

OPPOSE – AGRI Committee Amendment 107 to Article 35, which states:

“Member States shall ensure that projects classified as “severe” or any projects involving non-human primates are not carried out without prior authorization by the competent authority. All other projects shall be notified in advance to the competent authority following ethical review by the institution’s permanent ethical review body.”

Why this amendment must be REJECTED

This amendment has been universally condemned by animal protection organisations. Also, 80% of Member States (including major users such as the UK and Germany) have a comprehensive system that requires all experiments on animals to have prior authorization from the competent authority – as described in the Commission’s original proposal. The AGRI amendment means that as little as 2% of experiments would require prior authorization. This means alternatives and animal suffering will not be addressed for almost every experiment. It undermines the commitment to seek alternatives before animal use is authorized, and it undermines the main purpose of the Directive – the regulation of science and animal use.

Competitiveness of European Science and Industry (Will animal protection drive research out of the EU?)

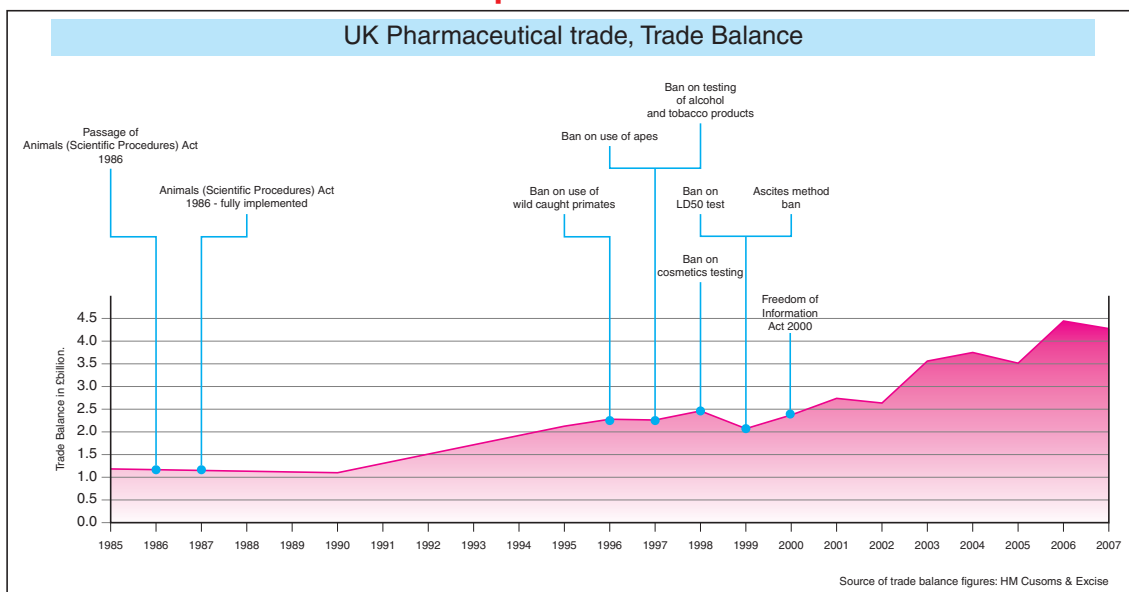
Introduction

It is often argued by animal trade and use industry representatives, as well as some MEPs, that improving animal welfare standards and regulations could drive research outside of the EU to China, Singapore and other countries. However, no evidence or statistics have been provided to support this claim.

The theory is that wherever animal welfare standards are high, scientific research will go abroad, damaging the competitiveness of European science and industry.

Nothing could be further from the truth. In this briefing, we examine this argument in detail and demonstrate, through readily available data, that increased animal welfare standards and a governing framework for scientific research has, in fact, a beneficial impact on the appeal of conducting research in a specific country.

There is no evidence that improved animal welfare and scrutiny of animal experimentation will drive research out of Europe. In fact to date the reverse is true.



Dynamism in the pharmaceutical sector where animal welfare standards are high: experiences in the UK and Switzerland

If high animal welfare standards were driving research abroad then the impact would be most obvious in those countries which already operate strict regulatory controls over use of laboratory animals, such as the UK and Switzerland.

The UK government claims to maintain the highest laboratory animal welfare standards in the world. Yet in this tight regulatory environment, the competitiveness of the UK pharmaceutical sector has rapidly improved over the last 20 years.

Indeed in 1985, the UK's **trade surplus was £1.184 billion (€1.258 billion)**. Despite more than 20 years of 'strict animal welfare regulation', the trade surplus has **grown to £4.276 billions (€4.548 billion) in 2007, a huge increase of 361%**¹.

In fact, **in 2007, the pharmaceutical industry became the most competitive industry in the UK, as it ranked number 1 in trade surplus**, beating all other British industry sectors. **Its value added in 2006 also ranked number 1**, a long way ahead of the other sectors such as aircraft, business services, motor vehicles or manufacturing².

The introduction in 1986 of the UK Animals (Scientific Procedures) Act, which went much further than the 1986 European Directive in its controls, licensing and codes of practice, has not affected the growth and effectiveness of the British pharmaceutical industry. This is in a climate of a three-tier licensing system; cost-benefit assessments and severity banding as part of the approval process; codes of practice and government inspections; bans on use of particular species, such as great apes; special provisions for approval of certain primate research; a ban on testing for cosmetics and other restrictions.

In 2001, the UK's Medical Research Council, the main public funding body in medical research, declared that it:

"is not aware of any specific instances of research being forced abroad as a direct consequence of the bureaucracy of UK system of regulation"³.

After a series of hearings and gathering of evidence over a two-year period, the UK's House of Lords Select Committee on Animals in Scientific Procedures reported on their findings, and discussed the claims that researchers might take their work outside of the UK.

The Select Committee concluded:

"there was no hard evidence supporting claims that the licensing regime was leading to research being undertaken abroad"⁴.

Clearly, the introduction of tighter scientific controls and improved protection for animals has not 'impeded' the work of those who wish to use animals. Quite the opposite – the evidence indicates that such controls have improved standards of scientific practice as well as animal protection.

A similar success story can be found in Switzerland, which hosts two of the largest pharmaceutical companies in the world: Novartis and Roche. **Globally, Switzerland leads the world in terms of trade in pharmaceuticals with £10.8 billion (€11.46 billion) in trade surplus**, beating the UK (£4.2 billion), Germany (£5.5 billion), France (£3.5 billion) Japan (minus -£2.8 billion) and the USA (minus -£18.3 billion)⁵.

As with the UK, the Swiss pharmaceutical industry is operating in an environment of strict laboratory animal welfare regulation. Before authorisation is given to use animals, the proposed experiments are automatically graded into a severity banding system which grades the amount of animal suffering according to the type of procedure. The system also provides for automatic feedback, with a retrospective review of what actually happened to the animal during the experiment⁶. **The Swiss legislation recognises the dignity of animals and the use of primates in experiments has recently been restricted, through case-law**⁷.

The Switzerland and UK cases demonstrate that there is no evidence to support the claim that research would be driven abroad by improved animal welfare regulations and strict controls over scientific experiments. In fact, a legal framework appears to enhance and improve standards of good laboratory practice and allows scientific development to flourish.

In comparison, the USA is a long way behind. With the largest trade deficit in pharmaceuticals in the world (-£18.3 billion); the USA has poor standards of animal protection and welfare, with poor controls over standards of science and animal use.

The US system of regulating animals in biomedical research, “specifically excludes rats of the genus *rattus* and mice of the genus *mus* as well as birds used in research”⁸. Clearly, lax standards and poor controls have not helped the USA to perform better in this sector.

The European Union: 20 times more attractive than China for foreign investment in research and development

China is frequently cited as one of the countries which would take European research if the EU takes the logical step of regulating and controlling its scientific research industry, and improving animal protection. However, a realistic assessment of the evidence does not show China to be an attractive destination for scientific research:

A recent report from the European Commission, ‘*Science, Technology and Competitiveness key figures report 2008/2009*’⁹ concluded:

“The EU remains an attractive location for R&D investment by US firms which invested 20 times more in R&D in the EU than in R&D in China in 2005.”

Indeed, the EU received 62.5% of all US foreign investment in R&D in 2005 (and this share is increasing compared to 2000), as compared to the 3.3% received by China and the 6.6% received by Japan.

The report also found that:

“in the period 2003-2005 the gap between EU-15 R&D spending in the US and US R&D spending in EU-15 in the US decreased by over a half.”

In other words, the EU R&D sector has never been more competitive, and this is especially true for the sectors where millions of animals are killed every year in experiments.

Thus, the pharmaceutical sector has become much more research-intensive in the EU between 1995 and 2003. The Commission report:

“Value added for a number of high-tech sectors in the EU has grown in real terms at a fast pace over this period: ‘aircraft and spacecraft’ (4.3 % per year on average), ‘pharmaceuticals’ (3.5 % p.y.a) and ‘medical, precision and optical instruments’ (2.7 % p.y.a). (...) the ‘pharmaceuticals’ sector has become much more R&D-intensive, while the ‘aircraft and aerospace’ sector has become less R&D-intensive.”

And:

“In the EU the decline in the share of high-tech value added was limited, since a large decrease of value added in ‘office, accounting and computing machinery’ and ‘radio, TV and communication equipment’ was to a large extent outweighed by a growth of value added in ‘pharmaceuticals’ and ‘medical, precision and optical instruments’.”

In other words, the pharmaceutical industry is one of the most dynamic sectors in the EU. The report further states that the number of researchers has grown twice as fast in the EU as in the US and Japan since 2000 and that the EU ranks as the world’s largest producer of scientific knowledge.

This picture is very different to the one presented by those who argue that that Europe suffers from a “regulatory burden”. In fact, the EU’s research is extremely dynamic, especially in the countries where animal welfare standards are high.

Industry sector lobbyists might be expected to be resistant to any change or control. However, the claims that improved animal protection will drive research abroad are clearly exaggerated and indeed, misleading.

The evidence is that a good regulatory framework benefits science and industry, as well as animal protection.

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