

# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	1996/0200(COD) Procedure completed
Dangerous preparations: classification, packaging and labelling	
Amended by <a href="#">2003/0256(COD)</a> Repealed by <a href="#">2007/0121(COD)</a>	
Subject 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>ENVI</b> Environment, Public Health and Consumer Protection	UPE <a href="#">BALDI Monica Stefania</a>	03/09/1996
	Former committee responsible		
	<b>ENVI</b> Environment, Public Health and Consumer Protection	UPE <a href="#">BALDI Monica Stefania</a>	03/09/1996
	Former committee for opinion		
	<b>BUDG</b> Budgets		
Council of the European Union	Council configuration	Meeting	Date
	Energy	<a href="#">2176</a>	11/05/1999
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a>	<a href="#">2117</a>	24/09/1998
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a>	<a href="#">2094</a>	18/05/1998
	<a href="#">Environment</a>	<a href="#">2033</a>	16/10/1997

Key events			
18/07/1996	Legislative proposal published	COM(1996)0347	Summary
04/09/1996	Committee referral announced in Parliament, 1st reading		
21/05/1997	Vote in committee, 1st reading		Summary
21/05/1997	Committee report tabled for plenary, 1st reading	<a href="#">A4-0186/1997</a>	
25/06/1997	Debate in Parliament		Summary
26/06/1997	Decision by Parliament, 1st reading	T4-0350/1997	Summary

23/09/1997	Modified legislative proposal published	COM(1997)0462	Summary
16/10/1997	Debate in Council	<a href="#">2033</a>	
24/09/1998	Council position published	<a href="#">08956/1/1998</a>	Summary
22/10/1998	Committee referral announced in Parliament, 2nd reading		
20/01/1999	Vote in committee, 2nd reading		Summary
20/01/1999	Committee recommendation tabled for plenary, 2nd reading	<a href="#">A4-0020/1999</a>	
09/02/1999	Debate in Parliament		
10/02/1999	Decision by Parliament, 2nd reading	T4-0092/1999	Summary
11/05/1999	Act approved by Council, 2nd reading		
31/05/1999	Final act signed		
31/05/1999	End of procedure in Parliament		
30/07/1999	Final act published in Official Journal		

### Technical information

Procedure reference	1996/0200(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
	Amended by <a href="#">2003/0256(COD)</a> Repealed by <a href="#">2007/0121(COD)</a>
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/4/10464

### Documentation gateway

Legislative proposal	<a href="#">COM(1996)0347</a> <a href="#">OJ C 283 26.09.1996, p. 0001</a>	18/07/1996	EC	Summary
Economic and Social Committee: opinion, report	<a href="#">CES0330/1997</a> <a href="#">OJ C 158 26.05.1997, p. 0076</a>	20/03/1997	ESC	Summary
Committee report tabled for plenary, 1st reading/single reading	<a href="#">A4-0186/1997</a> <a href="#">OJ C 182 16.06.1997, p. 0003</a>	21/05/1997	EP	
Text adopted by Parliament, 1st reading/single reading	T4-0350/1997 <a href="#">OJ C 222 21.07.1997, p. 0012-0026</a>	26/06/1997	EP	Summary
Modified legislative proposal	COM(1997)0462 <a href="#">OJ C 337 07.11.1997, p. 0045</a>	23/09/1997	EC	Summary
Council position	<a href="#">08956/1/1998</a> <a href="#">OJ C 360 23.11.1998, p. 0001</a>	24/09/1998	CSL	Summary
Commission communication on Council's position	SEC(1998)1699	14/10/1998	EC	Summary

Committee recommendation tabled for plenary, 2nd reading	<a href="#">A4-0020/1999</a> <a href="#">OJ C 150 28.05.1999, p. 0005</a>	20/01/1999	EP	
Text adopted by Parliament, 2nd reading	T4-0092/1999 <a href="#">OJ C 150 28.05.1999, p. 0153-0166</a>	10/02/1999	EP	Summary
Commission opinion on Parliament's position at 2nd reading	COM(1999)0115	11/03/1999	EC	Summary

#### Additional information

European Commission

[EUR-Lex](#)

#### Final act

[Directive 1999/45](#)  
[OJ L 200 30.07.1999, p. 0001](#) Summary

## Dangerous preparations: classification, packaging and labelling

**OBJECTIVE:** the proposal for a European Parliament and Council directive seeks to harmonize the provisions on the classification, packaging and labelling of dangerous preparations marketed in Europe in order to do away with obstacles to trade and guarantee a high level of health and environmental protection. **SUBSTANCE:** the proposal contains provisions which replace and consolidate the existing law on dangerous preparations (Directive 88/379/EEC), but also fresh provisions designed to: - update the directive in order to take account of the changes and bring the related directives into line with technical progress with a view to making them more user-friendly, particularly for SMUs and SMIs; - extend certain provisions of the directive to cover plant protection products, explosives and preparations which, without being dangerous within the meaning of the directive, may pose a danger to users; - introduce provisions on preparations which are dangerous to the environment. ?

## Dangerous preparations: classification, packaging and labelling

This proposal brings the current directive on classification, packaging and labelling of dangerous preparations up to date, while improving the presentation and introducing some new elements. Most of the proposed changes are timely and necessary, and the Committee approves the proposal subject to the comments below. Introduction of plant-protection products (PPPs): the Committee proposes that an annex under this directive give clear, unambiguous rules for labelling these products and to amend Directive 91/414/EEC as necessary, all of which needs to be achieved at the latest when the proposal comes into force. a) Extension of safety data sheets (SDS): full data sheets are justified in those cases where one substance has exposure limits at the workplace. In the case where one component substance poses health hazards (within the context of Article 16), there should be simplified information sheets giving only those details which are really needed for users or consumers. b) Environmental dangers: the annexes should deal only with the technical parts of the assessments, this would allow more rapid adaptations of the technical part in line with progress. c) Alternative names: the use of alternative names should be permitted when justified, and when it entails no additional risk for users and consumers and does not lower the level of information. The procedure of approval of these names is complicated and lengthy. d) Evaluation of health hazards: it needs to be made clear that the increase in the permitted variations only applies in the rare cases where properties of the preparation are first assessed by testing rather than by calculation from the constituents. e) Risk and safety advice phrases: the information given on the label must be really necessary and intelligible. f) Dates of application: application should start from the date of actual publication in the OJ with a five-year transition period. g) Additional labelling of certain sensitizers: putting the name of certain sensitizing substances on the label to alert sensitized persons is a sensible requirement. ?

## Dangerous preparations: classification, packaging and labelling

Provisions restricting tests on animals in a Commission proposal on dangerous chemical preparations were toughened by the Committee. The committee amended and adopted a proposal for a European Parliament and Council Directive on the approximation of national laws on the classification, packaging and labelling of dangerous preparations. The rapporteur was Mrs Monica BALDI (UPE, I). The amendment on animal tests stipulates that where tests on animals are provided for they may be carried out only if the toxicological properties of a preparation cannot be established in any other way, eg using a validated alternative method which does not involve animals. Another amendment says: "If a preparation is advertised on television, radio, in the printed media, posters, by mail shots or other marketing methods, there must be a clear reference to every hazardous property of the preparation." Moreover, information such as "environmentally-friendly", "eco" or any other statement indicating that the preparation is not dangerous or which might lead to an underestimation of its hazards must not appear on the packaging or labelling of preparations covered by the directive. The aim of the directive is to bring together in one document all existing EU legislation on dangerous preparations involving mixtures of two or more chemical substances. It will affect hundreds of thousands of products intended for both the general public and professional users. The directive will replace the Dangerous Preparations Directive (88/379/EEC), extending its scope to cover environmental classification and labelling, pesticides and biocides, safety data sheets, explosives and certain sensitizers which can cause an allergic reaction. Preparations classified as "dangerous to the environment" will have to carry a warning symbol consisting of a dead fish beside a dead tree. ?

## Dangerous preparations: classification, packaging and labelling

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Among other issues, the rapporteur called for safety data sheets to be introduced for preparations containing substances not classified as dangerous and for easily understandable labelling to warn consumers of the risks posed by a product and to provide precautionary advice. Commissioner Bangemann was in favour of Amendments Nos 1, 2, 3, 5, 7, 10, 13, 14, 15, 18, 19, 21, 22, 25, 27 and 31 to 39. He agreed with the principle of Amendments Nos 6, 17, 24, 29 and 30 but was against Amendment No 4 on tests on animals and Amendments Nos 8, 9, 11 and 12 on Austria. In this respect, the Commission took account of the specific nature of this country's legislation. It also did not accept the provision requiring the chemical names of all dangerous substances contained in a preparation, even in concentrations below the threshold level, to be mentioned on the label.

## Dangerous preparations: classification, packaging and labelling

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In adopting the report by Mrs Monica BALDI (UPE, I) by 216 votes to 125 with 3 abstentions Parliament strengthened the provisions of the Commission proposal on the classification, packaging and labelling of dangerous preparations. In its amendments Parliament states that tests on animals may be carried out only if the toxicological properties of a preparation cannot be established in any other way, possibly on the basis of the conventional method or validated alternative method not using tests on animals. It also requires that if a preparation is advertised on television, radio, in the printed media, on posters, by mail shots or other marketing methods there must be a clear reference to every hazardous property of the preparation. Parliament also demands that information such as 'non-harmful' and 'eco' or any other statement indicating that a preparation is not dangerous or which might lead to an underestimation of the hazards of such preparations should not appear on the packaging or labelling of the preparations subject to this directive. ?

## Dangerous preparations: classification, packaging and labelling

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The Commission's amended proposal incorporates, wholly or in part, 16 of the 26 amendments adopted by Parliament at first reading. These amendments relate mainly to labelling, classification and packaging. a) Regarding labelling, the amended proposal: - emphasizes the need for a study of label comprehensibility and a review of the existing rules on labelling if necessary; - introduces the possibility of not requiring full labelling on preparations classified as dangerous for the environment, when they are supplied in small packages (volume less than 125 ml); - prohibits using on labels of preparations covered by the Directive expressions such as 'environmentally friendly' and 'ecological' or expressions that lead to the danger being underestimated. In the case of Annex V, Part C, the amendments accepted are those which: - address the specific warning on sensitizing effects to all persons; - modify the phrase to be used on packages of non-classified preparations for which a safety data sheet is available on request; - propose an addition to Annex V, consisting of specific rules on the labelling of plant protection products. b) Regarding classification, the amended proposal: - introduces restrictions on animal testing where alternative methods are available, and adds provisions concerning data on effects on man; - expresses a clear preference for the conventional method or in vitro methods (alternative methods) for the classification of preparations; - introduces a lower concentration limit (0.1% instead of 0.5%) for classification of preparations containing ozone depleting substances. c) Finally, on the subject of packaging, the amended proposal: - enshrines a well-established practice, namely the need to adapt packaging to the mode of transport and delivery; - removes, from Annex IV, Part B, paragraph 2, the requirement for a tactile danger warning (a special warning for blind persons) on aerosols classified as extremely flammable or highly flammable. ?

## Dangerous preparations: classification, packaging and labelling

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The tenor of the common position of the Council was similar to that of the initial proposal by the Commission, and it incorporated many amendments adopted by the European Parliament at first reading. The Council particularly accepted the amendments seeking to: -require the Commission to submit a report, accompanied, if appropriate, by the necessary proposals concerning labelling requirements applicable to dangerous preparations (the Commission undertook to initiate without delay research into how well users understood labelling); -clarify the objectives of the Directive and specify that its scope includes non-dangerous preparations which may present a specific danger; -clarify the general principles of classification and labelling; -impose restrictions on animal testing where alternatives exist; -confirm the practice already in force with regard to packaging for transport and supply; -formulate the principles which apply to labelling requirements for preparations classified as dangerous for the environment when supplied in small packagings; -ban the inclusion in labelling of such indications as 'ecological' which might cause the dangers to be underestimated; -make it clear that safety data sheets are principally intended for professional users; -in the case of unclassified preparations, extend the requirement to draw up safety data sheets to preparations containing substances dangerous to the environment. As regards the annexes, the Council accepted the amendments seeking to: -insert in Annex III a lower concentration limit (0.1% instead of 0.5%) for classification of preparations containing ozone-depleting substances; -remove the requirement for a tactile danger warning on aerosols classified and labelled as extremely flammable or highly flammable. The Council also made changes with regard to the following points: -evaluation of health hazards and environmental hazards: this provision would make it possible to introduce into Annexes II and III other conventional methods, which might be necessary for alloys; -labelling of plant protection products: the principle underlying labelling of such products was developed further. The message on labels concerning risks would be complemented by a special phrase. Labels on plant protection products would moreover include the normal information about risks, particularly danger symbols and indications; -confidentiality of names of dangerous substances: the provisions concerning confidentiality of chemical names now covered safety data sheets as well. Requests for confidentiality would be authorised not only for dangerous substances but also for irritants. A less bureaucratic notification procedure was also introduced; -arrangements under the accession treaty: the new Member States (Austria, Sweden and Finland) would not be required to transpose the existing Community acquis at the beginning of 1999. The Council opted for a type IIIb committee for measures to implement the Directive. ?

## Dangerous preparations: classification, packaging and labelling

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The Commission supported the common position of the Council, as it retained the general substance of the initial proposal. It simplified the provisions on plant protection products, for example, and clarified the text. The Commission welcomed the prompt adoption of the common position and the special arrangements for Austria, Finland and Sweden. The Directive could be adopted before the end of 1998, which would make it possible to resolve the problems raised by the expiry of the derogations granted to the three new Member States by the accession treaty. The Commission could not accept the commitology procedure (type IIIb) proposed by the Council: it preferred type IIIa.?

## Dangerous preparations: classification, packaging and labelling

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Responding to Parliament's concerns, Council has inserted into its common position on the packaging of dangerous chemical preparations a clear reference to animal welfare and the obligation on manufacturers to use suitable alternatives to animal testing whenever possible. In view of the improvements introduced in the common position, the Committee adopted only three amendments to the common position in a recommendation drafted under the codecision procedure by Monica BALDI (UPE, I). The amendments to the proposed directive involved: improving the committee procedure for adapting the directive in future to technical progress; tightening up labelling where allergic reactions may occur; and taking account of earlier test results when determining acute aquatic toxicity. The aim of the directive is to bring together in one document all existing EU legislation on dangerous preparations involving mixtures of two or more chemical substances. It will affect hundreds of thousands of products intended for both the general public and professional users and will replace a 1988 dangerous preparations directive. Of the 26 amendments adopted by Parliament during its first reading of the original Commission proposal in June 1997, the common position took over 12 unchanged and accepted two in principle. Improvements introduced by the Council include: extending hazard classification to pesticides; widening the obligation to provide safety data sheets; requiring a warning on the labels of preparations containing 0.1% or more of a sensitising substance (ie which can cause an allergic reaction); and laying down transitional arrangements for Finland, Sweden, and Austria. ?

## Dangerous preparations: classification, packaging and labelling

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At second reading under codecision procedure, the European Parliament adopted the report by Monica Stefania Baldi (UPE,IT) on common position 54/98/EC adopted by the Council with a view to the adoption of a European Parliament and Council Directive concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. The report proposes three amendments to the common position: - requiring that the Commission be assisted by a committee of representatives of the Member States, chaired by a Commission representative; - exempting testing of algae, daphnia and fish if a test result is already available before the proposed directive enters into force; - amending labelling requirements for preparations containing a sensitising substance to state simply "may produce an allergic reaction" rather than limiting this warning to "persons already sensitised".?

## Dangerous preparations: classification, packaging and labelling

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The Commission accepts 3 amendments proposed by the Parliament on the second reading and modifies its proposal as a consequence of this. These amendments aim at : - switching from Committee procedure III b) to procedure III a); - introducing the possibility to use ecotoxicological results obtained before the Directive enters into force in order to assess the effects of preparations on the environment; - simplifying the text on the label of preparations containing sensitising substances by addressing the specific warning on allergic effects to all persons.?

## Dangerous preparations: classification, packaging and labelling

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**PURPOSE :** to improve the harmonised measures on the classification, packaging and labelling of dangerous preparations for the internal market; to support and improve the high level of protection of health, safety and the environment. **COMMUNITY MEASURE :** Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classifications, packaging and labelling of dangerous preparations. **CONTENT :** this Directive consists of a recasting of Directive 88/379/EEC in view of providing a coherent approach in all sectors, to rationalise and update existing Community law, to simplify the procedures of adaptation to technical progress and to resolve questions relating to the new Member States. For the purposes of this Directive, dangerous preparations are a mixture of different chemical substances which contain at least one dangerous substance and are considered dangerous (that is containing substance concentrations such as those which are very toxic, toxic, carcinogenic, mutagenic, toxic for reproduction, corrosive, harmful, irritant, sensitising or dangerous for the environment). The Directive: - broadens the field of application of the existing directive in order to cover phytopharmaceuticals (pesticides) which are at present subject to a separate law; - broadens the field of application in order to include measures relating to classification and environmental labelling; - extend certain requirements to preparations containing levels of dangerous substances lower than those which normally fall within the classification of dangerous; - solve the question of the three new Member States (Austria, Finland and Sweden) with whom the respective membership Treaties had agreed transitory regimes which expired at the end of 1998. The new Directive lays down the rules and principles for: the determination of dangerous properties of preparations, based on their physico-chemical properties, their properties that affect health and their environmental properties; classification and labelling; the evaluation of the dangers to health and the environment; the obligations and duties of the Member States; the conditions of packaging and labelling (danger symbols, risk phrases, indications of danger and safety advice, etc); the exemptions from the packaging and labelling requirements; distance selling; safety data sheet (principally intended for use by professional users to enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work) and the confidentiality of chemical names. There is also a safeguard clause provided for in the Directive which authorises a Member State to provisionally prohibit the placing on the market of a preparation, on the basis of a detailed reason for its decision. **ENTRY INTO FORCE :** 30/07/1999. **DEADLINE SET FOR THE TRANSPOSITION :** 30/07/2002.?

