

Project report **AUGUST 2016**

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# **THE TIME IS NOW!**



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This report is provided by One Voice as part of the European Coalition to End Animal Experiments (ECEAE) project 'The Time is Now'.

It aligns with the project aims of identifying (in France) as many examples of proposals or predictions by ministers, government bodies or reports by committees or research establishments of ways to reduce the number of animal experiments in the future, or concrete predictions that the number of animal experiments would fall by 2015.

## GENERAL FINDINGS

Extensive research has been carried out in compiling this report, in accordance with details requested within the ECEAE project as follows;

### Project Details

- What is the body or individual who made the statement/ recommendation?
- What is their status? (Minister, committee, etc.)
- What exactly did they say? Please include any reservations or ways in which they could say that they did not really mean it.
- What has actually happened?

General findings are that the national authorities in France are reluctant to provide any targets or pledges on reduction or replacement of animal experiments. Indeed, specific quotes and references to predictions that animal testing on French soil would fall by 2015 (or even prior to this) have been very challenging to find, as it would seem that government bodies, ministers or politicians are simply unwilling (or perhaps unable or discouraged in some cases) to make such predictions at the outset. Repeated requests from One Voice to provide information on animal experiments have received no replies from the national bodies concerned.

However, despite a clear lack of government transparency and accountability in reducing animal numbers, in this report One Voice provides the results of its research into all available evidence and resources on the current situation concerning animal testing in France, as well as initiatives to support the 3Rs. Much of the information

available is generic, evasive or vague (for example, mere repetition by national research bodies of the Russell and Birch '3Rs' criteria, rather than meaningful explanation of how the 3Rs are specifically being applied in such institutions, or any genuine commitments to targets to reduce or replace animal testing<sup>1</sup>).

One Voice believes this makes a strong case to carry forward as part of the project, at both national and European level, especially given France's status as the highest user of animals in experiments in the EU and even more critically, the continued active encouragement within the national research community to conduct animal testing<sup>2</sup>. Therefore, where the authorities have so far failed to provide predictions or targets, one of the next key steps is to establish a clear and firm lobbying strategy, to make the authorities provide such estimates, to which they can then be held accountable.

*“Not only France has status as the highest user of animals in experiments in the EU, but the continued active encouragement within the national research community to conduct animal testing.”*

## METHODOLOGY

In compiling this report, a number of sources of documentation have been searched; these

include parliamentary correspondence such as written questions and responses from the Senate and National Assembly; reports and written statements (for example on government research department websites) reports by scientific and political committees and press releases, as well as review of national pro-animal research materials. A comprehensive search of documentation at both French and EU level has been made.

Examples of political correspondence, reports and other information produced in previous years have been used to demonstrate a lack of commitment or failure to act.

## **BROKEN PROMISES ON PUBLICATION OF NATIONAL STATISTICS**

The competent authority for providing up to date annual statistics on animal experiments, the Ministry for Higher Education and Research<sup>3</sup> has provided no new annual figures since 2010. Even these were provided as part of the last EU wide report<sup>4</sup>, rather than nationally published. This is despite the ministry stating on its animal research homepage<sup>5</sup> in reference to release of statistics 'As part of the implementation of the new European Directive (Directive 2010/63 / EU), this rate will become annual from 2014 and its format will undergo major changes.'

It would seem that this now puts France in breach of Directive 2010/63/EU which states under Article 54 (2) that 'Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. Member States shall submit that statistical information to the Commission by 10 November 2015 and every year thereafter.'

Has the government submitted this data by the above deadline? If so where is it and when will new national figures be released? This lack of transparency and

failure to publish previous annual statistics was also recently highlighted in a parliamentary question by Laurence Abeille MP of the EELV party<sup>6</sup>. Ms Abeille also highlights in the same written question, the failure of the government to publish non-technical summaries, as required under Article 43(3) of the directive. At the time of writing this report, a response from the ministry is still outstanding.

To provide comparison, since the last statistics provided by France in 2010 for the EU report, other member states, for example the UK, Germany, Austria and the Netherlands have at least produced national annual statistics for 2011-2014 inclusive. How can France not be held to account for its failure to do the same?

## **FAILURE TO REDUCE AND REPLACE ANIMAL TESTS**

For two decades, France remains the highest user of animals in experiments across the EU, when compared to all other member states, consistently responsible for between 20 and 24% of all experiments since the mid to late 1990s. Figures have remained well over 2 million animals per year, yet the true figure is likely to be much higher, as national and EU based collection of figures differs across all countries.



(For example, in the UK in 2011, the total number of animals used was 3.79 million as declared in the national report, yet EU figures only report a total of 2.05 million for the UK in the same year<sup>7</sup>).

In 2012 it was stated that there were 245 animal research institutions (INRA, INSERM, CNRS, CEA, universities, private pharmaceutical companies) and almost 640 experimental authorizations were granted by the Board of Control for five years.<sup>8</sup>

The next EU-wide statistics are due at the end of 2016. This will be the eighth report on the use of animals for scientific purposes. The European Commission publishes these reports every three years and the data collected from most member states corresponds to two years earlier, with France usually providing data from three years earlier. It is therefore anticipated that France will provide figures corresponding to 2013 (or possibly 2014) to be included in the eighth report.

Despite references to the 3Rs and alternatives to animal testing elsewhere, the resistance to change in France is clear from opinions and speculations in some previous statistical reports. For example, in addition to data provided in the 2002 release, the Ministry for Research emphasised that there had been 'no breakthrough in alternatives' and 'the need for animal experimentation'. Also that it is 'difficult to make predictions' in why certain areas of animal use may rise or fall, 'without making any predictions about the future<sup>9</sup>.' Such unsolicited opinion in statistical reports is rare from other member states, who instead promote work done towards actively reducing animal use, or highlight progress made in research into alternative methods.

### **KEY AUTHORITIES AND NATIONAL BODIES CONCERNING ANIMAL EXPERIMENTS: THE LACK OF TRANSPARENCY**

The CNEA (Commission nationale de l'expérimentation animale) was set up by the national competent authority on animal testing (the Ministry of Research) in 1987 under article 27 of Decree No. 87-848 on practical experiments on animals<sup>10</sup>. The Decree states that the CNEA meets twice a year (after an amendment in 2001) and its members change as required.<sup>11</sup> Lists of current members are available.<sup>12</sup>

The CNEA is 'responsible for different missions in the use of animals for scientific purposes: it provides advice in particular on any proposed amendment of regulation or

legislation to animal testing, and for approval of training of personnel of institutions of animal experimentation.'

However, questions were raised in parliament in 1997, highlighting the failure of the CNEA a decade after its establishment, to be effective in carrying out its role in creating a commission for alternative methods<sup>13</sup>, also highlighting the fact that two legislative proposals to set up such a committee had been rejected. The Commission stated in its response that as early as 1991, it had set up a Sub-Committee on alternative methods, composed of members of the national commission and other selected experts from academia, research companies, animal protection organisations and industry, with three objectives: make an inventory of the disciplines for which alternative methods are currently under review or available; a reflection for a decrease in the number of animals used and; a role of Coordinator in order to promote and develop the research carried out in collaboration by public or private laboratories.

*"The competent authority for providing up to date annual statistics on animal experiments, the Ministry for Higher Education and Research, has provided no new annual figures since 2010."*

The response from the ministry also outlined how subsequently, the CNEA found that there was 'no match between the status of the Sub-Committee on alternative methods and the actions to be undertaken', and that it was appropriate to give the committee an official recognised identity. Yet it appears this took a further six years. Under the CNEA, the National Committee of Ethical Reflection on Animal Experimentation (CNREEA) was finally

announced in 2003 and established a further two years later (decree of 22 March 2005)<sup>14</sup>.

The CNREEA mission is to provide opinions on the ethical issues raised by animal experiments. One of the committee's first actions was to develop the National Charter on the ethics of animal experimentation, yet this wasn't until 2008<sup>15</sup> and provides no focus on alternatives methods.

The above demonstrates the painfully slow process of setting up committees to even acknowledge animal experiments, not to mention alternatives.

The parliamentary response of 1997 also stated that for several years, a scientific and financial effort was devoted to the development and evaluation of methods in vitro alternatives to animal testing and that such methods are already used on a large scale in the screening and the development of products, to reduce 'significantly' the number of animals used. Yet this appears to have made little or no impact on France's continued status as the highest user of animals. Furthermore, as is already known,





information on such funding for alternatives is difficult to obtain, even far more recently, as found by ECEAE's 2014 report when France (along with some other member states) failed to provide a response to requests to confirm amounts of funding devoted to alternatives<sup>16</sup> Yet France's scientific research and development (R&D) expenditure was €46,545 million in 2012<sup>17</sup>.

Extensive searching has failed to find any meaningful documentation (minutes, notes or other outcomes) of meetings or reviews of any kind by the CNEA or CNREEA, other than the National Charter described above<sup>15</sup>. Neither committee appears to have any status, website or documentation of its own, instead being referred to only via government research portals<sup>18/19</sup>.

The Ministry of Research lists 126 national ethical committees (as of 17 Dec 2015)<sup>20</sup> which are overseen by the CNREEA. While these provide intel on location and animal research sites (many of which are already known) they provide little or no information on what they actually do or outcomes of any reviews of animal experiments.

For example, CREMEAS (Comité Régional d'Ethique en Matière d'Expérimentation Animale de Strasbourg) is one such sub-committee tasked with for example, retrospec-

tive evaluation of animal experiments<sup>21</sup>. However no such documentation on this evaluation or outcomes appears to be publicly available. Similarly, The GRICE (French group of interprofessional reflexion on ethics committees applied to animal research) is a team created in 1991 to 'promote the development of ethics committees'<sup>22</sup>

The Ministry of Research's latest status report (June 2015)<sup>23</sup> makes no mention of animal testing or alternatives at all.

### **ALTERNATIVES TO ANIMAL TESTING - ATTITUDES AND CHALLENGES**

In 2009, Michel Lejeune et Jean-Louis Touraine of the Parliamentary Office for Evaluation of Science and Technology presented a very comprehensive report to the Senate and National Assembly entitled 'Animal testing in Europe -What alternatives? What ethics? What governance?'<sup>24</sup>

The report was accompanied by a letter, requesting that the President of the National Assembly chair a study on the assessment of animal experimentation, as well as alternative methods available and aimed to address the need for a balanced revision of the (then current) directive 86/609, with a phased implementation of the new provisions in addressing critical issues such as research,

development and the validation of alternative methods, education, training and information and the strategic involvement of public authorities. Many scientists throughout France were consulted in compiling the report.

Among other findings, the report provided the national authorities with seven recommendations; i) Update the rules on training of personnel, to include among others the 3Rs and alternative methods; ii) raise awareness of animal testing and replacement methods for students; iii) include alternatives in veterinary training; iv) development of an internet based care guide for researchers, students and the public; v) a request that the CNEA and CNREEA organize educational days for the general public, students and researchers; vi) create new chairs in animal testing and alternative methods; vii) promote the use of alternative methods in education. In courses for students, the use of live animals or euthanized for this purpose should be prohibited and only film screenings and use organs or tissues of animals killed for other purposes must be allowed; include in the curriculum, teaching elementary principles of animal life, the need to respect animal and human use of the animal.

No formal ministerial response to this report could be found.

As already known, the platform affiliated with the development of alternatives in France is FRANCOPA, created in 2007 and 'dedicated to development, validation, and dissemination of alternative methods in animal testing.'<sup>25</sup> And part of ECOPA (European Consensus Platform on Alternatives) FRANCOPA is composed mainly of government research bodies and medical research institutes<sup>26</sup> and states that its activities 'have been centered initially on the establishment of a state of the art on 3R methods and practices in France, together with recommendation to the French government'.

FRANCOPA published a report<sup>27</sup> in 2010 on alternatives to animal experiments in France which was laid before the Ministry of Research. The release of this report was preceded by parliamentary recommendation from the (then) Minister of Higher Education and Research who 'attaches great importance to alternative methods.'<sup>28</sup>

Some findings were highlighted in the report from a survey which FRANCOPA conducted at a number of national animal research institutes, which refer to the (then) EU directive 86/609. The report highlights that financial support for alternatives is 'rarely possible' in France and despite some 3Rs activity across key animal research institutions and government labs, those carrying it out do not

consider themselves to be focussed primarily on 3Rs due to lack of funding.

Other challenges stated included low incentive to develop alternatives, as traditional *in-vivo* methods are still considered the gold standard, any 3Rs initiatives are just considered as advantages as tools for investigation, rather than drivers for change. For example, 'the CNRS through the internal investigation of teams with approximately 370 employees and € 1.9 million, reported practice of the 'alternative', without saying that this is their main objective. It's the same in the INSERM, for some 700 employees that were involved in the internal investigation. These researchers are using alternative methods, but institutes insist on the fact that it would be wrong to think that the creation of alternative methods per se is an objective of fundamental research'. Another key setback is 'The passage of information between basic research and industry is presently lacking. Fundamental applied research as carried out by academic and government institutes could be "bridged" to help industry improve their present methods.'

*"Institutes insist on the fact that it would be wrong to think that the creation of alternative methods per se is an objective of fundamental research."*

Also, there is 'a confused perception of regulations by the researchers'. For example they tend to confuse the regulatory requirement to use alternative methods in research vs toxicity testing; the (then) 'Directive 86/609 applies in all areas of research and R&D and this same obligation with regard to 'demonstrations in the regulations applied to products (eg studies supporting...safety of products).'

On the subject of perception, this can also be extended to the interpretation of 'alternatives'. For example a brief PUBMED search of 3Rs publications in France results in (among others) the RETHINK project, a 2010 review on the proposed use of minipigs in toxicity testing as 'alternatives' to other animals, on the basis that 'being a food animal, testing in the minipig may be more acceptable to the public than animals such as dogs or monkeys.'<sup>29</sup>

As well as outlining its findings, FRANCOPA made some clear and meaningful recommendations within its 2010 report including;

- abandoning unnecessary animal tests;
- include alternative methods in the teaching of life sciences;
- to identify where research into alternatives is needed and develop incentives to research the 3Rs;
- encouraging knowledge transfer and validation of new methods;
- Set up of new policies to both reduce animal use and develop alternatives;

- Communicating the message that alternatives to animal testing are not just breakthroughs, but 'good science'.

A full version of the FRANCOPIA report (updated in 2012) is available<sup>30</sup> and represents perhaps one of the most advanced documents for taking further as part of a national lobbying strategy.

In September 2011, FRANCOPIA held a workshop on 'waiving animal testing for regulatory purposes'.<sup>31</sup> Ronan Stephan, the (then) director for research and innovation at the French Ministry of Higher Education and Research stated that "It appears that sharing knowledge and data is necessary in order to get the maximal relevance of the chosen methods. This is the aim of this event organized by the FRANCOPIA Platform to which the French Ministry of Higher Education and Research fully associates itself." As in FRANCOPIA's 2010 survey it was highlighted again that 'Technology transfer from basic research to applied research still needs to be more effective. In order to do this, it is necessary to identify the research carried on alternative methods and the needs for research and development.'

However, concrete predictions, statements or targets on reducing animal numbers are not found and in many

cases, repeated persuasive messages appear to be that 'animal testing can be reduced, but it will always be necessary.'

## NATIONAL AND EUROPEAN LAWS ON ANIMAL TESTING

Reciting any details of national or EU laws on animal testing are largely irrelevant to the aims of this report. However, to state some brief background, the provisions of Directive 2010/63/EU were transposed into national law (Decree 2013-118) in February 2013<sup>32</sup>. The regulation in France (articles R214-87 to R214-137 of the French rural code<sup>33</sup>) has also been updated by the 2013-118 decree and five orders from February 1st 2013, according to the 2010/63 directive. This regulation is under the responsibility of the French Ministry of Agriculture.

It is also relevant to mention, as highlighted in previous reports by One Voice, the serious failures on the part of the French Government concerning the application of the previous European animal experiments directive 86/609, transposed into national law by the Decree of October 19, 1987. The following year, the European Commission formally warned the Government of its intention to sanction breaches with regard to the proper application of six key measures of the directive<sup>34</sup>.





## FURTHER POLITICAL CORRESPONDENCE HIGHLIGHTING SYSTEMIC FAILURE AND RESISTANCE BY THE GOVERNMENT

In a very comprehensive written question in 2003<sup>35</sup> to the Minister of Agriculture, Food, Fisheries and Rural Affairs, Sylvie Desmarescaux MP highlighted the overwhelming opinion of the national public on the issue of animal experiments on dogs and cats and that 86% felt that any experiments causing suffering to an animal should be prohibited. Desmarescaux also raised the scientific report produced by One Voice in March 2003, showing how France used more cats than any other country in the EU and the rise in the number of dogs used in laboratories between 1993 and 1999, asking what measures the Ministry would put in place to protect animals. In its response, the Ministry not only failed to address the issues raised, but used poor arguments to try and answer them, for example in response to the rising number of cats and dogs used in France, the Ministry stated that *'a comparison of the absolute numbers of dogs and cats used for scientific purposes in the Member States would be unfounded statistically, insofar as the number of teams and research institutions is variable depending on the country. With reference to its scientific activity, it is therefore logical that France has a greater number of certain categories of animals.'*

It is not acceptable to simply state that a bigger country, with more research labs will use more animals. This reply clearly shows not only a total disregard for public opinion, but also the government attitude to use of companion (and other) animals in research both then and since, with France remaining one of the highest, if not the highest user of cats and dogs year on year, as a further ten years of statistics have shown.

Further MPs in support of ending animal testing also raised the findings of our 2003 report<sup>36</sup>, again emphasising the overwhelming majority of public concern for the suffering of animals used in laboratories. Responses from the Ministry of Research at the time suggest a very reactive, not proactive attitude to both ending animal testing and use of alternatives, with comments such as *'Currently only three test methods in vitro have been validated by the European laboratory used to centralize all alternative methods, they are used in France.'* This suggests that France will use alternative methods when available (and even then with some reluctance) but despite appearances, makes little or no effort in innovative research as a member state, to find such new methods. This attitude was again evident during this period, when the French authorities tried to challenge the forthcoming EU ban on animal testing for cosmetics<sup>37</sup> and as previously mentioned, on the failures concerning the

correct application of six of the measures of directive 86/609/EEC.

In response to recent parliamentary questions (for example to the Ministry of Agriculture on the continued use of primates and the opening of new primate research facilities), the government has been keen to repeat the mantra that *'Since the transposition of the European directive no 2010/63/EU in France in 2013, the new French regulations relies heavily on rule 3 R.'*<sup>38/39/40</sup>

The fact that the Ministry simply reproduces this same response to different questions emphasises its irreverent attitude to the issue of animal testing. The lack of publication of new statistics to demonstrate such 'reliance' on the 3Rs also means that claims like this are difficult to prove.

Furthermore, it appears that instead of commitments to reducing or replacing animal tests, efforts are spent more on continuing to promote the use of animals in laboratories. For example, one of the members of the CNREEA is AFSTAL (Association Francaise des Sciences et Techniques de l'Animal de Laboratoire)<sup>41</sup> Including such members in the CNREEA is in biased conflict with its alleged role as an ethical review body and the reason for its establishment.

### CONCLUSION

In researching and collating evidence for this report, several issues have been clear throughout; the French authorities continue to place emphasis on the promotion of animal testing and do not set targets in reducing or replacing animal experiments. Therefore, we must make them set them and this gives One Voice significant scope for a campaign, in which we can engage political and public pressure. Release of the next EU statistics later this year will be particularly useful in assessing the most recent situation, especially since these may give an indication of France's use of animals since the transposition of the new directive. However, in the meantime, One Voice can launch a sustained lobbying strategy, as part of the ECEAE 'Time is Now' project, to ensure that, no matter how long it takes, the authorities are meaningfully held to account.

*"86% of French felt that any experiments causing suffering to an animal should be prohibited."*

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