Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2003/0257(COD)	Procedure completed
Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC) Subject 3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PSE SACCONI Guido	27/07/2004
Former committee responsible		
ENVI Environment, Public Health and Food Safety	PSE SACCONI Guido	27/07/2004
ENVI Environment, Public Health, Consumer Policy	PSE SACCONI Guido	16/06/2003
Former committee for opinion		
ITRE Industry, Research and Energy (Associated committee)	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection (Associated committee)	PPE-DE NASSAUER Hartmut	28/07/2004
JURI Legal Affairs and Internal Market (Associated committee)	PPE-DE NASSAUER Hartmut	01/12/2003
ITRE Industry, External Trade, Research, Energy (Associated committee)	ELDR PLOOIJ-VAN GORSEL Elly	02/10/2003
INTA International Trade	The committee decided not to give an opinion.	
BUDG Budgets	PSE HAUG Jutta	31/01/2005
ECON Economic and Monetary Affairs	Verts/ALE HASSI Satu	23/09/2004
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
JURI Legal Affairs		07/10/2004

		PPE-DE LECHNER Kurt	
	FEMM Women's Rights and Gender Equality	The committee decided not to give an opinion.	
	PETI Petitions	The committee decided not to give an opinion.	
	BUDG Budgets	PSE KUCKELKORN Wilfried	16/12/2003
	ECON Economic and Monetary Affairs		
	EMPL Employment and Social Affairs	PPE-DE MANN Thomas	19/11/2003
	FEMM Women's Rights and Equal Opportunities	GUE/NGL ERIKSSON Marianne	20/01/2004

Council of the European Union	Council configuration	Meeting	Date
	Environment	2740	27/06/2006
	Competitiveness (Internal Market, Industry, Research and Space)	2731	29/05/2006
	Competitiveness (Internal Market, Industry, Research and Space)	2694	28/11/2005
	Environment	2684	17/10/2005
	Competitiveness (Internal Market, Industry, Research and Space)	2681	11/10/2005
	Environment	2670	24/06/2005
	Competitiveness (Internal Market, Industry, Research and Space)	2665	06/06/2005
	Competitiveness (Internal Market, Industry, Research and Space)	2645	07/03/2005
	Environment	2632	20/12/2004
	Competitiveness (Internal Market, Industry, Research and Space)	2624	25/11/2004
	Environment	2593	28/06/2004
	Competitiveness (Internal Market, Industry, Research and Space)	2583	17/05/2004
	Competitiveness (Internal Market, Industry, Research and Space)	2570	11/03/2004
	Environment	2556	22/12/2003
	Competitiveness (Internal Market, Industry, Research and Space)	2547	27/11/2003
	Competitiveness (Internal Market, Industry, Research and Space)	2539	10/11/2003

European Commission	Commission DG	Commissioner
	Internal Market, Industry, Entrepreneurship and SMEs	
	Environment	

Key events

29/10/2003	Legislative proposal published	COM(2003)0644	Summary
10/11/2003	Debate in Council	2539	Summary

27/11/2003	Debate in Council	2547	
03/12/2003	Committee referral announced in Parliament, 1st reading		
22/12/2003	Debate in Council	2556	
11/03/2004	Debate in Council	2570	
17/05/2004	Debate in Council	2583	
28/06/2004	Debate in Council	2593	Summary
16/09/2004	Committee referral announced in Parliament, 1st reading		
25/11/2004	Debate in Council	2624	Summary
20/12/2004	Debate in Council	2632	Summary
07/03/2005	Debate in Council	2645	
06/06/2005	Debate in Council	2665	Summary
24/06/2005	Debate in Council	2670	Summary
04/10/2005	Vote in committee, 1st reading		Summary
07/10/2005	Committee report tabled for plenary, 1st reading	A6-0285/2005	
11/10/2005	Debate in Council	2681	Summary
17/10/2005	Debate in Council	2684	Summary
15/11/2005	Debate in Parliament		
17/11/2005	Results of vote in Parliament		
17/11/2005	Decision by Parliament, 1st reading	T6-0435/2005	Summary
28/11/2005	Debate in Council	2694	Summary
29/05/2006	Debate in Council	2731	
27/06/2006	Council position published	07525/3/2006	Summary
07/09/2006	Committee referral announced in Parliament, 2nd reading		
10/10/2006	Vote in committee, 2nd reading		Summary
12/10/2006	Committee recommendation tabled for plenary, 2nd reading	A6-0345/2006	
11/12/2006	Debate in Parliament		
13/12/2006	Decision by Parliament, 2nd reading	T6-0553/2006	Summary
18/12/2006	Final act signed		
18/12/2006	End of procedure in Parliament		
30/12/2006	Final act published in Official Journal		

Technical information

Procedure reference	2003/0257(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	EC Treaty (after Amsterdam) EC 095; Rules of Procedure EP 57
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/34796

Documentation gateway

Legislative proposal		COM(2003)0644	29/10/2003	EC	Summary
Document attached to the procedure		SEC(2003)1171	29/10/2003	EC	
Supplementary legislative basic document		15409/2003	28/11/2003	CSL	
Economic and Social Committee: opinion, report		CES0524/2004	31/03/2004	ESC	
Amendments tabled in committee		PE357.761	02/05/2005	EP	
Economic and Social Committee: opinion, report		CES0850/2005 OJ C 294 25.11.2005, p. 0038-0044	13/07/2005	ESC	
Committee opinion	EMPL	PE357.617	20/07/2005	EP	
Committee opinion	ECON	PE355.467	14/09/2005	EP	
Committee opinion	JURI	PE357.853	16/09/2005	EP	
Committee opinion	IMCO	PE357.851	19/09/2005	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0285/2005	07/10/2005	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0435/2005	17/11/2005	EP	Summary
Commission response to text adopted in plenary		SP(2005)5015	15/12/2005	EC	
Council statement on its position		10412/2006	15/06/2006	CSL	
Committee draft report		PE374.491	23/06/2006	EP	
Council position		07525/3/2006 OJ C 276 14.11.2006, p. 0252-0254 E	27/06/2006	CSL	Summary
Document attached to the procedure		SEC(2006)0924	12/07/2006	EC	Summary
Commission communication on Council's position		COM(2006)0375	12/07/2006	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A6-0345/2006	12/10/2006	EP	
Text adopted by Parliament, 2nd reading		T6-0553/2006	13/12/2006	EP	Summary
Draft final act		03665/2006	18/12/2006	CSL	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2006/121
OJ L 396 30.12.2006, p. 0850 Summary

Corrigendum to final act 32006L0121R(01)
OJ L 136 29.05.2007, p. 0281 Summary

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

PURPOSE : to amend Directive 67/548/EC on packaging and labelling in order to adapt it to the provisions of the proposals on REACH (Please see COD/2003/0256). PROPOSED ACT : Directive of the European Parliament and of the Council. CONTENT : Directive 67/548/EEC sets out rules not only how to classify, package and label dangerous substances, but also how to notify new substances to the Competent Authorities in the relevant Member State before placing them on the market. The Commission has presented proposals on a single regulatory system for all substances (entitled REACH for the Registration, Evaluation and Authorisation of Chemicals) and giving industry the responsibility for generating data on the inherent properties of substances and for assessing the risks related to their use. The new REACH Regulation will introduce the same registration requirements for new chemicals as for the existing substances which means that the rules for notification of new chemicals in Directive 67/548/EEC have to be repealed. However, the REACH proposal does not at present include rules for classification, labelling and packaging of dangerous substances, and the relevant parts of Directive 67/548/EEC will continue to apply. Directive 67/548/EEC contains several Annexes related to information requirements and testing methods to be used. The content of these annexes will be taken over by the Annexes to the REACH legislation and thus they have to be repealed from the Directive. Moreover, a substantial number of references to testing methods and information requirements must be amended as a consequence of the introduction of the REACH legislation. In addition, the proposal seeks to repeal Commission Directive 93/67/EEC.?

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council took note of Commissioner Liikanen's presentation of the legislative proposal for a Regulation on the registration, evaluation, authorisation and restriction of chemicals (REACH) and instructed the Permanent Representatives Committee to examine the proposal as a matter of priority as soon as it has been transmitted. The objective of the REACH proposal is to improve the protection of human health and the environment against chemical hazards while ensuring the proper functioning of the internal market and maintaining the competitiveness of the chemicals industry. The following main issues emerged from the Council's debate which followed the presentation of this legislative proposal: - a large majority of delegations welcomed the amendments introduced by the Commission in its final proposal which takes into account some of the concerns expressed by different sectors consulted, primarily as regards the scope of the REACH system and the associated costs for industry; - sharing the need for a balanced approach taking into account competitiveness, environmental and health aspects as equally important, delegations welcomed the decision taken by the Permanent Representatives Committee to set up an ad hoc Working Party on Chemicals with a broad mandate to examine the proposal in all its aspects; - during the debate, the Commission underlined that it had presented an impact assessment of costs for industry. Many delegations stressed the importance of such comprehensive impact assessment, in particular as regards SME's and other users of chemicals; - some delegations were of the opinion that indirect costs resulting from the application of the REACH system would still be considerable and had to be examined carefully; and - several delegations underlined the role to be played by the proposed Chemicals Agency in coordinating the evaluation procedure and thus ensuring that there are no distortions in the application of the rules. It is recalled that the last European Council (16/17 October) indicated in its conclusions that "European Union legislation should not be a handicap to EU competitiveness compared to that of other major economic areas. To this end the Commission is invited to take into account the consequences of proposed EU legislation on enterprises through providing a comprehensive impact assessment. The forthcoming proposal on chemicals, which will be examined by the Competitiveness Council in coordination with other Council configurations, will be the first case for implementing this approach, taking in particular into account its effects on SMEs.?

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council held a policy debate on the proposals for a Regulation and for a Directive on registration, evaluation, authorisation and restriction of chemicals and on the establishment of a European Chemicals Agency, with a view to giving political guidance for further work by forthcoming Presidencies.

Delegations were invited to answer the following indicative questions suggested by the Presidency:

? whether, having regard to the relative roles and contributions of the authorisation and restrictions processes for the management of risks to human health and the environment from substances of very high concern, and the inter-relationship between these two processes, there is merit in exploring the scope for improving the workability of the proposal so that the underlying objectives are met in a timely and

resource-efficient manner ?

? whether the Council considers that the Commission proposal covers the essential elements to encourage substitution for substances of very high concern so as to reduce the risks to human health and the environment while stimulating innovation and enhancing the competitiveness of European industry ?

? whether the Council considers that the Commission proposal provides adequately for the quality of data provided by industry, or that there is merit, in the ongoing examination of REACH, in investigating the need for additional measures ?

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council held a policy debate on the draft Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and establishing a European Chemicals Agency. The debate took place on the basis of a Presidency Report which reflected discussions so far in the ad hoc Working Party on Chemicals, established in November 2003.

At the end of the debate, the Presidency stated that a number of key issues have been discussed during the policy debate, the purpose of which was to give political guidance for work under the subsequent Presidencies.

The Council took note of the Presidency's report on the basis of which it held a policy debate addressing a set of key issues, notably: conclusions and recommendations from the REACH Impact Assessment Workshop; mandatory sharing of nonanimal data, including agreements on core data sets and cost sharing; and information requirements for low volume substances.

As to the Workshop on REACH Impact Assessment held in The Hague on 25-27 October 2004, the Council welcomed the conclusions and recommendations and instructed its preparatory bodies in cooperation with the Commission to take account of them in the future work.

Concerning the issue of joint submission of data including cost sharing, the Council stressed the importance of avoiding unnecessary testing on animals and underlined the need to improve the protection of the human health and the environment while ensuring the competitiveness of the European chemicals industry, in particular of SMEs. In this context, the Council discussed a suggestion implying mandatory sharing of all data, including legally-binding rules on cost sharing, as a possible means to achieve these objectives. While there was support, the Council called for further examination of this issue, taking into account the Opinion of the Council Legal Service.

The Council discussed the question of a possible extension of the data requirements for low volume substances (1-10 tonnes per year). Member States acknowledged the importance of having sufficient data to enable appropriate classification and labelling and to ensure the protection of human health and the environment, especially as to the identification of substances of high concern, such as PBTs and vPvBs. Member States stressed the importance of achieving the right balance between costs of additional data (specifically for SMEs) and benefits. The importance of taking into account the competitiveness aspects of such a possible extension of data requirements was also emphasized by Member States and the Commission.

The Council instructed its preparatory bodies to examine in greater detail these issues while, besides considerations of human health and environment, taking into account the impact of REACH on competitiveness, in particular of SMEs, as well as a simplification of the administrative processes and an efficient use of scarce resources.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council held a policy debate on a draft Regulation and a draft Directive on registration, evaluation, authorisation and restriction of chemicals (REACH) and establishing a European Chemicals Agency.

The debate was aimed at providing general guidance for further work. At the end of the debate, the Presidency summarised as follows:

- As regards the Workshop on REACH Impact Assessment held in The Hague from 25 to 27 October 2004, the President noted that the Council welcomed the conclusions and recommendations and instructed its preparatory bodies, in cooperation with the Commission, to take account of them in their future work. The Council stressed the importance of avoiding unnecessary testing on animals and underlined the need to improve the protection of human health and the environment while ensuring the competitiveness of the European chemicals industry, in particular of SMEs.

- On priority-setting in registration, the importance of examining further options in this field was stressed, in particular by addressing substances of very high concern at an early stage. The necessity to explore workable, cost-effective solutions providing sufficient flexibility, while not overburdening the registration phase and providing a level of certainty for industry, was underlined. With this in mind, delegations considered it appropriate to explore a possible extension of priority-setting in the registration phase with the inclusion of potential PBTs and vPvBs.

The Council noted that a risk-based approach, whilst difficult to apply at registration, might be appropriate for subsequent phases of REACH and that should be further analysed. There was general recognition of the need for flexibility, ensuring that in the future appropriate priority is given to emerging or new concerns.

- The need to regulate substances in finished articles was recognised by some delegations but doubts were expressed as to the workability and the effect on competitiveness of the Commission?s proposal in this field.

Some concern was expressed regarding the registration of dangerous substances intended and/or likely to be released from articles. It was considered to focus on articles containing substances of very high concern in the early stages of REACH.

Concerns were also expressed regarding EU produced articles that might suffer competitive disadvantages compared to importers of articles into the EU. The Council noted the idea of professional customers' "right to know"with regards to dangerous substances in articles as well as a

possible role for the Agency in making relevant information available.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council held a policy debate on the state of play regarding the draft Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. The debate ranged over a whole series of issues such as the role of the Agency in the evaluation of dossiers and substances ? particularly as regards cooperation between the Agency and the Member States ? and the conclusions to be drawn from the work on the REACH impact analyses.

The Council reiterated its intention to take forward the REACH proposal with a view to reaching a political agreement following on from the European Parliament's opinion.

As for the evaluation of dossiers, debate within the Council confirmed the broadly positive attitude to the enhanced role of the Agency but reiterated the importance of retaining national capability to respond to challenges and of retaining capability to evaluate substances likely to constitute a risk to health and/or the environment. In this context, the Council calls on its preparatory bodies to consider the possible consequences of the alternative proposals with the same rigour as that applied to the analysis of the Commission proposal ? also in terms of Community resources required to implement them.

As regards the outcome of the REACH workshop, organised by the Luxembourg Presidency, the Council considers that the impact studies conducted hitherto have produced sufficient knowledge to enable negotiations to continue on the basis of the Commission proposal with a view to producing a feasible system.

The Council calls on its preparatory bodies to continue their negotiations on all aspects of the Commission proposal while taking due account of the impact of the new legislation on SMEs, on producers/importers of low-volume substances and on the international competitiveness of European industry.

Lastly, the Council is determined to take account of all the results obtained from impact studies when it takes a political decision.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

Pending the opinion of the European Parliament, the Council held a policy debate on a draft Regulation and Directive concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), and establishing a European Chemicals Agency, with a view to setting out general guidelines for future work.

The discussion concentrated on the authorisation regime, and in particular on:

- the scope of authorisation;

- the possible preparation of a list of chemicals of concern subject to authorisation;

- mandatory taking into account of technically and economically viable alternatives (substances or technologies);

- the conditions to which, where appropriate, authorisation would be subject (time-limits, review periods, monitoring).

At the close of the discussion, the Presidency summarised as follows:

As regards the scope of authorisation, the discussion in the Council highlighted the importance of applying scientific and technical criteria when taking account of chemicals of concern with serious and irreversible effects equivalent to carcinogens, mutagens or substances toxic to reproduction, and persistent, bioaccumulative and toxic substances (PBT) or very persistent and very bioaccumulable substances (vPvB).

While reiterating the need for a manageable and practicable authorisation regime, the policy debate confirmed the largely positive attitude towards drawing up a list of chemicals that would require authorisation.

With regard to taking account of technically and economically viable alternative technologies or substances in the context of granting authorisation, the discussion revealed that the authorization regime was an important part of REACH that could help replace chemicals of concern, and that the aim was to further encourage consideration of these alternative solutions before a decision was taken.

While recognising the merits of encouraging the development of alternative solutions, the discussion in the Council emphasised the importance of taking account of the specific constraints in production cycles when applying conditions to authorisation, yet without excluding authorization being subject to strict conditions, including time-limits, review periods and monitoring conditions.

Lastly, the Council called on its preparatory bodies to continue negotiations with a view to a political agreement, once the European Parliament's opinion was available, on all aspects of the Commission proposal, while taking account of the need to strike a balance between the international competitiveness of European industry and environmental and health protection.

It will be recalled that the Competitiveness Council on 6 and 7 June 2005 addressed the subject of the role of the European Chemicals Agency and the outcome of the in-depth analysis of the impact of REACH.

The Community chemicals policy aims at avoiding chemical contamination of air, water, soil and the human environment in order to preserve biodiversity and to safeguard workers' and citizens' health and safety. This policy seeks to balance health and environmental benefits with the need to sustain a competitive, innovative and job-creating European industry and the proper functioning of the internal market.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend.

Directive 67/548/EEC)

The committee adopted the report by Guido SACCONI (PES, IT) approving the proposal under the 1st reading of the codecision procedure, subject to just three amendments:

- the scope of the directive should be extended to include articles that contain dangerous substances;

- a requirement should be introduced to affix a label with a warning symbol on articles containing dangerous chemical substances, in order to make those articles safer for use by consumers;

- the provisions of the amended directive should only start to apply in 18 months' time, given that the current regime will have to be applied until it becomes obligatory to register under the REACH regulation.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

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Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council held a policy debate on the draft regulation and directive concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), and establishing a European Chemicals Agency, with a view to preparing the ground for a political agreement on the dossier at the 28-29 November meeting of the (Competitiveness) Council.

The REACH proposal for a new chemicals policy in the EU seeks to ensure a high level of protection of health and the environment while sustaining a competitive, innovative and jobcreating European industry and the proper functioning of the internal market.

The debate was particularly aimed at indicating whether the broad approach taken by the Presidency in its efforts to find a compromise takes adequate account of the views expressed in earlier Council discussions. It further dealt with 2 questions relating to substances in articles:

? Should substances intended to be released from articles be subject to a specific regime or should they be treated as any other substance or preparation?

? Should the requirement to notify potentially dangerous substances in articles be based on the presence of substances of very high concern or should there be, in addition, a consideration of exposure?

At the close of the discussion, the Presidency summarised as follows:

"Overall, the Presidency is encouraged by the positive response to the compromise proposal and the constructive contribution of all delegations. This debate has taken us an important step closer to achieving agreement on this dossier in November.

It appears to the Presidency that there is a broad consensus developing around the Presidency compromise and a recognition that the Presidency has struck the right balance between reducing the impact of the proposed Regulation on industry whilst maintaining a high level of protection of human health and the environment.

Quite a number of delegations stressed the importance of not shifting this balance further in the direction of reducing information requirements. It is important that the Regulation does indeed deliver the required benefits from having more information on chemicals.

Several delegations stressed the need to avoid transferring responsibility away from industry to public authorities. The Presidency considers that this would not preclude that the Agency could be involved in assisting industry decisions.

A number of delegations stressed the importance of a strong authorisation regime not least in encouraging substitution as much as possible.

It seems to the Presidency that there are a number of delegations in favour of a specific regime for substances intentionally released from articles.

The Presidency notes that a number of delegations would favour bringing these requirements into line with those for substances on their own or in preparations, particularly by including substances which are not already known to be dangerous.

It appears to the Presidency that there is broad consensus around its proposal to notify substances of very high concern where they are present in articles.

The Presidency notes that this would not preclude the possibility of an exemption from the notification requirement where exposure to humans and the environment can be excluded.

The Council instructs the Permanent Representatives Committee to examine the issues discussed in greater detail with a view to preparing for a political agreement on REACH at the next session of the Competitiveness Council at the end of November 2005.?

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The European Parliament adopted a resolution drafted by Guido SACCONI (PES, IT) and made a few amendments to the Commission?s text. (Please see the summary of 04/10/2005.)

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council held a policy debate on a draft Regulation on the registration, evaluation, authorisation and restriction of chemicals, (REACH). It instructed the permanent representatives committee to examine the remaining issues with a view to enabling the Council to reach a political agreement at its meeting on 13 December.

The debate was held on the basis of a report from the Presidency setting out the main outstanding issues, in the light of the European Parliament?s recent opinion during its first reading of the proposal. The President concluded the debate by noting that there is broad agreement on many of the key issues including registration and evaluation. The Council detects that there is a high degree of convergence between the delegations? positions and a very clear desire to finalise the Council?s position at the December meeting.

Where there are outstanding points, they relate principally to the question of authorisation and scope. Authorisation, being the part of REACH dealing with the most dangerous chemicals, is therefore of particular concern. Some delegations expressed the wish to see the requirements for substituting these chemicals to be strengthened further. They propose, in particular, that the availability of suitable alternatives should always be considered in authorisation decisions and, if these are available, an authorisation should not be granted.

Several other delegations, on the other hand, as well as the Commission, consider that, if it can be demonstrated that the risks from the use of some of these chemicals are adequately controlled, then it should be possible for industry to continue using these chemicals under stringent conditions.

Other delegations stressed the importance of clarity over how the concept of adequate control would apply. On the question of ?Scope?, some delegations requested further exemptions from the registration of specific substances. The Presidency notes that an early review of the relevant Annexes may provide the best opportunity for the important issue to be resolved.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Council adopted a common position on the proposal for a regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), and establishing a European Chemicals Agency. The text of the proposal was revised extensively during discussions carried out by the Council over the last two years. During this process, there has been a substantial convergence of views between the Council and the European Parliament. Accordingly, the Council has integrated into the common position about 200 of the European Parliament?s amendments, either in full, in part or in principle.

Recitals:

The Common Position is in line with around 20 amendments by the European Parliament, which correspond to the approach taken in the legal provisions (Articles and Annexes).

In addition, it takes on board the spirit of certain amendments which aim to: introduce a ?duty of care? for manufacturers, importers and downstream users (the amended Article 1 states that chemical substances shall not adversely affect human health or the environment); ensure the free circulation of goods while enhancing competitiveness and innovation; emphasise the need to pay special attention to small and medium-sized enterprises. A new recital underlines the need to take special account of the potential impact of REACH on SMEs and the need to avoid any discrimination against them.

Scope and definitions:

The common position reflects either in full, in principle or in part about 15 of the Parliament?s amendments. The Council has consolidated and clarified the scope of the regulation as well as clarified certain exemptions (e.g. for waste, substances used in foods or feedingstuffs and in certain cases in the interests of defence). Furthermore, the exemptions from registration for individual substances listed in Annex IV have not been amended (with the sole exception of the addition of cellulose pulp) but will be reviewed by the Commission, together with Annexes I and V, 12 months after entry into force of REACH. The categories of exemption from registration listed in Annex V have been amended, particularly in relation to natural substances such as ores, ore concentrates, minerals and cement clinker.

With regard to the amendment concerning alloys and their definition as special preparations, the Council welcomes the Commission's intention to develop guidance, in close cooperation with Member States and stakeholders, on the assessment of special preparations.

Registration:

The common position has integrated about 20 of the Parliament?s amendments. With a view to including the main elements of the "one substance - one registration" (OSOR) proposal, the provisions on multiple registrants of the same substance have been amended. The common position provides for all manufacturers or importers of the same substance to submit certain parts of the registration dossier jointly.

However, specific possibilities for opting out of this obligation have been introduced where there are differences of opinion between registrants on the selection of data, where joint submission would entail disproportionate costs and where it would lead to commercially sensitive information being exchanged.

Substances that are intentionally released from articles will in principle be treated like all other substances and registered according to the phase-in periods of 3, 6 and 11 years. In addition, producers and importers of articles will notify substances meeting the criteria for authorisation if they are contained in those articles above a certain level and if exposure to humans or the environment cannot be excluded throughout the life-cycle. Where the Agency considers that there are grounds for suspecting that a substance is released from articles and that this release presents a risk to human health or the environment, it may take decisions requiring producers or importers of articles to submit a registration.

In relation to information to be submitted at registration, registrants should be able to apply use and exposure categories voluntarily. Quality assurance of the registration dossier on a voluntary basis by an assessor chosen by the registrant as having appropriate experience would be a possibility.

The information submitted depending on tonnage, must be as follows:

-Low volume phase-in substances (those manufactured or imported in quantities of between 1 and 10 tonnes per manufacturer or importer per year): where a phase-in substance in this tonnage range meets simple criteria highlighting it as potentially of concern, the full Annex VII information is to be provided by the registrant. In other cases, only the physicochemical information listed in Section 5 of Annex VII, together with the information that is available to the registrant, would need to be provided. As Annex VII will only apply to a limited number of substances in this tonnage range, the common position includes additional information requirements in relation to acute toxicity, biodegradation and algal toxicity. Registrants of all non-phase-in substances would have to provide the full Annex VII information.

-Only one test for reproductive toxicity is proposed for Annex VIII (additional standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more per manufacturer or importer year).

-No significant changes have been introduced to Annexes IX and X (additional standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more and 1000 tonnes or more per manufacturer or importer per year, respectively). Within 18 months of entry into force, the Commission will adopt criteria defining what constitutes adequate justification for omitting certain tests in Annexes VIII-X based on the exposure scenario(s) developed in the Chemical Safety Report.

In relation to phase-in substances, the common position provides for the inclusion in the first phase of registration of substances that are potentially persistent, bioaccumulative and toxic (PBT) based on current classification criteria and manufactured or imported in quantities of over 100 tonnes per manufacturer or importer per year.

With regard to those amendments which aim to reduce the number of animal tests, the Council fully shares the objective expressed in these amendments but considers that this objective is taken into consideration within the framework of Article 13(2) that lays down that test methods will be revised, as appropriate, to refine, reduce or replace animal tests. The idea is also acknowledged within the framework of the OSOR proposal and related amendments made in Title III regarding data sharing, which should lead to fewer tests on vertebrate animals.

Lastly, since the risk due to exposure is generally considered to be relatively low and since it would put too much of a burden on Small and Medium-sized Enterprises (SMEs), the amendment introducing a requirement to make a Chemical Safety Assessment for all substances subject to registration has not been accepted.

Data-sharing and avoidance of unnecessary testing:

The common position takes on 30 of the Parliament?s amendments. It provides that potential registrants are obliged to share information generated from vertebrate animal tests. Information from non-animal tests must be shared if requested by another potential registrant. As a general rule, the sharing of costs will be agreed amongst potential registrants themselves in a fair, proportionate and non-discriminatory way, particularly in relation to SMEs.

In cases where the sharing of costs cannot be resolved amongst potential registrants, a clear and unambiguous provision to assign costs equally is included. To facilitate data sharing, a single pre-registration phase starting 12 months after entry into force of the Regulation and finishing 18 months after the entry into force of the Regulation has been introduced.

The Common Position does not incorporate the amendment which would make any summaries or robust study summaries of studies freely available only 15 years after submission in the framework of a registration procedure, since this could add to the overall cost of REACH and has the potential to increase the burden for industry, particularly SMEs. It also does not take on board two amendments stipulating that sharing of costs should be proportionate to the production volume.

Information in the supply chain:

12 amendments made by Parliament are integrated into the common position. The Council has included in the text an additional requirement for safety data sheets to be provided for substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative

and for certain preparations containing these substances. The role of distributors in ensuring that information flows through the supply chain has been clarified. Some changes to Annex I (General provisions for assessing substances and preparing chemical safety reports (CSR)) and Annex II (Guide to the compilation of safety data sheets (SDS)) have been introduced.

The common position does not include the amendment providing that workers would be granted access by producers to information given in the supply chain, since such a responsibility lies with the employer. The amendment concerning a supplier?s obligation to grant access to information on the substances sold has not been taken on board, since such a provision should be subject to the general rules on communication of information up and down the supply chain.

Downstream users:

The common position clarifies the role of distributors and downstream users in the supply chain, especially as regards how manufacturers, importers or downstream users should react to information on identified uses provided by distributors and/or downstream users. It also clarifies that downstream users can participate in a Substance Information Forum (SIEF). It clarifies the cases in which cases downstream users should conduct a Chemical Safety Assessment (CSA) and prepare a Chemical Safety Report (CSR), in particular by setting a minimum threshold of 1 tonne below which a CSR is not required. The Council has decided to delete Annex Ib (Chemical Safety Assessments for Preparations) given that the scientific methodology underpinning this Annex is still being developed.

Evaluation:

The common position includes 37 of the Parliament?s amendments. the Council has decided on the approach described below:

-as regards dossier evaluation, the responsibility (both for checking testing proposals and for compliance checks) has been transferred to the Agency. The Agency will be able to decide how best to discharge these obligations, including the possibility of using external sources.

-a minimum number of compliance checks should be performed. This is set in the legislation as 5% of dossiers received. These checks should focus (although not exclusively) on dossiers where disagreements come to light between registrants of the same substance, where dossiers are for a substance that is listed in the EU-wide rolling plan for evaluation or, in the case of 1-10 tonne substances, where the full information specified in Annex VII has not been submitted.

-as regards substance evaluation, a single EU-wide rolling plan for substance evaluation will be established, prepared by the Agency with input from the Member States.

-the Agency is responsible for co-ordinating the substance evaluation process relying on the Member States' competent authorities to perform the evaluations. Member State competent authorities can, if appropriate, use expert institutes to perform the evaluation.

The common position does not reflect the amendments which would give full responsibility for substance evaluation to the Agency. The Council considers that the most workable solution is for the Agency to be responsible for coordinating the substance evaluation process, relying on the Member States' competent authorities to perform the evaluations. It has also not accepted the amendment concerning mandatory consultation of the European Centre for Validation of Alternative Methods (ECVAM) before deciding on animal testing.

Authorisation:

The common position takes on board 18 of the Parliament?s amendments. Various amendments have been included which are designed to strengthen authorisation whilst ensuring that the provisions are workable. The scope of authorisation has not been amended, but it has been clarified. For reasons of increased transparency and to facilitate planning within industry, a candidate list of substances meeting the authorisation criteria will be published by the Agency. The published list will also state which substances are on the Agency's workplan for inclusion in Annex XIV. Substances will be identified and placed on the list following a period of public consultation. Authorisations will be granted where the risks from the use of a substance are adequately controlled or where it is shown that the socio-economic benefits outweigh the risks to human health or the environment arising from the use of the substance and where there are no suitable alternatives substances or technologies available.

In order to encourage the development of safer substitutes, all applications for authorisation will include an analysis of available alternatives considering their risks and the technical and economic feasibility of substitution. Furthermore, all authorisations will be subject to time-limited review periods and shall normally be subject to monitoring by the holder of the authorisation. The length of the time-limited review period will be set on a case-by-case basis. In order to close a potential loophole, the Agency will consider the need for EU-wide restrictions on the use of a substance in articles at the time of inclusion of that substance in Annex XIV.

The text does not include those amendments which would require mandatory substitution if suitable alternatives are available.

Restrictions:

7 amendments by Parliament are integrated in the common position. It provides for a transition period after REACH comes into force to allow Member States to update existing national legislation relating to current restrictions on the marketing and use of chemicals. Furthermore, clarifications to Annexes XV (Dossiers) and XVI (Socio-economic analysis) have been made.

Fees and charges:

The Council has introduced a new title making it clear that the fees and charges to be levied under the regulation shall be introduced in a Commission Regulation. The new title includes principles for these fees and charges, including the idea that some of the Agency?s revenue will be forwarded to the Member State competent authorities responsible for undertaking work as in compliance with REACH. Lower fees will always be charged to SMEs.

Agency:

The common position includes 13 amendments made by Parliament. It clarifies several points, including the following : each Member States will have one representative on the Management Board; a clarification of the procedures for appeal has been included; it has been specified that the rules governing languages in the Agency should be in accordance with Regulation No 1/58; the reference to the seat of the Agency in the REACH Regulation has been deleted; the Agency will get its funding from contributions from the Community budget, fees paid by industry, and voluntary contributions from Member States.

All the amendments stipulating that the Agency should have overall responsibility for the management of REACH or putting emphasis on the Agency as the main authority in the field of REACH, have not been incorporated in the common position.

Classification and labelling:

The common position extends the possibility of harmonised classification and labelling across the EU for other endpoints than those proposed by the Commission on a case by case basis. Pending the Commission's proposal on a Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and in line with the Commission's proposal on REACH, it was not considered appropriate to incorporate the Parliament?s amendments.

Information:

This title has been modified substantially with a view to bringing its provisions in line with Regulation 1049/2001/EC regarding public access to documents. The common position provides that the detailed rules for access to information held by the Agency should be drawn up by the Agency?s Management Board in accordance with the provisions of the Aarhus Convention and with Regulation 1049/2001/EC. The common position reflects the amendment stipulating that Member States, the Agency and the Commission will submit a report every five years on experiences gained. It also reflects in principle the amendment stipulating that the Agency will publish non-confidential information on the website.

Competent authorities:

In line with the principle of Parliament?s amendment, a clarification of the text concerning guidelines on how to inform the general public about risks arising from substances has been introduced in the common position. The Council has also introduced the principle of the amendment on special help and advice to SMEs. The Council considers that Member States helpdesks will be of great benefit to industry, in particular to SMEs.

Enforcement:

Some clarification of the sanctions regime to be established by Member States has been introduced. The common position does not reflect the amendments giving the Forum within the Agency the task to draw up guidelines on enforcement. However, the Forum shall identify enforcement strategies as well as best practice in enforcement. Certain other amendments have not been incorporated since Member States do not see the need for the Agency to be involved directly in enforcement of the Regulation and in drawing up of guidelines on sanctions to be taken as a result of infringement to it.

Transitional and final provisions:

The common position reflects in principle the amendment laying down that Member States have the right to maintain more stringent measures on the protection of workers, human health and the environment, provided that the area is not harmonised by the REACH Regulation. Regarding the amendment on the preparation of the establishment of the Agency, the Commission and the Council have committed themselves in a joint statement to providing the necessary support towards setting up of the Agency.

Annexes:

The Council has introduced several modifications to the annexes and taken into account some 36 amendments made by Parliament.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The Commission welcomes the adoption of the common position and considers that the principal aims of its REACH proposalare safeguarded in it.

In its assessment of Parliament?s first reading text and of the Council?s common position on REACH, the Commission has taken into account the substantial convergence of the positions of both institutions of the decision making process regarding the main elements.

The Commission considers that a suitable balance has been found on the most difficult and the most critical areas of REACH, namely, registration and authorisation. In the end all Member States and the Commission, supported the final compromise proposal that had been developed, having accepted it as a fair balance between those concerned about the need to provide greater encouragement to the substitution of dangerous substances and those concerned about the impact on competitiveness and investment in Europe. Two of the main elements of the compromise were: i) applications for authorisations should always include an analysis of possible alternatives by the registrant and ii) for substances of very high concern for which it is not possible to determine safe thresholds with current methods, a review of these methods should be foreseen within 12 months after entry into force of the regulation based on work in the REACH implementation projects.

On other important aspects such as scope, the Council has addressed Parliament?s concerns by providing for improved exemptions from registration, and by requiring a review of the annexes governing such exemptions within 12 months of the entry into force of the regulation. On evaluation, the Council has taken a similar line to the Parliament by significantly increasing the role of the Agency. The Commission believes that the Council?s approach to access to information and confidentiality is also consistent with the intentions of Parliament and strikes the right balance.

The net result is that around 90% of the European Parliament?s amendments to REACH that the Commission could accept totally, in part or in principle have been incorporated in the Common Position, using identical or similar wording. In addition, the political agreement includes 43 amendments which the Commission did not state it could accept. In addition 38, including 7 relating to persistent organic pollutants of the amendments where the Commission reserved its position have also been included.

Central to Parliament?s amendments was a compromise package on registration and pre-registration, all aspects of which the Commission said that it could support. Out of 47 amendments constituting this package, 37 are included in principle, in part or in full in the common position. The Parliament adopted other compromise packages, of which 96 amendments are included in the common position.

Accompanying the political agreement on the common position the Commission and Member States made a number of important declarations. Reflecting the importance of a performing European Chemicals Agency and the need for it to become fully operational before critical REACH procedures come into effect, the Council and the Commission made a joint statement on actions that are necessary for setting up the Agency. In that context also, the Commission takes the opportunity to stress the need for adequate budgetary provision for the increased costs falling on the Agency. The Commission also made statements on special preparations (including alloys), on free movement (Article 127(2) of the Regulation), and on Article 56(f) of the Regulation (in Annex II).

In addition, Denmark and Sweden made two declarations, jointly with Luxembourg on authorisation, and jointly with Germany on Article 2(2) of the Regulation. Poland and Ireland made a joint declaration on authorisation Poland made one on the effect of REACH on competitiveness and Germany made declarations on the income that Member States could derive from fees and on the need for a general discussion on the immunities of European agencies.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

Based on the political agreement on a common position reached by the Council on 13 December 2005, this revised legislative financial statement replaces the legislative financial statement presented by the Commission in conjunction with the ?REACH? proposal.

Accompanying the political agreement on the common position the Commission and Member States made a number of important declarations. Reflecting the importance of a performing European Chemicals Agency and the need for it to become fully operational before critical REACH procedures come into effect, the Council and the Commission made a joint statement on actions that are necessary for setting up the Agency. In that context also, the Commission takes the opportunity to stress the need for adequate budgetary provision for the increased costs falling on the Agency.

It should be noted that there is no impact on the revenue side of the Community budget. The Agency?s budget foresees (i) its own revenues consisting of fees and charges for items such as registrations, applications for authorisation, production and process oriented research and design applications, appeal fees, fees for confidentiality claims, etc. which the Agency is authorised to collect by virtue of the tasks entrusted to it, and (ii) a balancing subsidy from the Community budget.

For further information concerning the financial implications of this measure, please refer to the financial statement.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The committee adopted the report by Guido SACCONI (PES, IT) approving the Council's common position unamended under the 2nd reading of the codecision procedure.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

The European Parliament adopted a resolution based on the report by Guido SACCONI (PES, Italy) and approved the Council's common position.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

PURPOSE: to amend Directive 67/548/EEC to take account of new provisions set out in the REACH Regulation.

LEGISLATIVE ACT: Directive 2006/121/EC of the European Parliament and of the Council amending Council Directive 67/548/EEC on the

approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

CONTENT: the purpose of this Directive is to amend Council Directive 67/548/EEC in order to bring its provisions on notification and risk assessment of chemicals into line with that of Regulation 1907/2006/EC (see COD/2003/0256). The rules on notification and risk assessment of chemicals have been deleted from Directive 67/548/EEC.

ENTRY INTO FORCE: 19 January 2007. It will apply as from 1 June 2008.

Chemicals: classification, labelling, packaging, adaptation to the REACH Regulation (amend. Directive 67/548/EEC)

PURPOSE: Corrigendum to Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (Official Journal of the European Union L 396 of 30 December 2006).

The aims of the REACH Regulation are to ensure a high level of protection of health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation (see COD/2003/0256). The aim of the Directive is to amend 67/548/EEC in line with the changes to the current chemicals management regime introduced by REACH. In relation to the adoption of Regulation 1907/2006/EC, Directive 67/548/EEC has been adapted and its rules on the notification and risk assessment of chemicals have been deleted.

The Corrigendum concerns the entire text of the Directive.