area, which led to

[4] See, for example, in 2020 and 2021, CADA notices no. 20210258 on the activity reports, minutes or statements of conclusions of CNPAfis meetings and on the annual national activity reports of ethics committees; no. 20203330 on the minutes of CEEA meetings; no. 20205223 on non-technical project summaries; no. 20214781 on CEEA approvals, the CNREEA activity report, retrospective project assessments, *etc.*

necessitated referral to the administrative courts and questioning of the Minister way of written parliamentary questions[5].

5 proposals to increase the transparency of data on the use of animals for scientific purposes

1/ **To provide the public with information about establishments that carry out animal experimentation**, *at the very least* by making the list of authorised establishments in the département available at the prefecture on reasoned request. In addition, a map showing the number of establishments concerned by department should be published online on the Ministry of Research website, failing publication of the full list of establishments.

2/ **Animals disposed of in the context of experimentation but not "tested should be counted annually**, rather than every five years, without waiting for the 2010 directive to be adapted. In this way, the following would be counted in categories separate from that of animals

In this way, it is possible to distinguish between, on the one , "experimented" animals and, on the other hand, animals that are killed solely for their organs and tissues, and those that are born and bred for experimentation but remain "unused" and are finally eliminated. 3/ **Draw up statistics on the fate of animals** used in experiments (survival and reintegration rates, rate of re-use of the same animal, rate of death by euthanasia with indication of methods, rate of death resulting from the experiment).

4/ **Provide for and ensure the systematic and rapid** publication of the following information documents: the annual activity report of the Comité national de réflexion éthique sur l'expérimentation animale (CNREEA); the activity reports of the ethics convened by CNREEA each year; retrospective project evaluations; the annual audit reports of the CEEAs carried out by the Ministry. Continue the regular publication of RNTs on the ALURES database.

5/ **Ensure** the **integration of IRBA data into official statistics** and improve the transparency of the specific circuit planned for the corresponding research projects.

[5] See for example written question n° 18999 put by Mr Arnaud BAZIN, JO Sénat du 19/11/2020, p.5386.

2. Ethical assessment of animal experimentation projects in line with requirements European

Ethical questions about these practices are very lively throughout the world, and they oppose or bring together different currents: utilitarian, deontological, intuitionist, welfarist or abolitionist. Broadly speaking, some accept the use of animals for scientific purposes as a last resort and subject to strict conditions, particular "direct and urgent utility" (the utilitarian and welfarist currents, to which, following Jeremy Bentham, Peter Singer and Bernard Rollin, Carl Cohen and Raymond Frey belong), while others reject it outright (Tom Regan and Gary Francione). But it is the '3Rs ethical approach proposed by British biologists William Russell and Rex Burch *(The Principles of Humane Experimental Technique*, 1959) that directly inspires European regulations on the subject. It promotes three objectives: "Replacement" of live animals by alternative solutions wherever possible, "Reduction" in the number of animals involved, and "Refinement" of procedures, to minimise the suffering caused by all means possible. A compromise position consists of considering that animal experimentation (formerly known as "vivisection") is an evil, sometimes necessary, while awaiting effective alternative solutions. This evil can only be legitimised in specific cases, for experiments that are strictly necessary and have no possible alternatives, in compliance with ethical principles that must form the basis of **rigorous, impartial and transparent** authorisation and assessment processes, to keep the suffering inflicted to a minimum.

This is the inspiration behind the European Directive of 22 September 2010, Article 36 of which provides for prior authorisation of each project by "competent authority", following an ethical and scientific evaluation. Article 38 specifies that *"the competent authority carrying out the assessment of the project shall take account of the opinions of experts",* that *"the project shall be assessed in a transparent manner*" and that "*the assessment of the project shall be carried out impartially and may take account of the opinion of independent parties".*

The transposition of these requirements in France by the decree of 1er February 2013, specified by four orders of the same day, and modified by a decree of 17 March 2020, means that any scientific project using animals is subject obtaining prior **authorisation from the Ministry Research**, valid for a maximum of 5 years. Within the MESRI, a specialised "Afis unit within the DGRI issues these administrative authorisations on the basis of an ethical assessment of the project "delegated", under somewhat indeterminate legal conditions, to one of the 115 ethics committees (CEEA) spread across the country, which thus become "competent authorities" within the meaning of the directive.

Accredited ethics committees... without accreditation

In France, under the terms of article R214-117 of the CRPM, which came into force with the 2013 decree, the assessment of projects is entrusted to animal experimentation ethics committees (CEEA) to which the Ministry, as the naturally competent authority, grants prior approval. These committees are "set up at the initiative of the user establishments". All establishments carrying out experiments must report to a single committee. However, a committee may evaluate the projects of a single institution or of several institutions. The IRBA comes under a specific committee.

In order to guarantee the quality of the evaluation carried out, the Ministry is developing a fairly precise communication on the **strict conditions for obtaining approval**, **its criteria** (multidisciplinary skills of members, guarantees of independence and impartiality; sufficient operating resources) **and the conditions for its suspension or withdrawal if the conditions are no longer met.** The committees receive a registration number from the Centre national de réflexion éthique sur l'expérimentation (CNREEA). The conditions for verification of

conditions required for approval are not documented. Above all, the ministerial orders granting approval have not been published. As a result, associations have asked to see them on several , to no avail. The explanation came belatedly in the form of CADA notice no. 20214781 dated 23 September 2021, which revealed that **the approvals could not be sent because... they did not exist.** It turns out that the committees to which the Ministry, the competent authority under the terms of the 2010 directive, delegates its powers in terms of ethical evaluation have in reality had neither legal personality nor approval for a decade...

Although these revelations led the Ministry to react by granting emergency approval to around thirty of the committees, **it** turns out that not only **has it failed to apply a regulatory provision that it itself issued, but that compliance with the 2010 European Directive and the ethical principles that it promotes is not guaranteed**. It is difficult to understand how, since 2013, these committees could be sanctioned by withdrawal or suspension of their approval for failure to comply with the requirements of the 2010 directive if they are not approved. However, beyond their legal status, the composition and operation of these committees, in terms of the requirements of transparency, multidisciplinarity, independence and impartiality, raise questions. Of course, the CEEAs must be approved quickly, but do they meet the conditions for approval? In any case, approval orders should be issued after **careful consideration of the conditions required**. They should be granted for a fixed period. They should be published.

A multidisciplinary and impartial ethical assessment of projects?

Article 59 of the Directive allows each Member State to designate "*one or more competent authorities*", which may be "*bodies other than public authorities*", to carry out the tasks provided for, but "*only if it can be demonstrated that the body in question has the requisite multidisciplinary skills and infrastructure, and is free of any conflict of interest as regards the performance of those tasks*". These requirements are not currently guaranteed.

In view of the **minimum composition** provided for Article R214-118 of the CRPM, as amended by the decree of 17 March 2020 (5 people), the **balance of power is very much in favour of those practising**

animal experimentation or close to the research community that uses them. The only member

The only qualification required of an "outside" expert is that he or she is "non-specialised", which says a lot about the authority he or she enjoys in this Areopagus. It would be easy to imagine a researcher from the human and social sciences, a philosopher, an ethicist, or even a representative of the voluntary sector, whose legitimacy to sit on the committee is open to debate, as a **way of ensuring that the committee is multidisciplinary**.

In addition to the minimum membership required by the regulations, there are other members, whose list - which probably fluctuates - does not exist. Their titles, qualities and commitment to the are not documented. From the few CEEA audits available (due to the failure to carry out the planned annual audits), **it appears that the balance between designers, applicators, caretakers, veterinarians and outsiders has been heavily altered**, to the advantage of the former. As the task is not remunerated, it is also understandable that CEEA members are often linked to the establishments whose projects they have to assess, and sometimes even work for them. **All this does not favour their independence.** The point here is not to criticise the people who devote their time voluntarily to this difficult task, but to highlight certain shortcomings in the system with a view to improvement. The regulations should stipulate that the **proportion of the various skills represented should** be respected in the final composition of the committees. Annual audits, if carried out as planned, would enable compliance with these requirements to be verified.

Other points deserve attention:

1- It is the experimental establishments themselves that "allocate the necessary human and material operating resources to the ethics committees" and therefore **fund the activities of the committees responsible for evaluating their projects.** Moreover, human and material resources are still too limited (see CNREEA opinion of 8 April 2022 on the conditions for CEEA approval).

2- The fact that **115 committees share responsibility for evaluation** (compared with an average of less than twenty bodies in neighbouring countries) raises the question of **effectiveness of the harmonisation of assessment methods and criteria, which was** raised by the European Commission in its 2020 report. A reduction in the number of bodies would also make it possible to pool resources and facilitate the supervisory authority's monitoring role.

3- Documents that would inform public opinion about ethics assessment practices in favour of the "3Rs**are not accessible,** even though they are administrative documents that can be communicated according to the CADA, unless **they do not exist** (minutes of meetings of the CNPAfis and the CEEAs, list of members, etc.); list of annual audits of CEEAs conducted by the Ministry of Research; annual activity reports of CEEAs submitted to CNREEA, retrospective project evaluations), which CADA has been able to establish for some of these documents [6].

4- Specifically, the conditions under which the planned **retrospective project assessments** are or are not carried out, including when they are made mandatory article R214-120 CRPM (projects using primates and projects involving "severe experimental procedures in particular), are very poorly documented and these assessments, when they exist, are not published. 5- **The conditions under which** EAECs **deliberate and, where applicable, vote** are poorly documented.

6- The way in which the Minister for Research "*ensures that ethics committees operate in accordance with the regulations and, more specifically, that there are no conflicts of interest, by carrying out audits at least once a year*", under terms of Article 3 of the aforementioned Order of 1st February 2013, remains largely unknown. It would appear that very few CEEAs were subject to such audits in 2018.

4 proposals relating to the operation of animal experimentation ethics committees (CEEA)

1/ Amend article R 214-118 of the CPMR to limit conflicts of interest and ensure multidisciplinarity by including a person qualified in alternative methods, a researcher from the human and social sciences and a representative of associations. It should also be stipulated that the balance **between the additional members** must be ensured, while respecting the proportionality between the different skills.

2/Strengthen the **guarantees impartiality and independence** of their members by ensuring that **transparency in the operation of** the CEEAs, in accordance with the CADA's recommendations. Ensure the

[6] See CADA notice no. 20214781 of 23 September 2021, which states the documents mentioned do not exist.

provide the minutes of meetings, activity reports and annual audits of the EAECs on request, and therefore ensure that these documents are produced.

3/Proceed urgently with the **approval of CEEAs, subject to careful verification of** the conditions required and their operating resources. Publish the corresponding ministerial decrees. **Reduce the number of** committees to standardise assessments (proposal for 18 regional ethics committees).

4/ Ensure that all **retrospective project** evaluations **provided for by the CEEA - whether** mandatory under article R 214-120 CRPM or not - are carried out. Publish them, or at least make them available on request.

3. For effective transparency of the conditions and results inspections of establishments practising experimentation

The establishments carrying out the experiments are subject to regular checks by the veterinary services of the departmental population protection directorates, under the authority of the Ministry of Agriculture. Unfortunately, while the 2010 European directive recommends

"In France, **visits are generally announced** (10 to 30% of visits are unannounced, compared with an average of 40% in other European countries, according to the European Commission's February 2020 report). It is also **regrettable that the dates, timetables and procedures for inspections** (unannounced or scheduled) are not made public, contrary to the opinion of the CADA (n°20205211 of 11/02/2021). As for **inspection vademecum**, including the evaluation grid, it is available online on the

Ministry of Agriculture since 2021, following an appeal (CADA notice no. 20210459 dated 25/03/2021), in a version that could no doubt be updated and made clearer.

Above all, **inspection reports**, the results of controls, are not published, and obtaining access to them, in application of articles L 311-1 et seq. of the CRPA, **is akin to an obstacle course**, as shown by the dozens of opinions (favourable, sometimes with a few reservations) issued by the CADA, followed by a whole series of administrative court rulings in 2021 and 2022, following the persistent refusal of dozens of DDPPs to forward these reports to an association manager, or to forward them without unjustified blacking out.

This is all the more incomprehensible given that inspection reports on slaughterhouses and nuclear facilities are published without the names of the establishments or the irregularities observed being withheld, and that publicity is even extended to follow-up letters in the event of non-compliance. This system of publicity is also applied to most classified facilities (inspection reports from the Regional Directorates for the Environment, Planning and Housing, IRSN reports, etc.).

A clear signal from the administrative judge

The CADA has therefore confirmed that inspection reports on establishments carrying out animal experimentation are administrative documents **that can be disclosed, subject only to justified omissions in the very specific cases** provided for by the regulations (privacy, business secrecy) or risk to public safety attested by "precise and detailed information"[7].

As for the administrative courts subsequently seized, their position, which is commonly shared, is that the **inspection reports must be communicated without concealing the names of the establishments concerned or the non-conformities detected** [8] . Only the names of the persons concerned should be made anonymous.

[7] Opinions no. 20203189, no. 20202243, 20203205 and 20202211 of 29/10/2020; no. 20213705 of 8/07/2021.

[8] See, for example, judgments no. 2100379 of the Nice administrative court of 22/02/2022, no. 2003298 of the Nancy court of 20/12/2021, no. 2100069 and 2006819 of the Strasbourg court of 20/12/2021, no. 2005940 and 2005943 of the Montpellier court of 18/01/2022, or no. 2010551 of the Melun court of 12/01/2022.

and the omission of specific information covered by the exceptions provided for in the CRPA may be justified.

The relevant departments are therefore urged to comply with national regulations and, incidentally, with European texts that advocate transparency in these areas. This would enable **the administration's actions to be brought into line with the commitments it has made**. In January 2021, a "transparency charter on the use of animals for scientific and regulatory purposes in France" will be published, backed by the Ministry of Research (MESRI) and supported by the GIRCOR (an interprofessional group bringing together public and private establishments that carry out animal experiments). In particular, it affirms the right of every citizen "*to complete, clear and accurate information on the reasons for and conditions of the use of animals for scientific or regulatory purposes*". The implementation of these commitments, which are also legal obligations, **should no longer require the CADA and the administrative judge, who are** already very busy, **to be mobilised each time** to obtain, as is the case in other sensitive areas, respect for the right to public information and communication of administrative documents.

4 proposals to increase the transparency of controls on establishments carrying out animal experiments

1/Multiply the number of unannounced checks, to comply with European law. Bring the rate of unannounced checks up to the European average (40%).

2/Update the **vade-mecum** and analysis grid shared by the veterinarians responsible for inspections, to make it easier to understand the gradation of non-compliances.

3/ **Ensure that inspection reports are published** (on request to the DDPP, in accordance with the advice of the CADA, or systematically published online on the website of the relevant minister), with the possibility of blacking out only under the conditions set out in the regulations and strictly assessed by the administrative judge.

4/ Set up a **parliamentary fact-finding mission** on the use of animals for scientific purposes and the controls placed on it.

13 PROPOSALS A REFORM

We are proposing to increase the transparency of data on the use of animals for scientific purposes, to improve the operation of animal experimentation ethics committees (CEEA) and to increase the transparency of checks on establishments carrying out experiments.

1 Providing information to the public about establishments that carry animal experiments

At the very least, by making available to the prefecture, on reasoned request, the list of establishments in the department authorised to carry out animal experiments. A map showing the number of establishments concerned, by department, should be published online on the Ministry of Research website, if the full list of establishments is not published.

2 Make it compulsory, by regulation, for the Ministry to keep annual records of animals destroyed in experiments

Even those not 'tested, without waiting for the 2010 directive to be adapted (which only provides for an annual review every 5 years). Animals killed solely for their organs and tissues, and those born and bred for experimentation but left "unused" and eventually disposed of, would be counted in separate categories from experimental animals.

3 Draw up statistics on the fate of animals used in experiments

These statistics would include survival and reintegration rates, the rate of re-use of the same animal, the rate of death following euthanasia, and the rate of death resulting from the experiment.

4 Plan and ensure the systematic publication of information documents

This includes all non-technical summaries (RNT) of projects, which should continue to be published on the ALURES database, as well as the annual activity report of the Comité national de réflexion éthique sur l'expérimentation animale (National Committee for Ethical Reflection on Animal Experimentation); the activity of the ethics (CEEA) submitted to CNREEA each year and the annual audit reports of the CEEA carried out by the Ministry of Research.

5 Planning the dissemination of IRBA data

To ensure the integration of IRBA data into official statistics and to improve the transparency of the specific circuit planned for the corresponding research projects.

6 Modifying the composition of EAECs

Amend art. R214-118 CRPM, the minimum composition of ethics
(CEEA) to limit conflicts of interest and ensure multidisciplinarity, by including a person qualified in alternative methods, a researcher from the human and social sciences, and a representative of the voluntary sector. Provide that the final composition of ethics committees must respect proportionality in the representation of skills.

7 Reviewing the operation of CEEAs

Strengthen guarantees of the impartiality and independence of its members by ensuring transparency in the operation of the committees, in accordance with CADA's opinions (minutes of meetings and annual activity audits to be drawn up and made available on request).

8 Approve CEEAs that meet the required conditions

Proceed as a matter of urgency with the approval of ethics committees, subject to careful examination of the conditions required and their operating resources. Publish the corresponding ministerial decrees. Reduce the number of committees in order to standardise assessments (proposal for 18 regional ethics committees).

9 Strengthening project assessment and transparency

Ensure that all planned retrospective assessments - whether mandatory under the terms of article R 214-120 CRPM or not - are carried out and published.

10 Increase the number of unannounced checks

Bring the rate of unannounced inspections up to the European average. It does not exceed 30% in France, even though the 2010 European directive stipulates that an appropriate proportion of inspections must be carried out without prior warning.

11 Communicating more control data

Update the *vade-mecum* and analysis grid shared by the veterinarians responsible for inspections, to make it easier to understand the gradation of non-compliances.

12 Publish inspection reports

Ensure the publication of inspection reports (communication on request to the DDPP in accordance with the advice of the CADA, or even systematic online publication on the website of the competent minister). Obscultations should only be carried out under the conditions strictly provided for by the regulations and recently clarified by administrative case law.

13 Setting up a parliamentary fact-finding mission

To set up a parliamentary fact-finding mission on the use of animals in scientific purposes and the controls placed on it.