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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

Council's position at first reading on the adoption of a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes

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1. BACKGROUND

Date of transmission of the proposal to the EP and the Council(document COM(2008)543 final — 2008/0211 COD):	7 November 2008
Date of the opinion of the European Economic and Social Committee:	13 May 2009
Date of the opinion of the Committee of the Regions:	not applicable
Date of the opinion of the European Parliament, first reading:	5 May 2009
Date of adoption of the Council's position at first reading (qualified majority):	3 June 2010

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The aim of the revision of Directive 86/609/EEC is to strengthen the protection of animals used for scientific purposes and contribute to the reduction of animal use and ensure that the animals used in experiments receive appropriate care and humane treatment in line with Article 13 of the Treaty on the Functioning of European Union (TFEU) which recognises animals as sentient beings, as well as to integrate fully the "Three Rs" principle of replacement, reduction and refinement of animal use into legislation. Furthermore, specific provisions aim to reduce the use of non-human primates to an absolute minimum and lead to a gradual phasing out of wild-caught non-human primates used in experiments. The use of Great Apes is prohibited, however, with a safeguard clause to allow their exceptional use in strictly defined conditions. Finally, an important aim of the revised Directive is to balance animal welfare concerns with the obligation to pursue research for the benefit of human beings and the environment. It aims at ensuring a level playing field, throughout the EU, for industry and the research community. Research into life threatening diseases should not be hindered and European research should not be disadvantaged when compared with international counterparts.

3. COMMENTS ON THE COUNCIL'S POSITION AT FIRST READING

3.1. General comments

The European Parliament gave its opinion at first reading on 5 May 2009. The Parliament adopted 167 amendments out of the 202 that were tabled. It is important to note that when reacting to the Parliamentary amendments in first reading, the Commission moved little from its original proposal as the Council position on the proposal was not yet known.

On 3 June 2010 the Council adopted by qualified majority its position in a pre-negotiated early second-reading. 85 of the Parliament's amendments were taken into account in the position of the Council.

Out of 167 amendments adopted by the Parliament, 76 were acceptable to the Commission either fully, in part or in principle. The Commission considered that those amendments clarified the text and were consistent with the general objective of the proposal. The Commission rejected all amendments which would have altered the nature of the original objectives of the proposal, pending the views of the Council. The Commission considers that the position of the Council does not radically alter the approach or aims of the original proposal overall, or change significantly the core elements therein.

The recitals have been modified to reflect the changes that were made to the substantial part of the text. The Commission's position with regard to the amendments of the European Parliament to the enacting terms is as follows:

3.2. Detailed comments

3.2.1. Parliamentary amendments accepted by the Commission in full, in part or in principle and incorporated in full, in part or in principle in the Council's position at first reading.

41 amendments **(31, 33, 43, 48, 49, 56, 59, 64, 68, 69, 71, 78, 79, 81, 82, 84, 85, 87, 98, 100, 101, 102, 105, 108, 109, 114, 115, 116, 117, 119, 121, 126, 129, 145, 150, 161, 168, 169, 170, 185, 194)** were accepted by the Commission and incorporated to varying degrees in the Council's position.

Amendments **69, 161 and 185** introduced a new annex providing detailed criteria for the four severity classes of procedures, criteria which were originally foreseen 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.

3.2.2. Parliamentary amendments rejected by the Commission but incorporated in full, in part or in principle in the Council's position

At the time of responding to the EP first reading report, the Commission kept to its original proposal as the position of the Member States on these provisions was not yet known. Therefore, at that point in time, it was likely that the Commission would be able accept a greater number of amendments once Member State views were known.

44 amendments (**28, 30, 35, 37, 47, 50, 52, 53, 54, 60, 61, 65, 66, 67, 70, 72, 73, 74, 75 76, 77, 86, 89, 91, 92, 97, 103, 110, 112, 123, 124, 125, 127, 135, 136, 139, 140, 141, 142, 193,**

151, 152, 160, 175) 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 as set out by the Commisison or, if altering these objectives marginally, could still be acceptable in the spirit of compromise to reach an early second reading political agreement. On specific amendments.

Amendment **30** narrowed the scope of the proposal without taking into account the scientific knowledge available today on the sentience of a wider range of species and life forms than now protected. 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;

Concerning amendment **54**, to allow the adoption of stricter measures, it is important to note that it was not acceptable to the Commission as one of the objectives of the revision was the harmonisation of the single market. The final agreement allows for the maintenance of stricter measures, but not the adoption of new ones.

Amendment **60** 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 proposal was based on a solid impact assessment which had included a feasibility assessment, therefore in the Commission's view making a feasibility study superfluous. The concerns of the EP were, however, shared by the Member States and the resulting text reflects the amendment to a certain degree. The feasibility was linked by the Parliament to sourcing animals from self-sustaining colonies in amendment **61.** The Council separated the two obligations and inserted a requirement for the Commission to conduct a further study to analyse the feasibility of sourcing animals only from self-sustaining colonies;

Amendments **73, 74 and 75** were not in line with the Commission's policy objective not to allow for a re-use of animals having already been subject to a ‘moderate’ procedure. The Presidency modified the text in-line with the EP's wishes, allowing 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;

Amendment **103** was not in line with the policy objectives to improve enforcement. The proposed frequency of inspections was based on the conclusions by the Technical Expert Working Group. Furthermore, one of the main criticisms of the current Directive has been the lack of compliance and enforcement both of which are directly linked to inspections. The final 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. This is acceptable to the Commission as part of the overall compromise;

Amendment **125** was rejected by the Commission as it was unclear what could be conceived as a "standardised procedure" outside regulatory testing. However, the final wording was clarified further, and 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;

Amendment **139** was partly incorporated into the text through the requirement for an EU reference laboratory for the validation of alternative methods and its related tasks in a new Annex VII covering alternatives in the field of basic, applied research and regulatory testing;

Amendments **140 and 193** were both partly covered; Member Sates are required to identify and nominate suitable specialised and qualified laboratories for validation studies, which support the objectives as set out by the Commission.

3.2.3. Parliamentary amendments accepted in full, in part or in principle by the Commission but not incorporated in the Council's position

18 amendments **(29, 38, 39, 44, 46, 58, 83, 93, 94, 95, 96, 104, 143, 144, 148, 155, 156, 186**) 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.

It is important to note amendments **155 and 156** which increased the transitional period foreseen in Annex III for moving to second or higher generation purpose bred macaques (linked with amendments 60 and 61 above). The final text increased the transitional period, however, linking it to a feasibility study under Article 10(1). The feasibility study must be completed no later than 7 years after the date of entry into force of this Directive.

3.2.4. Parliamentary amendments rejected by the Commission and the Council and not incorporated in the Council's position

37 amendments **(32, 34, 36, 40, 41, 42, 51, 55, 57, 62, 63, 80, 88, 90, 99, 111, 113, 118, 120, 122, 128, 131, 132, 134, 137, 138, 147, 153, 154, 157, 158, 159, 167, 176, 178, 180, 187)** were rejected by both institutions.

As a result of the political agreement on the text, these amendments are unlikely to be re-tabled.

3.2.5. Changes made by the Council to the proposal

The Council proposed the following main changes to the Commission’s proposal:

- *Authorisation of persons* (Article 24): A three-way authorisation (authorisation of establishments, persons and projects) was the central pillar of the Commission proposal, essential for enhancement of animal welfare, and ensuring compliance. The current compromise text removes the requirement to authorise personnel working with animals and replaces it by a requirement to name a person who is responsible for the training and competence of personnel dealing with animals. This is departing from the Commission's initial proposal but could be accepted in a spirit of compromise as still a clear line of responsibility can be identified to secure the competence of personnel.

- The Commission proposal to have each MS nominate a national reference laboratory, was replaced by a more flexible system of identifying and nominating suitable specialised and

qualified laboratories as per the needs of the validation studies at hand (Article 47). This allows for a better utilisation of available resources whilst introducing a long-term commitment to the promotion of alternative methods. Furthermore, the same article requires each Member State to appoint a single point of contact to provide advice on the regulatory relevance of alternative methods. This will streamline communication and further contribute to a speedy uptake of alternative methods. In addition, Article 46 requires an EU reference laboratory for the validation of altenative methods to be set up. Since the objectives as set by the Commission are not altered and are likely to be achieved equally by the proposed measures, the Commission can accept these changes.

- Finally, to achieve a compromise between the institutions, two additional safeguard clauses were introduced which can only be evoked on exceptional and justifiable grounds; to surpass the upper limit of pain that the animal can be subjected to and to allow the use of non-human primates in applied research in areas that are not linked with debilitiating and life-threatening conditions in humans. In the name of the overall compromise, the Commission can accept these.

4. CONCLUSION

In its assessment of Parliament's First Reading and of the Council's Common Position, the Commission has taken into account the views of both institutions of the decision making process. The subject matter is a difficult one and needs to consider the interests of a number of different stakeholder groups, sometimes with opposing views and needs. These were mirrored in the discussions with the EP and the Council, however, the Commission considers that an appropriate balance has been found.

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. The EP's first reading report put 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. Finally, 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 it believes 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. The Commission calls upon the Parliament and the Council to facilitate an early adoption of the Directive which will allow the efforts to be concentrated on the preparation for a uniform transposition and implementation.

ANNEX

Statement of the European Parliament, the Council and the Commission on Article 290 TFEU

The European Parliament, Council and Commission declare that the provisions of this Directive shall be without prejudice to any future position of the institutions as regards the implementation of Article 290 TFEU or individual legislative acts containing such provisions.