Version 1 Jan 2014

Advisory notes on recording and reporting the actual severity of regulated procedures

Contents

1. Introduction

From January 2013 all regulated procedures carried out on animals under the Animals (Scientific Procedures) Act 1986 (ASPA) must have the actual severity of the procedure recorded.

At the end of the life of the animal, or when it is discharged from the controls of ASPA and no further scientific data are to be collected, the actual procedural impact can be determined and categorised. Actual severity must reflect the highest severity of the procedure, including any accumulation of lesser events, and not the severity at the end of the procedure or any estimate of 'average' severity. For the statistical Returns of Procedures, the need to allocate an actual severity means that, from 2014, procedures in the UK are reported **at their end** and not at their commencement.

This guidance refers to the EU working document on a severity assessment framework:

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus%20doc%20on%20severity%20assessment.pdf

Annex VIII of Directive 2010/63 EU: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:EN:PDF

and worked examples on severity provided by the Expert Working Group set up by the European Commission: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/examples.pdf

2. General principles

2.a Prospective versus actual severity assessments

Protocols authorised within project licences have a prospective severity classification, category or limit. This is based on the anticipated/expected 'worst case scenario' of the procedures to be applied to animals, and on the expected adverse effects of those procedures.

Actual severity assessment is based on the real (not predicted) impact (harms) alone. An animal used on a moderate protocol might, in retrospect, experience mild, moderate or severe suffering.

When determining the actual severity classification, it is essential to focus on the impact of procedures that have been carried out on each individual animal. Each of the techniques used will have had an impact that differs between individual animals. As this may be very different to the predicted harms, the prospective severity category of the protocol on which the animal was used should be disregarded when assessing actual severity.

2.b Requirements for all actual severity assessments

1. Responsibility for ensuring that actual severity is properly assessed and recorded lies with the project licence holder.
2. The assessment must be performed by a well-trained, competent person who is familiar with the species being assessed, usually the personal licence holder, taking into account the advice of a Named Animal Care and Welfare Officer (NACWO) or Named Veterinary Surgeon (NVS). Where there is disagreement, the local Home Office Inspector should be contacted for advice.

3. The severity category of the protocol should be disregarded when considering the actual severity assessment (AcSA).
4. Only harms caused during the procedure should be taken into account. Therefore the suffering caused by events preceding the start of the procedure, for example, transport, preliminary blood tests to determine health status performed under the Veterinary Surgeons Act should be disregarded. Experiences of animals between different uses, such as when an animal is returned to stock but later ‘re-used’, should also be disregarded when assessing the actual severity of a procedure.
5. Only harms that are procedure-related should be included in the assessment of actual severity. Non-procedural harms (see below) should be disregarded.
6. The severity assessment is based on the entire procedure, taking into account any cumulative impacts of serial techniques. The effects of serial techniques are not necessarily cumulative. The impact of repeated techniques may be potentiated, or may be lessened by habituation. A judgement will need to be made on whether/how the harms caused increase with increasing number of techniques.
7. All assessments assume a suitable level and competence of monitoring as the impact of a harm is related to its duration.
8. The severity reported will be the *highest level* of suffering experienced by the animal during the entire procedure. It is not based on the condition of the animal at the end of the procedure or on the ‘average’ of suffering over time. Assessment will be ongoing throughout the study. A final classification should be **assessed promptly** when the animal completes the series of procedures so that the severity can be accurately allocated.

A simple generic example is given at the end of this guidance.

2.c Monitoring and competence of those carrying out severity assessments

All assessments assume a suitable level of competence and frequency of monitoring appropriate to the procedure.

Checking an animal means that the animal has been observed in sufficient detail to assess its general appearance and demeanour. This may or may not necessitate opening the cage or enclosure.

Examination of an animal means that each individual animal has been closely and individually observed. In most cases this will mean that the animal has been handled and physically examined sufficient to make a detailed assessment of its health and well-being.

The severity of a procedure will relate to both the duration and intensity of pain, suffering or distress caused by the techniques applied as part of that procedure. The time period since the animal was last monitored and the level of detail with which the animal was monitored must be taken in to account when deciding the duration or likely time of onset of an adverse effect.

For particular clinical sign(s) to be regarded as identified at onset, the animal must have been observed within at least the last few hours. For clinical signs to be considered to have started 'recently' an animal has to have been adequately monitored at a frequency that should pick up any such signs rapidly and effectively. The level of monitoring that is required in practice may depend on the type of procedure that has been applied, and the likely speed and impact of the clinical signs on the animal. If an animal was last observed the previous day, it is not considered to have been very recently monitored.

An animal can only be described as having been in normal health the previous day if it had been carefully examined within the previous 24 hours. If this was not done (i.e. checked, but not examined in detail) then any adverse effects detected must be considered to have at least been developing for more than 24 hours, unless an informed decision can be made that the onset was more recent.

2.d Non-regulated procedures, non-procedural and procedural harms

Non-regulated procedures should not be included in the assessment. These are listed below.

- Non-experimental agricultural practices, for example, de-horning of cattle.
- Non-experimental, recognised veterinary practice, for example, treatment for disease. Note that recognised veterinary practice is carried out by, or under the direction of, a veterinary surgeon only, and is applied in the interests of the animal and not the science. This might include the surgical repair of a wound not related to the procedure, such as a fight wound, if the vet considers this is in the interest of the animal.
- Any techniques carried out in accordance with an animal test certificate granted under the Veterinary Medicines Regulations 2011.
- Recognised husbandry practices, such as temporary housing of paired rodents on grid floors to allow plug checks.
- Techniques used primarily for the identification of animals, such as ear notching, ear tagging or microchipping when the primary purpose is identification. Use of 'by-products' from these techniques to provide material

for scientific purposes does not alter this status. For example, ear notching rodents primarily for identification is not taken into account in the severity assessment even if the resulting tissue is used for genotyping. Similarly, the use of microchips for identification, which also transmit and/or provide data on body temperature, etc., would not generally be included. For practical purposes, this means that if the same technique is applied to an animal for both identification and another purpose simultaneously, this should be interpreted as having been primarily for identification and therefore not a regulated procedure.

- Schedule 1 listed methods of killing or other methods of killing listed on the establishment licence.

Non-procedural harms should not be included in the assessment. Non-procedural events would usually affect, or be liable to affect, animals not involved in the particular study, for example, animals in the same room, same shipment. Examples of non-procedural harms include the following.

- Failure of environmental controls, which result in harm to or loss of animals.
- Major disease outbreaks affecting animal units, which affect, or could affect normal animals.
- Fighting injuries where these are **not** due to phenotype or study.
- Death or disease of animals relating to factors/illnesses that are unrelated to the procedure, such as tumour development in an untreated wild type control animal or where the mortality rate is similar to an untreated group or the background strain.
- Incidents that might occur at any time (including at the time of the procedure) which might have occurred at any time during routine husbandry, for example, a mouse catching its tail in the cage lid.

When assessing actual severity in these cases an informed decision must be made as to what the suffering of the animals would have been without these incidents. If it is not possible to determine the procedural related component of suffering that would have occurred if there had been no harms related to non-procedural effects, then the total actual harm including the non-procedural incidents should be reported. This is to ensure that all harms from the procedure have definitely been included. If in doubt, cases should be discussed with the Home Office Inspector to determine appropriate classification.

Procedure-related harms. All procedure-related suffering should be taken into account. This includes expected, unexpected and unintended adverse effects or other harm that arises directly or indirectly from an action required to gain the

results/outputs of the study. It should include steps that would normally be expected to be below threshold, but that did in fact cause harm. This might consist of adding inert markers to the diet, restricted food availability or behavioural testing, for example. It will also include accidents and technical failures that are specific to or unique to the procedure.

Examples of procedure-related harms include the following.

- Expected harms listed in the adverse effects section of the protocol.
- Harms caused by failure of the equipment used.
- Harms caused by misdosing.
- Repair of a surgical wound after breakdown, whether or not performed by the NVS.
- Distress from restraint.
- Discomfort associated with cannula or implant care, or related infection.
- Distress unexpectedly observed during a non-regulated behavioural test that is required for data collection from an animal on procedure.
- Fight injuries where the fighting is related to specific needs of the study, such as repeated mixing of groups.

2.e Informed decisions

An informed decision is a decision based on knowledge of what an animal is known to have experienced, or is reasonably likely to have experienced. This requires a suitable level of competence in the person making that decision. If in any doubt advice should be sort from named animal care staff and the NVS. Information such as the purpose of the procedure, the nature of the procedure and what occurs in the peer group may be helpful in coming to an informed decision.

In all cases, the actual severity assessment should be based on informed decisions. In the absence of information on the nature, extent and duration of suffering, the assessment should default to the highest severity that is reasonably likely to have occurred.

2.f Animals found dead

Where such a death cannot reliably be ascribed to a non-procedural cause, the following considerations should be made to ascribe actual severity for the individual animal.

In the case of an animal found dead, and the cause of death is known, then it should be possible to determine what the reasonably likely pre-death experience/manner of death of the animal was, as well as the likely duration of any suffering. Determination of cause of death may include a combination of data from post-mortem examination, veterinary advice and knowledge of the specific model and its effects. Records of food consumption, body weight and body condition, other scoring systems and timings of monitoring undertaken could contribute to the understanding of what the pre-death experience was to allow a reasoned judgement to be made.

All animals undergoing regulated procedures should be regularly monitored as appropriate for the likely adverse effects anticipated. Where an animal is found dead after it has been carefully examined by a competent person at the last observation point, an informed decision on the severity of its experience may be made. The evidence to consider should include:

- the records noted above as well as the clinical signs evident at the last observation point;
- the period of time over which the animal may have suffered prior to death; and
- the likely adverse effects anticipated for the particular regulated procedures which the animal has undergone.

If there is no information or reasonable indicative evidence to conclude why an animal has died, then the likely suffering leading up to death cannot be determined based on an informed decision, and the severe classification should apply.

2.g Assessing overall severity of a procedure

Where procedures are prolonged there are likely to be variations in the severity at each stage of the total procedure. It is essential that records are kept of impact/severity throughout the duration of the procedure.

The reported level of severity must be based on the response of the individual animal to its experience. It will usually be the highest peak of severity at any time throughout the animal's procedural life, but a higher category should be assigned if there were repeated events at a lower level of harm and the harm was cumulative, or due to continuous long-term pain or suffering. Annex VIII of Directive 2010/63 EU indicates that prolonged suffering at a mild level should be considered moderate and prolonged suffering at moderate should be considered severe. How such harm accumulates will depend on a number of factors such as the success or otherwise of measures put in place to ameliorate harms and the response of individuals may well differ.

When there is no increasing impact with multiple steps or if the pain or suffering resolves completely between each step in a procedure, serial techniques may not be considered cumulative, and therefore do not increase the severity assessment. Serial steps may lead to cumulative suffering; this is certainly the case when the pain or suffering caused by individual steps in a series overlaps (i.e. no opportunity to recover between steps). In these cases a moderate or higher classification will often be appropriate even if each individual step in isolation would have been classified as mild.

There may be complete recovery between procedures and yet an additive effect of each individual impact may be appropriate because sensitisation to procedures has occurred. Similarly, there may be habituation to repeated procedures. The extent to which sensitisation or habituation occurs varies between individual animals. These factors should be considered in evaluating overall impact and determining the classification of actual severity.

2.h Re-use

In cases of re-use each individual use (procedure) should have actual severity assigned independently of previous uses or re-uses. Therefore one animal could have more than one severity category assigned during the course of its lifetime.

3. Definitions of severity categories

Procedures carried out on animals are considered ‘regulated procedures’ only if carried out for a scientific purpose and only if the severity is above the threshold defined as equivalent to the pain, suffering or distress caused by the insertion of a hypodermic needle in line with good veterinary practice.

3.a Sub-threshold severity

It is possible that procedures authorised under a project licence could result in below threshold severity. These will be few, but will occur when it was considered that a procedure might have caused above-threshold pain or suffering, but in retrospect this did not occur for some or all of the animals involved. Examples will be the breeding of genetically altered animals under project licence authority but without a harmful phenotype or dosing with a compound in feed where the animals ate normally and suffered no consequences of being dosed.

Any such procedures should be returned under the appropriate project licence as sub-threshold.

3.b Mild procedures

"Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as mild."
Annex VIII Animals Directive 2010/63 EU

The key characteristic of mild procedures is that any pain or suffering experienced by an animal is, at worst, only slight or transitory and minor so that the animal returns to its normal state within a short period of time. There is generally no lasting effect and no cumulative effect of serial steps within a protocol. An exception to this expectation that the animal will return to normal is genetically altered animals (GAAs) with a phenotype that falls into a mild categorisation (see separate advice note on GAAs – *Severity classification of genetically altered animals under the Animals (Scientific Procedures) Act 1986*).

Animals described as having experienced mild suffering in the actual severity assessment will have experienced essentially normal lives with only minor and transitory deviation from the 'five freedoms':

- freedom from hunger and thirst;
- freedom from discomfort;
- freedom from pain, injury or disease;
- freedom to express normal behaviour; and
- freedom from fear and distress.

Animals will have shown normal feeding and drinking behaviour throughout. Although there may have been a minor, transient disturbance, there will have been no significant weight loss associated with disease and no evidence of lasting systemic illness.

An example of mild pain could be the equivalent of the pain caused by injection by conventional routes, i.e. subcutaneous, intravenous, intraperitoneal or intramuscular (assuming competence of the person performing the procedure and that best practice guidelines for volume, pH, needle size, etc. are followed). Multiple injections by these routes may remain in the mild category if there are no cumulative effects.

Administration of anaesthesia is in itself a mild procedure under normal circumstances, provided the induction is rapid and the duration is such that the animal makes a rapid and uneventful recovery without the need for supportive treatment. The actual harm related to anaesthesia may increase or accumulate where anaesthesia is repeated. A regulated procedure carried out under general anaesthesia, regardless of how severe individual steps might be in a conscious animal, but having no adverse effects immediately after the animal recovers, could also be classed as an overall mild procedure. This excludes most surgical procedures where some level of discomfort if not pain will be present on recovery.

Mild distress is caused by low grade, non-painful or non-invasive stressors, such as those used in chronic mild stress protocols (repeated handling, cage changing and flooding, cage movement, introduction of unfamiliar cage mates but without fighting, etc.). It excludes aversive techniques, such as the use of electric shocks as a negative stimulus on treadmills and for fear conditioning, and stress caused by forced swimming. For the actual severity to have been mild, recovery should be immediate/rapid and there should be no lasting impact that is evident simply by examining the animal (although there may of course be, for example, biochemical or behavioural changes requiring particular tests in order to characterise effects), or as evidenced by sensitisation to later procedures.

Mild procedures generally have no lasting impact on animals; once each step within a procedure has been completed the animal should return to normality, or close to it, almost immediately. When pain or suffering does not resolve rapidly on completion of a step within a procedure, but continues, it may be considered long lasting.

3.c Moderate procedures

“Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as moderate.”
Annex VIII Animals Directive 2010/63 EU

The characteristic of moderate procedures is that they do cause **a significant and easily detectable disturbance of an animal’s normal state**, assuming that appropriate monitoring systems are in place and that they are used by trained and competent staff. The disturbance is **enough for an animal to show discomfort, abnormal behaviours, significant weight loss or other indicators of poor welfare, but does not prevent normal feeding and drinking** or other normal activities other than for short periods or to a limited extent for longer periods.

Pain of any significant intensity is of no more than a few hours duration and is not considered of a severe nature, as judged by species-specific criteria (for example, repeated vocalisation/persistent self trauma in rodents).

Animals that undergo procedures that produce chronic low-level pain or discomfort or dysfunction such as altered gait will usually be classified as moderate. A higher level of pain that persists, such as non-weight bearing lameness without improvement, even in the absence of other signs of severe pain, would be considered severe unless a diagnosis can be made that indicates the condition is associated with pain of a lower intensity.

Many chronic pain models, including those involving minor surgical procedures such as nerve ligation and including when this is carried out without post-operative analgesia, tend to cause allodynia rather than permanent pain. When pain detection methods are necessary to distinguish these animals from normal they are not considered to be suffering long-term pain and are classed as of moderate severity. If the animals show overt signs of pain for a prolonged period without improvement, for example, by persistently licking the affected part for more than three hours in a model such as formalin injection into the footpad, they should be classed as severe.

Self trauma is generally indicative of severe suffering. However, if it is minor and self-limiting and animals do not show evidence of pain on examination by competent staff, this can be classed as moderate. An example might be autotomy where the trauma is superficial (is restricted to nails and has not progressed to the soft tissue) and has stopped. If the autotomy is persistent or progressing, the classification would be severe.

Acute pain models, such as the writhing test or assessment of visceral pain using balloon inflation, may involve more severe pain. Where the pain is not sufficient to lead to distress and where the entire painful technique lasts no more than three hours these procedures will be classed as moderate.

If animals show signs of obvious illness, for example, piloerection, huddled posture, reluctance to move, isolation from the group in rodents, and if this is promptly detected and animals are killed immediately, procedures could be classed as moderate. If animals remain in this condition for more than 24 hours then a classification of severe will be appropriate.

3.d Severe procedures

"Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress or long-lasting moderate pain, suffering or distress, as well as procedures that are likely to cause severe impairment of the well-being or general condition of the animals shall be classified as severe."
Annex VIII Animals Directive 2010/63 EU

The characteristics of severe procedures are that they **cause a major departure from the animal's usual state of health and well-being**. It would usually include long-term disease processes where **assistance with normal activities such as feeding and drinking are required** or where **significant deficits in behaviours/activities persist.** This would include any state that a person would find difficult to tolerate or disease where clinical signs have progressed to such an extent that it threatens the life of an animal.

A severe classification should be given in any situation where animals are *in extremis.* Any animal that is found moribund should also be classified as severe unless there is evidence that a lower classification can be given, i.e. that the animal did not pass through severe suffering to reach the moribund state.

3.e Non-recovery

A classification of non-recovery is used if an entire procedure is carried out under general anaesthesia and the animal does not recover. It includes unintended death of animals on recovery protocols while under anaesthesia, provided that no regulated procedures had been carried out prior to the induction of anaesthesia.

Procedures involving GAAs with a harmful phenotype should **not** be classed as non-recovery, as the birth and maintenance of such an animal constitutes a procedure; in these cases the actual severity will be the severity of the phenotype in that animal up to the time of anaesthesia. In the case of GAAs that do not show any harmful phenotype *prior to the time of anaesthesia*, 'non-recovery' would be appropriate.

4. Severity for some commonly encountered procedures and effects

4.a Weight loss

Weight loss can be a very useful objective indicator of an animal's state of well-being. It is often used as a surrogate marker for suffering or severity associated with many disease states. **However, the use of weight loss in isolation from other considerations is likely to be inappropriate for setting the level of severity**.

The cause of any weight loss and of other indicators of welfare must be used in context. Some species show seasonal or physiological variations in weight, which should be considered within context when performing the welfare assessment. Similarly, the physiological state of the animal (for example, if it is lactating) may influence whether weight change is relevant to the well-being of the animal.

Correlation of weight loss with the general appearance and demeanour of an animal may modify the classification of any particular level of weight loss. It is also quite possible for animals to suffer significantly without losing weight, therefore absence of a significant level of weight loss does not necessarily mean that suffering was not moderate or even severe. Weight loss is a less useful indicator where other weight changes are occurring, such as tumour burden increasing or ascites is developing.

Gradual weight loss or divergence between adult experimental and normal animals of between 15 and 20 per cent (over a period of days) as a result of procedure(s), or a weight difference of this range against age/sex matched controls in growing animals, would usually be classified as moderate severity. However, very rapid weight loss (within 24 to 48 hours) within this range may indicate a significant element of dehydration and is likely to be an indication of severe suffering. Severe calorie restriction can be a cause of moderate or even severe suffering. In contrast, slow weight loss of even greater than 20 per cent due to mild calorie restriction, especially in obese individuals, may not in itself be an indication of even moderate suffering.

Where an established body condition scoring system is in place, a combination of weight measurement with body condition of the animal provides a more robust measure of likely suffering than weight alone. For example, a sheep that has dropped 15 per cent of its body weight and has reduced its condition score from 3 in 5 to 1.5 in 5 over a period of days, using the standard agricultural scoring system, is likely to be associated with at least moderate suffering, whilst a similar weight loss with a drop in body condition from 5 to 4 is not.

4.b Restraint

Restraint, including holding animals in spaces less than the Code of Practice minima, usually requires project licence authorisation. This may be found to cause sub-threshold, mild, moderate or even severe distress depending on such factors as the nature of restraint, the individual animal, the success of training and habituation. In determining actual severity the impact on the animal, not solely the duration of the restraint, should be considered.

Short-term physical restraint (no more than a few hours) or close confinement (less than one working day) in well habituated animals (where the habituation itself is non-stressful) will generally be classed as mild, although it is possible that when animals have reasonable freedom of movement and show evidence of complete lack of distress this may be considered sub-threshold. In contrast, the same level of restraint where training and habituation has been stressful could be moderate, or even severe.

4.c Surgery

Minor surgical procedures without complications might on some occasions be considered mild, such as a single insertion of subcutaneous minipump with analgesia, very rapid recovery and no apparent after-effects. The relative size of the pump to the animal is likely to affect recovery rate and so it is likely that actual severity for insertion of a similar minipump will be different for a sheep and a mouse, for example. Replacement of minipumps is generally too traumatic to be considered of mild severity. Major surgical procedures, such as those entering a body cavity, cannot be classified as mild.

Most surgical procedures performed aseptically with good post-operative care, including effective analgesia throughout the recovery period, judged effective using appropriate monitoring for the species and procedure, and where animals have returned essentially to normal within three to four days, will be classed as moderate.

A major surgical procedure carried out without post-operative analgesia will invariably be classed as severe. This situation is expected to be rare and based on specific scientific justification. Ongoing significant pain, distress or impairment to the animal's health as a result of surgery is likely to be severe. Similarly, any situation where animals appear to show signs of significant or more than brief moderate pain following surgery despite analgesia should be classified as severe.

4.d Systemic disease

Systemic disease models such as challenge with an inflammatory agent, infection or neoplasia, where these do not materially impact on the animal, or which cause only minor short-term clinical signs, may be considered mild where appropriate endpoints are instigated.

Short- to medium-term systemic illness should be classified as moderate if clinical signs are more than minor and short-term, but animals remain able to move, engage in species-appropriate behaviour (such as nest-building in rodents) and feed and

drink unaided even if there are appropriate supportive measures, for example, wet food on the floor of cage for rodents, provision of cut grass to ruminants.

Any systemic disease where animals are found moribund will be classed as severe.

4.e Seizures

Focal periodic seizures, or generalised seizures where the animal becomes rapidly unconscious and then does not recover consciousness at any point before death may be considered moderate or even mild. Short-term periodic generalised seizures may be considered moderate if animals recover with post-ictal signs being only minor and short-lived and appear normal between episodes.

Longer generalised seizures (in excess of one hour) with recovery will generally be considered severe.

4.f Paralysis

Paralysis is generally considered severe, but may be considered of moderate severity including the following scenarios.

- Partial paralysis not preventing movement around the enclosure or other normal activities and where animal has the ability to feed itself when food is given from food hoppers or by other normal presentation.
- Very short-term (less than 24 hours) total paralysis of hindlimbs only in small rodents, and animals still able to move around the cage.

Paralysis or hemiparesis in larger species, where the impact is likely to be significantly higher for the individual, would generally be classed as severe.

Conditions leading to limb paralysis (of more than one day duration in rats and mice), or any quadriplegia/paresis for any period and paralysis of any duration when coupled with signs such as marked weight loss or changes in behaviour such as aggression to cage/pen mates is likely to be severe.

4.g Procedures involving species or stages of development that are considered less sentient than adult mammals

It may be possible to assign a lower severity category for some species and stages of development when a higher severity would have been considered in other species/stages (Mellor *et al*., 2010). For example, neonatal (less than five days old)

rats or mice are known to have neuroanatomical development that is highly suggestive that pain and distress and/or ‘awareness’ pathways have not yet developed. In these cases, it may be justified to assign a mild severity to a procedure that in an adult mammal would have been assigned moderate or severe.

Consideration of the evidence of likely levels of consciousness for the species should be used in making the assessment of actual severity. For example, there is evidence that mammalian offspring do not have any conscious perception whilst *in utero* (Mellor *et al.,* 2005). Unhatched poultry chicks appear to become more responsive to environmental stimuli 24 to 48 hours prior to hatching (Deeming, 2011). Careful consideration as to the actual severity experienced by these animals in procedures that cause death should be given, reflecting current literature evidence in case this develops to support a greater level of suffering than for chicks that die earlier in incubation. Unhatched chicks are presently (as at January 2014) assumed to be unconscious (Mellor and Diesch, 2007). If an animal is never conscious to experience a harm, it would seem reasonable to assess its actual suffering as sub-threshold.

Condition 10 of the project licence requires that an actual severity is assigned to all protected animals undergoing regulated procedures. Mammals become protected under the Animals (Scientific Procedures) Act 1986 (ASPA) in the last third of gestation and birds and reptiles in the last third of incubation. Therefore a severity assessment must be performed for such animals and the records maintained by the project licence holder. However, where these animals die or are euthanased before birth/hatching there is no requirement to complete a Return of Procedures for them. These cases should be discussed with the local Home Office Inspector.

4.h Assessment of actual severity of animals released to the wild

Where animals are released to the wild during the course of or at the end of a (series of) procedure(s), the assessment of actual severity will be based on the experience of the animal whilst it is captured or under direct observation, as well as an informed decision of what its experience may be if the regulated procedure continues after release back to the wild. This informed decision will include consideration of the likely adverse effects of the procedure.

Where animals are recaptured, and there is evidence of procedure-related harm that has occurred between capture points, for example, injury from tracking equipment, then an informed decision on the suffering caused should be made based on the available evidence and included in the assessment of actual severity.

Where the animal is released to the wild during the course of the regulated procedure but is never recaptured, the end of the procedure should be determined either as the time when efforts to recapture the animal cease or the project licence under which it was used expires, whichever is the earlier. The actual severity classification should be assigned at this time.

4.i Non-Schedule 1 methods of killing

The majority of methods of killing authorised through project licences are likely, if performed competently, to cause no more than mild suffering. Consideration should be given to the form of restraint in terms of the possible distress caused.

5.Examples

5.a Simple generic example

Protocol involves giving an altered diet and a series of intraperitoneal injections of a drug not expected to be harmful. The protocol carries a mild severity limit, reflecting the expected harms; no more than the transient pain caused by the intraperitoneal injection.

Some animals do not receive any intraperitoneal injections and the dietary change had no effect. This would be classified as sub-threshold.

Most animals received intraperitoneal injections but showed no adverse effects other than transient pain at the moment of injection. This would be classified as mild.

Some animals became noticeably unwell for two to three days after some of the injections but recovered fully. This would be classified as moderate.

Some animals showed increasing pain and discomfort with each intraperitoneal injection and became withdrawn for several hours after the later injections, indicating a cumulative effect of serial injections. This would be classified as moderate.

One animal developed peritonitis and became severely ill requiring euthanasia. This would be classified as severe.

One animal was found dead. It appeared to be fine the previous day but had not been observed since. This would be classified as severe.

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