EN

European Communities

EUROPEAN PARLIAMENT

SESSION DOCUMENTS

25 SEPTEMBER 1990 English Edition A3-0230/90

** I

REPORT

by the Committee on the Environment, Public Health and Consumer Protection

on the proposal for a Council directive amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
(COM(89) 575 final. - Doc. C 3-0047/90 - SYN 0227)

Rapporteur: Mrs R. OOMEN-RUIJTEN

DOC_EN\RR\95429 PE 141.305/fin.
Or. NL.

A Series Reports - B Series Motions for Resolutions, Oral Questions - C Series Documents received from other Institutions (e g Consultations)

*	= *Consultation procedure requiring a single reading*	**II	= *Cooperation procedure (second reading) which requires the votes of a majority of the current Members of Parliament for rejection or amendment*
**I	= *Cooperation procedure (first reading)*	***	= *Parliamentary assent which requires the votes of a majority of the current Members of Parliament*

C O N T E N T S

By letter of 9 February 1990 the President of the Council of the European Communities consulted the European Parliament, pursuant to Article 100a of the EC Treaty, on the proposal from the Commission of the European Communities to the Council for a directive amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

On 12 March 1990 the President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs and Industrial Policy for its opinion.

At its meeting of 1 March 1990 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Oomen-Ruijten rapporteur.

It considered the Commission's proposal and the draft report at its meetings of 30 May, 16 July and 18 September 1990.

At the last meeting it approved the draft legislative resolution by 33 votes to one.

The following took part in the vote: Collins, Chairman; Schleicher, Scott-Hopkins and Iversen, Vice-Chairmen; Oomen-Ruijten, rapporteur; Amendola, Avgerinos, Bertens, Bjørnvig, Bowe, Ceci, de la Camara Martinez, Canavarro, Diez de Rivera Icaza, Di Rupo, Duarte Cendan (for Schmid, pursuant to Rule 111(2) of the Rules of Procedure), Gaibisso, Green, Guidolin, Hadjigeorgiou (for Alber), Caroline Jackson, Jensen, Llorca Vilaplana, Simone Martin (for Pimenta), Muntingh, Partsch, Plumb (for Seligman), Pollack, Roth-Behrendt, L. Smith, Valverde Lopez, Vittinghoff, Vernier and Vohrer.

The opinion of the Committee on Economic and Monetary Affairs and Industrial Policy will be published separately.

The report was tabled on 24 September 1990.

The deadline for tabling amendments will appear in the draft agenda for the part-session at which the report is to be considered.

on the proposal for a Council directive amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

Commission text[1]	Amendments
	(Amendment No 1) Second recital
Whereas disparities in these conditions in the Member States directly affect the functioning of the internal market;	Whereas disparities in these conditions in the Member States directly affect the functioning of the internal market and do not guarantee the same levels of safety for human health and protection of the environment;
	(Amendment No 2) Article 1(1)
OBJECTIVES AND SCOPE	OBJECTIVES AND SCOPE
1. The purpose of this directive is to approximate the laws, regulations and administrative provisions of the Member States	1. The purpose of this directive is to approximate the laws, regulations and administrative provisions of the Member States on:
(a) the notification of substances, (b) the exchange of information on notified substances, (c) the assessment of the potential risk to man and the environment of notified substances, (d) the classification, packaging and labelling of substances dangerous to man or to the environment,	(a) the notification of substances, (b) the exchange of information on notified substances, (c) the assessment of the potential risk to man and the environment of notified substances, (d) the classification, packaging and labelling of substances dangerous to man or to the environment,
which are placed on the market in the Member States	as soon as they are produced.

[1]For the complete text see COM(89) 0575 final - OJ No C 033, 13.02.1990, p. 3

(Amendment No 3)
Article 1(2)

(g) substances in transit which are under customs supervision provided they do not undergo any treatment or processing.	(g) substances in <u>transit</u>[1] which are under customs supervision provided they do not undergo any treatment or processing.
	<u>[1]Regulation No. 2504/88/EEC, OJ of 15.8.1988</u>

(Amendment No 4)
Article 2(1)(c)

(c) 'Notification' means the documents with the requisite information presented to the competent authority of a Member State:	(c) 'Notification' means the documents with the requisite information presented to the competent authority of a Member State:
- for substances manufactured in the Community, by the manufacturer established in the Community who places on the market a substance on its own or in a preparation;	- for substances manufactured in the Community, by the manufacturer established in the Community who places on the market <u>directly or via an intermediary</u> a substance on its own or in a preparation;
- for substances manufactured outside the Community by the legal or natural person established within the Community who, for the purpose of submitting the notification relating to a given substance in conformity with this Directive, is designated by the manufacturer as being his sole representative.	- for substances manufactured outside the Community by the legal or natural person established within the Community who, for the purpose of submitting the notification relating to a given substance in conformity with this Directive, is designated by the manufacturer as being his sole representative.
The person presenting a notification as described above shall hereinafter be referred to as 'the notifier'.	The person presenting a notification as described above shall hereinafter be referred to as 'the notifier'.

(Amendment No 5)
Article 2(1)(c) (new)

	<u>'Polymers' are as defined by the OECD in January 1990</u>

(Amendment No 6)
Article 2(1)(d)

(d) 'Placing on the market' means supplying or making available to third parties.	(d) 'Placing on the market' means supplying or making available to third parties.
Importation into the Community customs territory shall be deemed to be placing on the market for the purposes of this Directive.	Importation into or exportation from the Community customs territory and importation or exportation involving third countries shall be deemed to be placing on the market for the purposes of this Directive.

(Amendment No. 7)
Article 2(2)(i)
(applicable only to the Dutch text)

(Amendment No. 8)
Article 2(2)(o)

dangerous for the environment:	harmful to the environment:
substances and preparations which, should they enter the environment, present or may present an immediate or delayed danger for one or more compartments of the environment.	substances and preparations which, should they enter the environment, have or may have an immediate or delayed harmful effect on one or more compartments of the environment.

(Amendment No 9)
Article 3(1)

1. The physico-chemical properties of the substances and preparations shall be determined according to the methods specified in Annex V, Part A(1); their toxicity shall be determined according to the methods specified in Annex V, Part B(1) and their ecotoxicity according to those specified in Annex V, Part C[1].	1. The physico-chemical properties of the substances (two words deleted) shall be determined according to the methods specified in Annex V, Part A(1); their toxicity shall be determined according to the methods specified in Annex V, Part B(1) and their ecotoxicity according to those specified in Annex V, Part C[1].
Laboratory tests shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and the provisions of Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes[2].	Laboratory tests shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and the provisions of Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes[2].
[1]See the following adaptations to technical progress: - OJ No L 251, 19.9.1984, p. 1 - OJ No L 133, 30.5.1988, p. 1 [2]OJ No L 15, 17.1.1987, p. 29	[1]See the following adaptations to technical progress: - OJ No L 251, 19.9.1984, p. 1 - OJ No L 133, 30.5.1988, p. 1 [2]OJ No L 15, 17.1.1987, p. 29

(Amendment No 10)
Article 6(4)

4. Without prejudice to Article 9 any notifier of a substance already notified shall inform the competent authority:	4. Without prejudice to Article 9 any notifier of a substance already notified shall inform the competent authority:
- when the quantity of the substance placed on the market reaches 10t per year per manufacturer or when the total quantity placed on the market reaches 50t per manufacturer; in this case, the competent authority may require some or all the additional tests/studies laid down in Annex VIII, level 1 to be carried out within a time limit it will determine.	- when the quantity of the substance placed on the market reaches 5t per year per manufacturer or when the total quantity placed on the market reaches 25t per manufacturer; in this case, the competent authority may require some or all the additional tests/studies laid down in Annex VIII, level 1 to be carried out within a time limit it will determine.
- when the quantity of the substance placed on the market reaches 100t per year per manufacturer or when the total quantity placed on the market reaches 500t per manufacturer; in this case, the competent authority shall require the additional tests/studies laid down in Annex VIII, level 1 to be carried out within a time limit it will determine, unless the notifier can justify that a given test/study is not appropriate or an alternative time for the test/study would be preferable.	- when the quantity of the substance placed on the market reaches 50t per year per manufacturer or when the total quantity placed on the market reaches 250t per manufacturer; in this case, the competent authority shall require the additional tests/studies laid down in Annex VIII, level 1 to be carried out within a time limit it will determine, unless the notifier can justify that a given test/study is not appropriate or an alternative time for the test/study would be preferable.
- when the quantity of a substance placed on the market reaches 1 000t per year per manufacturer or when the total quantity placed on the market reaches 5 000t per manufacturer; in this case, the competent authority shall draw up a programme of tests/studies according to Annex VIII, level 2, to be carried out by the notifier within a time limit it will determine.	- when the quantity of the substance placed on the market reaches 500t per year per manufacturer or when the total quantity placed on the market reaches 2 500t per manufacturer; in this case, the competent authority shall draw up a programme of tests/studies according to Annex VIII, level 2, to be carried out by the notifier within a time limit it will determine.

(Amendment No 11)
Article 6(6) new

A Member State may require a producer or importer placing a substance on that Member State's market for the first time to supply the information referred to in Article 7 regardless of whether or not the substance has previously been placed on the market in another Member State.

(Amendment No 12)
Article 6(7) new

Where a substance that is notifiable pursuant to this Directive is to be exported to a third country by a Community undertaking, that undertaking shall submit the corresponding notification to the recipient country unless national notification rules are in force there.

(Amendment No 13)
Article 7(1) to first indent

REDUCED NOTIFICATION REQUIREMENTS FOR SUBSTANCES PLACED ON THE MARKET IN QUANTITIES LESS THAN ONE TONNE PER ANNUM PER MANUFACTURER	REDUCED NOTIFICATION REQUIREMENTS FOR SUBSTANCES PLACED ON THE MARKET IN QUANTITIES LESS THAN ONE TONNE PER ANNUM PER MANUFACTURER
1. Without prejudice to Article 1(4), 8(1) and 11(1), any notifier of a substance placed on the Community market in quantities less than one tonne per annum per manufacturer shall be required to submit to the competent authority referred to in Article 11(1) of the Member State in which the substance is manufactured, or in the case of a manufacturer located outside the Community, the Member State within which the notifier is established, a notification including:	1. Without prejudice to Article 1(4), 8(1) and 11(1), any notifier of a substance placed on the Community market in quantities less than one tonne per annum per manufacturer shall be required to submit to the competent authority referred to in Article 11(1) of the Member State in which the substance is manufactured, or in the case of a manufacturer located outside the Community, the Member State within which the notifier is established, a notification including:
- a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or Annex VII Part B, together with an indication of the methods used or a bibliographical reference to them;-a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose. As a minimum the dossier shall contain at least the information and results of the studies referred to in Annex VII Part B, together with an indication of the methods used or a bibliographical reference to them;	- a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or Annex VII Part B, together with an indication of the methods used or a bibliographical reference to them;-a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose. As a minimum the dossier shall contain at least the information and results of the studies referred to in Annex VII Part B, together with an indication of the methods used and a bibliographical reference to them;

(Amendment No 14)
Article 7(3)

In the absence of any indication to the contrary from the competent authority, the substance may be placed on the market 15 days after the receipt of the dossier by the competent authority subject to any conditions which may subsequently be imposed by the authority.	In the absence of any indication to the contrary from the competent authority, the substance may be placed on the market 30 days after the receipt of the dossier by the competent authority subject to any conditions which may subsequently be imposed by the authority.

(Amendment No 15)
Article 7(4)

In the case of a notifier who has submitted a reduced notification dossier in conformity with the second subparagraph of paragraph 1 then 15 days before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer or before the total quantity placed on the market reaches 500 kg per manufacturer, the notifier shall provide the competent authority with the additional information necessary to complete the technical dossier to the level of Annex VII, Part B.	In the case of a notifier who has submitted a reduced notification dossier in conformity with the second subparagraph of paragraph 1 then 15 days before the quantity of the substance placed on the market reaches 100 kg per year per manufacturer (fourteen words deleted), the notifier shall provide the competent authority with the additional information necessary to complete the technical dossier to the level of Annex VII, Part B.
Similarly when a notifier has submitted a reduced notification in conformity with the first subparagraph of paragraph 1 above, then before the quantity of the substance placed on the market reaches 1 tonne per annum per manufacturer, or before the total quantity placed on the market reaches 5 tonnes per manufacturer, the notifier shall submit a full notification according to the requirements of Article 6.	Similarly when a notifier has submitted a reduced notification in conformity with the first subparagraph of paragraph 1 above, then 15 days before the quantity of the substance placed on the market reaches 1 tonne per annum per manufacturer, or before the total quantity placed on the market reaches 5 tonnes per manufacturer, the notifier shall submit a full notification according to the requirements of Article 6.

(Amendment No 16)
Article 8(1)

1. The following substances are exempted from the provisions of Articles 6, 7, 9 and 10:

- substances which appear in the inventory referred to in Article 16(1),

- from the date of entry into force of Directive ../.../[1] 'on the placing of plant protection products on the market' to active substances intended for exclusive use in such products and as covered by the above Directive,

- additives and substances for exclusive use in animal feedingstuffs as covered by Directive 70/524/EEC and by Directive 82/471/EEC[2],

- substances used exclusively as additives in foodstuffs as covered by Directive 89/107/EEC[3].

[1]OJ No C 89, 10.4.1989, p. 22
[2]OJ No L 213, 21.7.1982, p. 8
[3]OJ No L 40, 11.2.1989, p. 27

1. The following substances are exempted from the provisions of Articles 6, 7, 9 and 10:

- substances which appear in the inventory referred to in Article 16(1),

- from the date of entry into force of Directive ../.../[1] 'on the placing of plant protection products on the market' to active substances intended for exclusive use in such products and as covered by the above Directive,

- additives and substances for exclusive use in animal feedingstuffs as covered by Directive 70/524/EEC and by Directive 82/471/EEC[2],

- substances used exclusively as additives in foodstuffs as covered by Directive 89/107/EEC[3] and substances used as flavourings in foodstuffs which are covered by Directive 88/388/EEC.

[1]OJ No C 89, 10.4.1989, p. 22
2OJ No L 213, 21.7.1982, p. 8
[3]OJ No L 40, 11.2.1989, p. 27

(Amendment No 17)
Article 8(2) last paragraph

2. The substances listed below shall be considered as having been notified within the meaning of this Directive when the following conditions are fulfilled:	2. The substances listed below shall be considered as having been notified within the meaning of this Directive when the following conditions are fulfilled:
- polymerizates, polycondensates and polyadducts except those containing 2% or more of any substance not listed in the inventory referred to in Article 16(1);	- polymerizates, polycondensates and polyadducts except those containing 2% or more of any substance not listed in the inventory referred to in Article 16(1);
- substances placed on the market in quantities less than 10 kg per annum per manufacturer;	- substances placed on the market in quantities less than 10 kg per annum per manufacturer;
- substances placed on the market in limited quantities, and in any case not exceeding 100 kg per manufacturer per annum, and intended solely for purposes of scientific research and development carried out under controlled conditions;	- substances placed on the market in limited quantities, and in any case not exceeding 100 kg per manufacturer per annum, and intended solely for purposes of scientific research and development carried out under controlled conditions;
- any manufacturer or importer making use of this exemption must maintain written records concerning the identity of the substance, labelling data, quantities and a list of customers; this information shall be made available upon request to the competent authorities of each Member State where the manufacture, importation, or scientific research and development takes place;	- any manufacturer or importer making use of this exemption must maintain written records concerning the identity of the substance, labelling data, quantities and a list of customers; this information shall be made available upon request to the competent authorities of each Member State where the manufacture, importation, or scientific research and development takes place;

- substances placed on the market for the purposes of process-oriented research and development with a limited number of registered customers in quantities which are limited to the purpose of process-orientated research and development. These substances shall qualify for an exemption for a period of one year provided that the manufacturer or importer communicates their identity, labelling data, quantity, the justification for the quantity and a list of customers to the competent authorities of each Member State where the manufacture, importation or process-orientated research and development takes place and complies with any conditions imposed by these authorities on such research and development. After this period these substances will normally be subject to notification.	- substances placed on the market for the purposes of process-oriented research and development with a limited number of registered customers in quantities which are limited to the purpose of process-orientated research and development. These substances shall qualify for an exemption for a period of one year provided that the manufacturer or importer communicates their identity, labelling data, quantity, the justification for the quantity and a list of customers to the competent authorities of each Member State where the manufacture, importation or process-orientated research and development takes place and complies with any conditions imposed by these authorities on such research and development. After this period these substances will normally be subject to notification.
The manufacturer or importer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled only by customers' staff in controlled conditions and will not be made available at any time either on its own or in preparation to the general public.	The manufacturer or importer shall also give an assurance that the substance or the preparation in which it is incorporated will be handled only by customers' staff in controlled conditions and will not be made available at any time either on its own or in preparation to the general public.
The one-year exemption period referred to above may in exceptional circumstances be extended for a further year if the notifier can demonstrate to the satisfaction of the competent authority that such an extension is justified.	Delete

(Amendment No 18)
Article 8(3)

3. The substances referred to in paragraph 2, must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 17 to 20 and with the criteria imposed in Annex VI. If it is not possible to label completely because the results of tests provided for in Annex VII Part A are not all available and in accordance with the principles set out in Article 18, the label should bear, in addition to the label deriving from tests already carried out, the warning: 'Caution - substance not yet fully tested'.	3. The substances referred to in paragraph 2, must, in so far as the manufacturer may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled by the manufacturer or his representative in accordance with the rules laid down in Articles 17 to 20 and with the criteria imposed in Annex VI.

(Amendment No 19)
Article 8(3)(a) new

	3a. Not later than 12 months after adoption of this directive by the Council, the Commission shall lay down criteria for granting the temporary one-year exemption from notification.

(Amendment No 20)
Article 10(1)

In the case of a substance which has already been notified in accordance with Articles 6(1) or 7(1), the competent authority may agree that the subsequent notifier of that substance may, for the purposes of items 3, 4 and 5 of Parts A and B of Annex VII and items 3 and 4 of Annex VIII Part C, refer to the results of the tests/studies carried out by the first notifier, insofar as the subsequent notifier can provide evidence that the substance renotified is the same as the one previously notified, including the degree of purity and the nature of impurities. The first notifier must give his agreement in writing to the reference to the results of the test/studies he has carried out before such reference can be made.	In the case of a substance which has already been notified in accordance with Articles 6(1) or 7(1), the competent authority may agree that the subsequent notifier of that substance may, for the purposes of items 3, 4 and 5 of Parts A and B of Annex VII and items 3 and 4 of Annex VIII Part C, refer to the results of the tests/studies carried out by the first notifier, insofar as the subsequent notifier can provide evidence that the substance renotified is the same as the one previously notified, including the degree of purity and the nature of impurities. Unless the first notifier has given his agreement in writing for reference to be made to the tests/studies he has carried out, placing on the market by the new notifier shall be deferred for three months and he shall pay over a sum corresponding to the estimated cost of carrying out the tests/studies required for notification. The sum shall be paid into a fund to be set up in order to develop new test methods involving fewer animals and less suffering for the animals concerned.

(Amendment No 21)
Article 10(3a) (new)

	3a. If, within 12 months after opening of negotiations between the first notifier and the prospective notifier, no agreement has been reached on the amount of payment, they may jointly request the Commission to issue an opinion which shall be binding.

(Amendment No 22)
Article 11(1)

RIGHTS AND DUTIES OF THE COMPETENT AUTHORITIES	RIGHTS AND DUTIES OF THE COMPETENT AUTHORITIES
1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Articles 6-9 and examining its conformity with the requirements of the Directive.	1. Member States shall appoint the competent authority or authorities responsible for receiving the information provided for in Articles 6-9 and examining its conformity with the requirements of the Directive.
Moreover, if it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, the competent authority may ask for further information, supplementary testing and verification/confirmatory tests concerning the substances or their degradation products (metabolites), of which they have been notified or have received information under this Directive; this may also include requesting any of the information referred to in Annex VIII earlier than provided for in Article 6(4).	Moreover, if it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, the competent authority may ask for further information, supplementary testing and verification/confirmatory tests concerning the substances or their degradation products (metabolites), of which they have been notified or have received information under this Directive; this may also include requesting any of the information referred to in Annex VIII earlier than provided for in Article 6(4).
Additionally, the competent authority may:	Additionally, the competent authority may:
- carry out such sampling as is necessary for control purposes;	- carry out such sampling as is necessary for control purposes;
- take appropriate measures relating to safe use of a substance pending the introduction of Community provisions.	- take appropriate measures relating to safe use of <u>any new substance which is dangerous for man and the environment</u> pending the introduction of Community provisions.

(Amendment No 23)
Article 11(2)

2. For notifications submitted in conformity with Article 6(1) the competent authority shall only accept the notification dossier when it is in full conformity with the Directive and shall inform the notifier in writing of this acceptance. The authority shall at the same time advise the notifier of the official number which has been allocated to his notification.	Delete

(Amendment No 24)
Article 11(3)

3. For notifications submitted in conformity with Article 7(1) the competent authority shall, within the period of 15 days following receipt of notification, decide whether the notification is in conformity with the Directive and, in the event that the notification is adjudged not to be in conformity, inform the notifier accordingly. In the event that the notification is in conformity with the Directive, the authority shall, within the 15 day period following receipt of the dossier, advise the notifier of the official number which has been allocated to his notification.	3. For notifications submitted in conformity with Article 6(1) and Article 7(1) the competent authority shall, within the period of 15 days following receipt of notification, decide whether the notification is in conformity with the Directive and, in the event that the notification is adjudged not to be in conformity, inform the notifier accordingly. In the event that the notification is in conformity with the Directive, the authority shall, within the 15 day period following receipt of the dossier, advise the notifier of the official number which has been allocated to his notification.

(Amendment No 25)
Article 11 new paragraph 6

	Ensuring the utmost confidentiality, the competent authorities of the Member States shall devise methods of coordinating measures to ensure that their tasks and responsibilities in respect of checking notifications and uses of substances which are potentially dangerous for man and the environment are carried out as efficiently as possible.

(Amendment No. 26)
Article 14(1)

THE CONFIDENTIALITY OF DATA	THE CONFIDENTIALITY OF DATA
1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Articles 6, 7, 8 and 9 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission. Full justification must be given in such cases.	1. If he considers that there is a confidentiality problem, the notifier may indicate the information provided for in Articles 6, 7, 8 and 9 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and which he therefore wishes to be kept secret from all persons other than the competent authorities and the Commission. Full justification must be given in such cases. In no circumstances shall confidentiality apply in respect of consumer protection, public health or safety at work.

(Amendment No 27)
Article 14(1)(e)

e) the summary results of the toxicological and ecotoxicological tests;	e) the content of the toxicological and ecotoxicological tests, including both the results and a description of the test conditions;

(Amendment No 28)
Article 16(4) - new

4. In the case of substances checked between 1 January 1972 and 18 September 1981, the Commission shall draw up a list of identifiable substances and allocate them an EEC number.

(Amendment No 29)
Article 17(1)(e) (new)

(e) containers with a capacity not exceeding 5 litres which contain dangerous substances intended for domestic use shall have child-resistant fastenings.

(Amendment No 30)
Article 17(2)

2. The Member States may also prescribe that:	2. The Member States may also prescribe that:
- packages shall be closed initially with a seal in such a way that when the package is opened for the first time the seal is irreparably damaged;	- packages shall be closed initially with a seal in such a way that when the package is opened for the first time the seal is irreparably damaged;
- containers with a capacity not exceeding three litres which contain dangerous substances intended for domestic use shall have child-resistant fastenings;	- containers of dangerous substances intended for domestic or industrial use shall have child-resistant fastenings.
- containers with a capacity not exceeding one litre which contain very toxic, toxic or corrosive liquids intended for domestic use shall carry a tactile warning of danger.	- containers of dangerous substances shall carry a comprehensible and preferably tactile warning of danger.
	- notwithstanding subparagraph 1a, one or more ventilation valves or other safety devices may be attached to the packaging for safety reasons or to maintain the quality of the product.

(Amendment No 31)
Article 18(1)

Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the following requirements.	Member States shall take all necessary measures to ensure that dangerous substances cannot be placed on the market unless the labelling on their packaging satisfies the following requirements. Substances exported to third countries shall be labelled in accordance with the same rules, and in a language agreed upon with the recipient country, unless equivalent labelling rules are in force in that country.

(Amendment No 32)
Article 18(3)

In the case of irritant, highly flammable, flammable and oxidizing substances, an indication of special risks and safety advice need not be given where the package does not contain more than 125ml. This shall also apply in the case of the same volume of harmful substances not retailed to the general public.	In the case of irritant neurotoxicological, non-allergenic substances (R 42 and 43) and highly flammable, flammable and oxidizing substances, an indication of special risks and safety advice need not be given where the package does not contain more than 125ml. This shall also apply in the case of the same volume of harmful substances used for laboratory purposes only.

(Amendment No 33)
Article 19(4)

4. Member States may make the placing on the market of dangerous substances in their territories subject to the use of the official language or languages in respect of the labelling thereof.	4. Member States must make the placing on the market of dangerous substances in their territories subject to the use of the official language or languages in respect of the labelling thereof, except in the case of small packs of chemicals for laboratory use.

(Amendment No 34)
Article 20a (new)

	Advertising
	1. Recommending or praising a substance belonging to one or more of the categories specified in Article 2(2) without mentioning the category or categories to which it belongs is prohibited.
	2. Referring to a substance in a manner which is misleading in respect of the effects of the substance on man or the environment is prohibited.

(Amendment No 35)
Article 21(1)

1. At or, if appropriate, before the first delivery of a dangerous substance or preparation, any manufacturer, importer or distributor shall communicate to the recipient the information necessary for the protection of man and the environment by the means of a safety data sheet. This data sheet must be communicated on paper or electronically. Subsequently, the manufacturer, importer or distributor shall forward to the recipient of the safety data sheet any new relevant information on the substance or preparation which has become known to him.	1. At or, if appropriate, before the first delivery of a dangerous substance (two words deleted), any manufacturer, importer or distributor shall communicate to the recipient the information necessary for the protection of man and the environment by the means of a safety data sheet. This data sheet may be communicated on paper or electronically. Subsequently, the manufacturer, importer or distributor shall forward to the recipient of the safety data sheet any new relevant information on the substance (two words deleted) which has become known to him.

(Amendment No 36)
Article 21(2)

2. Detailed regulations on the elaboration, distribution, contents and format of the safety data sheet referred to in paragraph 1 will be the subject of a future Community legal instrument.	2. Detailed regulations on the elaboration, distribution, contents and format of the safety data sheet referred to in paragraph 1 will be the subject of a Community legal instrument to be drawn up no later than twelve months after adoption of this directive by the Council.

(Amendment No 37)
Article 21(3) (new)

2

A Member State may require safety data sheets to be submitted on substances not included in Annex I. Insofar as there are, according to that Member State, powerful health-related and environmental arguments for maintaining this requirement, it shall not be possible for the Commission to circumvent this on the basis of the procedure under Article 26.

As a guide and until specific rules are laid down, the safety sheets shall contain at least the data listed in Annex ...

(Amendment No 38)
Article 25

Free circulation clause	Free circulation clause
The Member States may not prohibit, restrict or impede the placing on the market of substances which comply with the requirements of this Directive, on grounds relating to notification, classification, packaging or labelling within the meaning of this Directive.	The Member States may not prohibit, restrict or impede the production and placing on the market of substances which comply with the requirements of this Directive, on grounds relating to notification, classification, packaging or labelling within the meaning of this Directive.

(Amendment No 39)
Article 25(2) (new)

The provisions of paragraph 1 shall be without prejudice to the options open to the Member States pursuant to Articles 6(6) and 21(3).

Annex IIIB point 4.3.2. (new)

4.3.2. Teratogenicity: pre-screening test.

DRAFT LEGISLATIVE RESOLUTION

(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council[1]

- having been consulted by the Council pursuant to Article 100a of the EEC Treaty (Doc. C 3-47/90),

- considering the proposed legal basis to be appropriate,

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy (Doc. A3-0230/90),

1. Approves the Commission's proposal subject to Parliament's amendments and in accordance with the vote thereon;

2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;

3. Calls on the Council to incorporate Parliament's amendments in the common position it adopts in accordance with Article 149(2)(a) of the EEC Treaty;

4. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;

5. Instructs its President to forward this opinion to the Council and Commission.

---

[1] OJ No. C 33, 13.2.1990, p.3

EXPLANATORY STATEMENT

1. The purpose of the 'seventh' amendment

Since the sixth amendment to Directive 67/548/EEC[2] in September 1981, there have been 788 full notifications and 2 607 restricted notifications in respect of new chemical substances up to 31 December 1989.

In the light of experience of implementation of the sixth amendment, which came into force pursuant to Directive 79/831/EEC[3] and in the light of the need to respond to a number of new developments, the Commission has submitted a proposal to amend existing legislation in certain respects.

Although the system underlying existing legislation is not amended, the proposal nevertheless contains a number of important changes.

It should not be forgotten that as far as notification is concerned the directive is applicable only to dangerous substances marketed since the directive came into effect in 1981. These amounted to 384 by the end of 1989. The European Inventory of Existing Chemical Substances (EINECS) contains more than 100 000 substances. What this means is that the competent authorities and the Commission are unaware of the test results of most substances. However, the Commission is working towards bridging this enormous gap in knowledge of dangerous substances. These substances are, however, covered by the regulations on classification, labelling and packaging.

Comments on the various amendments are given below. A number of shortcomings are then outlined and the proposed amendments are then discussed in detail.

2. The main changes

The main changes are:

- the introduction of a symbol to indicate that the substance is harmful to the environment;

- extending the scope of some definitions and additions to the hazard categories;

- harmonization of 'restricted' notifications (notifications in respect of substances which are marketed in quantities less than 1 000 kilograms per annum);

- centralization of the procedure for notification for imported dangerous substances;

- the introduction of a distinction between purely scientific research and industrial research, which is important for the granting of certain exemptions;

---

[2]OJ No. L 196, 16.8.1967, p.1
[3]OJ No. L 259, 15.10.1979, p.10

- the desire to limit the number of animal tests and to pass test results on to subsequent notifiers;

- the gradual reduction in the scope of confidentiality of data;

- a risk-assessment of the substances;

- extending the scope of the 'basic dossier'

2.1. Substances harmful to the environment

One of the explicit objectives of the proposal for a directive is 'the assessment of the potential risk to man and the environment of notified substances' (Article 1(1)(c)). Article 2(2)(o) then defines 'dangerous for the environment'. Such substances are therefore a separate category and labelling for such substances must state 'dangerous for the environment' and the label must also bear a symbol indicating the risk to the environment (a dead tree and a fish gulping for air).

2.2. Harmonization of reduced notifications

Producers of dangerous substances which are marketed in quantities less than one tonne per annum are obliged, pursuant to the sixth amendment, to make a reduced notification in every Member State where the product is marketed. This procedure is unsatisfactory because the national authorities in one Member State may impose different requirements from those of another Member State. The requirements proposed by the Commission with regard to the tests that have to be carried out are the 'average' of existing requirements of the twelve Member States. The Commission does not therefore expect the number of animal tests to increase. The Commission's proposal is that, following notification to the competent authorities in one Member State, the product can be marketed in all Member States.

There are now six categories of substances with different notification requirements:

1. Substances marketed in quantities less than 10 kg per annum per manufacturer and substances marketed in a quantity of less than 100 kg per annum per manufacturer and intended solely for scientific research in laboratories: no notification requirements.

2. Substances which are marketed in quantities less than 100 kg per annum per manufacturer: reduced notification; technical dossier pursuant to Annex VII C.

3. Substances marketed in quantities less than 1000 kg per annum per manufacturer: reduced notification; technical dossier pursuant to Annex VII B.

4. Substances marketed in quantities of more than 1000 kg per annum per manufacturer: full notification; technical dossier pursuant to Annex VIIA.

5. Substances manufactured in quantities in excess of 10 000 kg per year per manufacturer or to a cumulative total of 50 000 kg per manufacturer: full

notification pursuant to Annex VII A +, where applicable, the requirements of Level 1 of Annex VIII.

6. Substances marketed in quantities in excess of 100 000 kg per year per manufacturer or a cumulative total of 500 000 kg per manufacturer: full notification pursuant to Annex VII A +, where applicable, the requirements of Level 2 of Annex VIII.

2.3. Imports of dangerous substances

Notification is compulsory, pursuant to the sixth amendment, in respect of every direct import of a dangerous substance into the Community. For certain substances this means several different notifications, with all the bureaucratic rigmarole for the importer, and also for the national authorities and the Commission. Since the quantities imported are often less than the annual production of producers in the Community, the current situation is such that importers are not compelled to carry out the (costly) supplementary test programmes which are obligatory if the thresholds of 100 tonnes and 1000 tonnes of dangerous substances marketed are exceeded. What this means in fact is a competitive disadvantage for Community producers, and it is unsatisfactory in the light of protection of health and the environment.

The Commission is now proposing that a producer outside the Community should appoint a representative (a natural person or legal entity) to act as his legal representative within the Community and who is responsible for notification.

2.4. Research and development

The seventh amendment makes a distinction between 'scientific research and development' and 'process-orientated research and development' (Article 2(e) and 2(f) respectively). These categories are subject to different exemptions which are covered by Article 8(2).

2.5. Tests on animals

In order to restrict tests on vertebrates, which the Commission has undertaken to do pursuant to Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes[4], the Commission proposes in the seventh amendment that producers considering notification are obliged to ask the competent authorities whether another producer has already made a notification in respect of the substance for which the first producer is considering notification. If this is the case, the authorities shall supply the prospective notifier with the name and address of the first notifier. The prospective notifier must then contact the first notifier, the intention being that the first notifier informs the prospective notifier of the results of his animal tests. The Commission hopes that in this way it can help reduce the number of animal tests. The question of cost however, is not covered by the proposal.

---

[4] OJ No. L 358, 18.12.86, p. 1

2.6. Confidentiality of certain data

Under the seventh amendment the identity of the notifier and the manufacturer, and data in respect of the purity of the substance (if irrelevant for classification and labelling purposes) and the summary results of the toxicological and ecotoxicological tests are no longer deemed to be confidential.

On the other hand, certain information specified in Articles 6, 7, 8 and 9 which is deemed to be commercially sensitive may be kept secret from everyone except the competent authorities.

2.7. Risk assessment

In its explanatory note to the proposal the Commission states: 'It should be possible, if protection of man and the environment is one of the major aims of the directive, to foresee a situation where a substance can be prohibited or restricted in its use, on the basis of the information contained within the notification dossier, irrespective of whether the classification, packaging and labelling are in conformity with the directive.'

Article 26 of the proposal provides accordingly that Member States may ban the substance temporarily. With the provisions of this Article the proposal for a directive takes on the aspect of an approval procedure.

3. Final remarks

The seventh amendment is a good step towards the protection of man and the environment. The safeguard clause introduced in Article 26 is particularly important since it permits a harmonized risk evaluation in the future.

Nevertheless, the Commission also needs to organize an information campaign to familiarize the public with the symbols for, and the use of, dangerous substances.

Furthermore, the Commissioner should also review the labelling of dangerous substances in the light of the scientific research that has been carried out in respect of the legibility of labels.[5]

In conclusion your rapporteur calls for the streamlining of the whole field of legislation on dangerous substances and preparations, because the legislation in force has become so complex that it is often not possible to see the wood for the trees.

---

[5] For example: the report by the Nederlands Instituut voor Consumentenonderzoek (Dutch Institute for Consumer Protection) with regard to 'Product Information for the Prevention of Accidents in the Home and during Leisure Activities', drawn up by A. Venema in 1989 and published by SWOKA, ISBN 19-6573 - 081-8; and as advocated by the 'Plain English Campaign', Stockport, UK.