



**COUNCIL OF
THE EUROPEAN UNION**

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STATEMENT OF THE COUNCIL'S REASONS

Subject : Position of the Council with a view to the adoption of the Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes
-Statement of the Council's reasons
-Adopted by the Council on 3 June 2010

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 5 November 2008, the Commission submitted to the Council the above proposal which is based on Article 95 TEC (Article 114 TFEU). Its objective is to ensure a level playing field throughout the EU for industry and the research community and to strengthen the protection of animals still used in scientific procedures.

The European Parliament adopted its first-reading opinion on 5 May 2009¹.

The Economic and Social Committee adopted its opinion on 13 May 2009².

The Council adopted its position at first reading in accordance with Article 294 of the TFEU on 3 June 2010.

II. OBJECTIVES

The main objectives of the proposed Directive is to ensure a level playing field throughout the EU for industry and the research community and to strengthen the protection of animals still used in scientific procedures. It aims at re-establishing the objectives of the internal market by rectifying a variety of weaknesses in the current Directive which have lead into considerable differences in its national implementation by the Member States. While recognising that the use of animals in scientific procedures today still remains essential for an unforeseeable future for ensuring a level of safety for human beings, animals and the environment, the proposal introduces a number of measures to promote alternative approaches, including their development, validation, acceptance and implementation, also at international level. Generally the proposal requires that the commonly accepted principles of the "Three Rs" - Replacement, Reduction and Refinement of animals in experiments - are fully taken into account when developing Community measures in this domain.

¹ Doc. 9312/09.

² NAT/422 - CESE 874/2009.

III. ANALYSIS OF THE COUNCIL'S POSITION

A. General observations

The Council's position confirms the objectives proposed by the Commission and incorporates the majority of the European Parliament's first-reading amendments, either verbatim, in part or in spirit.

The Council's position also includes a number of changes other than those envisaged in the European Parliament's first-reading opinion. These changes have been thoroughly negotiated with the European Parliament, which has confirmed its provisional agreement on the full text by a letter.

B. Specific comments

1. Main amendments to the Commission proposal

(a) Authorisation of persons

With the aim to reduce administrative burden and to better cater for different types of operators, the Council removed the proposed mandatory authorisation of persons carrying out or supervising procedures, putting the emphasis on the requirements on competence of staff. These requirements include the obligation to specify in the authorisation of each breeder, supplier and user a person responsible for ensuring the adequate education, competence and continuous training of the staff.

(b) Union Reference Laboratory

In line with an amendment of the Parliament, the Council strengthened the promotion of alternative methods at Union level by the introduction of a centralised Union Reference Laboratory, assigning it a set of responsibilities, including coordination and validation of alternative approaches and acting as a focal point for the exchange of information on their development.

(c) Safeguard clauses

The Council introduced two additional safeguard clauses to take into account possible future situations where, for scientifically justifiable grounds, Member States deem it is necessary to authorise the use of non-human primates in areas not linked with debilitating and life-threatening conditions in humans or to surpass the upper limit for severity of procedures. This authorisation could only be provisional and would be subject to a Union control procedure.

(d) Classification of the severity of procedures

Sharing the approach of the Parliament, the Council introduced in the Directive a system for a uniform classification of severity of procedures.

2. Council's position on the European Parliament's amendments

With the view to reaching an early agreement, the Council examined every amendment of the European Parliament. Whenever possible, amendments were accepted, either in full or partially; sometimes the spirit of an amendment was addressed in another Article or Recital.

Thus, in its position, the Council has

- Accepted fully (sometimes with redrafting), partly or in spirit the following amendments: 28, 30, 31, 33, 35, 37, 43, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 59, 60, 61, 64, 65, 66, 67, 68, 69, 70 + 175 , 71 + 185, 72, 73, 74, 75, 76, 77, 78, 79, 81, 82, 83, 84, 85, 87, 89, 91, 92, 97, 98, 99, 100, 101, 102, 103, 105, 108, 109, 110, 112, 114, 115, 116, 117, 119, 121, 123, 124, 125, 126, 127, 129, 135, 136, 139, 140, 141, 142, 145, 150, 151, 152, 160, 161, 168, 169, 170, 193 and 194;
- Not been able to accept the following amendments: 29, 32, 34, 36, 38, 39, 40, 41, 42, 44, 46, 57, 58, 62, 63, 80, 86, 88, 90, 93, 94, 95, 96, 104, 111, 113, 118, 120, 122, 128, 131+187, 132, 134, 137, 138, 143, 144, 147, 148, 153, 154, 155, 156, 157, 158, 159,167, 176 + 186, 178, and 180.
