ADDENDUM TO NOTE

from: General Secretariat of the Council

to: Delegations

No. Cion prop.: 15546/08 + ADD 1 et ADD 2 - COM(2008) 543 final

Subject: Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes

Further to the meeting of the Working Party of Veterinary Experts (Animal Welfare) of 24 and 25 September 2009, delegations will find in the Annex a contribution from the Hungarian delegation.
Main comments of Hungary to the Presidency compromise text st12787

Introductory remark:
Hungary highly appreciates the tremendous work and efforts the Presidency is making with the goal to reach a Council draft of the Directive to be sent to EP AGRI Committee before the Christmas break. Not only the amount but also the pace of the work is particularly impressive. At the same time, Hungary would like to express its concern that with the recently accelerated turnover of newer and newer draft versions, the time left for reviewing the text, tracking and digesting the changes, and finally commenting them may become too short for providing a well-established and well-elaborated member state opinion (not to mention the necessary national consultations). Considering the complexity of our topic, the variance in the opinions of the delegates and the number of substantial amendments, we think, more time is needed, more than one expert group meeting would be required to solve the open questions and reach a more or less consensual Council draft. Hungary is presenting this time only its major comments on the text st12787.

Scope (2/2): HU proposes to include only Cephalopods as non-vertebrates, free-feeding (and not free-living) larval forms, and not to include embryonic forms of birds.

Member States right to adopt more stringent provisions (2/6):
As to the PRES call to specify the areas where it is deemed possible, HU proposes the following cases as examples:

MSs shall NOT have the right to adopt more stringent measures regarding
- the scope of the Directive,
- purposes of the procedures
- regulations on NHPs,
- accommodation and care conditions (Annex IV),
- education elements (Annex VI),
- classification criteria (Annex IX)
- re-use of animals.
MSs may adopt more stringent measures regarding
- whether authorisation is required for persons referred to in Art. 23A,
- simplified authorisation and tacit approval referred to in 41A,
- extending the task of the Animal Welfare Body (Art. 26)
- national inspections (Art. 33)
- extending the task of the National Ethics Committee (Art. 47)

Methods of killing (6): see our text amendments below and a modified Annex V as a separate appendix at the end of this document.

2. Competent authorities may, when authorising a project, grant exemptions from paragraph 1A:
   a. to allow the use of another method provided that on the basis of scientific evidence the method is considered to be at least as humane; or
   b. when, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of a method of killing set out in Annex V.

Use of non-human primates (8):

A debilitating clinical condition in the context of this Directive is defined as a reduction of a person’s normal physical or psychological ability to function. Such a condition can be caused by illness, injury, drugs or be congenital, and result in a temporary or life-long impairment.

Animals bred for use in procedures (10): HU maintains its former proposal (st12760-ad11.en09)

Choice of methods (13): specify live animals (“methods not entailing the use of live animals”)

Anaesthesia (14): HU maintains its former proposal (HUcomments_st12742.en09; 15/09/2009)

Severity classification of procedures (15 and Annex IX): HU maintains its former proposal (HUcomments_st12742.en09; 15/09/2009) and supports the advice of the Legal Service that examples in Annex IX should be moved to some community guidance documents
Requirements for personnel (23A and 24): Changes in this area sensitively affected Hungary. We were quite happy with the original COM version (Art. 20, 24, 25, 26) as the Hungarian law prescribes authorisation of persons taking care of animals, carrying out or designing procedures. Further, the Hungarian law prescribes setting up so called Institutional Animal Experimentation Committees (IAEC) (in user establishments) whose tasks combine the tasks and functions specified in the original Art. 24(1) and 26. In the latest PRES version the content of the original Art. 20 is found in Art.23A but without authorisation. It is acceptable for HU, provided we can adopt more stringent measures that is, still prescribing authorisation. What is more problematic, is the transformation of the original Art.24(1) to the new Art 24 Suggestion A. This renewed article prescribes the authorisation of persons (including demonstration of competence) fulfilling the tasks specified in Art.24(1). Hungary has two problems with this authorisation requirement:

- the specified tasks or functions are rather of administrative, regulatory kind (responsibility, right to intervene into experiments including stopping them, ensure access to information); it is not clear for us what sort of education and training can be put behind them and what could constitute the demonstration of the requisite competence (cf. carrying out animal experiments which requires a lot of specific knowledge and competence),

- in Hungary, the tasks of Art.24(1) are fulfilled by the IAEC, which usually has a non-professional member with voluntary participation. The involvement/recruitment of these people would be hampered by the educational, competence-demonstration and authorisation requirements.

The IAECs are pivotal elements of the Hungarian animal welfare law. The current text (with the modified Art 24) would necessitate the complete re-structuring of our national regulation. For this reason, only Suggestion B is acceptable for Hungary (or the original COM version), but we are open to discuss further alternatives for which the schematic of the UK delegation provides a very good starting point.

We still emphasize that

Member States shall ensure the mutual recognition of education and training qualifications and authorisation to conduct designated procedures.

Animal welfare body (25): it should be confined to user establishments
Authorisation process (35-43): Hungary could support a so called „one-window” system (i.e. one application to be submitted)

Reporting (49): 1. it should be explicitly stated that larval, embryonic and foetal forms will NOT be reported; 2. information on the prospectively assigned and not the actual severity should be reported

Annex IV: 2012 and 2017 dates should be changed to 5 and 10 years after transposition, respectively
Appendix

Proposal from Hungary for a modified Annex V

Annex V was modified by HU through the following steps
- restoration of the list of methods according to the Presidency compromise text to Annex V (st11644-ad01.en09)
- harmonizing the applicability of the methods to various groups of animals with the content of Annex I of the „Protection of animals at the time of killing” directive
- further minor changes based on common sense or new scientific evidence vs. EFSA report. The latter refers to omitting the restriction of the CO2 method to gradual fill only.

This restriction was probably based on the report of the Newcastle Meeting (2006) which expressed preference for the gradual filling over the prefill method, though acknowledged that both have pros and cons. Overall, the Newcastle Report emphasizes that CO2 euthanasia is and will be an accepted method of killing. This opinion is a kind of rebuttal to the opinion of the EFSA report (2005) which proposed abandoning the use of CO2 for killing. (Interestingly, the majority of the EFSA arguments blamed the gradual fill technique...). Since the Newcastle Meeting, further studies have been published on this matter and the whole topic seems to be boiling. Let us show here the abstracts of three recent articles favouring the prefill method.

A comparative analysis of carbon dioxide displacement rates for euthanasia of the ferret
Fitzhugh D.C., Parmer A., Shelton L.J. and Sheets J.T.

Though carbon dioxide asphyxiation is a common method of euthanasia for laboratory animals, species-specific guidelines have not been established for this procedure in the domestic ferret (Mustela putorius furo). The authors investigated the efficacy and stress effects of carbon dioxide euthanasia in 24 ferrets that had participated in previous experimental protocols. They euthanized ferrets by placing them in cages that were either prefilled with carbon dioxide or gradually filled at a displacement rate of 10%, 20% or 50% of the cage volume per min. Blinded observers subjectively evaluated ferret distress. Prefilling the cage or filling it at a rate of 50% volume per min resulted in less time to recumbency and to last breath than did filling the cage at a slower displacement rate. Slower carbon dioxide displacement rates also caused an increase in ferret blood glucose concentrations, which may indicate distress. Overall, observers found that prefilling the euthanasia cage caused the least stress to ferrets.
Loss of cortical function in mice after decapitation, cervical dislocation, potassium chloride injection, and CO2 inhalation
Cartner S.C., Barlow S.C. and Ness T.J.
Comparative Medicine 2007 57:6 (570-573).

Electroencephalograms (EEG) and visual evoked potentials (VEP) in mice were recorded to evaluate loss of cortical function during the first 30 s after euthanasia by various methods. Tracheal cannulae (for positive-pressure ventilation, PPV) and cortical surface electrodes were placed in mice anesthetized with inhaled halothane. Succinylcholine was used to block spontaneous breathing in the mice, which then underwent continuous EEG recording. Photic stimuli (1 Hz) were presented to produce VEPs superimposed on the EEG. Anesthesia was discontinued immediately before euthanasia. Compared with that obtained before euthanasia, EEG activity during the 30-s study period immediately after euthanasia was significantly decreased after cervical dislocation (at 5 to 10 s), 100% PPV-CO2 (at 10 to 15 s), decapitation (at 15 to 20 s), and cardiac arrest due to KCl injection (at 20 to 25 s) but not after administration of 70% PPV-CO2. Similarly, these euthanasia methods also reduced VEP amplitude, although 100% PPV-CO2 treatment affected VEP amplitude more than it did EEG activity. Thus, 100% PPV-CO2 treatment significantly decreased VEP beginning 5 to 10 s after administration, with near abolition of VEP by 30 s. VEP amplitude was significantly reduced at 5 to 10 s after cervical dislocation and at 10 to 15 s after decapitation but not after either KCl or 70% PPV-CO2 administration. The data demonstrate that 100% PPV-CO2, decapitation, and cervical dislocation lead to rapid disruption of cortical function as measured by 2 different methods. In comparison, 70% PPV-CO2 and cardiac arrest due to intracardiac KCl injection had less rapid effects on cortical function.

Comparison of carbon dioxide, argon, and nitrogen for inducing unconsciousness or euthanasia of rats
Sharp J., Azar T. and Lawson D.

We compared CO2, Ar, and N2 for inducing unconsciousness and euthanasia of Sprague-Dawley rats. We determined time to unconsciousness and monitored heart rate (HR) and mean arterial blood pressure (MAP) by radiotelemetry to assess stress, recovery after exposure, and time of death. Unconsciousness (mean ± standard error) occurred 24 ± 3, 87 ± 8, and 93 ± 8 s after short-term exposure to CO2, Ar, and N2, respectively. During exposure, CO2 depressed HR, whereas Ar and N2 increased HR. Upon removal from the chamber, rats’ HR rapidly normalized after CO2 or N2 but remained elevated for 60 min after Ar. During exposure, all agents depressed MAP, which returned to resting levels 10 to 50 min after rats’ removal from the chamber. For euthanasia, CO2 at approximately 100% induced unconsciousness in 37 ± 3 s, increased and then depressed MAP and HR, and caused death at 188 ± 15 s. CO2 at approximately 30% induced unconsciousness in 150 ± 15 s, decreased HR and MAP, and induced death at 440 ± 9 s. Ar at approximately 100% increased MAP but decreased HR, induced unconsciousness with hyperreflexia at 54 ± 4 s, and caused death at 197 ± 20 s. N2 at approximately 100% decreased MAP but not HR and produced unconsciousness with hyperreflexia at 164 ± 17 s and death at 426 ± 28 s. We conclude that CO2 effectively produced unconsciousness and euthanasia, but we were unable to ascertain distress. Ar also appears effective but produced hyperreflexia and tachycardia. N2 was ineffective.

ANNEX V

Methods of Killing animals

The methods of killing listed below are appropriate for the animals listed in the corresponding entries only if the process of killing is completed by one of the methods listed below :-

(a) confirmation of permanent cessation of the circulation
(b) destruction of the brain
(c) dislocation of the neck
(d) exsanguination
(e) confirming the onset of rigor mortis
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<th>Species-remarks / methods</th>
<th>Fish</th>
<th>Amphibians</th>
<th>Reptiles</th>
<th>Birds</th>
<th>Rodents</th>
<th>Rabbits</th>
<th>Dogs, cats, ferrets</th>
<th>Large mammals</th>
<th>Non-human primates</th>
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<td>Shooting with a free bullet with appropriate rifles, guns and ammunition (12)</td>
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Shaded cells mean the given method is not acceptable for the given group of animals.

Other methods may be used on unconscious animals, providing the animal does not regain consciousness before death.

Where special equipment is needed (electrical stunning, captive bolt, maceration, microwave) it shall be adjusted to the species, size and age of the animal.

The person who performs the killing shall be properly skilled and experienced with the given method.

**Delimiters:**
1) For fish <500g
2) Only for fish <2cm in length
3) For large reptiles
4) For birds <3kg
5) For chicks up to 72 hours old
6) To be used with embryos or foetuses <4g
7) For rodents under 150g
8) For rabbits under 1 kg
9) To be used on neonates
10) Acceptable for pigs
11) Acceptable for piglets
12) To be used by experienced marksman. To be used in field conditions.