National Competent Authorities for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes

Working document on a severity assessment framework

Brussels, 11-12 July 2012

The Commission established an Expert Working Group (EWG) for the assessment of severity of procedures to facilitate the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes. All Members States and main stakeholder organisations were invited to nominate experts to participate in the work.

The EWG for the assessment of severity met twice: in December 2011 with the focus on genetically altered animals, and in May 2012 discussing a general framework for assessing the actual severity experienced by animals in procedures.

This document is the result of the work of the two EWG meetings, discussions with the Member States as well as legal input from the Commission on the understanding of a severity assessment framework, its components, participants and working tools and methods. It was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU at their meeting of 11-12 July 2012.

Disclaimer:

The following is intended as guidance to assist the Member States and others affected by this Directive to arrive at a common understanding of the provisions contained in the Directive. All comments should be considered within the context of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority.

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The related articles of Directive 2010/63/EU

- Article 4(3) "Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals."
- Article 15(1) "Member States shall ensure that all procedures are classified as 'nonrecovery', 'mild', 'moderate', or 'severe' on a case- by-case basis using the assignment criteria set out in Annex VIII."
- Article 16(1)(d) " it [reuse] is in accordance with veterinary advice, taking into account the lifetime experience of the animal."
- Article 54(2) "Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. ..."

General background

Directive 2010/63/EU on the protection of animals used for scientific purposes requires that a <u>prospective</u> assessment is made on the severity of each procedure in a Project (Article 15) and that a severity classification is assigned, which may be either "non-recovery", "mild", "moderate" or "severe". Annex VIII provides guidance on the factors to be taken into account in the consideration of <u>prospective</u> severity and provides some examples in each severity category.

Article 54 on reporting requires that for statistical information, <u>the actual severity</u> of the pain, suffering, distress or lasting harm <u>experienced by the animal</u> must be reported (in contrast to the prospective assessment, or prediction, of severity made at the time of the project evaluation). In addition, the actual severity of any previous procedures will be a key consideration in determining whether or not an animal can be reused in further procedures (Article 16).

These measures provide opportunities to improve the quality of science and welfare through prospective review of project proposals and, by inclusion of the actual suffering experienced by the animal, should provide greater transparency and understanding of the impact of scientific procedures on animal welfare.

Main benefits of prospective assessment, monitoring, assessing and recording actual severity include

- Opportunities in particular to implement Refinement and reduce suffering, although prospective discussions will generally also provide an opportunity to consider whether or not animal use is necessary (Replacement) and the study design is appropriate to minimise animal use (Reduction);
- Improved animal welfare, e.g. if suffering is recognised and alleviated sooner;
- Improved transparency, as statistics should better reflect the actual welfare costs to animals;

- Improved communication between those responsible for using, caring for and monitoring animals;
- Input to retrospective project assessment when this is carried out (Article 39);
- Improved scientific data quality due to better welfare;
- Increased knowledge about assessing severity and clinical signs, which will promote greater consistency in assessments provided that approaches and results are disseminated, e.g. via journals, discussion groups and meetings;
- Input into training courses for researchers, animal technologists and laboratory animal veterinarians, if results are used to provide examples;
- Evidence-based information that can be used in prospective harm-benefit assessments for similar, future projects.

General considerations for a severity assessment

The consideration of severity within a procedure should be a **continuous process** beginning with <u>initial study design</u>, through the <u>study-specific day-to-day monitoring</u> of animals during the project, to the <u>"actual" severity assessment</u> upon completion of the study, which provides opportunities to identify further refinements for future studies.



By approaching in this manner, there is a greater opportunity to ensure that the Three Rs are considered and implemented throughout, that communication among all involved will be improved and that consistency will be enhanced.

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Effective severity assessment requires

- A 'team' approach, with input from people with different expertise, experience and priorities, e.g. researchers, animal technologists and care staff, the attending veterinarian;
- Good planning;
- Appropriate continuing education and training of all personnel involved;
- Day-to-day severity assessment systems that are appropriately tailored to the species, strain and project, including informed and structured observations of animals at appropriate intervals (e.g. frequency increased during and after procedures);
- Well-informed, effective protocols for assessing behaviour and clinical signs;
- Analysis of the observations to make an informed judgement on the nature and level of suffering;
- Awareness of the severity of each procedure and what action to take if this is reached or exceeded;
- A consistent approach to overall judgements on actual suffering (mild, moderate, severe) for statistical reporting;
- Reflection upon how effectively the Three Rs were implemented and whether improvements could be made for future studies.

Pre-study considerations

The process for ensuring that severity is minimised during scientific procedures begins at the **design stage**, when considering whether or not it is necessary and justified to use live animals to meet the scientific objectives.

- Where the use of live animals is necessary and justified, it is important to ensure that an appropriate model is chosen and that the study design is robust;
- All aspects of the study that may cause pain, suffering, distress or lasting harm should be identified, and consideration given to how their effects can be minimised, for example by consulting the literature, colleagues, animal technologists, the veterinarian and the Animal Welfare Body if appropriate;
- The recommended prospective severity classification assigned to procedures should be based on the highest severity anticipated for any animal on the study;
- A plan for observing the animals that is suitable for and tailored to the study should be developed. A standardised terminology that can be understood by all those involved in the study will improve consistency in reporting and interpretation;
- It is important to ensure there are sufficient trained and competent staff available to conduct the study, and monitor and care for the animals.

Indicators of Severity

There are behaviours and clinical signs that may be used to assess the severity of procedures at the 'cage side' (or tank, pen etc.). The terminology used to describe these should be understandable by all those involved in the use, monitoring and care of the animals. For any severity assessment system, a sound understanding of the normal health, behaviour and welfare status of the species (strain, where applicable) being observed is essential.

The aim should be to:

- achieve the best possible quality of life for the animal;
- ensure that any suffering due to the scientific procedures is recognised and
- minimised, but

to remain consistent with the scientific objectives.

Any assessment system should effectively detect deviation from a normal state of health and welfare, enabling the observer to record and convey a clear, consistent assessment of each animal.

A simple, hierarchical approach can be used to define a severity assessment protocol that is appropriately tailored to the species, strain, individuals and procedure. The process for defining a cage side assessment protocol should identify any adverse effects that may occur throughout the animal's lifetime experience, including housing, husbandry, care and handling, as well as adverse effects due to the scientific procedures and their consequences. Consideration of all these adverse effects should identify indicators that can be used to effectively assess the animal's wellbeing at the cage side. These indicators should be tailored to the species, strain and experimental procedures being applied. They should also be easy to understand, to identify and to record consistently. However, it is important to ensure that there is also the facility to capture and record any unexpected adverse effects, for example in free text.

High level categories

A set of overarching, 'high level' categories that apply across all species is listed below as a starting point for producing a comprehensive list of specific indicators for each procedure or animal care programme. The aim is to produce a study-specific list of sufficient indicators to minimise the risk of missing signs of suffering, without devising an overly complex system that will be unnecessarily bureaucratic and time-consuming.

The high level categories are:

- Appearance
- Body functions
- Environment
- Behaviours
- Procedure-specific indicators

• Free observations (other relevant observations)

Indicators within each of these categories can be adapted to any species. They should be used to produce a list of observable characteristics that can be assessed by a suitably trained individual, in order to make a judgement on the overall health and welfare status of the animal.

These indicators should be discussed and selected in liaison with the person(s) responsible for oversight of the welfare of the animals, and the Animal Welfare Body if appropriate. They should then be used to develop study-specific cage side record keeping systems for day-to-day observation, monitoring and assessment.

Appendix I provides an example of how these high level categories can be further subdivided and used to develop suitable observational criteria, using common descriptive terminology.

Appendix II provides information on guidelines and online resources that can assist in the development of appropriate welfare assessments for animals undergoing scientific procedures.

Factors that should be considered in the assessment of actual severity

It is important to note that depending on the specific situation, a number of elements may have a positive or negative impact on severity, and species differences need to be taken into consideration.

The assessment of actual severity should be undertaken on an individual, case-by-case basis, using the observations taken from the animals during day-to-day monitoring. Additional parameters required for study purposes can also be used where appropriate and available. For example, non-observable indicators (such as body temperature, body weight, biochemical parameters or biotelemetry data such as heart rate) may also be needed for the study and should be taken into account in the assessment of severity if they can provide additional, relevant information.

The actual severity to be reported for the individual animal should be the highest level experienced during the course of the procedure and not based on the severity at the end of the procedure. Nor should the evaluation be considered a simple additive process e.g. a number of mild procedures = moderate severity. It should be based on an overall assessment of the animal's experience from the start of the procedure to the end.

The list below provides examples of the kind of <u>elements to be considered and weighed</u> when assessing actual severity.

Procedure, technique

- Surgical / non-surgical;
- Level and duration of restraint;

- Withholding analgesia/anaesthesia when either or both of these would otherwise be necessary;
- New model or procedure;
- Environmental elements (including housing and food/water restrictions);
- Stress /distress;
- Repeated procedures and intervals between these (also need to consider frequency and combination of "below threshold" interventions);
- Reuse or continued use.

Species, strain, stage of development, previous experience

- This should be a major consideration it is necessary to understand the biology and behaviour of the species and strain (and sometimes individual) to be able to predict and assess severity effectively;
- Species and strain;
- Origin of the animal, e.g. purpose-bred, feral or wild;
- Sourcing (including previous housing conditions) and transport;
- Genotype, phenotype, sex, age, immune status;
- Natural behaviour and biology (e.g. the relative importance of different senses, such as sight for primates and smell for rodents, and how these may be affected in a laboratory environment);
- Single/group housing justification to singly house social animals, or to separate them from established groups in the short or long term;
- Diurnal rhythms, e.g. impact of conducting scientific or husbandry procedures on nocturnal animals during the light phase;
- Maternal separation in all species, including rodents;
- Cognitive ability, awareness, memory, perception of effects of procedures.

Frequency, intensity

- There is no direct link between frequency and severity, i.e. increased frequency does not necessarily result in greater severity. This is because the effect on severity of repeating procedures or techniques depends on a number of factors, such as the intensity of each intervention, its duration, the species and the experience of the individual;
- When interventions are repeated, there is the potential for acclimatisation, which may reduce severity, e.g. in a non-human primate undergoing mild procedures. Conversely, repetition may increase severity, e.g. due to anticipation of a stressful procedure, or onset of hyperalgesia if surgery is involved;
- Potential for positive reinforcement training, or 'rewards' following procedures;
- The highest level of severity should be recorded instead of 'recovery level' severity.

Duration of effect

- Duration is *linked* with intensity (*and therefore with severity*);
- Whether it is possible to use early humane or scientific end-points.

Effectiveness of refinements

- Appropriate analgesia, anaesthesia and post-operative care;
- Enrichment both environmental enrichment and group housing of social animals;
- Housing, husbandry and care whether it is possible to refine these according to current best practice, or whether the procedure necessitates restrictions such as confinement to smaller enclosures (e.g. metabolism cages), grid flooring or exposure to environmental conditions that could cause stress;
- Training the animal to cooperate, or facilitating habituation to procedures;
- Effectiveness of cage side assessment protocols.

Cumulative severity

- Each animal's whole-life experience, in which restrictions on the ability to refine housing, or need for frequent capture, handing and restraint etc. may affect severity, must be taken into account within a procedure that involves a number of steps/ interventions;
- Previous procedures, in the case of reuse.
- The life-time experience, including elements such as sourcing (e.g. early 'weaning') and transport, is required to be taken into account when reuse is being considered.

How to ensure consistency in the assessment and assignment of actual severity

Input at the study design phase by relevant scientists, animal technologists, veterinarians and care staff is generally needed to ensure that there are appropriate data available to enable an informed decision on actual severity at the end of the procedure. <u>The final assignment of an actual severity category will be the result of an analysis of records of cage-side observations of behaviour, clinical signs and other relevant parameters.</u>

Elements contributing to consistency include:

- Incorporation of multiple expertise, experience and priorities a 'team approach';
- Training in using the day-to-day assessment protocol (including the common terminology used to describe observations);
- Expertise on animal health, welfare and behaviour;
- Regular review of outcomes;
- Communication between all those responsible for conducting the study and monitoring the animals (top-down, bottom-up, between and within);
- Oversight (locally (e.g. the Animal Welfare Body), regionally, nationally, EU).

The following key issues should be considered to ensure consistency in the assessment of actual severity:

Development of a procedure specific assessment sheet

- Assessment sheets that are tailored to the species, strain and study should be developed and agreed prior to the start of the project;
- All available, relevant information should be used effectively in the development of study-specific assessment sheets, for example previous experience, results of *in vitro* or *in silico* studies, literature searches, information from pilot studies and observed clinical signs in humans or other animals;
- Information on which parameters need to be observed and how the monitoring should be carried out should be available at the cage side;
- The prospective severity level classification will partly 'dictate' the level of involvement needed at the operational level, whether a team approach is required during the monitoring, and who should be involved in the actual observations and recording process. Those who developed the study-specific assessment protocol should carry out and/or confirm the actual, final severity assignment;
- Depending on the complexity of the study, separate assessment sheets for separate components may be helpful e.g. standard surgery/peri-operative care sheet used in combination with tailored study protocol assessment;
- In some cases, the study-specific assessment sheets may also need to include information relevant to colony management e.g. GA animal breeding and growth data.

Consistency in actual severity assessment

Assessment of actual severity is conducted at the end of the procedure and requires a judgement to be made on the overall severity actually experienced by the animal, on the basis of the day to day assessments and taking into account the procedures that were conducted.

- One commonly used approach is to define 'mild', 'moderate' and 'severe' levels for each of the indicators used in the day to day assessments, and then make a judgement about the severity of these on a case by case basis;
- As with the day-to-day monitoring, it is essential that the actual assessment criteria are tailored to the procedure, species and strain; e.g. a 10 % loss in body weight will have very different implications for the health and welfare of a juvenile, growing rat; an adult mouse with a rapidly growing tumour; or an adult dog.
- Consideration of the time period over which some of these indicators occur is also an essential factor, particularly with respect to weight loss and food/water consumption.

Assessment will be made by using the daily assessment records, taking into account the procedure performed on the animal, how long adverse effects lasted and whether or not the animal was reused. Although this will inevitably involve a certain degree of subjectivity, proper training of the observer should aim to reduce such subjectivity.

Assigning actual severity if animals are found dead

- If an animal is found dead, i.e. not euthanised, this may be either as a consequence of the experimental procedure, or other unrelated causes¹;
- The actual severity for animals found dead should be reported as 'severe' unless an informed decision can be made that the animal did not experience severe suffering prior to death;
- If it is unlikely that death was preceded by severe suffering, the actual severity classification should reflect the known experience prior to death. Factors such as frequency of monitoring, use of analgesia, etc. will need to be given due consideration.;
- "(lasting) harm" can only be experienced by a living animal.

<u>Examples to illustrate the process</u> of severity classification, day-to-day assessment and final, actual severity assessment should be developed and made available to the scientific community.

Who should provide input for the actual severity assessment?

- <u>Observation and recording</u> of effects are often <u>separate processes</u> from the <u>actual severity assignment;</u>
- Clear responsibilities should be set to ensure effective day to day monitoring of the animals, with the appropriate support and oversight;
- <u>A verification process</u> should be in place to promote consistency, e.g. by comparing assessment scores made by different people;
- Roles with respect to observing and monitoring animals and making the actual severity assessments should be <u>flexible and adjustable</u> on the basis of the complexity and severity of the study in question although the legal responsibility for ensuring that suffering is detected and minimised remains with the person named in the project authorisation;
- <u>Animal Welfare Bodies</u> should also play a role at establishment level to ensure consistency;

¹ For the purposes of statistical reporting, actual severity should primarily relate to the severity of the experimental procedures and not unrelated incidents such as disease outbreaks or cage flooding. These types of incident relate to health problems or to husbandry and care practices, not harms due to procedures, however, they should recorded, investigated further and followed up to prevent recurrence.

• <u>The National Committees</u> and Competent Authorities may also contribute to promoting consistency.

Monitoring tools, media and other considerations

- The use of score sheets should be considered at the project planning stage;
- Score sheets should be as simple as possible, but as detailed as needed, and tailored to the type of study;
- Previously developed assessment sheets can be used if these are appropriate to the study, species and strain;
- Electronic record keeping can help to ensure consistency and ease of access for all relevant information;
- The use of standardised language and terminology is recommended;
- The data recorded should be as objective as possible;
- The advantages and disadvantages of (i) numerical scoring and (ii) 'binary' (where indicators are marked as 'present' or 'absent') observation systems should be considered on a case-by-case basis;
- All types of observation record should include a facility to add free text, as well as predetermined indicators, so that unexpected observations can be recorded;
- Effective training for all relevant staff is essential covering specifically severity and welfare assessment as well as monitoring techniques;
- A communication plan should be established to encompass all relevant staff; this should include a mechanism to rapidly communicate unexpected outcomes to all appropriate individuals and, as applicable, to the Competent Authority;
- Monitoring should be proportionate to anticipated effects procedures that may cause 'severe' suffering will generally require more frequent and detailed monitoring;
- There should be clear criteria for intervention, for example, if particular parameters are observed or if a predetermined level of suffering is approached. All relevant staff should know what these criteria are, know what to do and whom to contact should they occur.

If the severity assessment process is implemented effectively, the animals and all personnel involved in their care and use will benefit from improved animal welfare, scientific validity and transparency.

Good internal and external communication on the severity assessment process and on the application of the Three Rs will afford even wider benefits.

Appendix I

Glossary of Clinical Observations

The success of any severity assessment scheme depends upon the selection of welfare indicators that:

- are readily and reliably recognisable;
- are effective at providing good measures of welfare;
- are relevant to the scientific study, species and strain (where appropriate);
- are practical to carry out and do not overly disturb the animal and
- lend themselves to consistent measurement, interpretation and analysis.

A common approach to recording clinical observations is therefore a desirable goal as this will help in the development of consistent approaches to severity classification. This would facilitate comparisons of clinical findings between studies, and inform those involved in severity assessment.

The observations are structured on the following six high level categories:

Appearance / Body Functions / Environment / Behaviours / Procedure-specific indicators / Free observations

High level	Areas to focus on when observing	Specific indicators to monitor
categories	animals	
Appearance	Body condition	Weight loss/gain
		Obese
		Thin

		Body condition score, if available		
	Coat and skin condition	Piloerection		
		Unkempt/lack of grooming		
		Greasy coat Hair loss Dehydration – skin tenting Skin lesions – swelling; scab; ulcer; injury/wound		
		Faecal or urine staining		
	Discharge Ocular; nasal; uro-genital; porphyrin staining in some species e			
	Eyes	Sunken or 'dull'		
		Closed/semi-closed		
		Damage/injury to eye (e.g. corneal ulceration)		
Mouth		Salivation		
		Malocclusion/overgrown teeth		
	Other	'Pain face' – e.g. semi-closed eyes and nose bulge in mice		
		Abdominal constrictions		
		Swollen body part, e.g. distended abdomen		
Body functions	Respiration	Accelerated breathing (tachypnoea)		
		Laboured breathing (hyperpnoea)		
		Very laboured breathing (dyspnoea)		
		Wheezing or other sound when breathing		
	Food/water intake	Increased/decreased		
Body temperature Increased/d microchip of extremiti Senses Impaired signal		Increased/decreased; measured body temperature if available (e.g. via		
		microchip or telemetry device, contact or non-contact thermometry); colour		
		of extremities in rodents		
		Impaired sight, hearing or balance		
Environment	Enclosure environment, including any	Presence and consistency of faeces		
	litter, nesting material, enrichment	Wet bedding, e.g. due to polyuria		
items		Presence of vomit or blood		

		Whether animal is using enrichment items e.g. nesting material, chew		
		blocks		
Behaviours	Social interaction	Change from normal temperament - apprehensive/aggressive interactions		
		with other animals; anxiety (e.g. marked escape responses, hiding)		
		Isolated or withdrawn from other animals in social group		
	Undesirable behaviours	Repetitive/ stereotypic behaviour		
		Barbering (rodents), trichotillomania		
		Increased aggression to humans or other animals		
Posture and mobility Abnormal posture		Abnormal posture		
		Abnormal gait; lameness; lack of movement/lethargy/reluctance to move if		
		stimulated		
		Uncoordinated movements		
		Hunched abdomen; tilted head		
	Other	Tremors		
		Seizures/convulsions/spasms		
		Vocalisation; spontaneous or invoked. (Note - Some species, e.g. rodents,		
		usually vocalise in the ultrasonic range, so audible vocalisations are of		
		special concern. Rabbit vocalisations are also generally inaudible to		
		humans unless the animal is in distress).		
Procedure-specific	These are identified on the basis of the	For example, in an EAE model these could include; loss of tail tone, hind		
indicators	individual project, its potential adverse	limb weakness, fore limb weakness, paralysis, loss of bladder function		
	effects and expected indicators of these			
Free observations	A severity assessment scheme should alwa	ys include a facility to note any observations of unexpected negative welfare		
	impacts.			

Appendix II

Background reading, guidelines and online resources on assessing the welfare of animals undergoing scientific procedures

American College of Laboratory Animal Medicine (ACLAM) (2006) *Guidelines for the* Assessment and Management of Pain in Rodents and Rabbits, download at http://www.tinyurl.com/65ez5vh

Assessing the Health and Welfare of Laboratory Animals (AHWLA) training resource. See <u>http://www.ahwla.org.uk/index.html</u>

Canadian Council on Animal Care (CCAC) *Welfare assessment*. See <u>http://www.ccac.ca/</u> and click on the Three Rs microsite, then search for 'welfare assessment' (English or French)

Categorising the severity of scientific procedures on animals - Summary and reports from three round-table discussions edited by Jane A. Smith and Maggy Jennings on behalf of the Boyd Group and the RSPCA, July 2004 Published by RSPCA Research Animals Department

FELASA Working Group on the Reporting of Clinical Signs in Laboratory Animals (2012) – (in press)

Institute for Laboratory Animal Research (ILAR) (2008) *Recognition and Alleviation of Distress in Laboratory Animals*. Washington, DC: National Academies Press Institute for Laboratory Animal Research (ILAR) (2009) *Recognition and Alleviation of Pain in Laboratory Animals*. Washington, DC: National Academies Press. See http://dels.nas.edu/animal_pain/

Johansen R, Needham JR, Colquhoun DJ, et al. (2006) Guidelines for health and welfare monitoring of fish used in research. *Laboratory Animals* **40**: 323–340

Joint Working Group on Refinement (2011) A guide to defining and implementing protocols for the welfare assessment of laboratory animals. *Laboratory Animals* **45:** 1-13

Leach MC et al. (2008) Identification of appropriate measures for the assessment of laboratory mouse welfare. *Animal Welfare* **17:** 161-170

National Centre for the Three Rs (NC3Rs) *Welfare assessment*. See <u>http://www.nc3rs.org.uk/welfareassessment</u>

National Health and Medical Research Council (2008) *Guidelines to Promote the Wellbeing* of Animals Used for Scientific Purposes: The Assessment and Alleviation of Pain and Distress in Research Animals. Canberra: Australian Government. See http://www.nhmrc.gov.au and search for "pain and distress"

Organisation for Economic Co-operation and Development (OECD) (2000). *Guidance Document on the Recognition, Assessment, and Use of Clinical signs as humane endpoints for experimental animals used in safety evaluation.* OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 19. Paris: OECD

Wells DJ, Playle LC, Enser WEJ, et al. Assessing the welfare of genetically altered mice. Full version at <u>http://www.nc3rs.org.uk/gamice</u>. Summary in *Laboratory Animals* **40:** 111–114

Workman P et al. (2010) Guidelines for the welfare and use of animals in cancer research. *British Journal of Cancer* **102:** 1555-1577, download at <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2883160/?tool=pubmed</u>

1.2 Suggested useful journals for further reading

Applied Animal Behaviour Science	http://www.applied-	
	ethology.org/applied_animal_behaviour_science.html	
Animal Technology and Welfare	http://www.iat.org.uk/publications/atw.htm	
Animal Welfare	http://www.ufaw.org.uk/animal.php	
Contemporary Topics in	http://www.aalas.org/publications/index.aspx#ct	
Laboratory Animal Science and		
Journal of the American Association		
for Laboratory Animal Science		
Lab Animal and Lab Animal	http://www.labanimal.com/laban/index.html	
Europe	http://www.labanimaleurope.eu/	
Laboratory Animals	http://la.rsmjournals.com/	

1.3 Suggested keywords for literature searches

The following keywords are helpful when searching for information on severity assessment:

affect	harm benefit assessment	positive indicators	severity scale
animal welfare	humane endpoints	positive welfare	sickness behavio(u)r
animal suffering	Needs	qualitative behavio(u)r assessment	stress

assessment	objective	quality of life	suffering
	assessment		
discomfort	Pain	refinement	welfare assessment
distress	pain assessment	score sheets	welfare indicator
harm assessment	pain measurement	scoring system	welfare outcomes

References relating to actual severity classification

CCAC (1998) Guidelines on: Choosing an Appropriate Endpoint in Experiments Using Animals for Research, Teaching and Testing. Canadian Council on Animal Care, available at: <u>http://www.ccac.ca/en_/standards/guidelines</u> (English) and <u>http://www.ccac.ca/fr_/normes/lignes_directrices</u> (French)

FELASA Working Group on Pain and Distress (1994) Pain and distress in laboratory rodents and lagomorphs. *Laboratory Animals* **28:** 97-112

Jones HRP, Oates J and Trussell BA (1999) An applied approach to the assessment of severity. In: Hendriksen CFM. & Morton DB (eds), *Humane Endpoints in Animal Experiments for Biomedical Research*. Proceedings of the International Conference, 22-25 November 1998, Zeist, The Netherlands. Royal Society for Medicine Press Ltd., London pp 40-47

LASA /APC (2008) Final Report of a LASA/APC Working Group to Examine the Feasibility of Reporting Data on the Severity of Scientific Procedures on Animals. Available at: http://www.lasa.co.uk/publications.html

Morton, DB and Hau J (2011) Chapter 18: Welfare assessment and humane endpoints. In *Handbook of Laboratory Animal Science*, 3rd Edition, Volume 1 Essential Principles and *Practices*. Hau J and Schapiro, SJ (eds), CRC Press LLC, USA, pp 535-572

Prescott MJ, Morton DB, Anderson D, Buckwell A, Heath S, Hubrecht R, Jennings M, Robb D, Ruane B, Swallow J and Thompson P (2004) Refining dog husbandry and care, Eighth report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement. *Laboratory Animals* **38 Suppl 1:** S1:1-S1:94

Wolfensohn S and Lloyd M (2003) *Handbook of Laboratory Animal Management and Welfare, 3rd Edition.* Blackwell Publishing Ltd, Oxford (4th edition in prep)

(All URLs last viewed 24 May 2012.)