

## The OECD Test Guidelines Programme and animal welfare concern: how to avoid major animal suffering

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In October 1991, the National Co-ordinators of the OECD Test Guidelines Programme—who are appointed by the governments of the respective Member countries—agreed that a more pro-active approach to animal welfare issues should be adopted by the Programme. They reached consensus on the following objectives and tasks:

- (i) to develop Test Guidelines for alternative tests;
- (ii) to revise existing Test Guidelines with the aim of reducing the number of animals needed for the tests;
- (iii) to develop Guidance Documents on animal welfare issues;
- (iv) to harmonize internationally criteria and principles for the validation and regulatory acceptance of alternative tests;
- (v) to provide a mechanism for the objective review of proposals for validation studies; and
- (vi) to advise on animal welfare issues in risk assessment strategies in Member countries.

Three new Guidelines describing alternative procedures to the conventional acute toxicity study (Test Guidelines 420, 423, 425, respectively) have since been adopted and are accepted by all Member countries as equivalent to the much disputed LD50 test. Furthermore, criteria and principles for the acceptance of new, alternative, methods have been globally harmonized after bridging the gap between initially divergent views from North American and European experts. The well-known 'Solna Workshop Report' on this

achievement is currently used as the basis for an extensive Guidance Document on validation approaches and strategies.

Several OECD Test Guidelines, especially those for acute toxicity studies, make reference to the need to humanely kill animals which are suffering severely. Whereas the earlier adopted Guidelines (401, 402, adopted in February 1987) are still rather vague in their recommendations for killing severely suffering animals: 'animals showing severe and enduring signs of distress and pain *may need* to be humanely killed', the more recently adopted Guidelines (420, 423, 425) include a considerably stronger recommendation: 'animals obviously in pain or showing signs of severe distress *should* be humanely killed'. However, there is still confusion about what constitutes 'severe distress', 'obvious pain', 'moribund condition' and other descriptions of animal suffering. Guideline 425 for the Up-and-Down method (adopted in September 1998) is the only Guideline that actually provides some guidance in this respect, and states: 'Moribund state is characterized by symptoms such as shallow, laboured or irregular respiration, muscular weakness or tremors, absence of voluntary response to external stimuli, cyanosis and coma'. But more comprehensive guidance is needed than can be provided in a test guideline on the recognition, assessment and use of clinical signs as indicators of severe suffering. These clinical signs, once harmonized, could then be used as humane endpoints for deciding to kill severely suffering animals. Understanding the importance of the harmonization of essential clinical signs, the National Co-ordinators of the Test Guidelines Programme decided in 1995 that work should start to develop a comprehensive Guidance Document cover-

\*The opinions presented in this paper do not necessarily represent the opinions of the Member countries of OECD and should therefore be viewed solely as those of the author.

ing this subject. In anticipation of its publication, Guidelines 423 and 425 already make reference to this document in preparation as follows: 'Criteria for making the decision to humanely kill moribund and severely suffering animals are the subject of a separate Guidance Document'. The work is

well underway and a small working group of experts drafted the first version of this Guidance Document. The document was subsequently circulated widely among experts for comments and was further discussed at a Nominated Expert Meeting in Zeist, The Netherlands in November 1998.