Netherlands National Committee
for the protection of animals
used for scientific purposes

Informal Workshop of (technical) representatives of National Committees for the protection of animals used for scientific purposes, 8 October 2015, EC DG Environment, Brussels

INTRODUCTION

Following an invitation to all EU National Committees, on October 8 2015, an informal workshop of technical representatives of 12 National Committees (NCs) was held in Brussels, hosted by the EU Commission. Ms Susanna Louhimies and Mr David Anderson represented DG Environment. In addition to the representatives of the 12 member states, Kirsty Reid of the Eurogroup for Animals attended the meeting as observer. The list with details of all attendants is attached to this brief report.

Dr Herman Koeter (The Netherlands) chaired the meeting and firstly explained the role of the observers present. He clarified the purpose and objectives of this meeting. Though the member states are at different levels of implementation their respective NCs, it was considered useful to identify technical issues of common concern on which the NCs may wish to cooperate. During the informal workshop the participants discussed the question on what areas cooperation is useful and mutually beneficial. The goal of the scientific/technical meeting was to define three priorities all would consider as urgent. The outcome of the meeting will be used as input for the first meeting of the NC-chairs in December this year.

TOUR DE TABLE

The meeting started with a brief introduction by each participant present. Information was shared about the various NCs and current activities and structure of the NC. This provided adequate general background for the technical discussions that took place during the day.

SUGGESTED PRIORITIES FOR HARMONISED CODES OF PRACTICE

In the run-up to this workshop the following priorities were identified for discussion by the representatives of the member States present.

- Syntheses of evidence / systematic reviews
  - The Dutch NC is preparing a position on this topic
- The 'justifiable reason' for killing surplus animals that occur during the process of generating transgenic mice
  - This topic was brought up by the German representatives. Justyna Chmielewska (Germany) mentioned that in Germany there are some legal provisions with regard to the killing of surplus animal. A 'justifiable reason' is required, but that concept is not yet defined in the context of animal experimentation law. This is in contrast to other contexts (such as killing farm animals for meat) where provisions or at least jurisprudence, when a justifiable reason exists. A legal opinion for animal experimentation is in preparation and will be soon published.
- Animal husbandry
  Several animal husbandry items were proposed that could be harmonised internationally. These included:

  - Best environmental enrichment practices for lab rodents (proposed by Iveta Kociņa from Latvia);
  - In-house animal breeding of transgenic animals, cryopreservation, genotyping, and zebrafish husbandry such as tank size (proposed by Bjorn Venstrom from Sweden);
  - Animal health monitoring policies, import/export/transport, hygienic standards, entry barrier, and other good laboratory practices with the aim of achieving a culture of good animal care (proposed by Bjorn Venstrom from Sweden);
    - Fasting, blood sampling, weight loss. These are often present in applications for various study types. In reply on a question Kirsten Bayer Andersen (Denmark) told they were not including fluid restriction in the fasting guidance document. Alois Haslinger (Austria) informed the meeting that Austria has a working group working on this topic.
- Pain recognition and pain relief in laboratory animals
  - The Dutch NC is currently working on this issue and hope to be able to finalise its advice in March/April next year
- Severity Assessment of genetically altered animals (mice)
  - Bettina Bert (Germany) introduced this topic in connection with the breeding of genetically altered animals, particularly mice and rats, zebra fish and Medaka. A paper concerning rats and mice is already available on the website. The one for fish will soon be published on their website (also in English). One option is to create a database of genetic lines. In Germany it is legally required to predict the likeliness of harmful phenotypes, and this is very difficult to determine.
  - In connection with this topic Adrian Smith (Norway) said that more and specific guidelines on severity assessment (what procedure is in which category) are needed.
  - Nicolas Dudoignon (France) said that when one creates a new line, an assessment should take place before one maintains the line. This should be promoted as a routine procedure.
- Use of Transgenic and Knockout rodents (lines, perspectives etc.)
  - This item was introduced by Iveta Kociņa from Latvia and was considered to be closely linked to the severity assessment related to the use of GMO animals
- The acceptability of stress models in rodents
  - This subject was proposed for harmonisation by Gabriel Beechinor from Ireland. He explained that in Ireland the authorities are facing a variety of stress models proposed in project submissions and considers it hard to judge what would be the most acceptable approach of this controversial practice. Sonja Beken (Belgium) said she was not sure whether it would be preferable to suggest one particular model as the best model as this would limit the freedom of research.
  - Adrian Smith (Norway) said researchers should include in their project proposals how they came to the conclusion that the model they propose was considered the best and how they found the information that supported their evaluation. This issue is a good example to support the need for a harmonised "synthesis of evidence" approach.
  - Pieter Roelfsema (NL) suggested a database of available models and said that a systematic review (of different kinds of stress models) would provide for making an informed choice.
- The usage of mice for antibody production by ascites
  - Samuel Vidal (France) suggested that a harmonization of assessment and compliance of antibody production is much needed. In some regions in France

certain production models are prohibited, while in others the same model is accepted.
    - David Anderson (EC) reminded the meeting that the ascites model is no longer acceptable in the EU and that the NCPs are currently discussing this.
- The usage of animals for training as a regular question
    - This issue was brought to the table by France but was not discussed in detail. The general view on this was that training can be very diverse and that judgement on the use of animals should be on a case by case basis.
    - Björn Vennstrom (Sweden) said that he wants to focus on practices requiring the largest amounts of animals and on those causing severe harm. He said that good laboratory practices aren't common, and stressed the importance of it.
- Data collection and data bases
    - Both Denmark (Kirsten Bayer Andersen) and Sweden (Bjorn Venstrom) proposed the sharing of information of the procedure, format and content of guidance documents and codes of practice: how to collect, review, approve and update. Similarly, the Netherlands is considering the establishment of a European repository for codes of practice and an open, searchable project database for projects conducted in the EU. Several participants agreed that a searchable database could be very valuable, but raised the concern about competition, financial aspects and the safety of researchers and staff. Pieter Roelfsema mentioned that the current legislation in the Netherlands is already ahead of other member states in its freedom of information policies.
    - Adrian Smith (Norway) informed the meeting of the database 3R Guide (http://www.3RGuide.info) produced by the Norwegian consensus platform Norecopa, which contains global information on guidelines, databases, information centres, email discussion forums and journals of relevance to the 3Rs.
    - The French representatives addressed the need for a database of examples for severity classification
    - It was also deemed valuable to have a platform where negative results can be published.

ROUND TABLE DISCUSSION AND RATING OF THE SUGGESTED PRIORITIES

In a round the table discussion all of the above listed topics were discussed in some detail and background was given by the country/countries that had prioritized the respective topics. Following a rating session it appeared that the following three topics were considered as the most relevant or urgent taking into account numbers of animals involved and the level of discomfort:

1. The development of a European Guidance Document or Code of Practice for the use of the **Synthesis of Evidence** approach as a tool to justify in a transparent and harmonised manner the choice to conduct a project or a specific study using animals and/or other models.
2. The development of one or more (species specific) EU Guidance Documents and/or structured open databases and database networks on the **severity assessment for animals used for scientific purposes**
3. The development of an EU Guidance Document or Code of Practice for **pain recognition, management and relief** in animals used for scientific purposes

Other topics, receiving support, but considerably less than the three mentioned above, were:

- Reducing the numbers of surplus animals that occur during the process of generating transgenic animals and are killed without being used;
- Establishing an accessible data warehouse providing up-to-date information on alternative tests and sources of 3R research;
- Codes of practice for a variety of animal husbandry procedures and approaches;
- Inventory of animal stress models;
- Guidance on harmonised procedures for fasting and subsequent weight loss;
- Guidance on conditions (if any) allowing usage of animals for antibody production;
- EU repository for codes of practice and guidelines;
- Best practice for the breeding of genetically altered animals.

BRIEF EXPLANATORY NOTES ON THE SELECTED HIGHEST PRIORITY TOPICS

1. The development of a European Guidance Document or Code of Practice for the use of the **Synthesis of Evidence** approach as a tool to justify in a transparent and harmonised manner the choice to conduct a project or a specific study using animals and/or other models.
    - There is a desire for a guideline on this topic. Besides advice for a systematic way of looking at data, a European guideline should provide guidance on how to inform and share information. One suggestion was a common platform where publicly available documents can be uploaded, collected and shared.
    - An explanatory document addressing the various levels of detail of the sought evidence and the project-specific need for the most appropriate level, is currently under development by the Netherlands NC and will be available by the end of 2015 as thought- starter document for the development of the EU Guidance Document. The Dutch document will also address how to search for data.

2. The development of one or more (species specific) EU Guidance Documents and/or structured open databases and database networks on the **severity assessment for animals used for scientific purposes**
    - In several member states, including Germany, France, and Norway efforts are made to produce guidance for the assessment of severity.
    - The EC published a guideline on severity assessment, which can be found at: http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm
    - In order to avoid divergence of approaches, definitions and descriptions of severity in animals, it seems timely to combine efforts towards an accessible living data collection, set up as a data warehouse and discussion platform, including worked examples of severity classification, proactive interaction among users and sharing information options .

3. The development of an EU Guidance Document or Code of Practice for **pain recognition, management and relief** in animals used for scientific purposes
    - Although a lot of work has already been done by different commissions, organizations and member states, improvements can be made in the area of development, sharing and continuous updating of knowledge. Furthermore, pain management options in animal studies such as the use of pain relief treatments and abstention of such treatments are not harmonised.

- The Netherlands NC is currently developing an outline of a possible Code of Practice on pain recognition and relief which is largely but not exclusively aimed at reaching scientists with less experience in pain recognition

OTHER REMARKS

The meeting agreed to share available documents on any of the issues discussed with all participants of this informal workshop, thus starting a technical and scientific network. The NCs should play an active part in this exchange.

Björn Venstrom (Sweden) informed the meeting about the web course that the Karolinska Institute developed and that can be used for education and training. They are working on a Felasa accreditation.

David Anderson (EC) mentioned ETPLAS.EU as a valuable platform on training. Calls for training, courses, scientific meetings, etc. can be send to Susanna, who can publish them on the website of the EC.

CLOSING REMARKS

In closing the meeting the Chair (Herman Koeter) reminded the participants that this was an *ad hoc* brainstorm meeting on scientific and technical issues of common concern to all NCs and, hopefully the starting point of a strong and efficient NC network supported and facilitated by the European Commission. He thanked all for their respective contributions, ideas and suggestions. A draft of the brief report of this meeting will be sent to all participants for comment, corrections and additional suggestions. Following receipt and consideration of all comments, the report will be sent to the Commission with the request to put the report and recommendations for priority activities on the agenda of the first meeting of the NCs in December this year.

Finally, the Chair thanked the Commission for its support and hospitality, allowing the meeting to be held at the Commission’s premises.