DOCTRINE

Do the regulations on animal experimentation really protect animals?

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The aim of European Directive 2010/63/EU of 22 September 2010 on the protection of animals used for scientific purposes is to protect animals and their "welfare" without hindering scientific research in a competitive international context. It is therefore a compromise regulation between several opposing objectives. On the one hand, animals are recognised as "sentient creatures" with a "human being".
"On the other hand, research laboratories can inflict more or less serious and lasting damage on them. On the other hand, research laboratories can inflict more or less serious and lasting damage on them, eventually killing most of them, provided they comply with the obligations set out in the regulations. These include guaranteeing a certain balance between the expected benefits (generally for humans) and the 'costs' (for the animals used).

Do these regulations really protect animals used for scientific and educational purposes? It is doubtful. Even if the aforementioned European directive does indeed aim to protect these animals, it is in fact ineffective due to the multiplicity of derogations, exceptions and wording that is not sufficiently explicit. In addition, certain elements of the European directive have not been correctly transposed into French law.

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in France in 2013. We also note the "minimal" involvement of the public authorities in our country, which leaves additional room for manoeuvre to breeding establishments, suppliers and users in applying the texts[4].

I. The legislative and regulatory framework in French law

In addition to article L. 214-3 of the French Rural and Maritime Fishing Code (CRPM), which is already in force, the 2010 European Directive was transposed into French law in a decree and five orders on 1st February 2013. All the provisions are set out in articles R. 214-87 to R. 214-137 of the CRPM.

A. Animal protection legislation

Article L. 214-3 of the CRPM (Chapter IV on animal protection) states that: "It is forbidden to mistreat domestic animals or wild animals that have been tamed or kept in captivity. [The same applies to medical and scientific biological experiments, which must be limited to cases of strict necessity".

For example, animal experimentation is explicitly included as an exception in an article that lays down a general ban on animal abuse. The notion of "strict necessity" is nowhere defined and, even if it seems to limit *a priori* the scope of the use of animals for scientific purposes, in the absence of a definition it leaves research teams free to interpret this notion as they see fit.

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[4] Here are some quantitative data on the scope of the European directive in France:

- In 2021: 1,893,897 animal uses.
- Slight downward trend since 2016; overall, between 2015 and 2019, the decrease is 2%. However, more animals were used in 2021 than in 2019, and almost as many as in 2015.
- Trends vary greatly depending on the species: a slight decline in the number of rodents and "livestock", a steady increase in the number of rabbits and zebrafish, and stagnation in the number of cats, dogs and primates...
- France accounts for around 16% of all uses in the European Union.

Quantitative data can be viewed and compared on the https://experimentation-animale.com/ website.

Who could consider that it is strictly necessary to inflict suffering and *ultimately* kill thousands of animals in order to develop treatments for baldness[5] or acne[6]? Similarly, how can we justify as "strictly necessary" experimental protocols aimed at increasing the productivity of animals bred for food[7]?

B. Regulations governing use of animals for scientific or educational purposes

The European directive was transposed by Decree 2013-118 of 1st February 2013 (amended by Decree 2020-274 of 17 March 2020) and five Orders dated 1st February 2013, covering the following topics:

- ***Conditions for the supply of certain animal species used for scientific purposes to approved user establishments***: the order specifies that the animals must be bred for this purpose and come from approved breeders or suppliers; non-human primates must have been bred in captivity or come from autonomous colonies by 10 November 2022 at the latest.
- ***Acquiring and validating the skills of the staff of establishments using, breeding and supplying animals used for scientific purposes***: the decree specifies the skills required for each category of staff in charge of the animals and the compulsory training for each of them (initial and continuing training).
- ***Conditions for the approval, layout and operation of establishments using, breeding and supplying animals used scientific purposes and their controls***: the annexes to this order specify the information to be included in the application for approval, the requirements relating to establishments and the conditions for the approval of establishments.

[5] For example: S. Orliac et al, "*Efficacy of subcutaneous injection of platelet-rich plasma in alopecia: A clinical and histological pilot study on a rat model with a six-month long-term follow-up experience*", J Cosmet Dermatol 2018, 17:214-219 (https://doi.org/10.1111/jocd.12425).

[6] For examples approved in 2022-2023 in France concerning acne research, see the non-technical summaries NTS-FR-827191, NTS-FR-937003 and NTS- FR-769636 on the European ALURES database (https://webgate.ec.europa.eu/envdataportal/web/resources/alures/submission/nts/list).

[7] For examples approved in 2022-2023 in France concerning research into the productivity of animals reared for consumption, see non-technical summaries NTS-FR-953341, NTS-FR-547209 and NTS-FR-999715 based on of data database ALURES (https://webgate.ec.europa.eu/envdataportal/web/resources/alures/submission/nts/list).

requirements relating to the care and housing of animals (premises, cages, animal care, specific requirements for each species, etc.), the documentary data to be drawn up (entry-exit register, animal traceability, individual file for cats, dogs and primates) and the authorised killing methods depending on the species. The decree also defines the tasks of the structures responsible for animal welfare (SBEA) within each approved establishment and the inspection regime in breeding, supplier and user establishments.

- ***Ethical assessment and authorisation of projects involving the use of animals in experimental procedures***: the decree specifies the procedures for approval of animal experimentation ethics committees (CEEA), the principles of ethical assessment of projects, the content of the application for authorisation of projects using animals and the assessment and authorisation process. An appendix details how the degree of seriousness of an experimental procedure should be determined.
- ***Supply and use of medicinal products employed by approved user establishments***: the decree specifies that the establishment must appoint a competent person responsible for the supply, stock management and use of these medicinal products in the establishment; storage arrangements are specific, and all incoming and outgoing medicinal products must be recorded.

II. Exclusions from the scope of the directive

Certain categories of animals are excluded from the directive's 'protection' and certain procedures or technical acts are not covered by it.

A. Exclusion of certain species and certain acts

The following are therefore outside the scope of the European directive and French regulations (art. R. 214-88 of the CRPM):

- use in procedures on invertebrates (excluding cephalopods) and mammalian foetal forms in the first two-thirds of their normal development;
- procedures carried out for the primary purpose of identifying an animal ;
- veterinary clinical trials required for the purposes of a marketing authorisation for a veterinary medicinal product (

research and preclinical trials on the same products are, however, covered by the directive).

Procedures carried out for non-scientific purposes on pet animals, animals farmed for their meat, milk or eggs, or animals farmed for hunting, as well as procedures carried out in the context of veterinary medicine, are also logically outside the scope of this field, as they are subject to other regulations.

B. Exclusion of practices according to level of pain or anxiety

Pursuant article R. 214-88 of the French Rural Code, the following are also excluded from the scope of this article
"practices which are likely to cause less pain, suffering, distress or lasting harm than that caused by the insertion of a needle carried out in accordance with good veterinary practice" - all acts inducing more pain than this minimum threshold defining what (within the meaning of the regulations) is considered to be an "experimental procedure".

Consequently, animals subjected to practices as defined above are not included in the annual statistics and these practices are not subject to a project authorisation request.

These are :

- non-genetically modified animals, bred and killed without having been used in a procedure, including individuals killed for their organs and tissues, individuals at the end of their life or in the process of
  This is the case of animals that are "overcrowded" on a farm, and individuals that are used in procedures without having reached the pain or distress threshold set by the regulations (see above);
- animals produced for the creation of a new genetically modified line and killed because they do not have the expected characteristics;
- animals produced for the maintenance of a genetically modified line - not showing any damaging phenotype - killed because they are surplus to requirements (too many due to fluctuating demand) or sick.

However, the European directive stipulates that these animals should be counted every fifth year. In the European Commission's report for 2017 (the first year in which these three categories of animals have been counted since the directive was adopted in 2010),

it appears that in France, around two million animals fell into these categories (which represents more than a doubling in the number of animals used compared to the statistics published annually).

C. Consequences

It seems legitimate to question the value of regulations which - *in the end* - only apply to half of the vertebrate animals used for scientific purposes, i.e. only those which will be included in a procedure[8].

The prism chosen by the legislator is that of the project. Animals are not considered for their intrinsic value (contrary to what the preamble to the European Directive suggests): it is the purpose for which they are used that, in a way, gives them a (relative) value and brings them within the scope of regulatory protection. The 'simple' act of killing an animal (animals killed during the upkeep and maintenance of genetic lines, supernumerary animals in breeding farms, etc.) does not fall within the criteria for defining an experimental procedure: "The killing of animals, for the sole purpose of using their organs or tissues, in accordance with a method defined by joint order of the Minister for Agriculture and the Minister for Research, is not considered to be an experimental procedure" (art. R. 214-89 of the CRPM). However, if the purpose is scientific, these animals should *at least* be counted every year, as is the case for animals used in experimental procedures.

Furthermore, since these animals are not "protected" by the regulations on the use of animals for scientific purposes (which does not seem justified to us), their killing could be requalified as "unjustified" killing[9].

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[8] "Procedure: any use, invasive or otherwise, of an animal for experimental or other scientific purposes, the results of which are known or unknown, or for educational purposes, likely to cause that animal pain, suffering, distress or lasting harm equivalent to or greater than that caused by the insertion of a needle in accordance with good veterinary practice". (point 1 of Article 3 of Directive 2010/63/EU).

[9] In 2022, German prosecutors launched an investigation into whether the killing of of these "surplus animals constitutes a crime: https://www.newsweek.com/killing-excess-lab-animals-could-one-day-considered-crime-germany-1704319. A parallel initiative was undertaken by One Voice in 2023, with an administrative appeal to the Paris court to request that the public authorities take the necessary measures to put end to this type of slaughter.

Similarly, the fact that "supernumerary" animals do not give rise to an annual declaration or to an application for authorisation of a project implies that their keeping itself is not considered to be a source of sufficient suffering to justify specific protection of the interests of the animals kept. However, according to the regulatory minimums defined by the regulations for animals within the scope of the Directive, two adult macaques can spend most of their time in a box measuring two square metres on the floor; two beagles can spend their lives in a box measuring four square metres; three mice can be kept in a box the size of half an A4 sheet, making it impossible, for example, to carry out the olfactory marking that is important for individuals of this species.

III. Derogations and other room for manoeuvre

For animals and procedures falling within the scope of the regulations, provision is made for derogations from the principles, subject to authorisation by the Ministry of Higher Education and Research (MESR). In addition, users are given a wide margin of discretion by wordings such as "as far as possible", "as far as possible", or by provisions "relating to the nature of certain procedures". This leeway considerably limits the impact of French and European regulations.
Here are the main illustrations.

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and to reduce the overall number animals bred for this purpose (https://one-voice.fr/en/blog/animaux-en-surplus-dans-lexperimentation-animale-recours-de-one-voice-au-tribunal-administratif.html.)In France, the absence of measures to control and reduce the number of 'supernumerary' animals killed seems to contradict the application Article 1 of the Directive and its transposition into Article R. 214-87 of the CRPM, which stipulate that the regulations (and in particular the principle of reducing the number of animals as much as possible) apply not only to animals used, but also to animals intended to be used for scientific purposes, whether or not they are ultimately used. Furthermorearticle R. 655-1 of the French Penal Code explicitly states that the unnecessary killing an animal is punishable: "The fact, whether publicly or not, of deliberately killing a domestic or tame animal or an animal held in captivity without necessity is punishable by a 5th class fine. / A repeat offence under this article is punishable in accordance with article 132-11 [...]". [...] ".

A. Origin of the animals

By default, it is forbidden to use in animal experiments (art. R. 214-90 to R. 214-94 of the CRPM):

- animals not bred for these purposes,
- domestic animals that stray or live in the wild,
- animals of protected or endangered species,
- great apes (Pan, Gorilla and Pongo genera).

It is also forbidden to use primates when other animals can be used.

But all these bans may be subject to exemptions granted by the MESR (and in some cases by the Ministry of Agriculture and the Ministry of the Environment), based on scientific justification, the limits of which are not specified.

Over 80% of the animals used in procedures each year come from approved farms in the European Union. However, the percentages vary widely depending on the species in question: close to 0% for long-tailed macaques, equids and cephalopods, for example, and close to for guinea pigs, rabbits and prosimians. In total, almost 400,000 animals come from suppliers who are not approved for breeding animals for scientific purposes under European regulations.

In the annual statistics published by the Member States of the European Union, wild animals captured/taken from the wild are not identifiable. However, we can get an idea of their numbers by consulting the data in the table of origins, in the category
"The number of 'other' species for each group of species considered. According to the complete binders of figures provided by the establishments to MESR[10], these may include deer, wild boar, bats, crows, canaries, freshwater fish and many other species. However, there is no way knowing whether stray domestic animals are captured.

[10] Files obtained on request from the Ministry by One Voice, the contents of which are analysed and presented graphically on the https://experimentation- animale.com website.

The ban on using individuals of endangered or protected species is based on Annex A of European Council Regulation 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein. The updating of Annex A depends in particular on the updating of Annex I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which is carried out every three years. Species newly classified as "threatened with extinction" by the International Union for Conservation of Nature (IUCN) - such as *Macaca fascicularis* in 2022, after being classified as "vulnerable" in 2020 - may therefore only be protected from capture for experimental use after several years, while the two appendices are updated.

No information is available on other requests for derogations and the conditions under which they were granted. However, no great ape has been used in an experimental procedure in Europe since 1999[11]. Moreover, any such derogation must be notified to the European Commission, which may object. But the mere fact that it is envisaged that this could happen makes the regulatory architecture rather fragile as far as animal protection is concerned.

B. Holding standards[12]

Precise standards are set out in the regulations governing the care and keeping of animals (art. R. 214-95 of the CRPM and the Order of 1th February 2013 setting the conditions for the approval, layout and operation of establishments that use, breed or supply animals used for scientific purposes and their controls, with its appendices). However, a number of derogations are provided for "for scientific reasons or reasons relating to animal welfare or animal health by joint decision" of the ministers responsible for the environment, agriculture and research (art. R. 214-95 of the CRPM).

[11] Vogel, G. 2001. *Dutch end chimp studies*. ScienceNOW. https://www.science.org/content/article/dutch-end-chimp-studies

[12] While the regulations use the term "housing" to refer to the living conditions of animals used in laboratories, we prefer to use the term "confinement", which better reflects the fact that these animals have strictly no choice and that their environment is generally very far from what we would expect from "housing" for anyone.

Some examples are given below:

- Social animals must be kept in groups, *unless the project authorisation provides otherwise* (" duration of isolation must be limited to the minimum period necessary and visual, auditory, olfactory and/or tactile contact must be maintained with the other animals");
- "Dogs must be allowed to exercise outdoors as much as possible", so from time to time they are kept indoors if the project so provides;
- "A dog housed with another dog or in a group may be confined to half of the total space provided (2 m^2 for a dog weighing less than 20 kg, 4 m^2 for a dog weighing more than 20 kg) while undergoing procedures within the meaning of this Directive, "*if such isolation is essential for scientific reasons*";
- *"Unless otherwise stipulated by the nature of certain procedures*, cages must be large enough to allow the animal to lie down, turn around or stretch out";
- "Pigs may be confined in smaller compartments for short periods of , for example by dividing the main compartment with partitions, if *this is justified on veterinary or experimental grounds*, for example when individual feed consumption is required."

The use of these exceptions by users can therefore seriously alter the conditions in which animals are kept, thereby excluding them from the protection (even relative) provided by the regulations.

In addition, the obligation to set up an animal welfare structure (SBEA) within each establishment may be waived by prefectoral authorisation for very small establishments, without the other means being specified in the regulations (art. R. 214-103 of the CRPM). Here again, data on the frequency of use of this derogation is not available.

C. Carrying out procedures and killing

Although the regulations stipulate that the procedures must be carried out in approved establishments that are subject to controls, it is possible to derogate from this prohibition on the basis scientific elements, the nature and scope of which are never specified (art. R. 214-99 of the CRPM).

The performance of the procedures themselves is subject to possible exemptions, particularly with regard to pain management:

- procedures "intense pain, suffering or distress likely to be prolonged without any possibility of relief" are prohibited, *except by derogation from the MESR* (art. R. 214-108 of the CRPM) - however, the derogation must be notified to the European Commission, which may object;
- procedures must be carried out under anaesthetic, *except in the case of "Experimental procedures incompatible with the use of anaesthetics or analgesics",* with scientific justification (art. R. 214-109 of the CRPM);
- pain following procedures must be relieved by analgesics or other methods "*insofar as this is compatible with the purpose of the experimental procedure*" (art. R. 214-109 of the CRPM);
- it is forbidden to re-use an animal that has undergone a severe procedure,
  unless an exemption is granted by the MESR (art. R. 214-113 of the CRPM).

Limit points are the thresholds that may not be exceeded during an experimental procedure; they represent the level of suffering beyond which the procedure must be stopped and/or the animal killed (art. R. 214-107 of the CRPM). They are set when the project is designed. Here again, it is regrettable that the wording of the text offers opportunities to circumvent the strict application of end points: "*Wherever possible*, death must be avoided as an end point of the experimental procedure and replaced by precise end criteria that are adapted and implemented *as early as possible*. When death cannot be avoided as a limit point, the experimental procedure must be carried out on *the smallest possible number of* animals, reducing *as far as possible* the duration and intensity of suffering and, *as far as possible,* ensuring the conditions for a painless death".

It is even "possible" to derogate from the authorised killing methods depending on the species, if the Ministry gives its agreement (art. R. 214-98 of the CRPM), "provided that, on the basis of scientific data, the alternative method is considered to be equivalent or on the basis of scientific evidence demonstrating that the purpose of the experimental procedure cannot be achieved by using a killing method specified in the decree". According to the *Animal Experimentation Manual* published in January 2023, this derogation has been used "a small number" of times up to the end of the year.

2021 and would notably concern "methods that have to be repeated for a large number of animals"[13].

D. Reuse of animals

Article R. 214-113 of the CRPM restricts the conditions for re-using an animal that has already been used in an experimental procedure. Re-use is only authorised on the basis of a veterinary opinion on the animal's state of health and if the previous use and the planned re-use do not involve 'severe' suffering for the animal. Here again, however, a waiver is possible with the agreement of the Ministry of Research, provided that the animal "has not been used more than once in an experimental procedure intense pain, distress or equivalent suffering".

Experimental procedures are subject to assessment of the degree of severity ("no awakening", "slight", "moderate" or "severe"), according to article R. 214-122 of the CRPM, the Order of 1er February 2013 on ethical assessment and authorisation of projects involving the use of animals in experimental procedures, and article 38 of the 2010 Directive. A "project" is made up of several "experimental procedures", as evidenced by articles R. 214-89, R. 214-105 and
R. 214-122 of the CRPM and articles 3 and 12 of the European Directive.

Consequently, it could be concluded that the re-use of an animal in a project after it has been used in a "severe" experimental procedure would be subject to derogation, and that the re-use an animal already involved in a "severe" procedure would be subject to derogation.
"In practice, this is not the case. In practice, this is not the case. As the Directive is not sufficiently explicit, a consensus document adopted in 2011[14] defined "continued use" as "the situation where the single use of an animal spans more than one project or several procedures within a single project", relying on Article 16 of the Directive to indicate that "re-use" only occurs when "a different animal on which no procedure has been performed could also be used". This interpretation, which seemed to depart from spirit of the Directive, was

[13] Sylvie Challon and Nicolas Dudoignon (2022), "Drafting, submission, evaluation and authorisation of projects", *in Manuel d'expérimentation animale - Principes généraux,* p. 147.
[14]

reinforced by point B.2.2 of Part B of Annex III to European Commission Implementing Decision 2020/569[15] , which states that "a 'single use' covers the period between the time when the first technique is applied to the animal and the time when the data collection and observations are completed or the educational objective has been achieved".

In short, while a derogation is required to re-use an animal already used in a severe procedure within a previous project, the same animal may be used in multiple procedures or stages involving severe suffering within same project (e.g. exposure to various stress and pain factors with the aim of making an animal depressive[16]), provided that these uses serve a single purpose that would not allow another animal to be used.

E. The 3Rs rule

The 3Rs rule (Replace, Reduce, Refine) is a principle of good practice (often referred to - incorrectly - as ethical rules) in the use of animals in experiments. This rule was developed by William Russell and Rex Burch and set out in their book *The Principles of Humane Experimental Technique*, originally published in 1959[17]. It consists of replacing the use of live animals by other research methods where these exist; if not, reducing the number of animals used in each project, in particular through experimental design and statistical calculations; and finally, refining the conditions under which animals are kept (by providing an "enriched" living environment) and the procedures (by using the least invasive techniques possible or appropriate analgesic methods). Directive 2010/63/EU makes numerous references in the recitals to the need to apply this principle. The first purpose mentioned in Article 1 is to lay down rules on the following aspects: "the

(15)https://eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:32020D0569&from=EN#ntc2-L_2020129FR.01001901-E0002

16 See for example the non-technical summary NTS-FR-130070 on the European database ALURES (https://webgate.ec.europa.eu/envdataportal/web/resources/alures/submission/nts/list).

17 Similar principles had already been set out by the English physiologist Marshall Hall in 1835: https://www.ahajournals.org/doi/10.1161/01.CIR.48.3.651. Russel and Burch's work is now available online in a special edition published in 1992 by the Federation of Universities for Animal Welfare (UFAW): https://caat.jhsph.edu/principles/the-principles-of-humane-experimental-.

replacement and reduction of animals in procedures and refinement of the conditions animals are bred, housed, cared for and used in these procedures". Article 4 is dedicated to this same principle.

We have already seen the amount of leeway left by the regulations in application Refinement (holding conditions and carrying out procedures). Project designers are also given a great deal of latitude when it comes to taking into account Replacement and implementing Reduction methods.

Although Article R. 214-105 of the CRPM states that compliance with the 3Rs rule is one of the two conditions to be met for an experimental procedure to be lawful (the first condition relates to the very purpose of experimental procedures), it immediately limits its scope by making its application subject to the scientific objectives pursued or by envisaging (in the case of Refinement) that (undefined) constraints may prevent its application:

- "Experimental procedures are strictly necessary and cannot be replaced by other experimental strategies or methods which do not involve the use of live animals *and which can provide the same level of information*;
- the number of animals used in a project is reduced to a minimum *without compromising the objectives of the project*. To this end, the sharing organs or tissues from killed animals is permitted between establishments;
- the conditions under which animals are reared, housed, cared for and the methods used are the most appropriate to *minimise* any lasting pain, suffering, distress or harm that they may experience".

One of the consequences of this room for manoeuvre is that even when a non-animal method exists with equivalent efficacy to animal methods, project designers do not systematically use it. This may partly explain why monoclonal antibodies continue to be produced using the ascites method, despite repeated recommendations from ECVAM since 1998[18], and why there has been a very high level of substitution of animal methods.

[18] France appears to have been responsible for the vast majority of the use of mice to produce antibodies using the ascites method since 2015: https://one-voice.fr/en/blog/des-centaines-de-milliers-danimaux-utilises-illegalement-par-les-laboratoires-francais.html

pyrogen tests in rabbits by monocyte activation tests validated since 2006[19].

Ultimately, the number animals used for scientific purposes is not being reduced either in France or in the European Union. This can be explained in part by the fact that the principle of reduction is applied individually to each project, while the total number of projects is multiplying.

It is clear from reading the regulations that research teams are given a great deal of leeway in applying the 3Rs rule, on the sole condition that they provide scientific justification for their choices. However, we do not know what criteria the administrative authorities use to judge whether this justification is acceptable. In any case, the regulations always give priority to the scientific objective over the suffering inflicted on the animals, even if this suffering is extremely severe. The regulatory authority seems to have great difficulty in formulating absolute bans on the use of animals for scientific or educational purposes.

IV. Problems transposing the European directive into French law

We have just detailed numerous cases of derogations and other linked to the European directive itself. In addition, several elements of the directive have been incorrectly transposed into French law.

A. Development of alternative methods

Article 47 of the European Directive stipulates that Member States must contribute to the development and validation of "alternative approaches capable of providing the same or a higher level of information as procedures using animals, but without involving the use of animals or by reducing the number of animals used or by resorting to less painful procedures", as well as to the promotion and dissemination of information about them.

[19] In mid-February 2023, a conference was organised by the Council of Europe to discuss the decision to withdraw the pyrogen test in rabbits from all European Pharmacopoeia texts within a few years. Yet France used more and more rabbits for these tests between 2015 and 2019, before a slight reduction in 2021: https://one-voice.fr/fr/blog/comme-one-voice-le-conseil-de- leurope-soutient-lafin-des-tests-pyrogenes-sur-les-lapins.html

While the application of the 3Rs rule is indeed required by regulations when projects are evaluated by animal experimentation ethics committees, there is no trace in national regulations of an incentive "develop and validate" alternative approaches.

Furthermore, with regard to the sharing of organs and tissues, Article 18 of the Directive states that "Member States shall facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of killed animals". However, transposing this recommendation into article R. 214-105 of the CRPM distorts its meaning: "the sharing of organs or tissues of killed animals is permitted between establishments".

B. Animal experimentation ethics committees

With regard to the assessment of projects using animals, there has been a major failure to transpose the European directive into French law.

1. Missions

According to article 38 of the European directive, the project assessment must verify that a certain number of conditions are met:

- "the project is justified from a scientific or educational point of view or is required by law" - hence the need to bring together multidisciplinary scientific expertise;
- "The objectives of the project justify the use of animals;
- "The project is designed to allow procedures to be carried out in conditions that are as respectful as possible of the animal and the environment.

In France, administrative authorisation for a project is issued by the MESR on the basis of the opinion issued by the animal experimentation ethics committee (CEEA) to which the establishment using the animals belongs (art. R. 214-117 to R. 214-126-1 of the CRPM).

2. Composition

In accordance with the first point of paragraph II of article R. 214-117 of the CRPM, each CEEA should be able to justify the multidisciplinary competence of its members in order to be approved. This meets one of the conditions set in article 59 of the European directive: the bodies responsible for

responsible for implementing the directive must have "the skills [...] required to carry out the planned tasks".

Article R. 214-118 of the aforementioned Code stipulates that the AECs must be composed of *at least* 5 people, whose qualifications are established as follows: a of experimental procedures on animals, an applicator of procedures on animals, a carer (or a person responsible for killing the animals), a veterinarian, and a person "not specialised in questions relating to use of animals for scientific purposes", often referred to as "a person who is not specialised in questions relating to the use of animals for scientific purposes".
"This article clearly contradicts the article on the right to privacy. This article clearly contradicts article
R. 214-117 which precedes it.

While four out of the five can claim a specific skill (theoretical or practical), they cannot be considered to be multi-disciplinary, since only two disciplines are represented: experimental research and veterinary science (3/5 for one and 1/5 for the other). The fact that the fifth discipline is 'non-specialist' does not in itself constitute a skill...

The competent authorities in each EU Member State must assess the projects submitted to them in accordance with Article 38 of the European Directive. To do this, the CEEAs (to which the French public authorities have "delegated" the task of assessing projects) should have a broad range of multi-disciplinary skills at their disposal: scientists specialising in different non-animal experimental approaches for replacement, biostatistics for reduction, veterinary algologists, ethologists for refinement, as well as lawyers, animal ethics specialists or people qualified in different disciplines are likely to bring a "non-scientific" perspective to the assessment of the project. However, this is not what is stipulated in article R. 214-118 of the CRPM on the composition of CEEAs.

3. Transparency

According to point 4 of article 38 of the European directive, projects must be evaluated "a transparent manner", "subject to ensuring respect for intellectual property and confidentiality information". The two injunctions of transparency and confidentiality can be contradictory and often irreconcilable. Respect for intellectual property and confidentiality" is mentioned once again

in Article 43 on non-technical project summaries[20]. Transparency is not mentioned anywhere else in the directive.

In France, the Order of 1st February 2013 on the ethical evaluation and authorisation of projects involving the use of animals in experimental procedures simply forgot to mention the transparency of the ethical evaluation (which makes it a poor adaptation of the European Directive). On the other hand, the duty of confidentiality appears in four articles of the decree (article 1, article 4, article 5 and article 14).

C. Inspections and penalties

1. Inspections

Article 34 of the European directive calls for the frequency of inspections to be adjusted on the basis of a "risk analysis" specific to each establishment, linked to previous non-compliances, the species held and the number of projects carried out by the establishment. It adds that "an appropriate proportion of inspections are carried out without prior warning". Article 5 of the Order of 1th February 2013 laying down the conditions for the approval, layout and operation of establishments using, breeding or supplying animals used for scientific purposes and their controls states that: "Depending on the results of the risk analysis referred to in a), an appropriate proportion of inspections must be carried out unannounced".

Unlike the European directive, the French transposition therefore makes the proportion of unannounced inspections of an establishment dependent on the risk analysis carried out on that establishment. In France, the proportion of unannounced inspections is therefore not the same for all establishments.

This limitation, and probably a problem of resources dedicated to this task, have resulted in a remarkably low rate unannounced inspections.

[20] Non-technical project summaries (NTS) are drafted anonymously by users of notified dossiers. This is one of the contributions of the European Directive: "In order to ensure that the public is informed, it is important that objective data on projects using live animals be made public. This should not infringe property rights or divulge confidential information" (recital 41). It must provide: "(a) information on the objectives of the project, including the expected harm and benefits, and on the number and types of animals to be used; (b) a demonstration of compliance with the requirements of replacement, reduction and refinement" (Article 43). https://ec.europa.eu/environment/chemicals/lab_animals/alures_nts_en.htm

low for France compared with the other Member States of the European Union (see below).

2. Penalties

With regard to penalties for breaches of national provisions, Article 60 of the Directive states that they must be "effective, proportionate and dissuasive". However, article R. 215-10 of the CRPM only provides for fines of 3th or 4th class depending on the type of offence, i.e. a maximum of €450 and €750 respectively in 2022. These are by no means proportionate or dissuasive penalties for the establishments concerned.

On the other hand, article 521-2 of the French Penal Code states that "carrying out scientific or experimental experiments or research on animals without complying with the prescriptions laid down by decree in the Council of State shall be punishable by the penalties laid down in article 521-1" - i.e. the penalties laid down for acts of cruelty and serious abuse of animals, which can amount to tens of thousands of euros in fines, combined with prison sentences. So the legislation does seem to provide for deterrent penalties. However, according to article R. 511-1 of the Criminal Code, the "prescriptions laid down by decree in the Council of State" mentioned in article 521-2 still correspond to decree no. 87-848 of 19 October 1987. However, this decree, which transposed European Directive 86/609/EEC, was repealed in 2003, and Directive 2010/63/EU was transposed in 2013 by Decree no. 2013-118 of 1 February 2013. It would therefore be useful to update article R. 511-1 of the French Criminal Code to reflect the current state of the regulations.

D. Ministry of Defence

In France, the Ministry of the Armed Forces receives special treatment (art. R. 214-127 to R. 214-129 of the CRPM) with regard to the application of regulations concerning the use of animals for scientific purposes. Applications for approval, project authorisation and exemption from the regulations, as well as inspections concerning establishments under the responsibility of the Ministry of the Armed Forces, are managed by the Ministry,
The Ministry of Defence is the "sole recipient of declarations and information concerning establishments under its authority or supervision". Although nothing in the directive prohibits the possibility of the Ministry of the Armed Forces being a national competent authority, as are the Ministries of Research and Agriculture, one point is worth noting: the Ministry of the Armed Forces was not cited as a competent authority in the

questionnaire completed in 2019 by the French administration in response to the European Commission's survey on the application of the directive in the various Member States[21] (even though the CEEAs appear in it as competent authorities "by delegation").

It also appears that the statistical data concerning the laboratories under the responsibility of the Ministry of the Armed Forces are not published (the MESR does not have them either). Requests from associations to the Ministry of the Armed Forces for this data have not received any response.

V. Failure apply regulations

In addition to the gaps in the law and the problems of transposing the European directive, on several points the existing regulations are not applied or are applied in a biased manner.

A. The origin of certain primates

The provisions concerning the origin of primates used in approved establishments stipulated that from a date to be set by joint order of the ministers for the environment, agriculture and research, primates must come from captive breeding farms or colonies maintained without the addition of outside stock (art. R. 214-90 of the CRPM).

The Order of 1st February 2013 setting the conditions for the supply of certain animal species used for scientific purposes to approved user establishments provides a specific deadline for primates: "No later than 10 November 2022, i.e. five years after the publication by European Union of the feasibility study relating to the requirement defined in Article 2 of this Order, and provided that the study does not recommend a longer deadline". The feasibility study in , published in July 2017[22], concluded that

[21] *Report from the Commission to the European Parliament and the Council on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union*, COM(2020) 15 final, 5 February 2020.
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1581689520921&uri=CELEX:52020DC0015

[22] *Feasibility study as required in Article 10 of Directive 2010/63/EU on the protection of animals used for scientific purposes*, 31st July 2017.
https://ec.europa.eu/environment/chemicals/lab_animals/pdf/related_topics/Article%2010%20Feasibility%20Study%20Final%20report%2031%20July%202017.pdf

to the *status quo* on regulation, observing however that exemptions for the continued use of some F1[23] animals (notably ageing animals already present in European establishments and used for longitudinal studies) would probably be necessary "to avoid loss of data and unnecessary waste of animals".

However, to date, the vast majority of long-tailed macaques (*Macaca fascicularis*, primate species most commonly used in animal experiments) used in France come from farms in Mauritius[24], which still capture them from the wild for breeding purposes[25,26]. The rate of F1 animals used in France is still high (29% in 2020, 24% in 2021) and has decreased little over the years according to statistics published by the MESR.

B. Animal experimentation ethics (CEEA)

1. Approval

Article R. 214-117 of the CRPM specifies that CEEAs must be approved by order of the Minister responsible for research. The conditions for approval are specified. However, up until February 2022, no approval order had been published. The Transcience association has requested

[23] The CITES nomenclature (https://cites.org/eng/res/10/10-16C15.php) is used to designate primates captured in the wild (F0), born in captivity to captured parents (F1), or born in captivity to parents born in captivity (F2+).

[24] R. Cash, "Y a-t-il encore des singes prélevés dans la nature pour la recherche biomédicale?", *Droit Animal, Ethique et Sciences*, LFDA, n° 111, November 2021.

[25] *Feasibility study as required in Article 10 of Directive 2010/63/EU on the protection of animals used for scientific purposes*, 31st July 2017. https://ec.europa.eu/environment/chemicals/lab_animals/pdf/related_topics/Article%2010%20Feasibility%20Study%20Final%20report%2031%20July%202017.pdf

[26] This is one of the reasons why many airlines now refuse to transport animals (and primates in particular) to laboratories. In the United States, the *National Association for Biomedical Research* filed a lawsuit against a number of airlines in 2018, complaining of unjustified discrimination. lawsuit was closed in December 2018, but the result is not yet known at November 2022 (https://www.regulations.gov/docket/DOT-OST-2018-0124/document). In France, following a campaign lasting more than twenty years and repeated letters from One Voice and then the MP Aymeric Caron, Air France has announced an end to the transport primates to laboratories from June 2023 (https://one-voice.fr/fr/blog/en-reponse-a-aymeric-caron-et-one-voice-air-france-communique-sa-d-d-arret-du-transport-des-primates-pour-l'-experimentation-animale.html).

and it turned out that the approvals did not exist (and therefore could not be communicated!)[27].

On 31 January and 28 February 2022 - nine years after the publication of decree no. 2013-118 on the protection of animals used for scientific purposes - following the legal appeals lodged by the Transcience association with the administrative court a few months earlier, the MESR finally signed thirty approval orders. However, it is not known on what criteria these approvals were issued. The MESR implicitly refused to provide the Transcience association with the corresponding approval application files, which are nonetheless communicable administrative documents, as attested by an opinion from the Commission d'accès aux documents administratifs (CADA)[28].

As Pauline Türk wrote in a note published by the Observatoire de l'Éthique Publique (OEP) in September 2022: "It turns out that the committees to which the Ministry, the competent authority under the terms of the 2010 Directive, delegates its powers in the area of ethical evaluation have in reality had neither legal personality nor accreditation for a decade [...]. [...] Not only has it failed to apply a regulatory provision that it itself enacted, but compliance with the 2010 European Directive and the ethical principles that it promotes has not been ensured"[29].

2. Assessment of the scientific justification for the project

Article R. 214-119 of the CRPM specifies that "the ethical evaluation verifies that the project meets the following criteria: 1) The project is justified from a scientific or educational point of view, or is required by law [...]", which is in line with Article 38 of the European Directive.

Article 4 of the Order of 1st February 2013 on the ethical evaluation and authorisation of projects involving the use of animals in experimental procedures states that "the ethical evaluation of projects shall be carried out at a level of detail appropriate to the type of project and shall include: a) an evaluation of the project's objectives, the expected scientific benefits or its educational value [...]". In other words, this first stage of the evaluation corresponds to the verification that the project is

[27] CADA opinion no. 20214781 dated 23 September 2021.
[28] CADA opinion no. 20225685 of 3 November 2022.
[29] Note from the Observatoire de l'Éthique Publique, Pauline Türk, September 2022 (https://www.observatoireethiquepublique.com/note-28-pauline-turk-pour-une-meilleure-transparence-en-matiere-dexperimentation-animale/).

well justified from a scientific or educational point of view. This stage is carried out by the competent authority responsible for evaluation, i.e. the EAECs.

Furthermore, there is no provision in the regulations for part of the assessment to be delegated to an organisation other than a "competent authority".

However, the *Guide to the ethical evaluation of projects involving the use of animals for scientific purposes* drawn up by Grice (Groupe de réflexion interprofessionnel sur les comités d'éthique attached to GIRCOR - Groupe interprofessionnel de réflexion et de communication sur la recherche), commissioned by the MESR (whose logo it bears) and approved by the Comité national de réflexion éthique sur l'expérimentation animale (CNREEA) on 17 September 2020, states that: "The ethical evaluation takes place independently of the scientific evaluation of the project and the CEEA does not replace a scientific or educational evaluation committee or a regulatory agency. The role of the CEEA is to ensure that the justification for the project has been considered relevant by a competent body with regard to its scientific, regulatory or educational purpose. For example, in the case of a project with a scientific purpose, the committee may rely on a scientific evaluation by a public research evaluation body, the scientific council of a private company or its management. It may also take into account a scientific evaluation carried out as part of an application for funding (public research funding agency, association, foundation)"[30].

Although article 38 of the directive provides that the competent authority responsible for project assessment may request the opinion of experts, this only concerns a certain number of items such as the fields of application for which animals will be used, consideration of the 3Rs rule, statistics, veterinary practice, animal care, etc.

The competent authority is also given the option of seeking the opinion of "independent parties" to assess the project. However, this is an advisory opinion and comes from independent structures (i.e. in no way linked to the project). It is never envisaged in the directive that the competent authority for project assessment can rely on the advice of "independent parties".

[30] https://www.enseignementsup-recherche.gouv.fr/fr/comite-national-de-reflexion-ethics-on-animal-testing-cnreea-51275

to the advice of an external organisation for part of the evaluation, and to comply with this advice with regard to the scientific justification of the project.

It therefore appears that the assessment procedure, insofar as it is partly "subcontracted" or delegated to external bodies that do not have the status of competent authorities, is only partially carried out by the CEEAs and therefore does not comply with the regulations.

3. Independence and impartiality

The members of the CEEAs, who are volunteers, are often salaried employees of the establishments or institutions applying for project authorisation, particularly in the case of "single-establishment" CEEAs to which only one establishment is attached. The problem was raised by CNREEA in its opinion 8 April 2022: "[...] to strengthen the principles of independence and impartiality, a CEEA should ideally be set up at the initiative of several user establishments from several institutions, and should be made up of members from these different establishments and members from outside these institutions, in order to allow a cross-section of views and prevent links of interest".

This major problem appears clearly in the 2021 assessment of the CEEAs published by the same CNREEA on 7 November 2022 on the MESR website. Of the 108 CEEAs in operation, "42.6% of committees are single-institution, 53.7% are single-institution and 13.9% are both multi-institution and single-institution. 2.8% of committees affiliated to a single institution are multi-institutional". There is also a significant difference here between public and private sector works councils: 80% of public sector works councils are multi-institutional compared with 5.6% of private sector works councils.

Even if it cannot be said that EAAC members are involved in conflicts of interest, the links of interest are quite obvious. The fact that, under the regulations, no EAAC member may take part in the assessment of a project in which he or she is involved is not a sufficient guarantee of independence and impartiality, even though this is required by article R. 214-117 of the CRPM and article 59 of the European directive.

4. Transparent assessment of projects

The lack of transparency on the part of the public authorities in this area is a further cause for concern[31].

We mentioned above that this lack of transparency contradicts certain provisions of the European Directive. However, Article 14 of the Order of 1er February 2013 on the ethical evaluation and authorisation of projects involving the use of animals in experimental procedures, commits CEEA members "to respect the confidentiality of the information provided in the dossiers submitted to the ethics committee", which may prove to be contrary to the right of access to administrative documents as established by Articles L. 311-1 et seq. of the Code des relations entre le public et l'administration (CRPA)[32]. However, the existence of confidential information in project authorisation applications cannot be an obstacle to the transmission of these administrative documents, since the said information could be concealed by the Ministry before the document is communicated to the applicant[33].

The same applies to retrospective assessments, which CEEAs must ensure are carried out. Article R. 214-120 of the CRPM provides for retrospective assessments of authorised projects. It is mandatory for projects using non-human primates and for projects involving severe class procedures. In addition to the regulatory obligations, the CEEA to which the user establishment belongs may request that a retrospective assessment be carried out once a project has been completed.

[31] Note from the Observatoire de l'Éthique Publique, Pauline Türk, September 2022 (https://www.observatoireethiquepublique.com/note-28-pauline-turk-pour-une-meilleure-transparence-en-matiere-dexperimentation-animale/).
[32] This was established in CADA opinions no. 20202358 and no. 20203330, issued on 29 October 2020, which stated that project authorisation applications and the minutes of the deliberations of ethics committees are communicable administrative documents. This state of affairs was reconfirmed by the CADA in its opinions no. 20224479 of 8 September 2022 and no. 20225119 of 13 October 2022, which made the disclosure of project authorisation applications and the minutes of the deliberations of ethics committees conditional on the removal of any information covered by the secrets protected by articles L. 311-5 and L. 311-6 of the French Code of Relations between the Public and the Administration (CRPA).
[33] CADA opinion no. 20226977 of 15 December 2022.

This retrospective assessment must make it possible to evaluate (Order of 1st February 2013 on the ethical evaluation and authorisation of projects involving the use of animals in experimental procedures):

"a) Whether the objectives of the project have been achieved;
b) The damage inflicted on the animals as well as the number and species of animals used and the actual severity of the experimental procedures;
c) Elements that can help reinforce application replacement, reduction and refinement requirements".

This process of feedback on practices is an essential link in a cycle continuous improvement in the quality methods and procedures. It is important to determine whether or not the objectives have been achieved, whether the project has led to publication, whether the actual damage differs from the expected damage, to analyse the reasons for any discrepancies found, to draw lessons for benefit/damage analyses, to disseminate the information to other teams to avoid repetition of the errors, etc.

In France, it is not known whether these retrospective assessments were actually carried out, as none have been published. As for the requests for these documents sent to the MESR by the associations, they revealed that the MESR did not have the retrospective assessments (according to the reply from the MESR, they are held by the CEEA, which cannot therefore confirm that they exist). This is a major shortcoming given the stated objective of transparency and process improvement.

However, the European Commission insists on the importance of this approach: "retrospective assessment is considered to be an extremely powerful tool to facilitate critical examination of the use of animals in scientific procedures, to identify improvements to be made in the area of the 'three Rs' and, if published, to guide future studies and improve transparency towards the public"[34].

5. Audits

Article 3 of the Order of 1st February 2013 on the ethical evaluation and authorisation of projects involving the use of animals in experimental procedures stipulates that CEEAs are subject to an audit

[34] " Methodological guide project evaluation and retrospective assessment", European Commission, September 2013.

The French Ministry of Research is to carry out an annual audit to ensure that "ethics committees are operating properly and, in particular, that there are no conflicts of interest". Between 2013 and 2021, only ten EAECs were "audited" in 2018, out of approximately 120 EAECs in operation that year in France, according to information published on the MESR website. It was not until 2022 that an initial assessment of the operation of all 108 CEEAs, carried out on the basis of a questionnaire, was published by CNREEA - which does not, strictly speaking, constitute an audit carried out by an independent body.

Finally, as in most EU Member States (with the notable exception of Italy), 100% of project authorisation applications receive a favourable response from the administrative authorities.

C. Inspection procedures and results

Article 5 of the Order of 1er February 2013 laying down the conditions for the approval, layout and operation of establishments using, breeding or supplying animals used for scientific purposes and their controls states that at least one third of the establishments concerned must be inspected every year. Establishments using primates, dogs or cats must be inspected every year, which means that some other establishments may inspected less than once three years[35].

1. Frequency and nature of inspections

Inspections serve three distinct purposes:

- check that an establishment is eligible for approval for its animal experimentation activities (by default, approvals are valid for six years);
- spot-check the application of regulations by animal experimentation establishments;
- check the application of corrections requested for non-conformities observed during a previous inspection.

[35] Assuming that one hundred of the six hundred establishments use primates, dogs or cats, these one hundred establishments will be inspected each year. To achieve the quota of one third of establishments inspected each year, it would therefore be sufficient to inspect one hundred of the remaining five hundred establishments each year, which suggests that, in this case, the five hundred establishments that do not use primates, dogs or cats will only be inspected on average every five years.

The French Ministry of Agriculture and Food Sovereignty (MASA) states that "the average number of inspections carried out each year is around 300 for a total number of approved establishments of around 640 (this figure is subject to change due to mergers and pooling between different research units)". In actual fact, the RESYTAL[36] database (an extract of which was obtained by the One Voice association after a request to MASA and an opinion from CADA[37]) indicates :

- 273 inspections (43% of establishments) including 76 unannounced in 2019 (compared with 244 including 64 unannounced according to the MASA website);
- 233 inspections (36% of establishments) including 23 unannounced in 2020 (compared with 227 including 23 unannounced according to the MASA website);
- 274 inspections (43% of establishments), including 63 unannounced inspections in 2021.

Overall, the annual number of inspections complies with the regulations (since more than a third of the establishments concerned are inspected each year), but the rate of unannounced inspections is low by European standards. Indeed, while EU Member States already had an average rate of over 40% between 2013 and 2017, France slowly climbed from to over this period. The figure 26% was reached in 2019, putting France still far behind the other EU Member States.

2. Results

With regard to inspection results, MASA only provides data for 2019:

- 43% of establishments in "compliance" (grade A) ;
- 38% of establishments in "minor non-compliance" (grade B);
- 17% of establishments in "average non-compliance" (grade C) ;
- 2% of establishments in "major non-compliance" (grade D).

According to MASA, 81.55% of establishments are "compliant overall or with a few minor non-compliances, which is a satisfactory result". It therefore interprets the overall A and B grades as meaning the presence of "a few minor non-conformities" at most.

[36] RESYTAL: Database and software environment in which the Ministry of Agriculture and the Ministry of Research register the approval of establishments, schedule inspections and record the results of these inspections.
[37] CADA opinion no. 20224538 of 9 September 2022.

In fact, among the more than 450 inspection reports produced between 2016 and 2022 and obtained through administrative litigation[38], can be seen that both A and B ratings cover a variety of situations ranging from establishments that presented only compliant items during the inspection to establishments presenting a dozen or so minor non-compliant items, several medium non-compliant items or even one major non-compliant item. The C rating is only applied to establishments with several major non-compliant items and many other non-compliant items.

Non-compliances concern in particular[39] :

- Lack of staff training (particularly in-service training, but also regulatory training on animal welfare, ethics and the 3Rs, and technical procedures, which must be provided in the first year of employment);
- poor management of veterinary medicines (to the extent that this item was the subject of an article in a recent issue of the specialist journal *STAL*[40]);
- the poor functioning of the structure responsible for animal welfare (which often only meets once a year, or even less, does not produce reports or check the application of its advice);
- failure to monitor the animals on a daily basis (the duty rosters for weekends and public holidays are regularly missing or incorrectly filled in);
- the lack of authorisation for a number of projects (as the Ministry of Research was very late in issuing authorisations from 2013 to 2019, projects often began before they were authorised and were therefore carried out illegally).

Without more extensive access to the RESYTAL database, it is difficult to say whether the frequency of non-compliance in these different categories has changed over the years.

[38] The communicability of these inspection reports without obscuring anything other than the names of individuals is now well established by repeated administrative case law (https://experimentation-animale.info/avis-cada).
[39] An analysis all the inspection reports obtained is currently being carried out the One Voice association and will be published.
[40] STAL n°49, 4e quarter 2021, p. 18-29.

These data show that there are many and frequent problems with the application of regulations, including such important issues as project authorisations and staff training. But are the penalties at least commensurate with the infringements observed?

D. Penalties

As mentioned above, the penalties provided for under French regulations in the event of non-compliance are neither proportionate to the seriousness of the offences nor dissuasive, since they are limited to fines of a symbolic amount. Moreover, they are almost never applied, with the inspection services of the Ministry of Agriculture more often than not preferring an 'educational' approach that involves giving advice to user establishments, possibly issuing warnings or even a formal notice to comply within a given timeframe.

1. Nature of penalties applicable

It should be remembered that in addition to the offences set out in Article R. 215-10 of the CRPM for a number of breaches of current regulations, Article 521-2 of the Criminal Code, which is referenced in Article L. 236-1 of the Research Code, deals specifically with experiments on animals: "The act of carrying out scientific or experimental experiments or research on animals without complying with the prescriptions laid down by decree in the Council of State is punishable by the penalties set out in Article 521-1".

Article 521-1 of the French Penal Code sets out the penalties for serious cruelty to animals, and provides for significant penalties:

- for individuals, between three and five years' imprisonment and a fine of between €45,000 and €75,000 (depending on whether or not there are aggravating circumstances, or whether or not the offence resulted in the death of the animal);
- for legal entities liable for the actions of their employees, the fines provided for in article 131-38 of the Criminal Code (up to five times the fine imposed on the natural person in question) and the penalties provided for in article 131-39 of the Criminal Code (judicial supervision, various bans for five years or more, or even dissolution).

2. Access to documents relating to sanctions

In practical terms, information on the penal consequences of non-compliance observed during inspections is not available to the public. Articles L. 213-1 to L. 213-8 of the French Heritage Code require a certain number of archives to be classified for between twenty-five and one hundred years before they can be released to the public, depending on the interests protected. The disclosure of documents "relating to cases brought before the courts" is therefore subject to a waiting period of seventy-five years by default. However, article L. 213-3 provides that it is possible, on request, to gain early access to these archives "insofar as the interest in consulting these documents does not lead to excessive harm to the interests that the law was intended to protect".

In its opinion no. 20222737 issued on 7 July 2022, the CADA ruled against the early disclosure, under the French Heritage Code, of fines and official notices issued against animal experimentation establishments since 2017. It justified its opinion as follows: "Given the very recent nature of the documents requested and the sensitivity of the information they are likely to contain, the Commission considers that access by way of derogation from the time limit for disclosure under the procedure provided for Article L213-3 of this Code would, in this case, excessively harm the interests that the law was intended to protect".

On the other hand, court rulings can be communicated through other channels - but have never been requested in relation to animal experimentation. The decree of 28 April 2021 "taken in application of article 9 of decree no. 2020-797 of 29 June 2020 relating to the availability to the public of the decisions of the judicial and administrative courts" provides for the availability to the public of court decisions by "31 December 2024 in the case of decisions handed down by the courts of first instance in respect of offences and misdemeanours", 31 December 2025 in the case of decisions handed down by appeal courts in respect of misdemeanours and offences" and "31 December 2025 in the case of decisions handed down in respect of criminal offences". Court rulings concerning animal experimentation establishments could therefore be publicly available online within a few years.

In addition, CADA's opinion no. 20222737 issued on 7 July 2022 repeats its opinion no. 20214234 issued on 2 September 2021, which states that, unlike documents relating to criminal proceedings, documents relating to administrative proceedings (formal notices, suspensions of approval, requests for corrections, etc.) may be disclosed - which has been the case for the past two years.

confirmed by the Paris Administrative Court in its ruling no. 2201251/5-2 of 9 February 2023.

3. Frequency and level of sanctions

As we have not obtained the documents needed to estimate the penalties actually applied, we can only rely on the only publicly available document: part II of the annexes to the report published by the European Commission in 2020 on the application of the regulations between 2013 and 2017[41].

According to information provided by France, out of 1,387 inspections carried out from 2013 to 2017, French public services :

- issued 78 "formal notices",
- suspended or limited eight approvals pending compliance following an inspection,
- withdrew the approval of an establishment that could not be brought up to standard (and was therefore closed),
- and referred two cases to the prosecutor.

If we apply the percentage of 19.45% (for the year 2019 shown on the MASA website) to the number of inspections carried out between 2013 and 2017 to assess the number of average non-compliances (grade C) and major non-compliances (grade D), we obtain the number of 270 inspections with an overall grade of C ("average non-compliance") or D ("major non-compliance") over this period. Although this is an extrapolated estimate, it should be close to reality.

However, between 2013 and 2017, only 78 inspections resulted in a formal notice. Of these, 9 were followed by administrative sanctions (limitations, suspensions or withdrawal of approval) and only 2 were the subject of complaints to the public prosecutor for possible prosecution. For the remaining two-thirds of establishments that received an overall rating of average or major non-compliance - 181 in all - MASA services did not deem it necessary to take any further action.

The only trace of the application of a criminal sanction can be found in the minutes of the meeting of 4 May 2017 of the CNEA (Commission nationale de l'expérimentation animale, now Commission nationale pour la protection des animaux utilisés à des fins scientifiques): "The DGAL representative

[41] The next report of this type is scheduled for 2022.

[Direction Générale de l'Alimentation] informed members that following an inspection, a non-compliance had been reported (a staff member, who had been in post for a long time, carrying out experimental surgical procedures without having undergone regulatory training). An official report was issued, classifying the incident as an act of cruelty (articles 521-1 and 2 of the French penal code). The manager of the user establishment (EU) received a fine (4th class) for failing to pay attention to the qualifications of his staff. The DGAL representative informed the members of the way in which the services of the Ministry of Agriculture operate: the case is forwarded to the public prosecutor, who does not proceed to a court judgment for an offence, but makes a proposal for a penal transaction (simpler and faster procedure) with a fine and announces a fixed fine (6,000 euros for the person who performed the surgery and 750 euros for the EU manager). The employee can then take legal action against his or her employer for failure to provide training. A letter is sent to the staff concerned, who must sign it and return it, and the offence is not recorded on the person's criminal record [...]".

The practice of experimental surgery by an applicator who had not undergone the *appropriate* regulatory training resulted in a criminal penalty of €6,750, with no prison sentence and no entry in the criminal record of the person concerned. The site manager, who was responsible for ensuring that staff received the necessary training, was only fined 750 euros. The establishment itself, although responsible under the Criminal Code, was not punished. It could only have been sanctioned if the technician who had performed the surgical procedures without specific training had taken legal action against his employer.

VI. Conclusion

A regulatory framework for the protection of animals used for scientific purposes has existed in the European Union since 1986, when the first directive was adopted. Although the second directive, adopted in 2010, contains provisions that are slightly more favourable to animals, the fact remains, as we saw earlier, that it provides (relative) protection for only some of the animals used for experimental purposes. In fact, a large proportion of the animals used are not covered by these regulations.

What's more, this directive contains loopholes and loopholes that leave Member States and institutions a great deal of room for manoeuvre.

This is due to the derogations it explicitly provides for, to the use of elusive formulas, and to the lack precision on how a number of provisions are to be implemented, the principle being that scientific objectives take precedence over the interests of the animals.

It should also be noted that the transposition of the directive into French law is deficient in several respects: the measures to encourage the development and dissemination of non-animal methods are inadequate; the ethics committees do not have the necessary skills to carry out their regulatory tasks, and their organisation and operation do not guarantee transparency, impartiality and the absence of conflicts of interest in the assessment of projects; the penalties provided for in the event of infringements are neither proportionate nor dissuasive; and so on.

In addition to these shortcomings in transposition, it should be noted that French regulations are not strictly applied, as evidenced by: the still high proportion of long-tailed macaques born to parents caught in the wild; the operation for more than ten years of animal experimentation ethics committees without accreditation and without reporting on their activities; the results of inspections, which are far from reassuring, and the extreme scarcity of penalties applied; etc.

Each of the points raised in the preceding development is not in itself sufficient to speak of a systematic desire on the part of the public authorities not to apply, in letter and in spirit, the terms of the 2010 European directive, but their combination tends to suggest this. This is why it seems urgent that the whole system be revised, with a real political will, to achieve the objectives of the directive, which is intended to represent
This is "an important step towards the ultimate goal of total replacement of procedures applied to live animals for scientific and educational purposes as soon as scientifically possible" (Recital 10).

Beyond this factual observation, we are entitled to wonder about the reasons that might explain both the reluctance of the European institutions to draft the articles of the directive and the lack of political will in a number of Member States to apply the recommendations contained in the directive rigorously and promptly.

There are several possible explanations:

- **The representation of animals in our societies**. Animals are never considered for themselves, as individuals, but for the utility we attribute to them: according to our needs and desires, they keep us company, they work for us, they serve as food or even clothing, they allow us to satisfy our (scientific) curiosity or to entertain ourselves... So-called "" animals are just one category of animals, constructed by humans in relation to the "function" we have attributed to them. Claude Bernard's old argument that it would be illogical to restrict the use of animals for scientific purposes when they are used for human consumption is still very much alive[42].
- **The place of science in our societies, particularly medical science**. Fear of death and disease leads many people to put their lives and health "in the hands of science". Many researchers claim that they are working "for the good of humanity". "In the name of science", all sorts of experiments can be accepted by the general public, as shown by a test carried out by Laurent Bègue-Shankland at Grenoble University[43]. However, progress in medical research based on animal experiments has been declining over the last twenty years[44].
- **Free movement of goods and people, competition in research**. Respect for

[42] Claude Bernard, *Introduction à l'étude de la médecine expérimentale*, 1865: "Now comes this other question. Do we have the right to carry out experiments and vivisections on animals? As far as I am concerned, I think we have this right completely and absolutely. It would be very strange, indeed, if we recognised that man had the right to use animals for all the purposes of life, for his domestic services, for his food, and if we forbade him to use them to learn one of the sciences most useful to humanity... if it is immoral to carry out an experiment on a man as soon as it is dangerous for him, although the result may be useful to others, it is essentially moral to carry out experiments on an animal, although painful and dangerous for him, as soon as they may be useful to man".

[43] Laurent Bègue-Shankland, "Face aux animaux - Nos émotions, nos préjugés, nos ambivalences", Paris, *Odile Jacob*, 2022.

[44] We are thinking in particular of toxicology, which still relies on the animal model paradigm as a reference, despite numerous arguments pointing to the imperfections of animal models for demonstrating the efficacy and non-toxicity of a given product in humans. On this subject, see the chapter entitled "The limits of animal experimentation" in the book *L'expérimentation animale en question - Accélérer la transition vers une recherche sans animaux* (Roland Cash, Paris, Éditions Matériologiques, 2022).

> the interests of animals used for scientific purposes remain subordinate to those of the laws of the market, based on the argument that any excessive restrictions on the use of animals in laboratories could harm the competitiveness of French research (or European) if the other countries are less "demanding'. The first recital in the preamble to the directive explains that the rationale for this regulation is partly linked to the desire to
> "to ensure the proper functioning of the internal market". Then in Article 2: "A Member State may not prohibit or impede supply or use of animals bred or kept in another Member State in accordance with this Directive, nor prohibit or impede the placing on the market of products developed using such animals in accordance with this Directive". This means that a Member State cannot introduce national measures that are stricter than the terms of the Directive.

However, as the latest opinion polls on the subject[45] seem to indicate, attitudes are changing with regard to animal consideration, and the socio-economic context should not hold back the development of regulations that are more favourable to animals.

Until now, very few national parliamentarians have been involved in this issue, but on 16 September 2021, the Members of the European Parliament showed the way by voting almost unanimously in favour of a resolution in which they pointed out the delay in implementation of the Directive by the Member States and expressed their wish that the latter should do necessary to speed up the transition to non-animal research[46].

It is clear that the Directive needs to be revised, in line with its own recitals, so that Member States are firmly encouraged to take far-reaching national measures. The mobilisation of EU citizens in favour of the transition to non-animal research would be an asset in convincing the institutions.

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[45] See summaries of recent surveys on https://www.transcience.fr/resultats-des-enquetes and on https://experimentation-animale.info/a-quel-point-le-public-connait-il- et-accepte-t-il-lexperimentation-animale/

[46] European Parliament resolution of 16 September 2021 on plans and measures to accelerate the shift to non-animal based innovation research, regulatory testing and education (2021/2784(RSP)): 667 votes in favour in favour, 4 against and 16 abstentions. https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=fr&reference=2021/2784(RSP)

This mobilisation is already underway. This mobilisation is already underway, as we saw in 2012-2013 with the "Stop Vivisection" European Citizens' Initiative (which is one of the first and rare ECIs to have obtained the one million signatures needed for a study by the European Commission)[47], and more recently in 2022-2023 with the ECI "Stop Vivisection".
"Save Cruelty-Free Cosmetics"[48] (the Commission's response is still awaited at the time of writing).

But it is possible to go beyond these proposals, by envisaging a radical change of perspective that would dare to question the very legitimacy of animal experimentation[49] by approaching the question from the angle of the fundamental rights of all sentient individuals, starting with their right not to be inflicted with suffering. The contribution of specialists in animal ethics and moral philosophy is therefore required to question certain representations and value systems that are obvious obstacles to the advent of non-animal research.

For the regulations governing the use of animals for scientific purposes to change significantly in their favour, people need to be prepared for the prospect of animal-free research. How can this prospect be made acceptable to those whose research is still largely based on animal experimentation, or to those who earn their living from it? This is one of the major challenges for the years to come.

[47] ICE: http://www.stopvivisection.eu/fr/
And the European Commission's response in 2015:
https://europa.eu/citizens-initiative/initiatives/details/2012/000007/stop-vivisection_fr
[48] https://europa.eu/citizens-initiative/initiatives/details/2021/000006_en
[49] This is the perspective of specialists in animal ethics and moral and political philosophy, who agree that the usual justification for animal experimentation is based on an arbitrary double standard between the human species (whose individuals are protected by deontological principles) and all other animal species (whose individuals are subject to utilitarian principles). This is what François Jaquet, a specialist in animal ethics and meta-ethics, explained at a round table on animal experimentation in December 2022: https://youtu.be/0CD0S3PGP18?t=1854