

# EUROPEAN PARLIAMENT

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*Session document*

**A6-0280/2008**

1.7.2008

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## **REPORT**

on the proposal for a directive of the European Parliament and of the Council on the colouring matters which may be added to medicinal products (recast) (COM(2008)0001 – C6-0026/2008 – 2008/0001(COD))

Committee on Legal Affairs

Rapporteur: József Szájer

(Recast – Rule 80a of the Rules of Procedure)

### ***Symbols for procedures***

- \* Consultation procedure  
*majority of the votes cast*
- \*\*I Cooperation procedure (first reading)  
*majority of the votes cast*
- \*\*II Cooperation procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\* Assent procedure  
*majority of Parliament's component Members except in cases  
covered by Articles 105, 107, 161 and 300 of the EC Treaty and  
Article 7 of the EU Treaty*
- \*\*\*I Codecision procedure (first reading)  
*majority of the votes cast*
- \*\*\*II Codecision procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\*III Codecision procedure (third reading)  
*majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

### ***Amendments to a legislative text***

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a directive of the European Parliament and of the Council on the colouring matters which may be added to medicinal products (recast)  
(COM(2008)0001 – C6 0026/2008 – 2008/0001(COD))**

**(Codecision procedure - recast)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0001),
  - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0026/2008),
  - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>1</sup>,
  - having regard to Rules 80a and 51 of its Rules of Procedure,
  - having regard to the report of the Committee on Legal Affairs and the opinion of the Committee on the Environment, Public Health and Food Safety (A6-0280/2008),
- A. whereas, according to the Consultative Working Party of the Legal Services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance,
1. Approves the Commission proposal as adapted to the recommendations of the Consultative Working Party of the Legal Services of the European Parliament, the Council and the Commission;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and the Commission.

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<sup>1</sup> OJ C 77, 28.3.2002, p. 1.

## EXPLANATORY STATEMENT

Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>1</sup> was amended by Council Decision 2006/512/EC of 17 July 2006<sup>2</sup>. Article 5a of amended Decision 1999/468/EC introduced the new 'regulatory procedure with scrutiny' (RPS) for *'measures of a general scope which seek to amend non-essential elements of a basic instrument adopted in accordance with codecision, inter alia by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements'*.

Following the screening of the existing legislation and on-going procedures<sup>3</sup>, the European Commission presented inter alia this recast proposal, transformed from a codification in order to incorporate the amendments necessary for the alignment to RPS.

In its decision of 12 December 2007 the Conference of Presidents designated the Committee on Legal Affairs as the lead Committee to deal with this 'comitology alignment' and the specialised committees as opinion-giving committees. The Conference of Committee Chairs agreed on 15 January 2008 on the modalities of cooperation between the Committee on Legal Affairs and the other committees involved.

In view of the fact that the proposed alignment to RPS is complete, the Committee on Legal Affairs does not propose any amendments, apart from the technical adaptations suggested by the Consultative Working Party of the Legal Services.

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<sup>1</sup> OJ C 203, 17.7.1999, p. 1.

<sup>2</sup> OJ L 200, 22.7.2006, p. 11.

<sup>3</sup> COM(2007)0740.

5.6.2008

**OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND  
FOOD SAFETY**

for the Committee on Legal Affairs

on the proposal for a directive of the European Parliament and of the Council on the colouring matters which may be added to medicinal products (Recast)  
(COM(2008)0001 – C6-0026/2008 – 2008/0001(COD))

Draftsman: Thomas Ulmer

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The Committee on the Environment, Public Health and Food Safety calls on the Committee on Legal Affairs, as the committee responsible, to propose approval of the Commission proposal.

## PROCEDURE

<b>Title</b>	Colouring matters for medicinal products (recast version)
<b>References</b>	COM(2008)0001 – C6-0026/2008 – 2008/0001(COD)
<b>Committee responsible</b>	JURI
<b>Opinion by</b> Date announced in plenary	ENVI 19.2.2008
<b>Drafts(wo)man</b> Date appointed	Thomas Ulmer 13.3.2008
<b>Discussed in committee</b>	5.5.2008
<b>Date adopted</b>	3.6.2008
<b>Result of final vote</b>	+: 54 –: 0 0: 0
<b>Members present for the final vote</b>	Georgs Andrejevs, Margrete Auken, Liam Aylward, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Anne Ferreira, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Gyula Hegyi, Marie Anne Isler Béguin, Christa Klaß, Eija-Riitta Korhola, Peter Liese, Jules Maaten, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Kathy Sinnott, Bogusław Sonik, María Sornosa Martínez, Antonios Trakatellis, Anja Weisgerber, Åsa Westlund, Anders Wijkman, Glenis Willmott
<b>Substitute(s) present for the final vote</b>	Inés Ayala Sender, Iles Braghetto, Bairbre de Brún, Genowefa Grabowska, Rebecca Harms, Henrik Lax, Johannes Lebech, Miroslav Mikolášik



**ANNEX: OPINION IN LETTER FORM OF THE LEGAL SERVICES'  
CONSULTATIVE WORKING PARTY**

Brussels, 28 February 2008

**OPINION**

**FOR THE EUROPEAN PARLIAMENT  
THE COUNCIL  
THE COMMISSION**

**Proposal for a directive of the European Parliament and of the Council on the colouring matters which may be added to medicinal products  
COM(2008)0001 of 11 January 2008 – 2008/0001(COD)**

Having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts, and in particular to point 9 thereof, the consultative working party consisting of the legal services of the European Parliament, the Council, and the Commission met on 22 January and 6 February 2008 in order to consider, among others, the above Commission proposal.

On examining<sup>1</sup> the proposal for a directive of the European Parliament and of the Council intended to recast Council Directive 78/25/EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products, the working party noted, by common accord, that, in Article 2, the words '*the general and specific criteria of purity*' should be replaced by the words '*the general specifications for aluminium lakes of colours and the specific criteria of purity*'.

Having considered the working document, the working party was thus able to establish, without dissent, that the proposal does not involve any substantive changes other than those identified as such in the text itself or in this opinion. The working party also concluded, as regards codification of the unchanged provisions of the earlier act with those substantive amendments, that the proposal is indeed confined to straightforward codification and does not substantially alter the acts in question.

C. PENNERA  
Jurisconsult

J.-C. PIRIS  
Jurisconsult

M. PETITE  
Director-General

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<sup>1</sup> The working party was able to refer to the English, French, and German versions of the proposal and based its proceedings on the French original version of the working document.

## PROCEDURE

<b>Title</b>	Colouring matters for medicinal products (recast version)
<b>References</b>	COM(2008)0001 – C6-0026/2008 – 2008/0001(COD)
<b>Date submitted to Parliament</b>	11.1.2008
<b>Committee responsible</b> Date announced in plenary	JURI 19.2.2008
<b>Committee(s) asked for opinion(s)</b> Date announced in plenary	ENVI 19.2.2008
<b>Rapporteur(s)</b> Date appointed	József Szájer 19.12.2007
<b>Date adopted</b>	26.6.2008
<b>Result of final vote</b>	+: 24 -: 0 0: 0
<b>Members present for the final vote</b>	Carlo Casini, Titus Corlăţean, Bert Doorn, Monica Frassoni, Giuseppe Gargani, Neena Gill, Othmar Karas, Piia-Noora Kauppi, Klaus-Heiner Lehne, Hans-Peter Mayer, Manuel Medina Ortega, Hartmut Nassauer, Aloyzas Sakalas, Francesco Enrico Speroni, Diana Wallis, Rainer Wieland, Jaroslav Zvěřina, Tadeusz Zwiefka
<b>Substitute(s) present for the final vote</b>	Sharon Bowles, Vicente Miguel Garcés Ramón, Jean-Paul Gauzès, Eva Lichtenberger, József Szájer, Ieke van den Burg