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## **JOINT SUBMISSION ON IMPLEMENTATION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS), REVISION 7 (2017)**

1. This is a joint submission of the New Zealand Anti-Vivisection Society and the New Zealand Animal Law Association on the parts of the five proposed changes that relate to the use of animal-based chemical testing.
2. We note that we are against animal experimentation and the harmful use of animals for research, testing and teaching (RTT) purposes, and notwithstanding this submission we do not condone or agree with the use of animals for RTT that we would define as harmful or as animal experimentation.

### **Overall Position**

3. We support the proposed changes on the basis that any current requirements for animal tests will be removed. While animal tests will be mentioned, they will not be required.
4. We understand and agree with the desire to keep up with international standards, but further consider that New Zealand should strive to be at the forefront of scientific and ethical advances.

### **Scientific Concerns**

5. Due to large numbers of differences between species used for animal-based testing and humans, including genetic, physiological, metabolic and psychological differences, animal tests cannot be used to accurately model potential impacts on humans.
6. The use of animals to predict outcomes in humans has a shockingly low predictive value; using animals to model human responses to diseases and drugs fails over 95% of the time.<sup>1</sup> In reality, animal models can be used only as approximate analogues for human systems.<sup>2</sup>
7. There is an absence of evidence to show that animal tests called for by the GHS have suitable predictive values for impacts on humans. The LD50 test, which is referenced in the GHS, has never been scientifically validated against human data.
8. One study that evaluated the LD50 values of rats and mice for 50 chemicals, found that these tests predicted toxicity in humans with only 65% accuracy. By contrast, a series of human cell-line tests was found to predict toxicity in humans with 75% to 80% accuracy.<sup>3</sup>

1 Moshe Shalev, "New FDA recommendations to speed drug development," *Lab Animal* 35, no. 3 (Mar 2006): 13.

2 T. Ryan Gregory, "The Failure of Traditional Arguments in the Vivisection Debate," *Public Affairs Quarterly* 14, no. 2 (April 2000): 166.

3 Overview of the Final MEIC Results: II. The In Vitro–In Vivo Evaluation, Including the Selection of a Practical Battery of Cell Tests for Prediction of Acute Lethal Blood Concentrations in Humans

## **Ethical Concerns**

9. Animal-based testing of chemicals causes pain, distress, injury and death in animals. For example, the LD50 test is used to find the amount of a chemical which, if administered in one go, causes the death of 50% of a group of test animals. Other animal-based testing of chemicals is likely to involve subjecting animals to harms such as irritation and corrosion of the skin and eyes.
10. It is morally wrong to cause harm to sentient beings in the course of animal tests of the kind referenced in the GHS. We note that the long title of the Animal Welfare Act 1999 recognises the sentience of animals. These ethical concerns are exacerbated by the limited scientific value of animal-based testing.

## **Addressing Concerns**

11. On the basis of these scientific and ethical concerns, we submit that industry should be required, or at least encouraged, to use only human-relevant, non-animal based and test methods when determining whether a substance is hazardous to humans.
12. Therefore, we recommend that any reference to animal tests in the classification system for hazardous substances be excluded. Alternatively, the classification system could include explicit recognition that animal-based tests should not be used due to their low predictive value, and the poor ethical outcomes of the harm caused to animals in the course of testing.
13. We encourage the EPA to review the validity of animal-based methods for measuring the potential of hazardous substances, and to promote ethical and human-relevant methods by publishing a clear position statement.
14. In summary, we support the proposed changes and encourage any further regulatory changes that will result in the replacement of animal-based test methods.

Yours faithfully

The New Zealand Anti-Vivisection Society and the New Zealand Animal Law Association