Basic information

2003/0256(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency Amending Directive 1999/45/EC 1996/0200(COD) Amended by 2007/0121(COD) Amended by 2018/0103(COD) Amended by 2025/0176(COD) See also 2009/2584(RSP) **Subject** 3.40.01 Chemical industry, fertilizers, plastics 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 8.40.08 Agencies and bodies of the EU	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	SACCONI Guido (PSE)	27/07/2004

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	SACCONI Guido (PSE)	27/07/2004
ENVI Environment, Public Health, Consumer Policy	SACCONI Guido (PSE)	16/06/2003

Former committee for opinion	Former rapporteur for opinion	Appointed
INTA International Trade	QUISTHOUDT-ROWOHL Godelieve (PPE-DE)	28/07/2004
BUDG Budgets	HAUG Jutta (PSE)	31/01/2005
ECON Economic and Monetary Affairs	HASSI Satu (Verts/ALE)	23/09/2004
EMPL Employment and Social Affairs	MANN Thomas (PPE-DE)	28/07/2004

ITRE Industry, Research and Energy (Associated committee)	EK Lena (ALDE)	30/08/2004
IMCO Internal Market and Consumer Protection (Associated committee)	NASSAUER Hartmut (PPE-DE)	28/07/2004
JURI Legal Affairs	LECHNER Kurt (PPE-DE)	07/10/2004
FEMM Women's Rights and Gender Equality	BREYER Hiltrud (Verts/ALE)	30/08/2004
PETI Petitions	HAMMERSTEIN David (Verts/ALE)	24/05/2005
BUDG Budgets	KUCKELKORN Wilfried (PSE)	16/12/2003
ECON Economic and Monetary Affairs	LANGEN Werner (PPE-DE)	02/12/2003
JURI Legal Affairs and Internal Market (Associated committee)	NASSAUER Hartmut (PPE-DE)	01/12/2003
ITRE Industry, External Trade, Research, Energy (Associated committee)	PLOOIJ-VAN GORSEL Elly (ELDR)	02/10/2003
EMPL Employment and Social Affairs	MANN Thomas (PPE-DE)	19/11/2003
FEMM Women's Rights and Equal Opportunities	ERIKSSON Marianne (GUE/NGL)	20/01/2004

Former committee for opinion on the legal basis	Former rapporteur for opinion	Appointed
JURI Legal Affairs	LÓPEZ-ISTÚRIZ WHITE Antonio (PPE-DE)	13/07/2005

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2624	2004-11-25
Competitiveness (Internal Market, Industry, Research and Space)	2645	2005-03-07
Competitiveness (Internal Market, Industry, Research and Space)	2665	2005-06-06
Competitiveness (Internal Market, Industry, Research and Space)	2681	2005-10-11

	Competitiveness (Internal Market, Industry, Research and Space)	2694	2005-11-28
	Competitiveness (Internal Market, Industry, Research and Space)	2583	2004-05-17
	Competitiveness (Internal Market, Industry, Research and Space)	2731	2006-05-29
	Environment	2593	2004-06-28
	Environment	2556	2003-12-22
	Environment	2740	2006-06-27
	Environment	2632	2004-12-20
	Environment	2773	2006-12-18
	Environment	2566	2004-03-02
	Environment	2684	2005-10-17
	Environment	2670	2005-06-24

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

Key events

Date	Event	Reference	Summary
29/10/2003	Legislative proposal published	COM(2003)0644	Summary
03/12/2003	Committee referral announced in Parliament, 1st reading		
22/12/2003	Debate in Council		
02/03/2004	Debate in Council		
17/05/2004	Debate in Council		
28/06/2004	Debate in Council		Summary
16/09/2004	Committee referral announced in Parliament, 1st reading		
25/11/2004	Debate in Council		Summary
20/12/2004	Debate in Council		Summary
07/03/2005	Debate in Council		
06/06/2005	Debate in Council		Summary
24/06/2005	Debate in Council		Summary
04/10/2005	Vote in committee, 1st reading		Summary
11/10/2005	Debate in Council		Summary
17/10/2005	Debate in Council		Summary
24/10/2005	Committee report tabled for plenary, 1st reading	A6-0315/2005	
15/11/2005	Debate in Parliament		
17/11/2005	Decision by Parliament, 1st reading	T6-0434/2005	Summary

17/11/2005	Results of vote in Parliament		
28/11/2005	Debate in Council		Summary
29/05/2006	Debate in Council		
27/06/2006	Council position published	07524/8/2006	Summary
07/09/2006	Committee referral announced in Parliament, 2nd reading		
10/10/2006	Vote in committee, 2nd reading		Summary
13/10/2006	Committee recommendation tabled for plenary, 2nd reading	A6-0352/2006	
14/11/2006	Results of vote in Parliament		
11/12/2006	Debate in Parliament		
13/12/2006	Decision by Parliament, 2nd reading	T6-0552/2006	Summary
13/12/2006	Results of vote in Parliament		
18/12/2006	Act approved by Council, 2nd reading		
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	2003/0256(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Regulation
Amendments and repeals	Amending Directive 1999/45/EC 1996/0200(COD) Amended by 2007/0121(COD) Amended by 2018/0103(COD) Amended by 2025/0176(COD) See also 2009/2584(RSP)
Legal basis	EC Treaty (after Amsterdam) EC 095 Rules of Procedure EP 57_o
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/34795

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Amendments tabled in committee		PE357.816	02/05/2005	
Amendments tabled in committee		PE357.817	02/05/2005	
Amendments tabled in committee		PE357.824	02/05/2005	

Amendments tabled in committee		PE357.825	02/05/2005	
Amendments tabled in committee		PE357.821	04/05/2005	
Amendments tabled in committee		PE357.823	04/05/2005	
Amendments tabled in committee		PE357.820	10/05/2005	
Amendments tabled in committee		PE357.826	12/05/2005	
Amendments tabled in committee		PE357.888	13/05/2005	
Amendments tabled in committee		PE360.104	04/07/2005	
Committee opinion	EMPL	PE357.617	20/07/2005	
Committee opinion	FEMM	PE357.536	18/08/2005	
Committee opinion	INTA	PE357.691	31/08/2005	
Amendments tabled in committee		PE360.338	09/09/2005	
Amendments tabled in committee		PE360.355	09/09/2005	
Committee opinion	PETI	PE357.971	12/09/2005	
Committee opinion	ECON	PE355.467	14/09/2005	
Committee opinion	ITRE	PE353.595	16/09/2005	
Committee opinion	JURI	PE357.686	16/09/2005	
Committee opinion	JURI	PE360.258	16/09/2005	
Committee opinion	IMCO	PE357.851	19/09/2005	
Amendments tabled in committee		PE360.356	28/09/2005	
Amendments tabled in committee		PE360.358	28/09/2005	
Committee report tabled for plenary, 1st reading/single reading		A6-0315/2005	24/10/2005	
Committee opinion	BUDG	PE353.540	09/11/2005	
Text adopted by Parliament, 1st reading/single reading		T6-0434/2005	17/11/2005	Summary
Committee draft report		PE371.746	23/06/2006	
Amendments tabled in committee		PE378.589	15/09/2006	
Amendments tabled in committee		PE378.597	15/09/2006	
Amendments tabled in committee		PE378.807	27/09/2006	
Committee recommendation tabled for plenary, 2nd reading		A6-0352/2006	13/10/2006	
Text adopted by Parliament, 2nd reading		T6-0552/2006	13/12/2006	Summary

Council of the EU

Document type	Reference	Date	Summary
Supplementary legislative basic document	15409/2003	28/11/2003	
Council statement on its position	10411/2006	15/06/2006	
	07524/8/2006		

Council position	OJ C 276 14.11.2006, p. 0001-0251 E	27/06/2006	Summary
Draft final act	03664/2006	18/12/2006	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2003)0644	29/10/2003	Summary
Document attached to the procedure	SEC(2003)1171	29/10/2003	
Commission response to text adopted in plenary	SP(2005)5015	15/12/2005	
Commission communication on Council's position	COM(2006)0375	12/07/2006	Summary
Document attached to the procedure	SEC(2006)0924	12/07/2006	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2006)0842	15/12/2006	Summary
Follow-up document	COM(2013)0049	05/02/2013	Summary
Follow-up document	SWD(2013)0025	05/02/2013	
Follow-up document	COM(2016)0814	20/12/2016	Summary
Commission working document (SWD)	SWD(2020)0247	15/10/2020	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0524/2004	31/03/2004	
EESC	Economic and Social Committee: opinion, report	CES1696/2004 OJ C 112 30.04.2004, p. 0092-0099	31/03/2004	
CofR	Committee of the Regions: opinion	CDR0238/2004 OJ C 164 05.07.2005, p. 0078-0081	24/02/2005	
EESC	Economic and Social Committee: opinion, report	CES0850/2005 OJ C 294 25.11.2005, p. 0038-0044	13/07/2005	

Additional information

Source	Document	Date

National parliaments	IPEX	
European Commission	EUR-Lex	

Final act	
Corrigendum to final act 32006R1907R(01) OJ L 136 29.05.2007, p. 0003	Summary
Regulation 2006/1907 OJ L 396 30.12.2006, p. 0001	Summary
Corrigendum to final act 32006R1907R(02) OJ L 141 31.05.2008, p. 0022	Summary

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 18/12/2006 - Final act

PURPOSE: to establish a regulatory framework for the management of chemicals at EU level and to establish a European Chemicals Agency.

LEGISLATIVE ACT: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

CONTENT: the Regulation was subject to a **corrigendum**. Please refer to the summary of the corrigendum to final act 32006R1907R(01) published in OJ L 136, 29.05.2007, p. 0003.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 17/10/2005

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."

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 28/11/2005

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 06/06/2005

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 20/12/2004

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 25/11/2004

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 18/12/2006 - Corrigendum to final act

CORRIGENDUM to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

LEGISLATIVE ACT: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

PURPOSE: to establish a regulatory framework for the management of chemicals at EU level and to establish a European Chemicals Agency.

CONTENT: the Regulation establishes **REACH** (**Registration, Evaluation, Authorisation and Restriction of Chemicals**). It provides for provisions for the manufacture, placing on the market or use of chemicals in the European Union.

The purpose of this Regulation is to ensure a high level of **protection of human health and the environment**, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. It is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the **precautionary principle**.

The Regulation applies to **all chemical substances manufactured, imported, marketed and used as such, in mixtures or products**. It shall not apply to certain types of substances, such as radioactive substances or waste that are already covered by other legislation.

The main elements of the Regulation are:

Registration: the Regulation obliges manufacturers and importers to **identify and manage the risks** associated with the substances they produce and market in the European Union by demonstrating the extent to which the substances in question may be used safely. This information must be transmitted to the European Chemicals Agency (ECHA) for **registration in a database**.

By 31 May 2018, all chemical products manufactured, imported or placed on the EU market in **excess of 1 tonne per year** must be registered. Without registration, chemicals may not be manufactured or imported into the EU.

Evaluation: the European Chemicals Agency (ECHA) is in charge of verifying the information submitted during registration. Member States shall evaluate substances in the light of specific concerns regarding human health and the environment. The Agency and the Member States may request from manufacturers, importers or downstream users further information on substances suspected of posing a risk to health or the environment.

Authorisation: the purpose of this procedure is to ensure that risks from substances of very high concern (for example, carcinogens, mutagens and reproductive toxins) are adequately controlled and that substances are **progressively replaced by less dangerous substances** or technologies where economically and technically viable alternatives are available. These substances shall be listed in Annex XIV of the REACH (List of substances subject to authorisation), in which case companies must obtain an authorisation to continue using them.

Restrictions: restrictions on the manufacture, use or placing on the market of certain substances are intended to **manage unacceptable risks** to human health or the environment that are not covered by other REACH processes or by other EU legislation. The European Commission or EU Member States may restrict the manufacture or use of certain substances if they consider that risk management is not appropriate.

Agency: the Regulation establishes a European Chemicals Agency for the management and, in some cases, the implementation of the technical, scientific and administrative aspects of the Regulation and to ensure a consist approach at EU level. It provides the Member States and the EU

institutions with the best possible **scientific advice** on questions relating to chemicals which fall within its remit. It is responsible for setting up and maintaining one or more **databases** containing information on all registered substances, the classification and labelling inventory, and the harmonised list of classifications and labels.

The Agency's **revenue** shall consist of: (i) a subsidy from the Community, entered in the general budget; (ii) fees paid by the undertakings; (iii) any voluntary contribution from the Member States.

Reports: Member States, ECHA and the Commission are required to submit periodic reports on the operation of the Regulation. The Commission must also make a number of reviews by different deadlines.

Lastly, the competent authorities of the Member States shall **inform the general public** about the risks arising from substances where this is considered necessary for the protection of human health or the environment.

ENTRY INTO FORCE: 1.1.2007.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 17/11/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution based on the draft by Guido **SACCONI** (PES, IT) and approved a large number of amendments to the REACH (Registration, Evaluation and Authorisation of Chemicals) proposal. The main elements of the position of the European Parliament were adopted by 398 votes in favour, 148 against and 36 abstentions. The actual vote on the report was 407 in favour, 155 against with 41 abstentions. Parliament sought to achieve balance between the need to protect public health and the environment on the one hand, while safeguarding the chemicals industry's interests in terms of competitiveness, on the other. It was necessary to draw up composite amendments on different aspects of the proposal, notably on authorisation, as a means of ring-fencing the vote.

On registration: This was one of the most controversial areas. The compromise reached by the PES, the EPP-ED and the ALDE groups was endorsed by plenary by 438 votes in favour, 144 against and 15 abstentions. French socialists refused to back the compromise. The provisions on registration were diluted: obligations regarding the quantity and quality of information to be provided, tests to be undertaken and the number of substances covered are significantly reduced. The compromise is based on the following elements:

-A single pre-registration phase has been introduced to simplify the procedure. The time for pre-registration has been increased to 18 months to take into account the time needed for the Agency to become operational.

-Registration will be staggered: within three years for the most dangerous chemicals and those produced in volumes of more than 1,000 tonnes a year; within six years for substances produced in volumes of 100 tonnes per year and more; and within 11 years for substances produced in volumes of between 1 and 100 tonnes per year.

-the introduction of a targeted approach on data requirements for 1-10 tonnes chemicals (those having been identified by the impact assessment studies as being the ones for which costs of REACH implementation would be higher)

- Parliament introduced scope in the proposal for requesting additional testing where necessary;

-it also introduced scope for companies to avoid the need to make certain tests on substances produced or imported in volumes of between 10 and 100 tonnes/year provided due justification is provided on the basis of criteria defined by the Commission.

-the scope of the Regulation is expanded by the addition of several substances to Annex II;

-on the issue of the burden of proof, it is the responsibility on industry to make available information on the hazards, risks, and risk reduction measures for chemicals. These provisions apply to existing chemicals. Safety data on new substances should be submitted in accordance with existing legislation. The most dangerous substances and those contained in everyday consumer goods that are harmful to human health or the environment will also be subject to comprehensive information requirements regarding safety data.

-Parliament confirmed the "One Substance, One Registration" (OSOR) principle. This requires companies to share data (notably on animal testing to reduce the numbers involved) and costs, which should be "proportionate" to the volumes produced/imported by each partner. A company can ask to dispense with this obligation provided it notifies and provides due justification to the Agency ("opt-out"). Both the sharing of data (notably regarding testing on animals) and the sharing of costs are provisions that respond directly to the concerns of SMEs.

On Authorisation: The issue of authorisation was one of the most controversial. This series of amendments, broadly rallying left-wing parties (PES, ALDE, Greens, European United Left) restores the environment and health protection to the heart of the system by strictly limiting the duration of authorisations and making substitution mandatory, whereas the compromise on registration leant heavily towards industry.

The European Parliament endorsed by 324 votes in favour, 263 against and 13 abstentions the approach of the Environment Committee which is based on the following elements:

- the granting of licences by the Agency following an evaluation of substances regarded as being dangerous for a limited duration of five years, with provision for a review at the end of this period. Where substances have not been modified and the producer provides evidence that efforts have been made to produce the substance in an environmentally-friendly manner, renewal procedure may be simplified;

-the introduction of the obligation to replace dangerous products with less harmful substances as soon as alternatives become available. These provisions are designed to encourage industry to invest in research and innovation. By extension, authorisation will only be granted for the most dangerous chemicals where there are no alternatives.

On Substances in Articles: Parliamentendorsed by 291 in favour, 290 against and 16 abstentions a slightly revised version of the approach adopted on this issue by the Environment Committee. The amendments provide notably for equal treatment of imported products and those produced in the EU through simple notification of substances contained in consumer goods, where they are already registered as being of grave concern, and the application of an equivalent authorisation procedure.

For SMEs: Parliament endorsed the approach of the Environment Committee (supported also by Internal Market and Industry Committees). It made provision for an aid mechanism (to be established notably by the member states local and/or regional authorities) in the form of an assistance and guidance bureau on implementation of the REACH system. The text also acknowledges that the system must not result in an increase in bureaucracy. Parliament clarified requirements and obligations regarding communication of risks and transparency on the part of large enterprises for the benefit of downstream users.

On the Agency: Parliament endorsed the approach of the Environment Committee (supported by Internal Market and Industry Committees). The amendments adopted enhance the role and powers of the Agency, specify its tasks and responsibilities and emphasise that it will be answerable to EU institutions for its management of chemicals policy. The responsibilities of the committee on risk assessment are extended. It is entrusted with the task of drawing up a research policy on alternative methods of evaluation. Parliament established a new committee charged with examining new alternative testing methods (alternatives to testing on animals). Parliament called for additional funding for research into alternative testing methods. It granted additional powers to the Agency by making existing provisions on the sharing of testing data mandatory: by refusing to provide such information a company runs the risk of seeing its request for registration and authorisation rejected.

On animal testing: The European Parliament endorsed the approach of the Environment Committee. It sought to minimise animal testing through regular adaptation of testing methods and avoidance of duplication of testing. Parliament gave priority to in vitro tests and extended the obligation to share data from tests on both vertebrates and invertebrates.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 12/07/2006

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 11/10/2005

On the basis of a report from the Presidency, the Council held a policy debate on a number of key aspects of the draft Regulation for REACH and establishing a European Chemicals Agency. The issues discussed related to information requirements at registration of chemicals and data sharing among registrants. In the light of the debate, the Council instructed the Permanent Representatives Committee to examine the issues discussed in more detail with a view to reaching for a political agreement on REACH at the next session of the Competitiveness Council at the end of November 2005.

At the end of the debate the President made a summing-up:

"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 at our next meeting in November.

I would like to make the following concluding remarks:

With regard to the registration of substances between 1 and 10 tonnes, it seems to the Presidency that there is broad support for a targeted approach to information requirements as proposed by the Presidency including additional information in Annex V.

Some delegations have expressed a preference for the approach only to apply to existing substances.

It appears to the Presidency that a significant number of delegations are in favour of a system in which the requirement for determining whether further information is to be provided is kept with the registrant.

The Presidency notes that this approach would not preclude that the Agency could be involved in assisting industry decisions.

Regarding the registration of substances between 10 and 100 tonnes, it appears to the Presidency that there is broad consensus that the Presidency's proposal to reduce the information requirements is appropriate, though some delegations signalled an openness to consider the possibility of exposure-based waiving of information in this tonnage range.

The Presidency notes a broad consensus towards sharing of all data and joint submission of information for registrants of the same substance provided that further consideration is given to provisions aiming to ensure that companies are able to act in a cost-efficient way and adequate protection of commercial business information."

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 27/06/2006

The Council, following its political agreement on 13 December 2005, adopted two common positions on the draft regulations on REACH.

The main issues of the Council's common position can be summarised as follows:

Scope of application and substances concerned

REACH will apply to all substances manufactured or imported in quantities over 1 tonne per year. As the definition of a substance has a wide ranging scope, the Council has consolidated and clarified the scope of the Regulation as well as the scope of certain exemptions (e.g. for waste, substances used in foods or feeding stuffs and in certain cases or defence purposes).

The Council also made changes to the definition of existing substances ("phase-in substances") in order to cover all substances listed in the European inventory of existing commercial chemical substances (EINECS).

Furthermore, the Council did not amend the exemptions from registration for individual substances on which sufficient information is known and, because of their intrinsic properties, are not expected to be hazardous (with the sole exception of the addition of cellulose pulp). This list will however be reviewed by the Commission within 12 months after the entry into force of the Regulation.

The Council decided to exclude from registration a number of "natural substances" such as ores, ore concentrates, minerals and cement clinker. 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

Overall, the Council's common position is aimed at designing a workable system for registration while ensuring that enough information is generated by industry to allow a substance to be used safely and information to be made available to the authorities and downstream users. In this context, the original provisions on multiple registrants for the same substance have been modified by the Council in order to include the main elements of the "one substanceone registration" proposal. Thus, 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. To reduce the impact on SMEs, which has been one of the Council's main concerns, key elements of a proposal for targeted information requirements for low volume substances have been included in the Council's common position. Manufacturers or importers of low volume substances (1-10 tonnes) would only have to submit already available data with regard to these substances unless the substances were identified as meeting simple criteria highlighting them as of potential concern. Regarding substances manufactured or imported in quantities of 10 tonnes or more per manufacturer or importer and year, it is proposed that only one test for reproductive toxicity would normally be required in addition to the information requested for low volume substances of potential concern. The Council decided not to introduce significant changes to additional standard information requirements for substances falling into the two categories manufactured or imported in quantities of 100 tonnes to 1000 tonnes 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 based on the exposure scenario(s) developed in the Chemical Safety Report.

Substances in articles

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 be obliged to notify to the Agency if substances meeting the criteria for authorisation are contained in their articles above a certain level and 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 require producers or importers of articles to submit a registration.

Evaluation

The Council decided to give the Agency a more central role than foreseen in the proposal in the evaluation phase of REACH under which registration dossiers will be examined and substances of potential concern identified for further examination. The aim is to ensure that evaluation is carried out more efficiently and consistently across the EU. At the same time, the Council considered that the core scientific work on evaluation of substances would still need to be done in Member States, which have the requisite expertise. Therefore under the terms of the common position, responsibility for dossier evaluation has been transferred to the Agency while substance evaluation will be carried out by Member State competent authorities based on a single EU-wide rolling plan prepared by the Agency, with input from Member States.

Authorisation

The agreement by the Council on authorisation rules aims to achieve a balance between the need of providing for strong incentives or even requirements to substitute dangerous substances and the impact on industry if excessive requirements for authorisation were to be adopted. The Council decided that 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 substances for which there are no suitable alternative substances or technologies available. At the same time, the common position provides that adequate control is not a sufficient ground for granting authorisations in the case of substances that are persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB).

For substances where it is not possible to determine safe thresholds with current methods, the proposal provides for a review within 12 months after entry into force of the regulation based on work in the REACH implementation projects (RIPs). In addition, it was agreed that applications for authorisations should always include an analysis of possible alternatives by the registrant. To make the system more transparent and facilitate planning within industry, a candidate list of substances meeting the authorisation criteria will be published by the Agency. Substances will be identified and placed on the list following a period of public consultation.

Restrictions

The Council has included in its common position 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.

Information

The Council modified substantially rules on access to information with a view to bringing its provisions in line with Regulation 1049/2001 regarding public access to European Parliament, Council and Commission 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 also stipulates that the Agency will publish non-confidential information on the website, in order to facilitate registration, inter alia for SMEs.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 28/06/2004

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:

– 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 ?

– does the Council consider 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 ?

– does the Council consider 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 ?

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 12/07/2006

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 29/10/2003 - Legislative proposal

PURPOSE : to establish the European Chemicals Agency, and set rules on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH), and to amend Directive 1999/45/EC on Persistent Organic Chemicals. PROPOSED ACT : Regulation of the European Parliament and of the Council. CONTENT : the present system for general industrial chemicals distinguishes between "existing substances" i.e. all chemicals declared to be on the market in September 1981, and "new substances" i.e. those placed on the market since that date. New substances must be tested and assessed for possible risks to human health and the environment before they are marketed in volumes starting at 10 kg. Only 3000 new substances have been placed on the market. In contrast, existing substances amount to more than 99% of the total volume of all substances on the market, and are not subject to the same testing requirements. This has encouraged the continued use of "existing", untested substances and inhibited research and

development and innovation. Other problems with the current regime include: - the risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively; - the allocation of responsibilities is inappropriate because the public authorities are responsible for the assessment instead of the enterprises that produce, import or use the substances; - only the manufacturers and importers of substances must provide information, but there are no similar obligations on downstream users (industrial users and formulators). - current liability regimes are insufficient to remedy the problems. Establishing a causal connection is often virtually impossible for injured parties if cause and effect occur far apart in time and if adequate test data on the effects of substances are not available. This proposal establishes the REACH system and creates a European Chemicals Agency. REACH consists of the following elements: 1) Registration - there is a general obligation to register substances manufactured or imported in quantities starting at 1 tonne. The registration provisions oblige manufacturers and importers of substances to obtain knowledge on the substances they manufacture or import and to use this knowledge to ensure responsible and well-informed management of the risks which the substances may present. Manufacturers and importers must address the risks of any use identified to them by their downstream users. A downstream user has the right not to identify a use, in which case he would have responsibility for performing a chemical safety assessment. Conversely, the manufacturer is not obliged to supply a substance for a use that he feels he cannot support. The Regulation exempts certain substances that are adequately regulated under other legislation or that generally present such low risks as not to require registration. Registration requires submission of a technical dossier containing information on the substance and information on risk management measures, as well as - starting at 10 tonnes -the chemical safety report that documents the choice of these measures. For the registration of substances in articles, a special regime applies: certain substances incorporated into articles have to be registered. This is required when the substance in questionhas hazardous properties, which will be released from the article. For substances that are released incidentally to the use of the article, a simple notification is required, on the basis of which the Agency may request a registration. These requirements for certain substances in articles are necessary because of their potential impact on human health and the environment. It should be noted that no declaration of contents in articles is required from importers. The provisions place the same duties on importers and EU manufacturers of articles. Polymers are exempted from the requirement to register. The Commission may introduce certain polymers into the requirement to register following a report on the risks posed by polymers in comparison with other substances and the need, if any, of registering certain types of polymers. A limited form of registration is required for certain isolated intermediates. The following should also be noted: - a number of rules regarding data sharing are set out in order to reduce testing on vertebrate animals and to reduce costs to industry; - information must be passed both up and down the supply chain, and between all actors in that supply chain; -downstream users must consider the safety of their uses of substances, based primarily on information from their supplier, and to take appropriate risk management measures. For an identified use, a downstream user may use the risk management measures prepared by the manufacturer or importer but he must satisfy himself that the relevant exposure scenarios are consistent with his use and that he has implemented all the relevant risk management measures. Guidelines will be developed to ensure that this process is manageable, in particular for small and medium enterprises. If a downstream user is using a substance in a way not covered by a manufacturer's or importer's chemical safety assessment (including incorporating it into an article) or if he intends to use different risk management measures, then he must send a short report to the Agency. Downstream users are not required to submit chemical safety assessments to the authorities because the administrative burden on both industry and authorities would be disproportionate. 2) Evaluation - there are two types of evaluation: - dossier evaluation which is twofold again: - one aim is to prevent unnecessary animal testing. Therefore the Regulation requires authorities to examine proposals for testing in order to check the quality before a test is performed and to prevent the same animal test to be performed repeatedly; - the regulation gives authorities the task of checking the compliance of registration dossiers with the requirements of the registration title; - substance evaluation: provides a mechanism for an authority to require industry to obtain and submit more information in case of suspicion of a risk to human health or the environment. To promote a consistent approach, the Agency will develop guidance on prioritisation of substances for evaluation. Member States then prepare rolling plans of the substances that they wish to evaluate. 3) Authorisation - a system for uses of substances and the placing on the market of substances for such uses is established for the substances of very high concern. The substances selectedfor the authorisation system have hazardous properties of such high concern that it is essential to regulate them through a mechanism that ensures that the risks related to their use are assessed, weighed and then decided upon by the Community prior to actual use. In line with the general REACH approach, the requirements for the applicants under the authorisation approach are risk-based, as he has to demonstrate that the risks related to the use of the substance concerned are adequately controlled or that they are outweighed by socio-economic benefits. Substances of very high concern are defined as: substances that are category 1 and 2 carcinogens or mutagens; substances that are toxic to the reproductive system of category 1 and 2; substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative; and substances such as endocrine disrupters which are demonstrated to be of equivalent concern. 4) Restrictions - the provisions enable risk reduction measures to be introduced across the Community where this is shown to be necessary. The restrictions provisions act as a safety net for the whole REACH system as well as for the Community legislation as a whole because any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if a risk needs to be addressed. The Regulation creates the European Chemicals Agency (Agency) to manage the technical, scientific and administrative aspects of the REACH system, and ensuring consistency of decision making, at Community level. The Agency manages the registration process, plays a key role in ensuring consistency of evaluation, provides criteria to guide Member States' selection of substances for evaluation and takes decisions requiring further information on substances under evaluation. It also provides opinions and recommendations in the authorisation and restriction procedures and has duties with regard to confidentiality. The Regulation also contains provisions on classification and labeling inventories, enforcement, and competent authorities in the Member States. The direct costs of REACH to the chemicals industry are estimated at a total of some EUR 2.3 billion over an 11-year period. The costs to downstream users of chemicals are estimated at EUR 2.8 to 3.6 billion over a period of 11 and 15 years respectively - if the market reacts as expected with 12 per cent of substances being withdrawn because continued production would not be profitable. Costs could rise to EUR 4.0 to 5.2 billion if industry faced higher supply chain adaptation costs. These estimates include the direct costs passed on from the chemicals sector to downstream users. The total costs for the chemicals industry and the downstream users are thus estimated to EUR 2.3 to 5.2 billion.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 15/12/2006 - Commission opinion on Parliament's position at 2nd reading

On 13 December 2006, the European Parliament adopted a compromise package which had been agreed with the Council in view of reaching a second reading agreement. The Commission accepts in full amendment 191 which constitutes the compromise package.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 24/06/2005

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 18/12/2006 - Corrigendum to final act

PURPOSE: **Corrigendum** to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999 /45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (*Regulation initially published in Official Journal of the European Union L 396 of 30 December 2006).*

The corrigendum in English concerns the entire text of the Regulation.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 13/12/2006 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution based on the report by Guido **SACCONI** (PES, Italy) on the Council's common position. Parliament arrived at an agreement with Council on outstanding issues a few days before the vote in plenary. The compromise package agreed with the Council and tabled by 4 political groups (EPP-ED, PES, ALDE and UEN), was approved with 529 in favour, 98 against and 24 abstentions. The key points are as follows:

Registration of substances: REACH will require manufacturers and importers to gather information on the properties of all substances produced or imported in quantities higher than 1 ton per year and to submit the necessary information to demonstrate their safe use in a registration dossier to the European Chemicals Agency (the Agency). Failure to register will mean the substance cannot be manufactured or imported into the EU market. Currently about 30,000 substances are in the EU market in volumes above one tonne.

Quantities above 10 tonnes per year additionally require the submission of a Chemical Safety Report (CSR) to document the safety assessment of the substance. Accordingly, substances imported in low volumes (below ten tonnes per year) will not require the submission of a Chemical Safety Report.

The Commission must decide in 12 years' time whether or not to recommend extending the requirement for chemical safety reports to substances produced or imported in amounts of less than 10 tonnes per year. This deadline was shortened to seven years for cancerous or mutagenic substances or those toxic to reproduction.

Substitution: substitution plans - or at least an analysis of possible alternatives - aiming to replace the most dangerous substances where a safer alternative is available, must be submitted to the Agency by producers alongside authorisation applications. The Economic and Social Committee, scientific committees and interested third parties will be able to intervene to submit additional (and/or contradictory) information. Where an alternative product exists, substitution is compulsory on the basis of a precise timetable outlined in the substitution plan. If, on the contrary, no substitute product exists, producers should present a research plan with a view to developing such a product. There are exceptions to this rule based on the criteria of adequate control.

Provisions relative to 'high-concern' chemicals: around 1500 substances of very high concern may become subject to authorisation, including:

- CMRs (substances that are carcinogenic, mutagenic or toxic to reproduction), category 1 and 2;
- PBTs (substances with persistent, bio-accumulative and toxic properties);
- vPvBs (substances that are very persistent, very bio-accumulative).

Substances identified from scientific evidence as causing probable serious effects to human health and the environment equivalent to those of the other categories mentioned above, for example certain endocrine disrupting substances (substances disturbing the body's hormone system). These will be identified on a case by case basis.

For certain substances that are carcinogenic, mutagenic or toxic to the reproductive system (CMR substances), an authorisation will be granted if the producer or importer can show that risks from the use in question can be adequately controlled. This means that scientists can agree on a "safe threshold" below which a substance does not create negative effects to the human body or the environment. Endocrine disrupters will be subject to the 'adequate control' criteria. A review clause nevertheless provides scope for looking into their possible inclusion among the substances subject to specific authorisation (see below) six years after the entry into force of the regulation on the basis of the latest available scientific data and in view of the results of a cost/socioeconomic benefits analysis of their use.

The agreement does not enforce mandatory substitution of substances of high concern in all consumer products.

For other CMR substances and substances with persistent, bio-accumulative or toxic properties (PBT, vPvB substances), where adequate control is not possible, a specific authorisation will be granted if no safer alternative exists and if the socio-economic benefits of the use of the substance outweigh the risks.

Burden of proof: instead of national authorities having to justify concern about particular chemicals, the responsibility for proving that their products are safe will now rest with the manufacturers. The industry will have to prove the safety of chemicals produced or imported in large volumes (above 10 tonnes a year).

Duty of care: The agreement of Council and Parliament clarifies in two recitals the general responsibility of industry to avoid adverse effects on health and environment when manufacturing, importing, using or placing on the market chemicals.

Animal welfare: the promotion of alternatives to the animal testing of chemicals is now included among the goals of REACH. To avoid duplication of animal testing, interested parties will have 45 days to state their views before each new plan for animal tests. Information on toxicity to human beings should if possible be discovered using means other than tests on vertebrate animals, through alternative methods such as in vivo procedures. These alternative methods must be validated by the Commission, once recognised by the agency, or international institutions. The Commission will submit a report every three years on the use of alternative tests and, if necessary, bring forward fresh legislative proposals.

European Chemicals Agency: Parliament will appoint two members of the Helsinki-based European Chemicals Agency and the text also specifies the agency's responsibilities and its role in relation to the relevant national authorities. The Board of Administration will comprise one delegate per member state, two members appointed by the European Parliament and six by the Commission (including three non-voting stakeholder representatives). The Executive Director will have to undergo a hearing with MEPs before his/her appointment is confirmed. However, Parliament's demands for guarantees of the independence of the agency's members vis-à-vis industry and the publication of declarations of interest were not accepted. The agency will have one year (until 1 June 2008) to be fully operational (staff recruitment and training, establishment of various committees, etc). It should present its first recommendations on dangerous substances two years after the entry into force of the regulation, i.e. after 1 June 2009.

Communication of information: a clause was added on the duty to inform the public about dangerous substances contained in products. The distribution chain, including consumers who request it, must be informed of the presence of any chemical in an amount greater than 0.1% of the total product weight. The Commission must consider the possibility of establishing a European quality mark for chemical products.

Comitology: the Council accepted a number of amendments bringing REACH into line with the new comitology provisions, which give the EP a right of scrutiny over certain Commission decisions.

Timeline for the implementation of REACH:

- June 2007: entry into force of REACH.
- June 2008: European Chemicals Agency becomes operational.
- June 2008 to November 2008: pre-registration of so-called phase-in substances.
- November 2010: registration deadline for substances in quantities of 1000 tonnes and above as well as carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) above 1 tonne/year and substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes.
- June 2013: registration deadline for substances in quantities of 100 tonnes and more.
- June 2018: registration deadline for substances in quantities of 1 tonne and more.
- Voluntary registration prior to the deadline is of course possible. Registration dossiers can be submitted as of 1 June 2008.
- New substances need to be registered before they are placed on the market. Their registration will start on 1 June 2008.
- June 2018: Registration phase closes with substances produced in smaller quantities (1-10 tonnes).

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 27/06/2006 - Council position

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.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 20/12/2016 - Follow-up document

The Commission presented a report on the review provided for in Article 138(7) of the REACH Regulation to assess the need to extend the scope of Article 60(3) to the substances identified under Article 57(f), which have endocrine disrupting properties.

Background: the Commission should review how certain substances of very high concern, i.e. those with **endocrine disrupting properties**, should be treated as part of the REACH authorisation procedure.

Endocrine disrupting substances (EDs) can be identified as substances of very high concerns under REACH based on Article 57(f) provided that there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to carcinogenic, mutagenic or toxic to reproduction category 1A or 1B (CMR Cat. 1A/1B) and persistent, bioaccumulating and toxic or very persistent and very bioaccumulating.

For the purpose of this review, the Commission is going to apply the WHO International Programme on Chemical Safety definition of endocrine disruptor.

Authorisation procedures: for an authorisation to be granted, one of the following conditions must be fulfilled:

- the risks from the use of the substance are adequately controlled (‘Adequate Control Route’), or;
- it is shown that socio-economic benefits of continued use outweigh the risks to human health or the environment arising from the use of the substance and there are no suitable alternative substances or technologies (commonly referred to as ‘Socio-Economic Route’).

The REACH Regulation therefore provides for two authorisation procedures depending on the possibility to determine a threshold or not for a substance of very high concern (with the exception of persistent, bioaccumulative, toxic or very persistent and very bioaccumulative substances which are always subjected to the ‘Socio-Economic Route’).

Existence or not of threshold for EDs: in 2013, the ED’s expert advisory group on EDs concluded that most experts considered that thresholds of adversity are likely to exist for EDs but may be very low for individual EDs, depending on the mode of action, potency and toxicokinetics.

Several experts also expressed the view that, although thresholds may exist, it might be difficult to estimate with any confidence the biological thresholds of adversity based on currently available standard tests.

In addition, **several uncertainties surrounding the determination of thresholds** were highlighted in the debates between scientists. Some are specific to EDs, while most are common to all chemicals.

Conclusions: the report noted that Article 60(3)(a) of the REACH Regulation already lays down that for substances for which it is not possible to determine a threshold, the 'Adequate Control Route' for authorisation is not possible.

The information set out in the report showed that it is not appropriate to extend *a-priori* the scope of Article 60(3) to all substances identified under Article 57(f) as substances with endocrine disrupting properties which have an equivalent level of concern.

Consequently, **Article 60(3) of REACH will continue to be applicable to those EDs for which it is not possible to determine a threshold,** only the 'Socio-Economic Route' can be used when a threshold cannot be determined.

It remains the responsibility of applicants for authorisation to demonstrate that a threshold exists and to determine that threshold in accordance with Annex I to REACH. It is up to RAC to assess the validity of the assessment and ultimately decide on the possible existence or not of this threshold. Furthermore, as for other substances, the Risk Assessment Committee may on a case-by-case basis set reference Derived No Effect Levels (DNELs), or reference dose-response curves, which industry can use when applying for authorisation.

Given that regulatory stability is desirable, **the Commission will not propose a change to the legislation**.

Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 05/02/2013

In accordance with the requirements of Regulation (EC) No 1907/2006 (REACH), the Commission presents a report on the operation of the Regulation. The report also examines certains aspects of the operation of Regulation (EC) No 1272 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP Regulation).

Human health and the environment: whilst it is still too early to quantify the benefits, the Commission states that overall, **progress towards meeting the human health and environment objective of REACH is materialising**, and will accelerate as the remaining key benefit drivers become fully operational. However, the Commission notes some key shortcomings which may hinder achievement of the benefits:

- many registration dossiers have been found to be **non-compliant**, including with regard to substance identity;
- **insufficient assessments** by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties;
- problems with regard to the **content and format of the extended safety data sheet**.

The Commission discusses ways for industry, Member States and the ECHA to improve the situation, with particular reference to the quality of registration dossiers, and enhancing the use of safety data sheets as a central risk management tool.

Internal market and competitiveness: the report notes that industry acknowledges the **positive economic effects of REACH**. However, the Commission will (i) explore ways to **reduce the financial impact of the Regulation, in particular for SMEs**, and (ii) encourages ECHA and industry to address concerns about transparency, and cost sharing in the Substance Information Exchange Forum (SIEF).

Innovation: the report states that REACH has had a **positive impact on research into new substances**, due to generally equal treatment of new and phase-in substances. REACH fulfils its objective with regard to innovation even if, with regard to R&D, an innovation gap with regard to the US and Japan still exists and pressures from the emerging economies are increasing.

Alternative methods: considerable efforts to develop alternative methods to animal testing have been made and will continue: the Commission has made available EUR 330 million to fund research in this area in the period 2007-2011.

Enforcement: enforcement is the sole responsibility of the Member States and all of them have nominated enforcement authorities. The Commission wants Member States to maximise the effectiveness of available resources through better coordination and knowledge sharing. It will **develop enforcement indicators** and calls on Member States to monitor the effectiveness of enforcement.

Review of the requirements for registration of 1 to 10 tonnes substances and on the need to register certain types of polymers: at present, the Commission has insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages. Similarly, it is reviewing the need, if any, to register certain types of polymers.

Scope of REACH: overall, the Commission is of the view that the scope of REACH was set well and no major overlaps with other EU legislation have been identified. Nonetheless, it discusses the minor overlaps which were identified and adds that it has also identified certain areas where information generated under REACH processes could be used in the context of EU sector-specific legislation requirement.

Amendments: some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concludes that changes to the enacting terms of REACH will not be proposed.