Norwegian Food Safety Authority

Update on the EU directive and Council of Europe Convention

23. September 2009

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Mattilsynet

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Bente Bergersen The Norwegian Food Safety Authority Department of Legislation Section for Animal Welfare and Fish Health EUROPEAN CONVENTION FOR THE PROTECTION OF VERTEBRATE ANIMALS USED FOR EXPERIMENTAL AND OTHER SCIENTIFIC PURPOSES

Opening of the treaty: 18th March 1986 Entry into force 1st January 1991

Preamble: Recognising that man has a moral obligation to respect all animals and to have due consideration for their capacity for suffering and memory;



Accepting nevertheless that man in his quest for knowledge, health and safety has a need to use animals where there is a reasonable expectation that the result will be to extend knowledge or be to the overall benefit of man or animal, just as he uses them for food, clothing and as beasts of burden;



Declaration of intent 4th December 1997

... despite their differences in arguments and approach ... as a way of establishing a common basis for a first step towards solutions to the problems met in this field. ... recalling that the two main objectives of the European Convention ... are first to guarantee as far as possible that animals are treated properly and humanely before, during and after a procedure

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Declaration of intent 4th December 1997

and second to reduce and, as soon as another scientifically satisfactory method is available,

to replace the use of animals -



agreed to improve the breeding, keeping and use of animals in accordance with the provisions of the Convention.



Convention

Ratified by 20 countries also by EU



Declaration of intent

signed by 16 countries but also by several organisations

Other signatories of declaration of intent:

- •Canadian Council on Animal Care (CCAC)
- •European Biomedical Research Association (EBRA)
- •European Federation of Pharmaceutical Industries and Associations (EFPIA)
- •EUROGROUP for Animal Welfare
- •Federation of European Laboratory Animal Science Associations (FELASA)
- International Council for Laboratory Animal Science

Resolution on education and training of persons working with laboratory animals adopted by the Multilateral Consultation on 3 December 1993

Qui sommes nous ?

Category A: Persons taking care of animals **Category B**: Persons carrying out procedures as defined in Article 1 paragraph **2.c of the Convention Category C**: Persons responsible for directing or designing procedures as defined in Article 1 paragraph 2.c of the Convention Category D: Laboratory animal science specialists referred to in Article 20 aragraph d





Training of persons taking care of animals:

- 1. Basic instruction in ethical and legal aspects of the care of laboratory animals.
- 2. Animal handling and husbandry
- 3. Recognition of health and disease
- 4. Recognition of pain, suffering and distress
- 5. Local practices relating to security,
- administration, transport, receipt of animals and supplies, disposal of animals.
- 6. Specific training if necessary for any tasks associated with assisting in procedures.

Article 4



No provision in this Convention shall affect the liberty of the Parties to adopt stricter measures for the protection of animals used in procedures or for the control and restriction of the use of animals in procedures.



Proposal for a Directive ... on the protection of animals used for scientific

purposes



Proposed by the Commission: DG Environment

Follows a <u>co-decision procedure</u> that is: neither institution (European Parliament or Council) may adopt legislation without the other's assent.

5 May 2009: <u>First reading</u> of the Parliament

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Now awaits Council common position

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Article 5



Any animal used or intended for use in a procedure shall be provided with accommodation, an environment, at least a minimum degree of freedon of movement, food, water and care, appropriate to its health and well-being

New directive proposal Art. 32

1. Member States shall, as far as the care and accommodation of animals is concerned, ensure the following: (a) all animals are provided with accommodation, an environment, <u>at</u> least some freedom of movement, food, water and care which are appropriate to their health and wellbeing;

Environment

Text adopted 5th May 2009 First reading

) all animals are provided with ccommodation, an nvironment, freedom of movement, food, water and care which are appropriate to their health and well-being and which allow them to satisfy their ethological as well as physical needs;

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Article 5

3 The well-being and state of health of animals shall be observed sufficiently closely and frequently to prevent pain or avoidab suffering, distre lasting harm.

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Proposal art. 32 paragraph 1 letter

(d) the well-being and state of health of animals are observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm;

(d) the well-being and state of health of animals are observed by a competent person at least once a day to prevent pain or avoidable suffering, distress or lasting harm;

Article 6





A procedure shall not be performed for any of the purposes referred to in Article 2, if another scientifically satisfactory method, not entailing the use of an animal, is reasonably and practicably available.



Note also Art.

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Where a method of testing, experimentation or other scientific activity not involving the use of living an mals exists which from a scientific point of view, is a satisfactory method or testing strategy for obtaining the result sought and which may be used in place of a procedure, Member States shall ensure that the alternative method is used, provided it is not prohibited in the Member State concerned. ...

However <u>Member States are obliged to:</u>

ensure that funding is provided for training and research

>ensure that 3R aim is used when considering authorisation of projects

>ensure that training is provided on 3R strategy

Proposal Art. 45a (new)

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The remit of the European Centre for the Validation of Alternative Methods shall be extended so that it includes the co-ordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by performing the following functions:



Opinion adopted 8th April 2009

The complete replacement of animal experiments while maintaining the same level of food and feed safety is not possible at present.

The status of the science can be summarised as follows:

Toxicokinetic studies: several *in vitro* methods have been developed, however they cannot at present replace *in vivo* methods.

. . . .

Conclusion (among other)



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2. Sometimes, legal requirements inhibit the implementation of the Three R's alternatives

Diarrhetic Shellfish Poisoning The EU still requires animal testing due to food safety Paralytic Shellfish Poisoning Chemical alternatives permitted.

Resolution on the interpretation of certain provisions and terms of the <u>Convention</u> adopted by the Multilateral Consultation on 27 November 1992

Qui sommes nous ?

A. For the purpose of Article 1:

(5) The Parties to the Convention consider the amount of pain, suffering or distress caused by the introduction of a needle into the body of an animal as illustrating the level at which the use of an animal becomes a "**procedure**". Some studies on the behaviour of animals may result in sufficient suffering or distress for the study to be c sidered as a procedure, even if it does not imply p al interference.



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Article 9

1 Where it is planned to subject an animal to a procedure in which it will or may experience severe pain which is likely to endure, that procedure **must be specifically** declared and justified to, or specifically authorised by, the responsible authority. 2 Appropriate legislative and/or administrative measures shall be taken to ensure that no such procedure is carried out

unnecessarily.

EUROPEAN PARLIAMENT Art. 15 (proposed

2. Member States shall ensure that th procedures classified as "severe" are scientifically justified, and ethical monitored if the pain, suffering or distress is likely to be more than transient . Such procedures must be exceptional and shall be subject to particular harm/benefit analysis and scrutiny by the competent authority.

Proposal by expert working group July 2009

Moderate:

...animals are likely to experience short term moderate pain, suffering or distress, or longlasting mild pain, suffering or distress.

... likely to cause moderate impairment of the wellbeing or general condition of the animals. **Severe:**

... animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress.

... likely to cause severe impairment of the wellbeing or general condition of the animals.

Appendix A

of the European Convention for the Protection of vertebrate Animals used for Experimental and other Scientific Purposes **Guidelines for Accommodation and** Care of Animals the Multilateral Consultation adopted on 15 June 2006 mes nous ?



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2.2 Water quality Water quality is the most important factor in maintaining the well-being of fish and in reducing stress and the risk of disease.



Water-quality parameters should at all times be within the acceptable range that sustains normal activity and physiology for a given species.

... requirements of individual species may vary between different life-stages e.g. larvae, juveniles, adults or according to physiological status for example metamorphosis, spawning, feeding, previous history of exposure.



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2.1. Water supply It is essential that an adequate water supply of suitable quality is provided at all times.



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Water flow in recirculatory systems or filtration within enclosures should be sufficient to remove suspended solids and wastes and to ensure that water quality parameters are maintained within acceptable levels.



Monitoring systems should be in place to ensure fish are provided with an appropriate quantity of water of appropriate quality. Water flow should also be appropriate to enable fish to swim correctly and to maintain normal behaviour.



3. Health 3.1. General ... The health of fish is intimately bound up with their environmental and husbandry conditions. Most diseases are associated with stress arising from deficiencies in these conditions and any attempt to control disease should address these areas if problems are to be successfully eradicated.

4.2. Enrichment



... may be necessary to take account of their behavioural traits, for example, in reproduction or predation. Examples ... include provision of hiding places for wrasse, or substrate such as sand for

some flatfish.



4.3.3. Open-water enclosures ... The enclosure dimensions, including depth, should permit active swimming and shoaling of the fish. Mesh size should permit good water exchange while preventing escape of fish. 4.3.3. Open-water enclosures (continued)

Enclosures should be designed to minimise the risk of attack by predators. Enclosures should be rigged so as to prevent their shape distorting in tidal flows or running water and thus trapping fish.