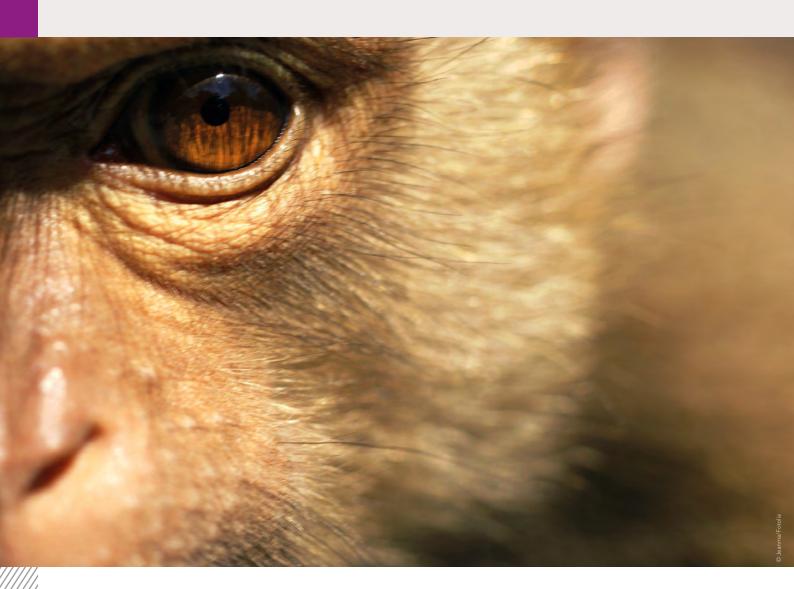
Research report, April 2023

ANIMAL TESTING AND PRIMATES







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INTRODUCTION

Since its creation in the middle of the 1990s, the One Voice association has been fighting for an end to animal testing and to defend animals used in laboratories at each stage of their life. This issue, perhaps still more than others, is an integral part of its DNA. As well as its research and proceedings, the association has, thanks to its investigators, revealed what happens in breeding farms and laboratories and raised public awareness of the realities of the situation.

Thus our investigation in Cambodia¹ allowed us to reveal unpublished images of the capture and breeding conditions of the macaques sent to laboratories. The association has also led a campaign for more than twenty years with numerous partners against the transportation of animals to laboratories by airline companies, and in particular Air France². At the start of the 2000s, we led and investigation within a French toxicology laboratory³, where we discovered detestable practices and carried out the first lawful rescues of animals used in French laboratories, allowing thirty-six macaques⁴, eighteen lemurs⁵ and nine beagles⁶ to be adopted and to escape from any new experiments, reassuring us that the aforementioned laboratories will not subsequently reopen. Today, One Voice is a partner of numerous associations on an international level (among them are the Asia for Animals coalition and Action for Primates in the United Kingdom). In France, we also represent the two biggest European coalitions for an end to animal testing (the ECEAE and Cruelty-Free Europe). We are leading several campaigns together, often relying on the right to access administrative documents to obtain detailed information on practices and failures in laboratories, but also on essential whistle-blowers. In doing so, we benefit from the expertise of different specialists to produce pragmatic legal and political statements.

This report is more specifically interested in the use of primates in French laboratories – a use which is particularly criticised, and which could be radically reassessed in the context of current affairs at the beginning of the 21st century.

Primates and animal testing

Each year, thousands of primates are used in French laboratories. The majority of them are long-tailed macaques, a species listed as 'in danger' of extinction by the International Union for the Conservation of Nature (IUCN) in 2022. Despite this, one third of new individuals used each year are born to parents captured in the wild. In laboratories, primates are exploited for basic and applied research on nervous system and immune system pathologies but also for other disorders as well as for biological and ethological experimental studies, and for cell, blood, and different tissue tests that are used in ex vivo research. As well as the suffering caused by experiments themselves, primates are subjected to the stress of being kept in variable conditions which range from the regulatory minimum (two square metres of ground for two adult macaques) to larger

spaces such as enclosures. Either way, they are enclosed and these are restrictive spaces for this species that is adapted to frequently moving around in large spaces.

Regulations

French and European regulations are very defectively. In France, committees that assess projects to authorise them are almost exclusively comprised of people who practice animal testing, often employed by the establishments whose projects they must assess, on often very limited ethical principles.

Inspections by prefectures are most often announced in advance. Despite the fact that they frequently state non-conformities such as a lack in staff training or a lack of checks being carried out on the animals on weekends and bank holidays, they are very rarely followed up with sanctions to discourage this and prefectures prefer to work in a 'pedagogical' way.

An urgent need for change

The year 2022 marked not only the classification of long-tailed macaques on the IUCN list of species in danger of extinction but also the ban on the use of primates born to captive parents (in November 2022), Air France's decision to stop transporting primates for laboratories and the continuation of the Chinese ban on exporting its primates. But instead of drawing logical conclusions by predicting a progressive end to testing on primates, the industry structured itself to resist it.

We have known about primate consciousness for a long time, however, and moral and political philosophy specialists have the general consensus that sentient animals should not undergo exploitation that can cause them suffering. Furthermore, alternatives exist or can be developed, whether it be methods of experimentation without animals or prevention and support work, which is still very underestimated nowadays.

Our statements

Faced with this analysis, our main request is for the revision of the European Directive of 22 September 2010 relating to the protection of animals used for scientific purposes, in order to integrate remedial help into it for the stated problems as well as a schedule establishing a roadmap for an end to animal testing.

THE FACTS

Numbers and origin

Several thousands of primates are used each year in French and European laboratories. The majority of them are long-tailed macaques that come from Asian and African breeding farms. Many are captured in the wild and exploited for breeding.

Each year, the Ministry of Research publishes a "statistical investigation" on the data from the year n-2 specifically regarding the number of animals used directly in experimental procedures*, the type of research, the animals' origin, and the degree of suffering or stress that is inflicted on them. This investigation is based on declarations of the use of animals by establishments being collected in a folder.

We have obtained the folders by requesting them from the ministry and have produced a webpage allowing this data to be explored in a detailed and illustrative way (https://experimentation-animale.com). In December 2022, the latest investigation available and the last complete folder were provided by the ministry regarding the year 2020.

SPECIES CONCERNED				
5	Long-tailed macaques (also called macaca fascicularis, cynomolgus monkeys, crab-eating macaques)		Baboons	
	Marmosets and tamarinds	T	Vervets	
Prosimians (lemurs, mouse lemurs, tarsiers)			Other primates (Southern pig-tailed macaques, collared mangabeys)	
T	Rhesus macaques		Saimiris (Also called squirrel monkeys)	

FRENCH AND EUROPEAN FIGURES							
		Number of annual uses	Proportion of individuals reused	Origin	Individuals born to captive parents	Conservation status	
		3 000	35%	Mauritius,	30%	vulnerable (2020) threatened (2022)	
CON		9 000 ~ 10 000	20 ~ 30%	South Asia (Including China before 2020)	30 ≽ 15%		
6		230 ≥ 150	70%	Fillbrack to Comm	< 10%		
AY.		600 ≽ 400	30 ~ 40%	EU breeding farms	< 5%	good ↔ threatened	
		50 ~ 160	0%	Autonomous	0%	la Calala O addad	
		120 ~ 250	20 ~ 25%	colonies in the EU	0%	vulnérable ↔ critical	
Van		70	50%	Fillbrandt of form	10 ~ 30%		
		450 ~ 630	35 ~ 45%	EU breeding farms	< 10%	good	
		25 ~ 100	50%	F11 1: 6	< 20%		
		40 ~ 100	0 ~ 50%	EU breeding farms	< 30%	good	
		15 ~ 35	10%	A	< 20%		
		30 ~ 60	30 ~ 50%	America	< 30%	good	
		20 (2017-2020)	0 ~ 100%	Asian	35% (2017-2020)	#h	
		25 ~ 40	25 ~ 100%	breeding farms	50 %	threatened ↔ critical	
		15 \(\sum 0\) (2015-2017)	0%	EU or American	30-60% (2015-2017)		
		15 ~ 25 ≥ 0 (2015-2019)	0%	breeding farms	50 ≥ 0%	good	

^{*} The animals used solely as breeders or sentinels, as well as the animals that are dead or were killed without being used in any procedures, are not counted in these annual statistics and are the subject of a report every five years. The next report of this kind will relate to 2022.

THE FACTS

Suffering and types of research

Having arrived in laboratories, monkeys endure a life of suffering, linked not only to the conditions they are kept in but above all the experiments that are inflicted upon them: research on the biology of various diseases, toxicity testing, and tests on the efficacy of medicinal products, or cell and tissue testing for 'ex vivo' testing.

In laboratories, primates are widely used in research on the nervous system and neurological diseases, the immune system and infectious diseases, and other diseases that will lead to respiratory disorders (with the suffering that accompanies them) or to blindness (which involves killing marmosets to remove their eyes). While individuals from other species can be used in many more varied ways, the regulations[®] theoretically limit the exploitation of primates to the study of disabling diseases or those that can be fatal. Furthermore, using protected species or those referenced in annexe A of the European regulations[®] based on the Convention for International Trade in Endangered Species of Wild Fauna and Flora (CITES)¹⁰ for basic research is forbidden.

Basic research is the study of a principle or function without the perspective of direct application, but with the aim of developing new understandings of scientific dispositions for future applied research. For example, it is about better understanding the function of a healthy or diseased immune system by infecting primates, studying the mechanisms of vision and focus by implanting monitoring devices in the retina, or discerning the function of different populations of neurons by observing them in real time using electrodes implanted in their brain.

'Translational or applied' research is the study of a subject with the perspective of developing or testing a product or applicable procedure. For example, it is about carrying out measurements or repeated tests on primates who have been inoculated with a serious disease, testing certain individuals' reactions to being kept in different conditions, or pre-testing the efficacy of a vaccine on animals by exposing them to the relevant pathogens.

Primates are also exploited to test the toxicity of medications for human use before proceeding to clinical trials, which occasionally involves significant suffering when medications are toxic or they are tested on primates that are unwell. Lastly, they are used as factories to produce blood, cerebrospinal fluid, bone marrow, and other cells of interest for pharmaceutical groups.

As well as the suffering caused by these usages, primates are subjected to stress linked to being captured or bred and to them potentially being transported and being kept in captivity – being kept in conditions that can range from a box in which they can only just turn around to outdoor enclosures that are a bit less restricting on behaviours.



© Somrerk/Adol

THE FACTS

THE USE OF PRIMATES IN FRENCH AND EUROPEAN LABORATORIES							
		Nervous system/ neurological diseases	Immune system/ infectious diseases	Other	Behaviour/ animal biology	Toxicity testing for human medication	Various samples
1	Long-tailed macaques	В	B/A	A (respiratory problems)		TT	S (blood, cerebrospinal fluid, bone marrow)
	Marmosets and tamarins	В		A (blindness)		тт	S (blood)
	Prosimians	В		B (endocrine system)	В		
T	Rhesus macaques	B / A		A (sensory problems)			S (blood)
	Baboons		А		В		
	Vervets		А				S (blood, cells)
	Other primates			A (haemophilia)	В		
The state of the s	Squirrel monkeys	В					

B: basic research. A: Applied research. TT: Toxicity testing. S: samples

Most frequent level of suffering: non-recovery mild moderate severe

The suffering endured by primates in laboratories is very variable – for example, even if toxicity tests most often involve 'mild' suffering, they cause 'moderate' or 'severe' suffering in many cases.



WHERE DO PRIMATES COME FROM?

Capture and breeding

While individuals from certain species (marmosets, prosimians and baboons) are often directly bred by the laboratories that exploit them, this is not the case for long-tailed macaques, the primates most frequently used in animal testing — and this is despite them being classified as 'endangered' by the **IUCN** in 2022.

We note that still in the 2020 statistics, almost one third of long-tailed macaques used in France (and 15% of individuals used in the European Union) are born to captive parents, which is denoted by the 'F1' acronym (first generation born in captivity). In fact, the majority of long-tailed macaques exploited in French laboratories come from Asian (Indonesia, Cambodia, Vietnam, Laos, Philippines) or African (Mauritius) breeding farms that capture them from the wild to ensure they have a stock of breeders, and that send primates by plane to recipient countries. Although these primates are not sent to laboratories, these same breeding farms can sell them so that they can be eaten or used as 'companion animals'11 – and sometimes violently trained from a very young age to be put on stage in 'cute' videos on social networks¹².

France and the other European Union member states have no power to control these breeding farms – which does not bode well when we know the state of the non-conformities in French laboratories, despite being subject to inspections.

Investigating to expose what is hidden

Between 2008 and 2019¹³, breeding farms sent more than 450,000 long-tailed macaques (of which at least 50,000 were captured in the wild, without counting illegal trafficking and the production of fake export certificates 14) and hundreds of thousands of organs and tissue from these macaques to laboratories worldwide.

The images available of breeding farms that capture wild primates generally come from animal rights associations who infiltrate with hidden cameras. Also, in 2008, One Voice infiltrated a breeding farm in Cambodia 15 where thousands of primates destined for laboratories worldwide were kept. In 2013, Animal Equality published an investigation on capturing and breeding farms in Mauritius that produce primates condemned to breed to use their offspring who will be sent to the Spanish breeding centre in Camarles, which will exploit them to sell to laboratories.

At the beginning of 2022, Action for Primates, One Voice's partner, published footage¹⁷ showing macaques being captured in the wild in Indonesia. Each time, the reports are the same: primates are trapped, dragged around by their tails, held down on the ground, brutally manhandled to be put into bags or wooden boxes, babies snatched from their mothers' arms... no compassion is seen in these videos which show the current reality.



In 2021, the Mauritian breeding farm Biosphere Trading Ltd. received authorisation to grow in size 18 to increase its macaque production tenfold. In order to facilitate this growth, the company provided traps 19 to those living there, proposing that they would buy the primates captured while confirming to the media that the captures would be carried out using "human methods [that] would cause minimal stress for the animals". A decision which caused a reaction from European MEPs²⁰, unfortunately without success.

One Voice is asking for...

- the inclusion of long-tailed macaques (Macaca fascularis) in CITES annexe I and in annexe A of the (CE) n° 338/97 Council Regulation 09/12/96, which would allow a ban on their use for basic research.
- a ban on importing primates from countries outside of the European Union for animal testing.

WHERE DO PRIMATES COME FROM?

Air transport

While numerous airline companies have refused to participate in the transportation of animals for laboratories over the years, Air France has, in 2022, just committed to putting a stop to supplying primates once its current contracts come to an end. Good news, especially as the French centre Silabe plays a large part in this trafficking.

Once bought by laboratories, primates there are sent in wooden boxes, piled up one on top of the other in the plane's hold. Often, the journey through France is just one step. For years, One Voice (in France), Action for Primates (in England), and Stop Camarles (in Spain) have joined together to report on this situation.

One example among many: on 14 April 2022²¹, one hundred macaques imported from Mauritius arrived at the Roissy

Airport after an eleven-hour journey on board an Air France flight without anyone on board suspecting a thing. Arriving in France, they were given to another transporter who took them to a toxicology testing laboratory in England.

France at the centre of European trafficking

Others spend a period of quarantine at the primatology centre at the University of Strasbourg, a hub for the European trade of primates for laboratories.²²

Silabe: the University of Strasbourg and primate trade in Europe

Created in 1978 as a breeding centre and ethological observation centre for primates, the Primatology Centre²³ at the University of Strasbourg (renamed Silabe – Simian Laboratory Europe) was transformed in 1995 to start trading primates. Its maximum capacity was increased to more than 800 primates in 2004, then to 1600 in 2014.

More than a place for experimentation, Silabe is a transit area for primates that are imported and kept in quarantine there before being sold to other laboratories in Europe. That is what the documents provided by whistle-blowers and others, obtained through a legal battle brought against the University, which was reluctant to enforce the law on access to administrative documents.

In 2009, the University of Strasbourg created the ADUEIS association to benefit from a large public grant. Michel Deneken, President of the University, had for several years been the president of ADUEIS, which was a very vague situation²⁴ due to him being in contract with himself. At the end of 2017, the University's board of directors learnt that ADUEIS had been dissolved a few months prior²⁵, and had to take note of this on the basis that an incomplete stack of documents was provided the day before the meeting. Since 2018, Silabe has therefore depended directly and officially on the University of Strasbourg.

Airline companies commit and the industry attacks them

Faced with numerous decisions by airline companies refusing to transport animals to laboratories, an industrial lobby based in the United States launched legal proceedings²⁶ in 2008, complaining about "discrimination" by the airline companies involved (United, British Airways, China Southern, and Qatar Airways), who continue to transport animals for other types of animal exploitation. The case hearing was concluded in December 2018, but the result is still not yet known in November 2022.

Despite the persistent fight of One Voice and other associations since the middle of the 1990s, Air France was the only large European airline company²⁷ not yet committed against the transportation of primates for laboratories. This is finally a done deal in 2022: Air France will stop transporting primates to laboratories from June 2023. Unfortunately, this commitment does not include other animals sent to laboratories (horses, fish, snakes²⁸, but also beagles²⁹ and individuals from many other species).

REGULATIONS

Possession

Once they arrive at the laboratories, primates are subjected to awful living conditions, marked out by the regulatory minima under which it is difficult to imagine any animal of any kind possibly being fulfilled. In such a context, the notion of 'accommodation norms' and the 'enrichment' of the places they are kept in more resemble papering over the cracks than a true commitment in the interests of the animals.

According to regulations³⁰, the primates used for experimentation "must have a certain degree of control of their environment and a certain freedom of choice in order to avoid behaviours induced by stress", which assumes that the habitat has 'enrichment' to encourage a variety of behaviours. Furthermore, "the space must allow them to adopt behaviours that are as varied as possible, giving them a feeling of safety and offering them a fairly complex environment to allow them to run, walk, climb, and jump".

Minimum requirements

The minimum requirements for keeping primates are very telling, however: we have to ask how a two square metre space of ground is supposed to allow two adult macaques to run and express varied behaviours without succumbing to perpetual boredom. Furthermore, no requirements are mentioned for prosimians and 'other primates'.

MINIMUM REQUIREMENTS				
Species	Size of an adult individual	Size of ground for two adult individuals	Minimum height	Additional volume per individual
Marmosets	15-25 cm	0.5 m²	1.50 m	0.2 m³
Tamarins	20-30 cm	1.5 m²	1.50 m	0.2 m³
Squirrel monkeys	25-35 cm	2.0 m²	1.80 m	0.5 m³
Macaques and vervet monkeys	40-60 cm	2.0 m²	1.80 m	1.8 m³
Baboons	60-100 cm	7.0 m²	1.80 m	6.0 m ³



Example of a supposedly exemplary area for them to be kept in (virtual visit of a CNRS laboratory³¹ – Gircor 2015)

Visuels © AdobeStock

'Enrichment' to clear a guilty conscience

"Television sessions' and being let out once a week into bigger enclosures are often provided but more generally it is about reducing boredom to help individuals to thrive by giving them active control of their environment. In some contexts, the irony of 'enrichment' is clear: thus, during its tests on the effects of diesel vehicle emissions on primates in 201432, Volkswagen 'enriched' animals' environments by showing them cartoons while they were slowly poisoned with exhaust fumes.

Keeping them in enclosures, which are bigger and have less metal, seems more appropriate to respond to some of primates' physical and cognitive needs. However, it would be very difficult to know for sure what this involves on a

psychological level for them, when it is still a very restrictive environment that they can only leave to be handled and subjected to experiments.

One Voice is asking for...

- a reform of standard keeping conditions to allow for systematic and unconditional application, making it possible for animals to run, walk, climb, and jump in an environment that is always rich in varied interests.



REGULATIONS

Project authorisation

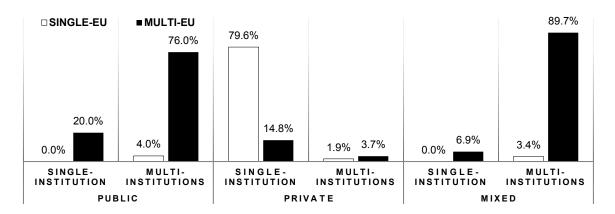
Before starting an experimental project, establishments must obtain a favourable opinion from their ethical committee and authorisation from the Ministry of Research. But shortcomings are plentiful and ethical committees, judge and jury, have never refused a project in France, even though non-animal alternatives have existed for more than twenty years.

Since 2013, European regulations have made evaluations of animal testing projects by 'Animal Testing Ethics Committees' (ATECs), which are comprised of at least four people with practical skills in animal testing (project design, carrying out procedures, care or killing of animals, veterinary work) and a 'non-specialised' person in these matters, obligatory.

Structural and fundamental issues

The ATEC's annual business report³⁴ (produced by the French National Committee for Ethical Reflection on Animal Testing, or CNREEA) revealed that there were 108 active committees in France in 2021, often linked with a single institution that often groups together several laboratories (this is the case in most universities), in particular in the private sector.

DISTRIBUTION OF COMMITTEES DEPENDING ON THEIR STRUCTURE ACCORDING TO INDUSTRY



These committees mainly group together between 5 and 13 members, but up to a maximum of 89 members. While those who carry out project design and carry out procedures here were very well represented, the 'non-specialists' found a marginal role here, making up at best 20% of the total number, at worst less than 10%.

The hundred ethical committees registered in France is comprised mainly of those who practice animal testing,

and a large part of them only represent a single institution, which far from allows impartiality and independence as required by the "National Charter on Ethical Animal Testing"³⁵.

In 2022, the CNREEA gave their opinion on the function of ethical committees³⁶, highlighting their lack of financial, logistical, and human resources, as well as the problems caused by a lack of impartiality in evaluating projects.

Ethics committees for people: a model to follow

Yet beyond these operational problems, the basic thinking of the Animal Testing Ethics Committee (ATEC) is already biased for many reasons, which becomes evident when we compare them to a Persons³⁷ Protection Committee (PPC), in charge of assessing research projects involving humans.

ATEC	PPC		
minimum 5 members	14 members + 14 substitutes		
A 'non-specialised' person	50% of people in civil society		
No requirement for specialists in non-animal methods and animal ethics to be present	Integration among external people with varied specialisms (sociological, psychological, legal, ethicists)		
No integration of associations dedicated to non-animal research and/or animal protection	Integration of associations for patients and those who use the health system		
Evaluation of establishments' files who have decided on the composition of the committee	Anonymous and random assignment of each file to one of the 38 committees in the country		
Conditioning the animals to accept being handled and kept	Principle of free and clear consent of those involved		
Possibility of making the animals used suffer and killing them as long as there is some benefit for us	Ban on all suffering except in the case of a potential credible direct benefit for the individual concerned		

These differences perhaps explain how ethics committees can endorse a project while alternatives without animals have existed for a long time (pyrogen testing on rabbits,

or the ascites method for creating monoclonal antibodies³⁸ for example), or other authorised uses that are explicitly forbidden by regulations.

One Voice is asking for...

a reform on Animal Testing Ethics Committees; so that, on one hand, associations for the defence of animal
interests as well as sociology, psychology, law, and animal ethics specialists are represented; and so that, on
the other hand, committees can be independent from the establishments that they are evaluating projects for
through the random distribution of files.

INSPECTIONS

Principles and reality

French laboratories are, on average, inspected every three years to ensure that they are following regulations. For establishments that use primates, inspections take place every year. But these inspections are generally not announced in advance, due to a restrictive interpretation of the 'appropriate' proportion of inspections without prior warning being required by the regulations.

Beyond the internal auto-controls managed by animal welfare bodies³⁹, the regulations provide for the inspection of establishments that breed, supply, and use animals for scientific purposes by prefectural veterinary services, led by the Ministry of Agriculture and responding to the authority of the Ministry of the Interior.

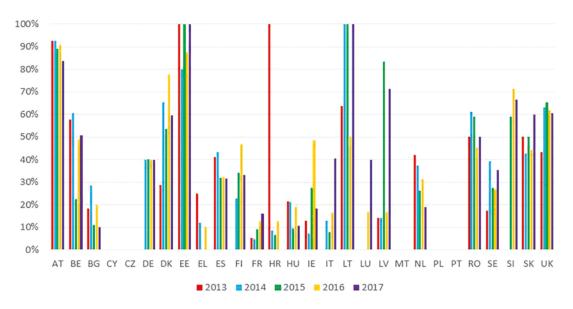
According to regulations⁴⁰, at least one third of establishments must be inspected each year. Among these inspections must be any establishment that uses primates, cats, or dogs. According to the Ministry of Agriculture⁴¹, almost half of the 600 registered establishments in France are inspected every year. No specific figure is given on the number of the establishments that use primates. It is therefore impossible for the public to ensure that regulations are being followed on this point.

France lags behind Europe when it comes to unexpected inspections

European regulations⁴² also allow for an 'appropriate proportion' of inspections 'without prior warning'. On this point, the adaptation of these regulations under French law⁴³ is lacking, since the results of the 'risk analysis' for each establishment, linked to prior non-conformities, the places they are kept in, and the number of projects, are dependent on the proportion of unexpected inspections – a limitation which has not been provided for within the European Directive.

This probably explains why France did not pass 15% of unexpected inspections between 2013 and 2017⁴⁴ when the European average is around 40% and certain member states reached almost 100%. A database obtained by One Voice from the Ministry of Agriculture shows that France reached its maximum of 28% for unexpected inspections in 2019, still not attaining the European average.

PROPORTION OF UNEXPECTED INSPECTIONS BY MEMBER STATE FROM 2013-2017 (IMAGE BY THE EUROPEAN COMMISSION)



'Surprise' inspections announced the day before

Furthermore, discussions with inspectors and prefecture staff allowed us to discover that the 'unexpected' investigations are often announced the day before, for practical reasons. They are therefore not inspections 'without prior warning' (like trading standards, for example). With no data available on the presence or lack of primates in animal testing establishments, we are not able to know if the situation is better or worse when it comes to primates.

Results and sanctions

If a laboratory does not follow regulations on animal testing, it will get a tap on the hand and some friendly advice. This is what has emerged from recent investigations and inspection reports, crippled with non-conformities and yet not followed up with sanctions. To blame: too-loose regulations and difficulties in obtaining a criminal justice response against those responsible for cruelty to animals.

One Voice has gathered hundreds of inspection reports carried out between 2019 and 2021. Upon analysing these reports, we noted that, unsurprisingly, the unexpected inspections often find more non-conforming elements than inspections that are expected. The non-conformities relate to a lack in staff training, the poor use of medications, a lack of the animals being looked after at weekends and on bank holidays, or a lack of authorisation for ongoing projects.

Still, without precise data on the establishments that do or do not keep primates, it is impossible for us to know more on the specific nature of these establishments.

What do laboratories risk?

French regulations⁴⁵ intend to limit animal testing to cases of 'strict necessity', but the notion of 'strict necessity' is not defined by them. Legal arguments must therefore fall back on an article in the Rural Code⁴⁶ which sets sanctions for a small number of offences with fines of an amount (€750 maximum) that is insignificant for many establishments. Unfortunately, even though these minimum sanctions are not applied in most cases⁴⁷, public powers prefer them to formal notices and other administrative warnings.

It must be said that the criminal justice response when it comes to the environment is generally weak⁴⁸, which

encourages prefectures to take matters to court: they rationalise this shortcoming by confirming that it is better to proceed with education – despite the failures shown by the educational method for almost ten years; the proportion of non-conformities remains stable and high.

A laboratory that is not in good order during the annual inspection therefore does not have much to worry about if there is no reminder of the regulations, which will only turn into an administrative or (minimal) criminal sanction if the non-conformity persists for several years.

Flagrant offences in Europe

his lack of proportionate sanctions perhaps explains why recent infiltrations by Cruelty-Free International and SOKO-Tierschutz in a German laboratory⁴⁹ and a Spanish laboratory⁵⁰, subject to the same regulations as French laboratories and boasting online about their exemplary nature, were able to inform them about acts of undeniable

cruelty here. Problems which apparently have not been noticed by inspections...



elty Free International / Carlota Saor

In France, an inspection carried out in March 2022 in one of the CEA (French Alternative Energies and Atomic Energy Commission) research centres⁵¹ revealed that the macaques there were not registered on the French national register of protected wildlife (i-fap⁵²) and that the establishment systematically used deprivation of water to condition them, without taking into account recommendations from the French National Committee on Animal Testing Ethics (CNREEA⁵³). Worse, the lack of any clinical follow-up for a female monkey during the two-month summer holidays led to her death. The inspection report noted that the establishment had committed a 'minor non-conformity'.

One Voice is asking for...

- the systematic application of appropriate and proportionate sanctions in order to act as a deterrent for establishments for each non-conformity noted during inspections.
- an improvement in the inspection system, due to:
 - checks by the European Commission on any inspections carried out by France;
 - an obligation for France to put its implementation of the regulations right for inspections so that the proportion of unexpected inspections no longer depends on risk analysis.
- an obligation for transparency during the entire animal testing process by systematic publication of the
 documents relating to the websites of the administrations involved: establishments' approval decrees, project
 authorisation application files, ethics committees' deliberation minutes, individual follow-up documents for
 cats, dogs, and primates, inspection reports, and follow-ups on non-conformities.

URGENCY

The 2022-2023 turning point

The year 2022 was an historic moment for primates used in animal testing. Between the classification of long-tailed macaques on the IUCN Red List, a ban on importing new primates born to captive parents into the European Union, and the refusal from airline companies to transport primates to laboratories, this is the ideal time for a fundamental change.

Those who defend animal testing⁵⁴ suggest the idea that captures would be a solution to cohabitation problems with primates in zones where they are considered overpopulated by local human populations. But the captures never actually solved anything and have even created a new problem.

Endangered species

Since the 2000s, a report by CITES⁵⁵ mentioned the risk represented by capturing these long-tailed macaque populations. And it was not wrong: this species was classified as 'vulnerable' in 2020, then 'endangered' in 2022 on the IUCN Red List⁵⁶.

With the idea of "putting a stop to capturing non-human primates in the wild for scientific and breeding purposes", the use of new primates from the first generation born in captivity ('F1) has been banned since November 2022. This ban followed on from a report by the European Commission given in 2017⁵⁷ drawn up on the basis of a feasibility study.

This classification echoes the Chinese ban⁵⁸ on exporting primates since the start of the Covid-19 pandemic (which led to an increase in the number of primates exported in 2021 by Mauritius⁵⁹), but also to the recent decision by Air France⁶⁰ to stop transporting primates to laboratories as soon as possible under the framework of its social and environmental responsibility strategies. A decision already taken by Kenya Airways⁶¹ at the start of the year, but which remains uncertain when we know that the new transportation contracts refused by EgyptAir⁶² this year have been taken over by Hainan Airlines⁶³.

The industry's reaction to the news about primates in 2022

Between pressure from associations, announcements from airline companies, supply restrictions, and environmental concerns regarding the conservation of species, everything does in fact seem to be coming together for the best conditions possible to put an end to testing on primates. The president of EARA tirelessly qualifies these current events as a "perfect storm"⁶⁴ – we understand that, according to him, this is bad news.



Faced with Air France's announcement in June 2022, it did not take long for reactions to start coming in, in particular on behalf of Gircor and BioSimia⁶⁵, who suggest that it would become too difficult to use primates in France and research would move to countries who are less worried about animal welfare. Inherently, we understand that French researchers would be ready to carry on regardless of the animals' welfare to continue their research if they were authorised to do so.

Radio France⁶⁶ and Le Point Vétérinaire⁶⁷ exclusively gave the floor to lobbies about these issues in 2022; we read with pleasure the nuances given by a primatologist⁶⁸, who criticised their hypocrisy and highlighted that there would be a need to be satisfied with local breeding farms, and for perspectives to be opened up to a forum⁶⁹ which would call for an opportunity to progress towards an end to testing on primates.

Resistance to change

Historically, the animal testing industry has not been favourable of practical regulations in the interest of animals. On the other hand, since regulations being brought in, laboratories have organised themselves into associations and lobbies to win public favour, influence political representatives, and avoid seeing their scope being reduced where possible.

In 1908⁷⁰, the director of the National Veterinary School of Alfort "refused to believe that we may never find a government in our country who would dare to support a business as retrograde against French science" as one that would involve regulating vivisection. And in 1990⁷¹, while the first European regulations had finally just (basically) limited animal testing, the French Veterinary Academy badly hid its consternation, expressing their wish "that any new regulation does not become established which does not guarantee both a definitive improvement in animal welfare and the promotion of scientific and therapeutic progress".

The idea behind this wish was that scientists should be able to continue to act as they please and benefit from the unconditional trust of the public and the political world without being challenged. With this goal, they were still in need of catastrophic speeches demonising the opposition and foreseeing an end to scientific progress in the case of an end to animal testing – and this, despite numerous scandals revealed over the years and very guarded data on the interests and validity of animal models in numerous domains

Organised resistance in the industry

In fact, when England implemented its first regulations on vivisection in the 19th century, vivisectors organised themselves into associations to take control and avoid that which would limit them in their practices, all while distributing their propaganda to the public⁷².

A century later, Gircor (interprofession and French lobby grouping public and private establishments) was founded following the adoption of the 1986 European regulation.

While its objective is today masked by its objective for transparency and putting forward alternative



methods, Gircor's aim was very explicit when it was founded: "to promote and defend the interests of its members" (which is to say the animal testing establishments and the industry that encompasses them).

It was joined by the EARA, a European lobby active since the 2010 introduction of the new European Directive, then by the Research Group BioSimia⁷⁴ in 2016 in France, centred around promoting the use of primates.





These entities are very outspoken and very active in the media and political circles, passing themselves off as specialists deprived of conflicts of interest while they represent the interests of numerous laboratories whose financing relies mainly on animal testing.

When change is needed: the case of chimpanzees

The ban on using chimpanzees in United States laboratories is a good case study: a report ordered by the Institute of Medicine in 2010 on the scientific benefit of each use⁷⁵ concluded, contrary to protests from the industry, that the majority of these experiments were not necessary. In 2015, the listing of chimpanzees as an endangered species, pressure from associations, and the application of strict criteria in evaluations by a multidisciplinary project board planning to use individuals from this species ended with the use of them becoming thing of the past.

The use of large monkeys (gorillas, bonobos, chimpanzees, and orangutans) is banned in the European Union, but regulations⁷⁶ allow exemptions if the use of another species is not deemed sufficient, for research on the preservation of the species or on unexpected emerging diseases likely to be fatal. Fortunately, no uses have been identified and published in Europe since 1999, even with the appearance of SARS-CoV-2.



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ETHICS

Is animal testing 'necessary'?

Can we talk about ethics in animal testing? For those who conceptualise and implement this research, as long as certain principles are followed and the experiments are considered necessary, the answer is yes. But the projects approved in France show that this idea is very easily influenced, to the point where industry interests are sometimes considered 'necessary' and no practices are absolutely forbidden.

Nowadays, animal testing generally integrates ethics with the work by the committees in charge of assessing that projects

follow regulations or take into account the 3Rs (see box below).

The 3Rs of animal testing - Replace, Reduce, Refine

These principles were proposed in 1959 as a way of improving the conditions under which animal testing was carried out. Each of these principles has very clear limits in its application. They are comprised of:

Replacing the animal with other experimentation methods (if the exact same result can be obtained)

Reducing the number of animals used (for a project and not in absolute terms)

Refining methods in order to reduce animal suffering and stress (if this does not compromise the project objectives)

For those who defend animal testing, the ethics of this rely on the idea that they are only used in the best conditions and when 'necessary' – an argument which sometimes worsens ridiculous caricatures, such as the idea that research will stop⁷⁷ or even that we will return to the Middle Ages⁷⁸ if we refuse to practice animal testing.

In fact, the law itself (article L. 214-3 of the Rural Code⁷⁹) intends to limit animal testing "to cases of strict necessity", without better defining what this necessity refers to.

Some examples of supposedly necessary practices

In 2022, we can however ask ourselves if it is really 'necessary' to genetically modify 'livestock' animals to make them produce more^{\$0} in a context where epidemics are increasing in breeding farms^{\$1} and where climate specialists^{\$2} warn of the urgency of transitioning into plant proteins. Likewise, inducing anaphylactic shocks on guinea pigs^{\$3} whose lungs serve as an ingredient in homeopathic products can pose a question as to 'necessity'.

In reality, in the animal testing world, any use of an animal is deemed 'necessary' to reach a goal set by an experimental protocol which cannot be achieved by any other means. But the goals set are so specific that the data is false – without taking into account the fact that animals continue to be exploited using procedures for which alternative methods have been approved for twenty years⁸⁴. Why not, from then on, use only these new methods?

The example of water restriction: a substantial problem

The problem already existed in fact. Research involving human beings cannot in any case subject them to significant suffering, even with their consent and even if the scientific benefits could prove to be immense. On the other hand, animal testing ethics boards cannot absolutely ban a practice even when it is deemed unethical, as long as it serves a scientific objective. That is how the recommendations on water restriction in primates by the French National Committee for Ethical Reflection on Animal Testing⁸⁵, falls into the same category as French and European regulations, suggesting that they avoid this practice 'wherever possible' while it is still a source of suffering for the animals concerned.

Water restriction involves progressively reducing the animals' ration of water until the prospect of getting a few drops of it motivates them to do what is expected of them in the framework of the experiment. This method is widely used in the initial conditioning of primates to get them to go into the restraint chairs, then within the framework of studies carried out using these restraint chairs. These studies often involve observing the cerebral function of primates using electrodes and other devices implanted in their brain while they carry out cognitive tasks with no benefit to them, sometimes under the influence of various pharmaceutical products.

Sentience

For decades, we have discovered that 'humanness' is far from being easy to define, and that individuals from numerous other species that we exploit are not only sentient, but also capable of performing and experiencing empathy, jealousy, and other complex emotions. In short, they are sentient, and this state of facts must have inevitable consequences ethically as well as legally.

Animals are sentient and the law must reflect this

On 7 July 2012, a group of neuroscientists met at the University of Cambridge and produced the Cambridge Declaration⁸⁶ which made history in understanding animals. According to detailed explanations on observations, among human beings and individuals from other animal species, intentional behaviours, emotions, and reactions to different situations, the Declaration states that:

Humans are not the only ones who possess neurological substrates of conscious states. Non-human animals, including all mammals and birds, as well as numerous other species such as octopuses, also possess these neurological substrates.

On 29 March 2019, a group of specialists declared the Toulon Declaration⁸⁷ in response to a lack of this animal consciousness being taken into account in national and international law. This declaration states that non-human animals should be given the same legal status as non-human persons and the related rights.

Sentience and moral philosophy

Nowadays, the major criterion taken on by animal ethics and moral philosophy specialists is sentience, which is an individual's capacity to feel pleasure, pain, and emotions, and to have a point of view and an interest regarding the world surrounding them. This is what the Montreal Declaration set out, signed in October 2022 by hundreds of moral and political philosophy specialists of various authorities (see box below).

Moral philosophy is generally divided into two large schools of thought in 'normative ethics': consequentialists, who believe that an action is good or desirable if the consequences are positive; and deontologists, who define moral responsibilities on the basis of different criteria.

From a consequentialist view, the criterion of sentience leads to the idea that the differences between human and other species are not morally pertinent to justify authorising the breeding, use, and slaughter of certain sentient animals in laboratories while we ban these practices on the human species.

From a deontologist view, the criteria of sentience leads to the 'subject-of-a-life' statute being attributed to all sentient animals, and considering that each sentient individual, human or non-human, has value it its own right and therefore cannot be used as a way of profiting from others.

Two schools of thought that lead to the same conclusion via two different paths. Michael Fox is one of the rare moral philosophy specialists to have defended animal testing in an extensive way in his work, *The Case for Animal Experimentation*⁸⁹, published in 1986. A few months after its publication⁹⁰, having read the criticism of his peers and debated with several other specialists, he renounced his own work and decided, repeatedly, against animal testing⁹¹.

Sentience and animal testing

If the sentience of certain individuals (worms, mosquitos...) remains uncertain, the sentience of all birds, fish, and mammals is no longer in doubt. Also, non-human primates experience empathy for their fellow kind, play, communicate

with gestures and sounds that sometimes present complex syntaxes, create and use tools, and form complex, dynamic, and organised social structures in different ways. Their use in animal testing is an aberration.

One Voice is asking for...

a ban on experiments classified as 'severe', which generate significant suffering and cannot be justified in view
of current knowledge on animal sentience and from an established consensus among animal ethics and moral
and political philosophy specialists.

ALTERNATIVES

Research without animals

Throughout history, some discoveries have been made by using animals. All were eventually demonstrated again, or can be today, by using new experimental methods that do not use animals; all knowledge can be developed in different ways. At a minimum, this situation must push us to be prudent when it comes to saying that animal testing is 'necessary'.

The European Directive⁹² presents a 'total replacement' of animal testing by other research methods as its 'eventual

objective'. These methods can mainly be grouped into three categories⁹³: in vitro, in silico et in humano.

Experimental methods without animals



In recent years, 'humans-on-a-chip' have allowed in vitro modelling of molecules passing from different organs linked by microfluidic systems. Culture mediums are often carried out using animal cells, but *xeno-free*⁹⁴ initiatives (which look to work on cultural mediums without animal derived products) are being developed.



Artificial intelligence, in silico, already allows the correct predictions of the likely toxicity of numerous molecules and can be widely developed to replace the use of animals in many cases on the basis of data already gathered on human persons and on individuals from other species.



Clinical research and epidemiology, in humano, with the clear consent of supportive human subjects, are precious sources of information not to be overlooked. These methods are just waiting to be developed in accordance with bioethical thinking which is already well-supported.

'Replacing' or Researching methods without animals?

In its report published in 2021 on genome editing⁹⁵, the European Group on Ethics in Sciences and New Technologies proposed to reinforce regulations relating to testing on non-human primates by introducing a fourth 'R' involving researching alternative methods.

"Thus, financing bodies could make researchers who lead experiments on NHPs assign some of their budget to researching alternative methods, and the projects financed by the EU could set an obligation to establish

an integrated work package or clearly defined activities focusing on the development of alternative methods."

One Voice entirely supports this proposition, with the aim of achieving total replacement, particularly in basic research domains for which non-animal alternatives are more difficult to explore. Such a requirement, when it comes to experiments on primates or on other animals, would be less costly and would allow, thanks to the publication of the results of this mandatory research, the creation of important steps forward to facilitate a transition towards a fairer world.

One Voice is asking for...

- "Non-animal research methods" as a fourth 'R' making it compulsory, for each project that uses animals, to finance or carry out research for non-animal methods, experimental or not, likely to allow the avoidance of the use of animals in the future for the type of research concerned.
- the establishment, in partnership in particular with associations dedicated to defending animal interests and with specialists in the development and use of non-animal methods, and application of the Resolution issued by the European Parliament on 16 September 2021:
 - an unconditional exit strategy for animal testing for regulatory tests;
 - an unconditional exit strategy for animal testing for basic and applied research in the European Union.

Beyond animal testing

The concept of 'Replacement' is limited to assessing experimental alternatives in animal testing. However, between the huge investment into social and political change for prevention, and the resolution of problems that corrupt scientific settings currently, other ways are possible to reach the main objectives that are advancing science and reducing suffering and diseases.

In July 2022, the Ministry of Research opened a Data Gouv Research 96 platform, which allows research establishments to make their databases, images, videos, scripts, and any other document relating to their research available. This is one of the many initiatives from recent years in terms of Open Science 97. This principle is significant not only for the public-facing transparency of scientific practices, but also for the practice of science itself and to avoid infinitely repeating experiments without knowing if they have already been carried out by others.

Pre-declaration of research

The best example is found in the clinical research domain (meaning intervention research involving human persons): pre-declaration.

After the implementation of local registers (in particular in the United States⁹⁸ and in Europe⁹⁹) in 2005, the WHO centralised these registers with an international search engine, the ICTRP¹⁰⁰. All clinical studies worldwide can be found here before they have even begun.

In animal testing, the PreclinicalTrials.eu¹⁰¹ system was officially launched in 2018 by the Netherlands with an international scope concerning all research on animals, and the Animal Study Registry¹⁰² was launched by Germany in 2019. But three years later¹⁰³, despite a worldwide acknowledgement of the importance of these platforms in advancing research, they both contain hardly more than 200 protocols, which can be explained specifically due to the fact that pre-declaration is not an obligatory step.

Acting without experimentation



Many contemporary diseases are linked to our environment and our ways of life. A huge financing of prevention campaigns and support of populations at risk would therefore be particularly useful, just as a drastic reduction in environmental pollution would be.

Cohabitation with liminal primates

Cohabitation between the human population and other primates is sometimes difficult – whether it is damage to plants, bagging waste, or direct aggression in one way or another. Faced with these difficulties, Malaysia has massacred hundreds of thousands of macaques¹⁰⁴ in recent years.

However, non-violent solutions ¹⁰⁵ exist, which rotate around two axes:

- ligation of female macaques' fallopian tubes using laparoscopic surgery, in a way which avoids repeated

captures and counteracts polygamy in the species concerned (a single male can impregnate all of the females in his group); - educating the human population on sharing of space and good prevention practices (such a proactive management of waste and locals or tourists not feeding liminal and wild macaques).

In towns and countries where difficulties are faced when cohabiting with macaques all living in breeding farms being fed by captures, the implementation of these kinds of programmes would allow a peaceful existence with other inhabitants of the planet to be encouraged.

One Voice is asking for...

- financial, technical, and logistical assistance in areas concerned by a difficulty in cohabiting with primates in order to permit raising awareness among populations about sharing space and the implementation of nonviolent solutions in monitoring troops.
- an extension of the notion of 'Replacement' with non-experimental methods such as awareness campaigns and political action relating to prevention in public health.

CONCLUSION AND STATEMENTS

One Voice has been fighting to defend animals used in laboratories since the end of the 1990s. Unfortunately, still today, thousands of primates are exploited in France and in the European Union every year for animal testing. In this context, they are used for research on various biological systems and diseases, enduring toxicity tests for medications before them being put on the market, or used as biological factories in order to produce blood, antibodies, spinal bone marrow, or other tissues.

While bodies defending animal testing constantly boast about the regulations in place and their application, the reality is much different. Ethical boards who assess the projects, as well as functioning in a completely opaque way,

are judge and jury and do not have the power to refuse anything as long as a handful of principles are more or less respected. Inspections, most of the time announced in advance, reveal numerous non-conformities which very rarely give rise to sanctions being discouraged.

Yet the ethical question is simple: these animals are sentient, which means that they have an interest in living and having positive experiences, all while avoiding negative experiences. As well as this simple state of facts, they are capable of empathy, jealously, and many other complex emotions. Their use in experimentation is a fundamental injustice which must be stopped as quickly as possible.



Our statements

For better or for worse, 2022 claims to be an historic period, with long-tailed macaques being classified on the IUCN Red List and a ban on importing new primates born to parents captured in the wild into the European Union, but also with the announcement of an end to transporting primates for laboratories by the airline company Air France. There has never been a better opportunity to revise the regulations on animal testing to finally schedule a definitive end to it.

The One Voice association therefore makes the following statements:

- The inclusion of long-tailed macaques (*Macaca fascularis*) in CITES annexe I and in annexe A of the (CE) n° 338/97 Council Regulation 09/12/96, which would allow a ban on their use for basic¹⁰⁶ research.
- Financial, technical, and logistical assistance in areas concerned by a difficulty in cohabiting with primates, in order to permit raising awareness among populations about sharing space and the implementation of non-violent solutions in monitoring troops.
- A revision of the European Directive on the use of animals for scientific purposes, in particular to include:
 - a reform of standard keeping conditions to allow for systematic and unconditional application, making it possible for animals to run, walk, climb, and jump in an environment that is always rich in varied interests;
 - a reform on Animal Testing Ethics Committees; so that associations for the defence of animal interests as well as sociology, psychology, law, and animal ethics specialists are represented; and so that committees can be independent from the establishments that they are evaluating projects for through the random distribution of files:
 - an extension of the notion of 'Replacement' with nonexperimental methods such as awareness campaigns and political action relating to prevention in public health;
 - "non-animal research methods" as a fourth 'R', making
 it compulsory, for each project that uses animals, to
 finance or carry out research for non-animal methods,
 experimental or not, likely to allow the avoidance of
 the use of animals in the future for the type of research
 concerned;
 - a ban on importing primates from countries outside of the European Union;

- a ban on experiments classified as 'severe', which generate significant suffering and cannot be justified in view of current knowledge on animal sentience and from an established consensus among animal ethics specialists and in moral and political philosophy;
- the systematic application of appropriate and proportionate sanctions in order to act as a deterrent for establishments for each non-conformity noted during inspections.
- An obligation for transparency during the entire animal testing process by systematic publication of the documents relating to the websites of the administrations involved: establishments' approval decrees, project authorisation application files, ethics committees' deliberation minutes, individual follow-up documents for cats, dogs, and primates, inspection reports, and follow-ups on nonconformities.
- The establishment, in partnership in particular with associations dedicated to defending animal interests and with specialists in the development and use of nonanimal methods, and application of the Resolution issued by the European Parliament on 16 September 2021¹⁰⁷:
 - an unconditional exit strategy for animal testing for regulatory tests;
 - an unconditional exit strategy for animal testing for basic and applied research in the European Union.
- An improvement in the inspection system, due to:
 - checks by the European Commission on any inspections carried out by France (on the basis of article 35 of the European Directive);
 - an obligation for France to put its implementation of the regulations right for inspections (article 34 of the European Directive) so that the proportion of unexpected inspections no longer depends on risk analysis.

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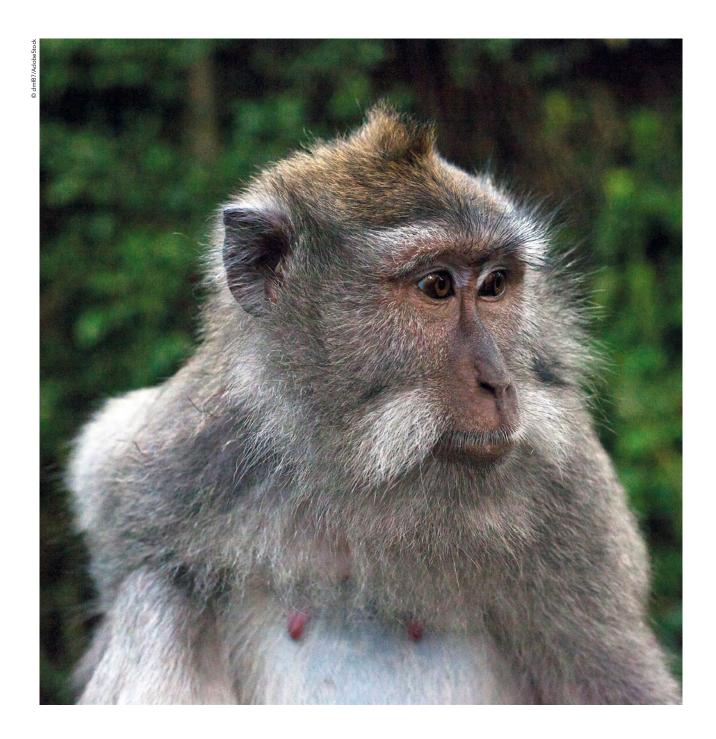
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