LEZING OVER HET DIERENWELZIJN IN HET BRUSSELS HOOFDSTEDELIJK GEWEST

EXPOSÉ CONCERNANT LE BIEN-ÊTRE ANIMAL DANS LA RÉGION DE BRUXELLES-CAPITALE

DEPARTEMENT DIERENWELZIJN

AFDELING INSPECTIE EN VERONTREINIGDE BODEMS

bruxelles environnement leefmilieu brussel .brussels

BIEN-ÊTRE ANIMAL DIERENWELZIJN

WELKOM

BIENVENUE

Véronique Goldsztajn

HOOFD DEPARTEMENT DIERENWELZIJN
AFDELING INSPECTIE EN VERONTREINIGDE BODEMS

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JAARLIJKSE STATISTIEKEN IN VERBAND MET HET GEBRUIK VAN PROEFDIEREN

Programma:

09u30 – Onthaal met koffie

10u00 – Verwelkoming van de deelnemers door Véronique Goldsztajn, Departementshoofd van het Departement Dierenwelzijn (afdeling Inspectie & verontreinigde bodems) van Leefmilieu Brussel

10u10 – Lezing betreffende de jaarlijkse statistieken in verband met het gebruik van proefdieren, door Susanna Louhimies, (*Policy Co-ordinator, Unit B.2 Sustainable chemicals, Directorate-General for the Environment, European Commission*)

11u00 – Vragenronde met het publiek

11u30 – Afsluitend woord door Véronique Goldsztajn, Departementshoofd van het Departement Dierenwelzijn (afdeling Inspectie & verontreinigde bodems) van Leefmilieu Brussel

COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE

3R 3V

BRUSSELSE COMMISSIE VOOR DIERPROEVEN

Brusselse Commissie voor dierproeven

Commission bruxelloise de l'expérimentation animale

Roels Stefan DVM PhD, Voorzitter / Président

comexpan_comdierpr@environnement.brussels

COMPOSITION DE LA COMMISSION

(MANDAT DE 4 ANS : 2018-2022)

Compétences des membres:

Bien-être animal, comportement animal, expertise spécifique à une espèce, expertise sur le plan vétérinaire, éthique, sciences, méthodes alternatives, conception de projets, législation, y compris l'évaluation de la réglementation/sécurité et la protection des animaux

- **Membres liés à des utilisateurs sur le territoire bruxellois (N=5)**

  Représentation de chaque institution de la 'Région Bruxelloise concernée par des expérimentations animales (VUB, ULB, UCL, SCIENSANO)

- **Membres non liés à des utilisateurs sur le territoire bruxellois (N=5)**

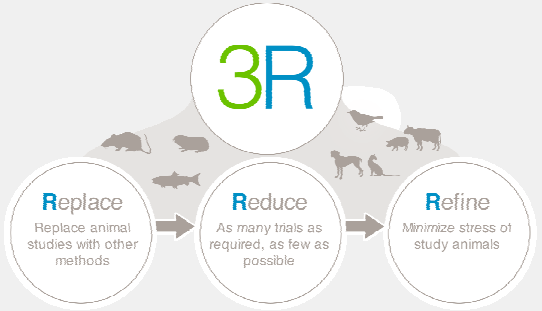
- **Membre représentant Bruxelles Environnement (N=1)**

- **Membres proposés par le Conseil bruxellois du bien-être animal (N=2)**

COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE
3R 3V
BRUSSELSE COMMISSIE VOOR DIERPROEVEN

LA COMMISSION EN PRATIQUE

- **Conseiller** les autorités compétentes et les structures chargées du bien-être des animaux
- **Rédaction/distribution** de documents des meilleures pratiques:
  - 3Rs
  - Estimation du degré de gravité
  - Analyse coûts– bénéfice
  - Points limites (« Humane endpoints)
  - Statistiques



- **Standardisation** de l'évaluation des projets
- **Standardisation** du fonctionnement des cellules chargées du bien-être animal
- Distribution d'une « **newsletter** » aux Commissions éthiques
- Mise en place de **programmes de formation** pour les employeurs impliqués dans l'expérimentation animale
- **Révision** des **demandes d'agrément** (éleveurs, fournisseurs, utilisateurs)
- Révision des **retraits** des agréments
- Révision des demandes de **dérogation**

Ceci en collaboration et en concordance avec les autres régions et les autres états-membres

COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE
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TOPIQUES ACTUELS DE LA COMMISSION

Standardisation des protocoles:

- **Guidelines** pour le rapportage des statistiques annuelles
- Evaluation des demandes d'agréments/de dérogations (**plateforme** en ligne)
- Rédaction d'un **règlement d'ordre intérieur**
- Document concernant les **conflits d'intérêts**

Avis:

- Concernant la **note de principe** sur la diminution des animaux d'expérience dans la région bruxelloise
  - https://leefmilieu.brussels/sites/default/files/20180228_adviesprincipenota_nl_finaal.pdf
  - https://environnement.brussels/sites/default/files/20180228_avisnoteprincipe_fr_final.pdf

COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE
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BRUSSELSE COMMISSIE VOOR DIERPROEVEN

TOPIQUES ACTUELS DE LA COMMISSION

Participation à des réunions européennes

- Participation à un nouveau **groupe de travail** composé de collègues de différents **comités nationaux** souhaitant échanger leurs expériences, avis / conseils, documents d'orientation et codes de pratiques (12.04.2018)
- **2ième réunion** des comités nationaux concernant la directive 2010/63 / UE à Bruxelles (15-16.11.18): **réunion préparatoire** (31.10.18) avec les trois régions

COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE
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COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE

Plus d'informations sur le site internet de BE:

https://environnement.brussels/thematiques/bien-etre-animal/lexperimentation-animale-une-pratique-tres-encadree/commission

https://leefmilieu.brussels/themas/dierenwelzijn/dierproeven-een-strikt-omlijnde-praktijk/brusselse-commissie-voor-dierproeven

COMMISSION BRUXELLOISE DE L'EXPÉRIMENTATION ANIMALE
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BRUSSELSE COMMISSIE VOOR DIERPROEVEN

Directive 2010/63/EU

Transparency and statistical reporting

Brussels, Belgium
20 November, 2018

Susanna Louhimies
DG Environment, European Commission

Transparency and statistical reporting

- *Transparency and legislation*
- *Key principles and terms*
- *Reporting severity*
- *Other shortfalls to watch out*
- *Q&A*

Why transparency?

- *Compliance and accountability*
- *Societal acceptance through demonstration of adherence to societal values*
- *Trust building*
- *Provide factual data as basis for policies and decision making*
- *Combat "fake news"*

Transparency through the Directive

- *Publication of **non-technical project summaries***
- *Improved **reporting**:*
  - *revised **statistical** reporting and*
  - *5-year **implementation** reports*

Statistical reporting

- *Article 54(2) of the Directive – legal obligation*
- *Annex II of Commission Implementing Decision 2012/707/EU*

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012D0707-20140115

  - *Part A : detailed data categories*
  - *Part B : instructions*

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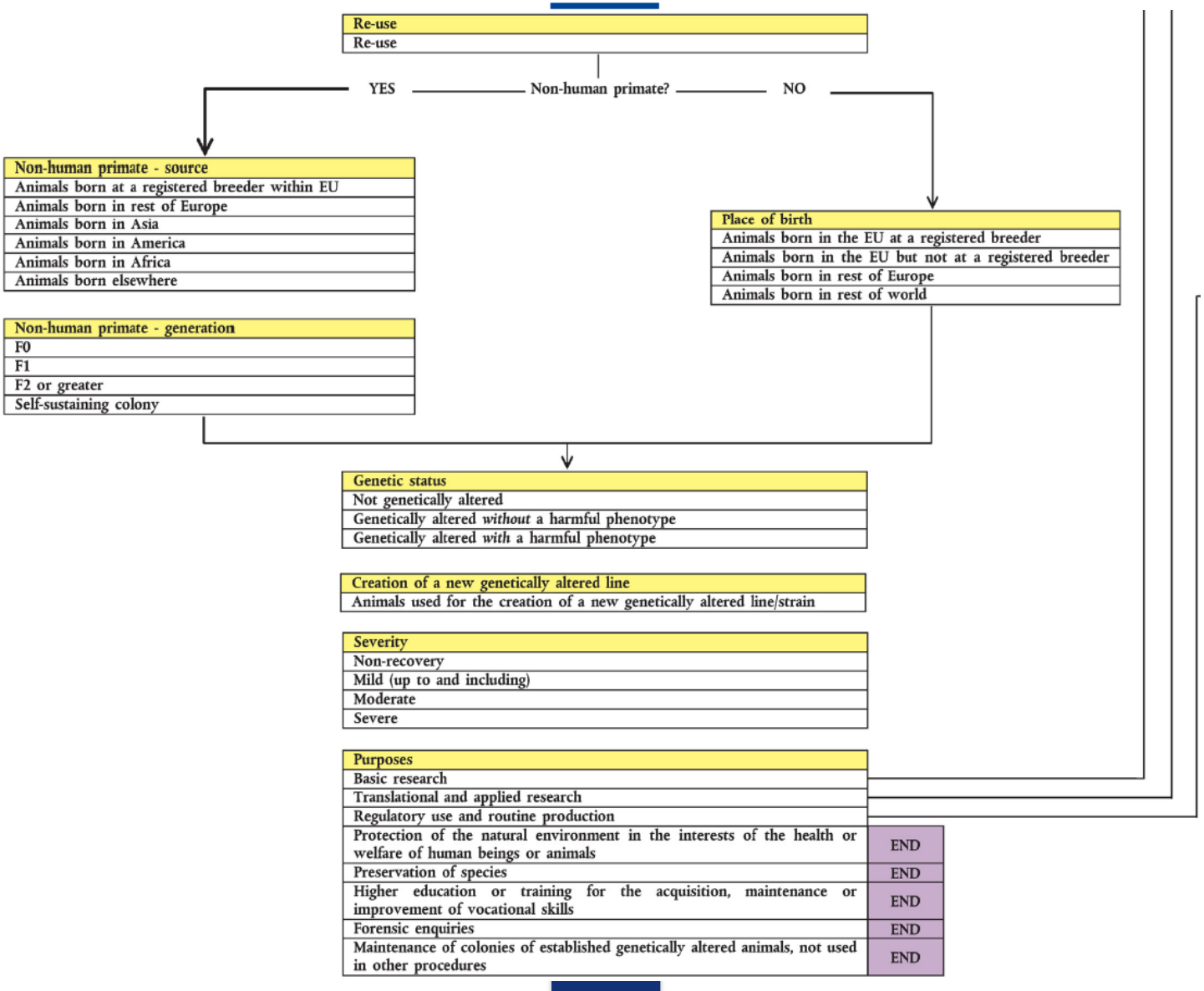


European Commission

Basic research studies
Oncology
Cardiovascular Blood and Lymphatic System
Nervous System
Respiratory System
Gastrointestinal System including Liver
Musculoskeletal System
Immune System
Urogenital/Reproductive System
Sensory Organs (skin, eyes and ears)
Endocrine System/Metabolism
Multisystemic
Ethology / Animal Behaviour / Animal Biology
Other
END

Translational and applied research
Human Cancer
Human Infectious Disorders
Human Cardiovascular Disorders
Human Nervous and Mental Disorders
Human Respiratory Disorders
Human Gastrointestinal Disorders including Liver
Human Musculoskeletal Disorders
Human Immune Disorders
Human Urogenital/Reproductive Disorders
Human Sensory Organ Disorders (skin, eyes and ears)
Human Endocrine/Metabolism Disorders
Other Human Disorders
Animal Diseases and Disorders
Animal Welfare
Diagnosis of diseases
Plant diseases
Non-regulatory toxicology and ecotoxicology
END

Quality control (incl batch safety and potency testing)
Batch safety testing
Pyrogenicity testing
Batch potency testing
Other quality controls

Toxicity and other safety testing by test type
Acute (single dose) toxicity testing methods (including limit test)
Skin irritation/corrosion
Skin sensitisation
Eye irritation/corrosion
Repeated dose toxicity
Carcinogenicity
Genotoxicity
Reproductive toxicity
Developmental toxicity
Neurotoxicity
Kinetics (pharmacokinetics, toxicokinetics, residue depletion)
Pharmaco-dynamics (including safety pharmacology)
Phototoxicity
Ecotoxicity
Safety testing in food and feed area
Target animal safety
Other

Ecotoxicity
Acute toxicity
Chronic toxicity
Reproductive toxicity
Endocrine activity
Bioaccumulation
Other

Regulatory use and routine production by type
Quality control (incl batch safety and potency testing)
Other efficacy and tolerance testing
Toxicity and other safety testing including pharmacology
Routine production

Repeated dose toxicity
< and 28 days
29-90 days
> 90 days

Testing by legislation
Legislation on medicinal products for human use
Legislation on medicinal products for veterinary use and their residues
Medical devices legislation
Industrial chemical legislation
Plant protection product legislation
Biocides legislation
Food legislation including food contact material
Feed legislation including legislation for the safety of target animals, workers and environment
Cosmetics legislation
Other

Acute and sub-acute toxicity testing methods
LD50, LC50
Other lethal methods
Non lethal methods

Legislative requirements
Legislation satisfying EU requirements
Legislation satisfying national requirements only (within EU)
Legislation satisfying Non-EU requirements only

END

Use of animals for regulated production by product type
Blood based products
Monoclonal antibodies
Other

European Commission

PART B

DETAILED INSTRUCTIONS FOR THE PROVISION OF STATISTICAL DATA ON THE USE OF ANIMALS FOR SCIENTIFIC PURPOSES UNDER ARTICLE 54(2)

REPORTING FORMAT FOR THE SUBMISSION OF THE INFORMATION REFERRED TO IN ARTICLE 54(2) OF DIRECTIVE 2010/63/EU

1. The data should be entered on each use of an animal.

2. When entering data for an animal, only one option *within* a category can be selected.

3. Animals killed for organs and tissues, as well as sentinels, are excluded from the provision of statistical data, unless the killing is performed under a project authorisation using a method not included in Annex IV or where the animal has gone through a previous intervention, prior to being killed, and which has been above the threshold of minimum pain, suffering, distress and lasting harm.

Transparency and statistical reporting

- *Transparency and legislation*
- *Key principles and terms*
- *Reporting severity*
- *Other shortfalls to watch out*
- *Q&A*

What is a procedure?

3(1) 'procedure' means any use, **invasive** or **non-invasive**, of an animal for experimental or other scientific purposes, with **known** or **unknown** outcome, or educational purposes, which **may cause** the animal a level of pain, **suffering**, **distress** or **lasting harm** equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice**.**

When to report, by whom?

- ***At the end*** *of the procedure*
- *2-step/multi-step procedure –* ***at the end*** *of* ***all steps*** *by the* ***last 'user'***
- *Only* ***<u>one</u> person*** *reports one use*

Re-use vs continued use

- *Re-use: when another, naïve, animal could have been used instead of that animal*
- *Continued use: when only that animal can be used and cannot be replaced by another, naïve, animal*
  - *Surgical preparation*
  - *Genotyped to confirm a specific genetic strain before use*
  - *Earlier study (e.g., early feeding study as pre-requisite to adult feeding study)*

2-step procedures

Example A:

- *Genetically altered animal genotyped at breeder (= step 1)*
- *Animal subsequently used at User B (=step 2)*

Example B:

- *Animal prepared by installation of a telemetric device at establishment A (= step 1)*
- *Animal subsequently used at User B (=step 2)*

2-step procedures

- *User B reports the animal in both cases at the end of the procedure, and takes into account cumulative severity including from step 1*

  N.B. Important that information of the severity of first step is provided with the animal

- *If animal is killed as surplus at breeder/ establishment A, then they must report that animal with the related actual severity of step 1*

Prospective versus actual

Prospective
Non-technical project summaries
▪ *Maximum numbers likely to be used*
▪ ***All animals** in a procedure 'classified'…*
▪ *…according to **worst case scenario** that an individual animal in that group may attain*

Prospective versus actual

Prospective	Actual
Non-technical project summaries	***Statistical reporting***
▪ *Maximum numbers likely to be used*	▪ *Actual, used numbers of animals*
▪ ***All animals** in a procedure 'classified'…*	▪ ***Real numbers** of animals…*
▪ *…according to **worst case scenario** that an individual animal in that group may attain*	▪ *… reported according to **actual level of suffering** as experienced **by each animal***

Prospective versus actual impacts numbers & severities

Prospective
➢ ***Non-technical project summaries***
▪ *E.g.* ***300*** *animals*
▪ *300 animals in a '**severe**' procedure*

Prospective versus actual impacts numbers & severities

Prospective	Actual
➢ ***Non-technical project summaries***	➢ ***Statistical reporting***
▪ *E.g.* ***300*** *animals*	▪ ***280*** *animals used*
▪ *300 animals in a '**severe**' procedure*	▪ *15 animals as '**severe**'* ▪ *243 animals as '**moderate**'* ▪ *22 animals as '**mild and up to mild**'* *[= **three entries** in the stats]*

Terminology used for purposes

- ***Regulatory use and routine production***
- ***Education and training***
  - *Acquiring knowledge*
  - *Obtaining manual skills*

Terminology used for severities

- ***Mild*** *(and up to, including animals that did not experience any harms)*
- ***Moderate***
- ***Severe***

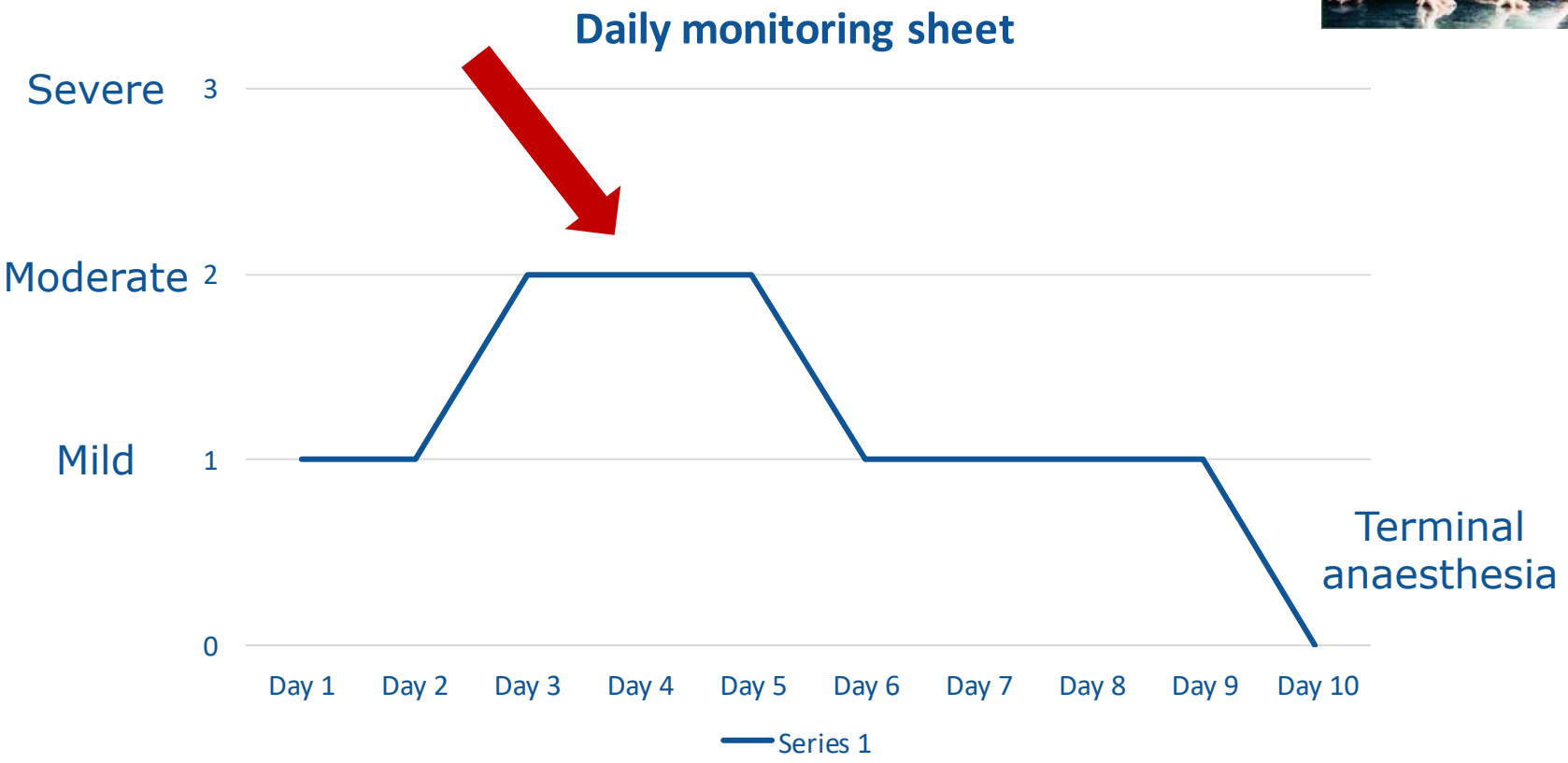
- ***Non-recovery*** *= nothing is done to a conscious animal. All interventions on an unconscious animal under a general anesthesia, and the animal is killed without gaining consciousness*

Transparency and statistical reporting

- *Transparency and legislation*
- *Key principles and terms*
- *Reporting severity*
- *Other shortfalls to watch out*
- *Q&A*

Determining actual, reported severity

- *Agree procedure specific, tailor made **daily scoring sheets***
- *Agree and **communicate** how to monitor with all staff involved*
- *Agree points of **intervention** and **humane end-points***
- *Determine actual severity **at the end**, on the basis of **highest reached** severity*
  - *For **each animal** individually*


Daily monitoring sheet
Severe
3
Moderate
2
Mild
1
0
Terminal anaesthesia
Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7
Day 8
Day 9
Day 10
Series 1

Severity of Death

How to report "death"?

- ***Procedure vs non-procedure related***
- ***Informed vs non-informed decision***

If found dead, class as 'severe' **unless** information/evidence indicates otherwise

Severity of Death (unrelated)

Is the death unrelated to the procedure the animal was under-going?

For example:

- *Equipment failure (e.g. heating/ventilation)*
- *Inappropriate husbandry or care practices (e.g. inappropriately balanced/contaminated diet)*
- *Aggression between animals*
- *Unrelated disease and infections*

Severity of Death (unrelated)

The death is <u>unrelated</u> to <u>the procedure</u> the animal was under-going:

- *The actual severity for the animal **should reflect the <u>highest level</u> of severity <u>experienced</u>** during the **course of the procedure** by the animal - **<u>excluding</u>** the level of severity related to the death*

Severity of Death (un/related)

***Ageing animals**: deaths in animals on long-term studies should be evaluated to clearly differentiate deaths*

- *as a **consequence of the natural ageing process** from those (=unrelated)*
- *as a **result of the procedure** (=related)*

Severity of Death (related)

Death is related to the procedure the animal was under-going:

Can an informed decision be made about the events leading to the death?

Yes, for example:

- *Failing to recover consciousness in post-operative period, but under appropriate analgesic regime;*
- *No clinical abnormalities recorded, nor anticipated, but found dead a few hours after a clinical examination*

Severity of Death (related)

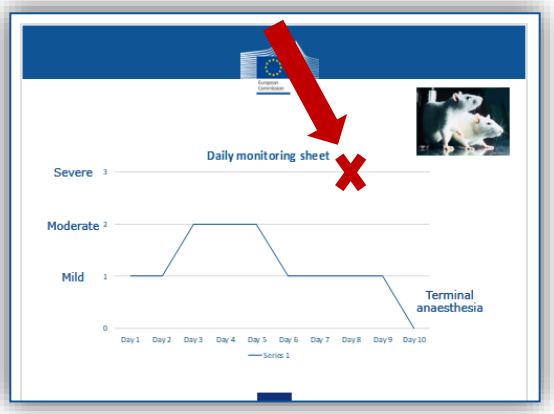
Death is related to the procedure and an informed decision can be made about the events leading to the death:

- *The recorded severity of death should reflect the severity as the result of the assumed events leading to death*
- *The highest reached severity should be reported (death or otherwise)*

Severity of Death (related)

The death is <u>related</u> to <u>the procedure</u> but <u>no informed decision</u> can be made about the events leading to death:

- *The actual severity should be reported as "**severe**"*



Capture in the wild

- ***Actual severity*** *reported should* ***only*** *relate to the effects of the scientific "**procedure**" carried out on that animal*
- ***Capture and transport*** *(unless these are the specific, or a component of the, objective of the scientific procedure) should therefore* ***not be taken into account*** *in reporting of the actual severity.*

Common problems identified during Severity Workshops

- *Unrelated health/welfare issues included in actual severity assessment*
- *Severity of death not consistently reported*
- *Cumulative effects not taken into account*
- *Severity of last event reported **instead of highest**, including when final event is terminal anaesthesia*
- ***Misunderstanding** what is **non-recovery***

Common problems identified during Severity Workshops

- *Classification done by scientist in isolation – no consideration of records*
- *Done at year end, instead of continuously at the end of procedures*
- *Poor/no involvement of veterinary/technical staff*
- *No drive within establishment for consistent approach – AWB involvement*

More on Severity Assessment

Available in all EU languages

http://ec.europa.eu/animals-in-science

Transparency and statistical reporting

- *Transparency and legislation*
- *Key principles and terms*
- *Reporting severity*
- *Other shortfalls to watch out*
- *Q&A*

Reporting “other” categories

- *Need to be **sufficiently detailed** to be interpretable and useful*
- *Can**not be too detailed** to be digestable – both for users and audience*
- *Striking the balance with:*
  - **“Other species”**
  - **“Other purposes”**
  - **“Other legislation”**

Reporting “other” categories

Please provide meaningful information!

Reporting "other" categories

Species:

- Other rodents
- Other carnivores
- Other OW/NW NHP
- Other mammals
- Other birds
- Other amphibians
- Other fish

Purposes:

- Other basic research
- Other human disorders
- Other quality controls
- Other toxicity/safety testing
- Other ecotoxicity
- Other products

- Other legislation

Reporting "specify other" - free text fields !

Other Mammals	llama glama / vicugna pacos	53
Other Mammals	lama glama / alpaga	43
Other Mammals	llama glama	33
Other Mammals	lama glama	11

Other Fish	oncorhynchus mykiss	1,888
Other Fish	nothobranchius furzeri	1,871
Other Fish	cyprinus carpio carpio	1,814
Other Fish	dicentrarchus labrax	1,370
Other Fish	cyprinus carpio	654
Other Fish	scortum barcoo	648
Other Fish	oncorhynchuys mykiss	630

Importance of correct spelling

Reporting "specify other" - species

Issues identified:

- *Multiple species in one entry*
- *"wild fish" not helpful*
- *Multiple variations for the name of the species*

Recommendations:

- ***One species** per entry*
- *Use **latin names***
- *Specify if **early stages** e.g. larval forms (for fish, amphibian) or foetal forms*

Other species : fish

Fish	2015	%	2016	%
Total	1 500 000	100 %	1 600 000	100%
Zebra fish	560 000	37%	740 000	47%
Other fish	940 000	63%	860 000	53%

Reporting under 'other':

Scientific name	English name	Entries 2015	Entries 2016
dicentrarchus labrax	european bass (300 000 larval form?)	363 567	208 000
oncorhynchus mykiss	rainbow trout	91 021	107 086
salmo trutta	brown trout	56 390	35 586

Reporting "specify other" - purposes

Issues identified:

- *One of the pre-fixed purposes should have been used*
- *Instead of purpose, identifying techniques*

Recommendations:

- *Think for which **purpose** the procedure was carried out!*

Reporting "specify other" - purposes

Basic Research -> Other

production d'anticorps polyclonaux

Remarks

Animals used for the production and maintenance of infectious agents, vectors and neoplasms, animals used for other biological material and animals used for the production of polyclonal antibodies for the purposes of translational/applied research, but excluding production of monoclonal antibodies by ascites method (which is covered under category 'Regulatory use and routine production by type') should be reported in the respective fields of categories 'Basic research studies' or 'Translational and applied research'. The purpose of studies needs to be carefully established, because any listings under the two categories could apply and only the main purpose shall be reported.

Reporting "specify other" - purposes

Basic Research -> Other	production d'anticorps polyclonaux
Basic Research -> Other	essais zootechniques et de digestion
Basic Research -> Other	onderzoek naar zika virus, enterovirus, encephalitis, malaria, norovirus, yellow fever virus en usutu virus
Basic Research -> Other	stimulatie van het immuunsysteem
Basic Research -> Other	zootechnie (sélection)
Basic Research -> Other	onderzoek naar malaria en chikungunya virus
Basic Research -> Other	eischaalkwaliteit einde leg o[illegible]haliseren
Basic Research -> Other	nutrition animale
Basic Research -> Other	ondezoek naar malaria
Basic Research -> Other	différenciation cellulaire
Basic Research -> Other	materiel biologique

For which **purpose** was the procedure carried out?

Other purposes : other routine production

Reg & Routine Prod	2015	%	2016	%
Blood-based products	270 000	59%	250 000	56 %
Monoclonal antibodies	34 000	7%	50 000	11%
Other	150 000	34%	150 000	33 %

Reporting under 'other purpose':

Other purpose	Nr of uses 2015	Nr of uses 2016
antigen production	91,576	89,214

Reporting "specify other" - legislation

Issues identified:

- *No legislation given*
- *Origin instead of the type of legislation*
- *No number/identifier given*

Recommendations:

- ➢ *Precise the legislation e.g. wastewater legislation*
- ➢ *Provide the number of the legislation*

Reporting "specify other" - legislation

Other legislation	oecd203 (1992) en iso 7346-1 (1996). bepaling van de toxiteit in afvalwaters.
Other legislation	anticorps destinés à des test invitro

Finally, the unexpected can happen!

For example, an animal is being re-used, but gets an infection, which is subsequently treated

- *Re-use not authorised for 'severe' procedures*
- *Actual severity, however, reported as 'severe'*

➢ ***Use the reporting as a your communication tool!***

The unexpected can happen!

Animal Use Details Form

< Previous | Current 4 | Go! | Next >

Row Content

EU Submission *: [Y] Yes

Id 1: | Id 2:

Id 3:

Animal Species *: [A8] Rabbits (Oryct… uniculus)

Specify other: | Number of Animals *: 1

Re-use *: [Y] Yes | Place of birth (origin):

NHP Source (origin): | NHP Generation:

Genetic status *: [GS1] Not genetically altered | Creation of new GL *: [N] No

Purpose *: [PB11] (Basic Research) Multisystemic | Browse

Specify other:

Testing by legislation:

Specify other:

Legislative Requirements (origin of the legislation) :

Severity *: [SV4] Severe | Custom Severity:

Comment 1/Explanation of warnings: | Comments 2: Animal got an infection following an intramuscular injection and temporarily reached severity level 'severe' during 3 hrs before medication took effect.

Save | Save & Duplicate | Cancel

Provide clear and accurate explanation to help answering questions from the public and press!

Entries of concern to public

- *Severe with Re-use*
- *Severe with Education and training*
- *Severe with Re-use and Education and training*

- *Skin and/or eye irritation/corrosion tests*
- *Pyrogenicity testing*
- *Production of monoclonal antibodies (=ascites method)*

ALTERNATIVES EXIST!

Likely errors in entries

Should be checked for correctness:

- *Non-recovery with regulatory toxicity*
- *Non-recovery with batch (safety/potency) tests*
- *Non-recovery with maintenance of GA lines*

Errors in entries

- *Legislative type with non-regulatory use*
- *Legislative origin with non-regulatory use*

Conclusions

- *Quality has improved from the first years*
- *Revisit and use*
  - **information in Annex II of Commission Implementing Decision 2012/707/EU**
  - **other provided guidance**
- *Focus on parts relevant to your work*
- *Use given categories; otherwise be meaningful*
- *Ask if any questions!*

European Commission

Statistics are fun!

Transparency and statistical reporting

- *Transparency and legislation*
- *Key principles and terms*
- *Reporting severity*
- *Other shortfalls to watch out*
- *Q&A*

Q&A

"Non-recovery"

- ***In general, non-recovery procedures are always planned****. I.e. animal is put under a general anaesthesia without any prior interventions, and killed without gaining consciousness*

- *An exemption to the rule is a procedure in which animal* ***accidentally dies under a general anaesthesia, provided no prior intervention has taken place****. This should also be recorded as non-recovery*

Q&A

*A genetically altered animal of a **harmful phenotype** is killed at the breeder's. Do I record this animal in the annual statistics?*

- *Only if it has **suffered from the harmful phenotype** before being killed*

N.B. Please note that genotyping is discussed separately in the next slides.

Q&A

When do I need to report genotyping?

- ***Genotyping*** *(tissue sampling/genetic characterisation)* ***is reported*** *when* ***an invasive genotyping method*** *such as toe/tail tipping is used [= w/in the definition of a procedure]* ***unless*** *the tissue is* ***obtained as a by-product from identification*** *e.g. ear clipping*

- *If tissue is obtained* ***as a by-product****, genotyping is not reported in annual statistics*
- *If* ***non-invasive*** *method is used e.g. hair sampling – then not reported*

Q&A

Who reports genotyping?

a) *If the animal **is used in a subsequent procedure for which that genotype is necessary**, information that the animal has been genotyped and its related actual severity must be provided with the animal*

*The reporting is done **only by the user** at the **end of the procedure**. The actual **severity must reflect the highest reached** (taking into consideration also the severity related to the genotyping)*

Q&A

Who reports genotyping? […continued]

*b) If the animal is **not used in a subsequent procedure**, the animal is reported **by the establishment** where the animal is killed, **with the actual severity** related to the genotyping*

Q&A

- *"**Maintenance** of colonies of **genetically altered** animals, **not used in other procedures**" contains three types of entries:*

1. Animals (both from **harmful** or **non-harmful** lines) that have been **genotyped** using **invasive methods** (which is not a by-product of marking e.g., ear notching), **and** which have been **killed without being used** in any subsequent procedure	2. Animals that are of **harmful phenotype**, and which have **expressed** (suffered adverse effects from) **the harmful phenotype** before being killed.

3. Combination of the above.
The actual severity must reflect the highest of the two.

Q&A

How do I report procedures which studies multiple organs?

- *Basic research "Multisystemic" - should only include research where **more than one system** is the **primary interest**, such as on some infectious diseases (excluding oncology)*

  *Otherwise, the reporting should be done under the **main target organ***

Q&A

In reference to basic, translational and applied research, instructions in Part B of Annex II state that

- *"The purpose of studies needs to be carefully established, because any listings under the two categories could apply and* ***only the main purpose shall be reported****"*

Thank you for your attention!

More information at:

http://ec.europa.eu/animals-in-science

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