

# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Electro-medical equipment used in veterinary medicine: approximation of the laws of the Member States (repeal. Directive 84/539/EEC)	
Subject 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	

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

Key events			
07/08/2007	Legislative proposal published	<a href="#">COM(2007)0465</a>	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	<a href="#">A6-0431/2007</a>	
29/11/2007	Decision by Parliament, 1st reading	<a href="#">T6-0545/2007</a>	Summary
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		
	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

Legislative proposal	<a href="#">COM(2007)0465</a>	07/08/2007	EC	Summary
Committee draft report	<a href="#">PE396.461</a>	11/10/2007	EP	
Committee report tabled for plenary, 1st reading/single reading	<a href="#">A6-0431/2007</a>	12/11/2007	EP	
Text adopted by Parliament, 1st reading/single reading	<a href="#">T6-0545/2007</a>	29/11/2007	EP	Summary
Economic and Social Committee: opinion, report	<a href="#">CES0063/2008</a>	16/01/2008	ESC	
Draft final act	<a href="#">03699/2007/LEX</a>	11/03/2008	CSL	

## Additional information

National parliaments	<a href="#">IPEX</a>
European Commission	<a href="#">EUR-Lex</a>

## Final act

[Directive 2008/13](#)  
[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)

**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 listed 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)

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The Committee on the Internal Market and Consumer Protection adopted, without amendment at 1<sup>st</sup> reading of the codecision procedure, the report drafted by Arlene McCARTHY (PES, UK) on the proposal for a directive 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.

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

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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.

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

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**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.