



PRESS RELEASE

For immediate release

19th November 2009

Shock findings from UK undercover investigation shows inadequacies of proposals for EU animal experiment directive

The **BUAV**, the UK's leading animal group campaigning to end animal experiments, is handing over a crucial dossier of evidence this week to the European Commission and key MEPs, Members of the Agricultural Committee. The shocking findings obtained during a major undercover investigation carried out in a UK animal laboratory highlight the inadequacies of the current proposals concerning the revision of European animal experiments rules, Directive 86/609/EEC. The **BUAV** is calling for these findings to be taken into account when the proposals are being considered by the Council of Ministers and the Parliament, under the Swedish Presidency.

The findings of the investigation are of direct relevance to the revision of Directive 86/609. In particular to the issues of transparency, severity of suffering, the ethical evaluation for licensing experiments, regulatory testing, the re-use of animals and the implementation of alternatives. (See notes below for further details.)

Between January and October 2009, the **BUAV** conducted an 8-month investigation at Wickham Laboratories in Hampshire, England. Wickham is a contract-testing laboratory. The investigation revealed graphic disturbing evidence of the cruelty and suffering inflicted on thousands of animals every year, largely relating to quality control of drugs and other products, including, the appalling suffering typically inflicted on mice in laboratories around the world for the craze of using botox products for vanity purposes. Animal tests carried out included the archaic poisoning test LD50 (lethal dose 50 - this is the dose at which 50% of the mice would be expected to die when injected with the toxin), and pyrogen tests where rabbits can be starved for up to 30 hours, restrained in stocks for up to 8 hours and are re-used repeatedly in further pyrogen tests, adding to their distress.

The BUAV has accused the Home Office, which regulates animal experiments in the UK, of breaking the law in several ways including not enforcing the use of non animal alternatives and failing to minimise the suffering inflicted on animals. In addition, some animals suffered in tests that are no longer required by national and international regulations. This destroys the often made claim that companies have to do animals tests because regulators require them.

BUAV's Chief Executive, Michelle Thew states: "The BUAV investigation has come at a critical time during the revision of EC Directive 86/609. Our findings show the total inadequacy of the proposals that are currently on the table. We call on the Council to throw out these proposals and instead fulfill their obligations and give animals in laboratories the protection they need."

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NOTES:

The BUAV's findings are of direct relevance to the revision of EC Directive 86/609 and highlight just how inadequate the current proposals are. In particular:

1. **Transparency:** only undercover investigations can reveal the truth about animal experiments. The BUAV investigation has revealed an appalling catalogue of animal suffering and failure to use available alternatives.
2. **Implications for the directive:** the current proposals for transparency are wholly inadequate. The proposal is that only 'non-technical summaries' need to be provided. In practice, these are likely to be very short and would not enable the public – or courts - to understand what is really happening.
3. **Severity:** Wickham carries out the notorious and discredited Lethal Dose 50 poisoning test on tens of thousands of mice for a type of botox (Dysport) every year. The LD50 is designed to determine the dose of a particular substance which will kill half the animals. The mice in the higher dose groups suffered grievously – paralysis, suffocation, weight loss, dehydration. The project licence acknowledges that the symptoms are 'very severe'. Euthanasia prior to death (the so-called 'humane endpoint') resulted in only a small proportion of the animals being killed, the majority died from the effects of the poisoning.
4. **Implications for the directive:** the latest Council draft would allow experiments of this nature where death is an 'endpoint'. Indeed, it would in practice allow suffering which is both *severe* and *long-lasting* – even, under a very wide derogation, where suffering cannot be ameliorated.
5. **Ethical evaluation:** Dysport is licensed in the UK for some relatively rare medical indications and the UK Government claims that it only allows animal testing on botox products for those indications. However, both Dysport and other botox products are used on a massive scale for cosmetic treatment and the Government cannot control what use animal-tested botox is put.
6. **Implications for the directive:** this highlights the need to limit the purposes for which animal experiments are permitted. Article 5 is drawn very widely and would allow animals to be used for just about any purpose, despite the high suffering which may be involved.
7. **Re-use:** at Wickham, rabbits are used in pyrogenicity tests, to determine whether injected substances are contaminated. A *single* test involves: starving the rabbits for up to 30 hours; placing them in stocks by the neck for 6-8 hours with a temperature probe inserted into their rectum; depriving them of water for this period and injecting the foreign substance into their ears. Damage to ear veins and back injuries can occur and, not surprisingly the rabbits are very distressed. The UK Government classifies the experiments as 'moderate'.

Rabbits are repeatedly re-used. During the first 6 months of 2009, there were 944 pyrogen tests; the colony at any given time is around 100.

8. **Implications for the directive:** the latest Council text proposes that individual animals could be used endlessly in 'moderate' experiments, with weak safeguards. This investigation demonstrates the appalling implications. A *single* use in 'moderate' experiments can involve multiple surgical procedures and multiple other adverse effects.

9. **Alternatives:** a UK government laboratory developed alternatives to the LD50 over 10 years ago, specifically for Dysport. Botox companies are refusing to co-operate to validate the alternatives which are already provisionally accepted by the European Pharmacopeia.

In addition, both the European Pharmacopeia and the US version specify and prefer a non-animal method for most of the drugs for which the rabbit pyrogen test is carried out at Wickham.

10. **Implications for the directive:** this once again highlights the fact that there is a chasm between the rhetoric about alternatives and the reality of their use.
11. **Regulatory testing:** so-called humane endpoints (early intervention to prevent unnecessary suffering) were set and applied improperly, suffering was not kept to a minimum in other ways and alternatives were not used when clearly available.
12. **Implications for the directive:** the latest Council draft would allow '*multiple generic projects carried out by the same user when those projects are to satisfy regulatory requirements or product or diagnostic purposes with proven methods*' and would allow '*tacit approval*' for such experiments where the competent authority delays giving express approval. This would mean that competent authorities would be very unlikely to prevent the type of legal breaches revealed by the BUAV investigation, and would be unable to conduct an ethical evaluation as to whether animal tests should be allowed for particular substances or products.