

Basic information	
<p>2007/0168(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Directive</p>	Procedure completed
<p>Electro-medical equipment used in veterinary medicine: approximation of the laws of the Member States (repeal. Directive 84/539/EEC)</p> <p>Subject</p> <p>3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.40.11 Precision engineering, optics, photography, medical 4.60.08 Safety of products and services, product liability 8.50.02 Legislative simplification, coordination, codification</p>	

Key players				
European Parliament	Committee responsible		Rapporteur	Appointed
	IMCO Internal Market and Consumer Protection		MCCARTHY Arlene (PSE)	12/09/2007
	Committee for opinion		Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		The committee decided not to give an opinion.	
Council of the European Union	Council configuration		Meetings	Date
	Education, Youth, Culture and Sport		2848	2008-02-14
European Commission	Commission DG		Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		VERHEUGEN Günter	

Key events			
Date	Event	Reference	Summary
07/08/2007	Legislative proposal published	COM(2007)0465 	Summary
03/09/2007	Committee referral announced in Parliament, 1st reading		
05/11/2007	Vote in committee, 1st reading		Summary
12/11/2007	Committee report tabled for plenary, 1st reading	A6-0431/2007	
29/11/2007	Decision by Parliament, 1st reading	T6-0545/2007	Summary

29/11/2007	Results of vote in Parliament		
14/02/2008	Act adopted by Council after Parliament's 1st reading		
11/03/2008	Final act signed		
11/03/2008	End of procedure in Parliament		
19/03/2008	Final act published in Official Journal		

Technical information	
Procedure reference	2007/0168(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/6/52297

Documentation gateway				
European Parliament				
Document type	Committee	Reference	Date	Summary
Committee draft report		PE396.461	11/10/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0431/2007	12/11/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0545/2007	29/11/2007	Summary
Council of the EU				
Document type	Reference	Date	Summary	
Draft final act	03699/2007/LEX	11/03/2008		
European Commission				
Document type	Reference	Date	Summary	
Legislative proposal	COM(2007)0465 	07/08/2007	Summary	
Other institutions and bodies				
Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0063/2008	16/01/2008	

Additional information		
Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act	
Directive 2008/0013 OJ L 076 19.03.2008, p. 0041	Summary

Electro-medical equipment used in veterinary medicine: approximation of the laws of the Member States (repeal. Directive 84/539/EEC)

2007/0168(COD) - 11/03/2008 - Final act

PURPOSE: to repeal Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine, in order to simplify the regulatory environment.

LEGISLATIVE ACT: Directive 2008/13/EC of the European Parliament and of the Council repealing Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine.

CONTENT: within the context of the Better Regulation initiative, the Commission identified 43 new initiatives, which could potentially be simplified for the period 2006-2009. Included in this list was Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine.

The method of conformity assessment provided for by Council Directive 84/539/EEC is no longer necessary for the purposes of the internal market and trade with third countries. The functioning of the internal market and the protection of users and animals can be better ensured by other Community legislation.

Directive 84/539/EEC is therefore repealed, with effect from 31 December 2008.

ENTRY INTO FORCE: 08/04/2008.

TRANSPOSITION: 31/12/2008.

Electro-medical equipment used in veterinary medicine: approximation of the laws of the Member States (repeal. Directive 84/539/EEC)

2007/0168(COD) - 07/08/2007 - Legislative proposal

PURPOSE: to repeal Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine and not to replace it with any other legislative act.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: within the context of the Better Regulation initiative the Commission identified in 2006 43 legislative acts that require simplification. Included in this re-examination was Council Directive 84/539/EC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine.

The starting point of the review was whether or not to keep the Directive. The question of repealing and not replacing the Directive was raised by certain Member States and by industry who noted that the Directive was no longer being applied in the trade of these devices.

Prior to presenting this proposal the Commission held a wide-ranging consultation that involved both the Member States and industry. The consultation process lead to the same conclusion – i.e. that the Directive no longer serves the purpose for which it was originally drafted.

The reasons for this are fourfold:

- Firstly, most manufacturers rarely rely on this Directive, preferring instead to apply Directive 93/42/EEC on medical devices (for human use). Further, most of the products manufactured are of “dual use” purposes meaning that they can be used both for humans as well as for animals. The market for electro-medical equipments used in veterinary medicine is, therefore, very small.
- Secondly, in cases where products are manufactured to be used specifically for veterinary medicine, manufacturers rely on other Community legislative acts since they are deemed a better option than Directive 84/539/EEC. The other legislative acts are: Directive 2006/42/EC on machinery; Directive 2004/108/EC relating to electromagnetic compatibility; and Directive 85/374/EEC on product liability.
- Thirdly, standards adopted within the context of Directive 84/539/EEC have been revised and are currently lists as harmonised standards under the Directive on medical devices.
- Fourthly, the Directive does not prevent a distortion of the single market since no complaints have been recorded.

It is important that the repeal of Directive 84/539/EEC be followed by the repeal of corresponding national implementing measures. Further, it should be ensured that the repeal of this Community act will not be cancelled out by new national rules or new technical barriers. Accordingly, it is important to note that any national rules on electro-medical equipment used in veterinary medicine is consistent with the principles of Article 28 of the EU Treaty.

To conclude, the purpose of this proposal is to repeal Directive 84/539/EEC and not to replace the Directive by any other legislative act.

Electro-medical equipment used in veterinary medicine: approximation of the laws of the Member States (repeal. Directive 84/539/EEC)

2007/0168(COD) - 29/11/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Arlene **McCARTHY** (PES, UK) on the proposal for a directive repealing Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine. The report was adopted by 360 votes in favour to 3 against with 11 abstentions.