Comment

The Myth of *Replacement* and the Legal Reality

Edwina Bowles

Despite EU law being in force, animals are often used where alternative methods already exist and are readily available

As a trustee for the UK Centre for Animal Law (A-law) and a solicitor specialising in Animal Protection Law (which includes acting as a legal consultant to Cruelty Free International), my focus is on using the legal tools available to ensure the law is being properly followed and adequately enforced to secure protection for animals. The arguments and evidence presented in this article have been generated in conjunction with my colleagues at Cruelty Free International, and in particular, David Thomas, Katy Taylor and Laura Alvarez. We are pursuing these points with the European Commission, as well as with individual EU Member States, and this aspect of our work is funded by the Cruelty Free International Trust.

What Is The Argument?

The idea that animals will not be used in research in the European Union (EU) if an alternative method exists, is often used as an argument to support the notion that animals are only used when absolutely necessary. Whilst I do not challenge the sincerity of people who have said this, I do feel that it is often necessary to challenge the accuracy of the statement. Animals are often used where alternative methods do exist. The focus of this article will be on *replacement* methods, rather than *refinement* or *reduction* methods, as it is only through the more rigorous use of *replacement* methods that animal use is altogether avoided.

What the Law Says

The law that governs animals used in research in the EU is *Directive 2010/63* (the Directive).[1] There are two main articles in the Directive that dictate when an alternative should be used:

— Article 4(1) states:

Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure

— Article 4 has to be implemented in accordance with Article 13, which states:

Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union…' (emphasis added)

As sometimes interpreted, the wording of these two articles creates nuanced, but noteworthy, situations that can result in animal tests being carried out, even when a validated alternative exists. Examples of these situations are outlined below (with reference to the emphasised Article 13 text).

'Recognised under the Legislation of the Union'

It is worth noting that, in practice, there is a difference between a 'validated' alternative and a 'recognised' alternative. The former is the outcome of the scientific step to ensure the method is reliable and can be reproduced, and the latter is the outcome of the regulatory step to bring a validated alternative into the legal system. To keep things simple, I will only focus on the chemical testing that takes places under *Regulation (EU) No 1907/2006* (REACH)[2] to illustrate this point:

— In Article 13.1 of REACH, the need to use an alternative method wherever possible, instead of an animal test, is reiterated.

— Article 13.3 then requires that tests be carried out in accordance with Commission *Regulation 440/2008* (the Test Method Regulation [TMR]),[3] which under Article 13.2 needs to be reviewed regularly with a view to reducing animal tests.

Updating the TMR is instigated by the Commission, and is carried out in accordance with a process known as 'regulatory procedure with scrutiny'. This aims to scrutinise proposed amendments to legislation, to ensure that they are compatible with the EU legal/regulatory framework. If followed without reasonably avoidable delays, the procedure to amend the TMR should take somewhere in the region of nine to 12 months. This means that, once an alternative method for chemical testing has been validated, for REACH purposes it should be included into the TMR within a year. Once this process is complete, testing under REACH would need to be carried out in accordance with the updated TMR. The absolute requirement to use the alternative method would also be reinforced by the fact that inclusion in the TMR means that it has been 'recognised' under EU law for the purposes of Article 13(1) of the Directive.

Even if a method is not (yet) recognised under EU legislation, under Article 4(1) of the Directive it should still, in my view, be used, if it is judged as capable as the animal equivalent of generating the required information.

Unfortunately, in practice, the Commission waits for approval of an alternative method by the Organisation for Economic Co-operation and Development (OECD) before updating the TMR.

The OECD is an international body that aims to 'promote policies that will improve the economic and social well-being of people around the world'. One of the roles it has assumed is the harmonisation and mutual recognition of testing methods by its Member Countries. The OECD currently has 35 Member Countries, including 22 of the 28 EU Member States.[4] So, not every EU Member State is an OECD Member Country. The standard process for OECD acceptance of a test method can vary, depending on the level of agreement amongst the Member Countries, but for recent alternative methods it has taken about three years to reach an agreement, although there are examples of it taking much longer. This is before the regulatory procedure of scrutiny at the EU level has even been factored in.

I will not go into the legal issues surrounding whether the Commission is entitled to add the OECD ratification step to the TMR updating process, but there are strong arguments that it is not: Cruelty Free International has recently made a complaint to the European Ombudsman about this. The effect of including the OECD means that the total time taken to amend the TMR, and consequently have an alternative test method recognised in EU law, is significantly increased. In practice, this extends the period when animal tests are still being used unnecessarily.

The Commission does allow itself to have an option of using a streamlined procedure instead of the standard OECD process, if the latter would cause 'undue delay'. In theory, the streamlined procedure should take around five months, but it has only actually been used twice. In both cases it concerned the same method, and on both occasions it appears to have shaved off roughly one year, as compared to the standard OECD route.

'The Result Sought'

Another issue surrounds the use of the 'result sought' wording in Article 13(1) of the Directive. This term refers to scientific objectives, not regulatory requirements. An example of this distinction was described in the Commission's Q and A,[5] which offers guidance for Member States with regard to the regulatory requirements in force in third countries (i.e. non-EU member states), on page 19:

A replacement alternative, recognised by the EU legislation that identifies a toxic hazard but is not able to differentiate between different levels of that toxicity (for example as required under a legislation for Classification and Labelling depending on the endpoint); if the third country regulatory requirement is to be able to identify only the existence of that toxicity, the respective animal method could no longer be used. However, if the third country requirement is to identify between different levels of that toxicity, the animal method could still be used.

The issue that arises here stems from the differing opinions on what information is needed. In the above example, the EU scientific community could have reached a consensus that identifying toxicity was enough to determine the safety of a substance, whereas a country outside the EU might wish to know the specific toxicity level, before it concluded that a product was safe. If the wishes of that country were allowed to prevail, it would mean that an animal test would still be carried out in the EU, where that same animal test would not be able to be carried out if the substance was for the EU market. I do not believe that that can be correct.

The problem stems from a misunderstanding about what 'result sought' means. Cruelty Free International argues that whether a third country regulator accepts an alternative as scientifically valid is legally irrelevant. If the information sought falls within its technical scope (as recognised under EU legislation), the animal test should not be conducted in the EU. For example, an *in vivo* test to confirm a negative *in vitro* skin irritation finding would not be permissible, because paragraph B.46 of the TMR says that the *in vitro* method can adequately detect non-irritants. The Commission appears to accept this, but, despite this, there are concerns that tests of the above

nature (and other tests with recognised alternatives) are still being carried out for third countries. For example, the following data have been recently collated by Cruelty Free International:

— Austria conducted 14,794 pyrogenicity tests on rabbits in 2015, the UK conducted 2,609;

— Poland conducted 1,028 skin sensitisation tests in guinea-pigs in 2014 (none in mice);

— The UK conducted 340 skin irritation tests in rabbits in 2015, and across six EU Member States in 2014 there were 970 *in vivo* skin irritation tests.

Importantly, even if neither Article 13(1) nor Article 4(1) of the Directive apply, competent authorities still have to apply the harm–benefit analysis in Article 38(2)(d):

A harm–benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;

Where EU legislation does not require information for a particular endpoint, it is very difficult to see that there could be any legitimate benefit in conducting the animal test. However, the UK conducted 19,040 animal tests for non-EU purposes in 2015.[6]

Conclusions

What should be apparent from the above is that there are often cases where animal tests take place where validated (and even EU-recognised) alternative methods exist. It is essential that the unlawful animal tests do not take place, and that appropriate sanctions are applied, if they do. There should be no excuse for the extensive delays that occur between the successful outcome of a validation process and the recognition and acceptance of the validated test within EU law. There should also be no excuse for inadequate harm–benefit assessments; if the EU has deemed a test unnecessary, then there would be little benefit in carrying it out for a third country that has more onerous requirements to satisfy. It is generally accepted that economic benefit alone is not sufficient.

We need to ensure that the EU is an area where the available alternative methods are always used instead of animal tests, and that regulators do not just pay lip service to the concept. In the meantime, it is very important that the public does not receive misinformation; the statement that animal tests are not carried out where alternative methods exist is by no means always true.

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