Protection of animals used for scientific purposes

2008/0211(COD) - 15/06/2010 - Commission communication on Council's position

The Commission notes that out of 167 amendments adopted by the Parliament, 76 were acceptable to the Commission either fully, in part or in principle.

41 amendments were accepted by the Commission and incorporated to varying degrees in the Council's position. These include the introduction of a new Annex providing detailed criteria for the four severity classes of procedures, criteria which were originally envisaged as part of implementing acts. However, the Commission welcomed this amendment and convened an expert meeting to agree on the detailed criteria. This allowed the annex to be updated by the Presidency with the latest expert understanding of the severity classes.

44 amendments were rejected by the Commission but have been incorporated in full, in part or in principle in the Council's position. These are all considered acceptable by the Commission as they do not endanger the original objectives or, if altering these objectives marginally, could still be acceptable in the spirit of compromise to reach an early second reading political agreement:

- in addition to vertebrate species including their larval forms, the scope now covers foetal forms only of mammals from the last third of their development and cephalopods as the only group of invertebrate animals. The Commission can accept this in the spirit of overall compromise;
- the final agreement allows for the maintenance of stricter measures, but not the adoption of new ones;
- Parliament asked for a feasibility study to be carried out on the sole use of second or higher generation purpose-bred non-human primates, and a modification of the deadline set out by the Commission for sole use of these animals. The Commission will conduct a further study to analyse the feasibility of sourcing animals only from self-sustaining colonies;
- the text now allows for a systematic re-use of animals already subject to 'moderate' procedures where the subsequent procedure can also be of 'moderate' severity. However, all Three Rs (the principle of replacement, reduction and refinement of the use of animals in procedures) have to be balanced when projects are evaluated, including decisions on re-use, and thus this amendment can be acceptable to the Commission;
- the text text puts the emphasis on risk analysis, however, requiring a minimum of one third of user establishments to be inspected annually, with the exceptions of breeders, suppliers and users of non-human primates which require annual inspections. An appropriate proportion of inspections shall be carried out without prior notice;
- Member States may now allow the authorisation of multiple generic projects which are also carried out for production or diagnostic purposes with established methods, in addition to those carried out to satisfy regulatory requirements.

18 amendments were accepted in full, in part or in principle by the Commission but not incorporated in the Council's position. However, it is important to note that a number of these were considered to be already covered in other articles or an Annex and thus considered superfluous. In light of the political agreement, these amendments are unlikely to be re-tabled.

37 amendments were rejected by both institutions. As a result of the political agreement on the text, these amendments are unlikely to be re-tabled.

The Council’s position also included a number of amendments over and above those set out in the European Parliament’s first reading. These amendments concern: (i) the authorisation of persons; (ii) EU

reference laboratory; (iii) safeguard clauses; (iv) the classification of procedures according to their degree of severity.

The Commission concludes that the final text retains all key objectives that the Commission had set for the revision; namely to address the current problems of the uneven playing field, to fully incorporate the principle of the "Three Rs", including the promotion of the alternatives to animal testing, and to improve significantly the welfare of the animals still needed for scientific purposes. Parliament's first reading placed a lot of emphasis on the reduction of administrative burden and the continuity and viability of European research and industry relying still on the use of animals.

The Council has addressed Parliament's concerns by providing for more flexible rules for the implementation of project authorisation as well as for re-use of animals and by agreeing on a risk management based inspection scheme to ensure appropriate enforcement and compliance with the revised Directive. The concerns of administrative burden have *inter alia* been taken into account in more generous transposition times of the housing and care standards as well as in the way in which animal welfare bodies are to be implemented.

Lastly, both institutions voiced the need for further promotion of alternatives to animal testing. In response an EU reference laboratory for the validation of alternative methods, supported by Member States' efforts to bring in further resources in terms of suitable specialised laboratories, is envisaged.

The Commission supports the common position which strikes the right balance between the needs of the industry and research community whilst upgrading and harmonising the animal welfare standards for animals used or intended to be used for scientific purposes.