



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 28 April 2006**

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**Interinstitutional File:  
2003/0256 (COD)  
2003/0257 (COD)**

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**7524/06  
ADD 1**

**COMPET 72  
ENV 189  
CHIMIE 12  
CODEC 252  
OC 224**

**STATEMENT OF THE COUNCIL'S REASONS**

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Subject : Common position adopted by the Council on [.....] with a view to adopting a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} and a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

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**STATEMENT OF THE COUNCIL'S REASONS**

## **I. INTRODUCTION**

1. On 5 November 2003, the Commission submitted a proposal for a Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and a proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to the REACH Regulation. The proposal is based on Article 95 of the EC Treaty.
2. The Economic and Social Committee delivered its Opinion on 31 March 2004<sup>1</sup>.
3. The European Parliament delivered its Opinion at first reading on 17 November 2005.
4. On 13 December 2005, the Council reached a Political agreement by unanimity on a compromise text with a view to adopting its Common Position.
5. The Council adopted its common position in accordance with Article 251 of the EC Treaty on [.....]

## **II. OBJECTIVES**

Against the background of the considerable gap in knowledge of chemical substances, which has been seen as a major weakness of the current EU chemicals policy, the proposal on "REACH" seeks to balance protection of human health and the environment with the impact on competitiveness, particularly that of SMEs, as well as simplifying the administrative processes and making efficient use of scarce resources.

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<sup>1</sup> OJ C 112, 30.4.2004, p. 92

More specifically, some of the main objectives of the new system are:

- To establish a coherent registration system designed to provide basic hazard and risk information on new and existing substances manufactured in or imported into the EU;
- To reverse the burden of proof, moving it away from Member States' authorities to producing and importing companies, who will be responsible for demonstrating that substances can be used safely;
- To introduce responsibility for downstream users to provide information on uses and associated risk management measures relating to substances;
- To maintain the existing restriction system and to introduce an authorisation procedure for the most hazardous substances as a new instrument;
- To ensure greater transparency and openness for the public by providing easier access to relevant information on chemicals;
- To establish a central entity to facilitate the administration of REACH and ensure that the system is applied in a harmonised way across the EU.

### **III. COMMON POSITION**

Taking into account the above objectives and the complex structure of the chemicals industry and its supply chain, the Council has agreed on a text which seeks to ensure a high level of protection of human health and the environment whilst limiting the administrative burdens and costs for European industry in order to maintain its competitiveness and innovative capacity.

The text of the proposal was revised extensively during discussions carried out by the Council over the last two years. During this process, the Presidencies of the Council had frequent contacts with the European Parliament, which resulted in a substantial convergence of views between the two Institutions. Thus around 200 amendments from the European Parliament's Opinion at first reading have been reflected either in full, in part or in principle in the Common Position.

All modifications to the original proposal introduced by the Council have been accepted by the Commission.

## **Recitals**

In general, 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, the Common Position takes on board the spirit of certain amendments:

Concerning amendment 11 (partly linked to amendments 59 and 364 on Article 1(2)) that introduces a “duty of care” for manufacturers, importers and downstream users to use or place substances on the market in such a way that they do not damage human health or the environment, the Council considers that the provisions of Article 1, as amended to state that chemical substances shall not adversely affect human health or the environment, are sufficient.

As regards amendments 3, 416 and 419, which refer to the competitiveness and innovation capacity of the European Chemicals industry as well as the compatibility of the REACH Regulation with WTO requirements, the Council considers that REACH is in line with all WTO obligations and in itself should stimulate innovation and thereby maintain or enhance competitiveness. Again, the Council considers that the provisions of Article 1, as amended to state that one of the purposes of the Regulation is to ensure the free circulation of goods while enhancing competitiveness and innovation, are sufficient.

In general, several amendments included in the Common Position cover the spirit of amendments 22 and 363, which put the emphasis on the need to pay special attention to Small and Medium-sized Enterprises (SMEs). In addition, the Council considers it necessary to introduce a new recital 8, underlining the need to take special account of the potential impact of REACH on SMEs and the need to avoid any discrimination against them.

Other amendments to recitals have not been reflected since they would not be compatible with the approach taken by the Council in its Common Position (amendments 2, 5, 6, 7, 9, 12, 13, 15, 17, 23, 24, 25, 27, 28, 30, 31, 32, 33, 34, 35, 37, 38, 42, 43, 44, 45, 46, 47, 52, 54, 55, 56, 57, 58, 90, 361 and 424).

## **Title I – Scope and definitions**

In its Common Position, the Council has consolidated and clarified the scope of the Regulation as well as clarifying 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. Definitions in Article 3 have been adjusted to take account of the approach taken by the Council in its Common Position.

On this basis, the Common Position reflects either in full, in principle or in part the European Parliament's amendments 65, 68, 69, 74, 79, 372, 376, 377, 462rev, 463rev, 464rev, 465rev, 466rev, 469rev and 983..

As regards amendment 67 concerning alloys and their definition as special preparations, the Council welcomes the Commission's intention, expressed in a new recital, to develop guidance, in close cooperation with Member States and stakeholders, on the assessment of special preparations.

Amendments, which are not in line with the Council's approach, are not reflected in the Common Position (amendments 59 and 364 (see above under "Recitals"), 60, 66, 70, 71, 75, 76, 77, 78, 80, 82, 673 and 676).

## **Title II – Registration**

With a view to including the main elements of the "one substance - one registration" (OSOR) proposal introduced during the Council's examination, 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 by an assessor chosen by the registrant as having appropriate experience would be a possibility on a voluntary basis.

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. The above criteria are established in Annex III. These aim to be clear, simple for industry to apply and related to the information known about a substance's properties, uses and likely exposure.

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.

Overall, the Council has aimed at designing a workable and less burdensome system of 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 line with the above considerations, the Common Position reflects completely, in principle or in part the following amendments: 88, 89, 97, 99, 104, 108, 109, 112, 116, 117, 118, 119, 373, 380, 381, 382, 386, 387 and 436.

The Common Position does not take on board some amendments which would not be in line with the approach outlined above (Amendments 90, 96, 105, 106, 110, 113, 114, 121, 374, 375, 422, 469rev, 433, 549, 575rev, 584, 593, 594, 595, 596, 611 and 960).

More specifically, concerning amendments 96, 106, 108 and 549, 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.

Other amendments, such as amendments 593, 594, 595 and 596 have not been taken on board simply because it would not be appropriate to introduce provisions on company groups in this Regulation.

Finally, 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), amendment 110 has not been taken on board, which would introduce a requirement to make a Chemical Safety Assessment for all substances subject to registration.

### **Title III – Data-sharing and avoidance of unnecessary testing**

The Common Position 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 fact that 30 of the amendments adopted by the European Parliament at first reading have been reflected in the Common Position either in full, in principle or in part (amendments 27, 123, 125, 126, 128, 130, 131, 132, 134, 136, 137, 138, 142, 143, 147, 148, 149, 151, 153, 154, 358, 367, 369rev, 370, 371, 379 and 384) shows that the European Parliament and the Council share the same objectives, particularly in relation to reducing testing on vertebrate animals and facilitating data sharing.

The Common Position does not incorporate amendment 383, 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.

The Common Position does not take on board two amendments stipulating that sharing of costs should be proportionate to the production volume (amendments 150 and 155).

Other amendments have not been reflected since they would not be in line with the approach taken by the Council (amendments 129, 135, 139, 140, 150, 152, 155, 156, 368, 383 and 385).

#### **Title IV – Information in the supply chain**

The Council has included in its Common Position 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.

Based on this approach, most of the amendments adopted by the European Parliament at first reading (amendments 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 366 and 710) are reflected in the Common Position.

The Common Position does not include amendment 365, which provides that workers would be granted access by producers to information given in the supply chain, since such a responsibility lies with the employer. Amendment 168 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.

#### **Title V – 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. Similarly to amendment 719, the Common Position also clarifies that downstream users can participate in a Substance Information Forum (SIEF). Finally, the Common Position 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. Finally, the Council has in its Common Position decided to delete Annex Ib (Chemical Safety Assessments for Preparations) given that the scientific methodology underpinning this Annex is still being developed.

On this basis, the Common Position does not take on board certain amendments adopted by the European Parliament at first reading (amendments 169, 726). Concerning amendment 169, which would introduce a lighter procedure for SMEs, the Council shares the view that the burden on this group of companies should be alleviated. This is clearly expressed in recitals 8 (special account should be taken of the potential impact of REACH on SMEs), recital 34 (guidance), Article 73 (reduced fees for SMEs) and Article 76 (Agency assistance).

## **Title VI – Evaluation**

In its Common Position, 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.

On the basis of the approach adopted, the Common Position reflects in full, in principle or in part amendments 171, 174, 175, 178, 179, 180, 181, 182, 183, 184, 185, 187, 188, 190, 191, 192, 193, 195, 196, 197, 199, 201, 205, 206, 207, 208, 209, 211, 213, 470rev, 729, 730, 733, 739, 744, 745 and 746.

The Common Position does not reflect the amendments which would give full responsibility for substance evaluation to the Agency (amendments 170, 202, 203, 742 and 743) although the Common Position has been moved significantly in this direction. As stated above, the Council considers that the most workable solution is for the Agency to be responsible for co-ordinating the substance evaluation process, relying on the Member States' competent authorities to perform the evaluations. In line with this approach, the Council supports the European Parliament's view that the Agency should be given a more prominent role in the whole evaluation process, e.g. through developing criteria for prioritising substances and through the establishment of the Community rolling action plan of substances to be evaluated.

As regards amendment 177, which concerns mandatory consultation of the European Centre for Validation of Alternative Methods (ECVAM) before deciding on animal testing and has not been acknowledged directly in the Common Position. However, Article 13(2) stipulates that test methods will be revised as appropriate to refine, reduce or replace animal tests which goes in the same direction, since ECVAM will play a role in this work.

Since this would not be in line with the approach taken the Common Position does not include amendments 173, 176, 186, 189, 194, 198, 200, 204 and 212.

## **Title VII – Authorisation**

Various amendments have been included in the Council’s Common Position designed to strengthen authorisation whilst ensuring that the provisions are workable.

The scope of authorisation as set out in Article 56 (a) to (e) of the Commission proposal has not been amended. However, in line with amendment 217, the wording of Article 56(f) as been clarified.

For reasons of increased transparency and to facilitate planning within industry, a candidate list of substances meeting the authorisation criteria of Article 56 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. This is similar to the view taken by the European Parliament with the introduction of Annexes XIIIa and XIIIb (amendment 215).

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. It has been made clear that the “adequate control” route to authorisations does not apply to PBTs, vPvBs, or substances meeting the criteria in Article 54(a) – (c) and (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I. It has also been made clear that the Commission shall review Annex I within twelve months after the entry into force of the Regulation.

The existence of an authorisation procedure would in itself encourage substitution since less harmful substances would not require an authorisation. In addition, in order to further 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.

In line with this approach, the Common Position incorporates in full, in principle or in part amendments 215, 216, 217, 219, 223, 226, 227, 229, 235, 236, 237, 241, 242, 243, 245, 470rev, 471 and 568.

The Common Position does not take on board amendments 214 and 232, which would require mandatory substitution if suitable alternatives are available. With a view to safeguarding the European chemicals industry's competitiveness while at the same time protecting human health and the environment, the Council considers that the measures included in the Common Position provide for a solution which is more balanced and workable.

In line with this philosophy, the Common Position reflects amendment 221 concerning the five-year limitation on the review period for substances included in Annex XIV, or the part of amendment 235 concerning the five-year time limit for authorisations granted.

In general, a number of amendments (218, 220, 222, 224, 225, 228, 230, 231, 232, 233, 234, 238, 239, 240, 244 and 246) have not been reflected in the Common Position since this would not be in line with the approach taken by the Council.

## **Title VIII – 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. Furthermore, clarifications to Annexes XV (Dossiers) and XVI (Socio-economic analysis) have been made.

In line with this approach, the Common Position reflects in full, in principle or in part amendments 247, 569, 570, 571, 572, 789 and 985.

The amendments 248 and 251 are not reflected in the Common Position.

## **Title IX– 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.

## **Title X– Agency**

The Council's Common Position clarifies this Title on several points, including:

- 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.

- With a view to avoiding any ambiguity in relation to Decision 2004/97/EC of 13 December 2003 in which it was decided that the seat of the Agency should be Helsinki, the Council has decided to delete the reference to the seat of the Agency in the REACH Regulation (amendment 291).
- The Agency will get its funding from contributions from the Community budget, fees paid by industry, and voluntary contributions from Member States.

In line with what has been outlined above, the Common Position reflects in full, in principle or in part amendments 258, 259, 260, 261, 265, 266, 270, 285, 288, 291, 293, 294, 418, 796 and 801.

All the amendments stipulating that the Agency should have overall responsibility for the management of REACH (in particular amendments 253, 256 and 795) or that part of the amendments putting emphasis on the Agency as the main authority in the field of REACH (amendments 260, 261, 262, 263 and 796) have not been incorporated in the Common Position.

In the Common Position, the Agency has been given a more prominent role in the whole evaluation process whilst clarifying that Member States should perform substance evaluations.

Furthermore, amendments 267, 269, 360 and 1037 have not been included since it would not be appropriate to involve the European Parliament directly or indirectly in the appointment of members of the Management Board.

In general the Common Position takes on board the following amendments: 252, 253, 254, 256, 257, 264, 267, 269, 271, 272, 273, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 286, 287, 288, 289, 290, 292, 295, 795 and 1037.

## **Title XI– Classification and labelling**

The Council's 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 amendments 295, 296, 472rev and 473rev.

## **Title XII– Information**

This Title has been modified substantially with a view to bringing its provisions in line with Regulation 1049/2001<sup>2</sup> 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 (Article 117) should be drawn up by the Agency's Management Board in accordance with the provisions of the Aarhus Convention and with Regulation (EC) No 1049/2001.

In line with the above, the Common Position reflects in principle amendment 297 stipulating that Member States, the Agency and the Commission will submit a report every five years on experiences gained.

The Common Position also reflects in principle amendment 301 stipulating that the Agency will publish non-confidential information on the website.

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<sup>2</sup> O.J. L 145, 31.5.2001, p.43

In order to bring the provisions on access to documents in line with Regulation No 1049/2001, the principle of amendments 304, and 814 have been reflected. In line with this approach, it was not considered appropriate to incorporate amendments 298, 300 and 808.

### **Title XIII– Competent Authorities**

In line with the principle of amendment 305, 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 amendment 306 concerning special help and advice to SMEs. The Council considers that Member States helpdesks will be of great benefit to industry, in particular to SMEs.

### **Title XIV – Enforcement**

Some clarification of the sanctions regime to be established by Member States has been introduced in the Common Position.

The Common Position does not reflect amendments 307 and 816 giving the Forum within the Agency the task to draw up guidelines on enforcement. However, in line with the Commission's proposal, the Forum shall identify enforcement strategies as well as best practice in enforcement.

As in case of amendment 306, the Council considers that the principle of amendment 362 would be covered by the Member States' helpdesk, which would be of great help to SMEs. This provision is also underpinned by recital 8 stipulating that special attention should be given to SMEs.

The Common Position does not reflect amendments 817 and 818 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.

#### **Title XV– Transitional and final provisions**

The Common Position reflects in principle amendment 309 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 amendment 822 on the preparation of the establishment of the Agency, the Commission and the Council have committed themselves in a joint statement to provide the necessary support towards setting up of the Agency. The transitional period in relation to the setting-up of the Agency (and subsequent amendments to the transitional period relating to existing legislation) has been amended in line with the Commission's stated intention not to fulfil the functions of the Agency in the period between the entry into force of the Regulation and the establishment of the Agency.

The Common Position takes on board the editorial modification suggested in amendment 317 in its Common Position.

In line with the amendment 573 (and related amendments in other Titles), the Council also considers it more appropriate not to regulate Persistent Organic Pollutants (POPs) within the framework of REACH.

Since this would not be in line with the approach in the Common Position, amendments 311, 312, 313, 314, 315, 316, 318, 474 and 823 have not been incorporated.

## Annexes

The following key changes to the Annexes have been introduced in the Common Position:

- 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 the entry into force of REACH.
- Categories of exemption from registration listed in Annex V have been amended, particularly through the addition of natural substances such as ores, ore concentrates, minerals and cement clinker.
- Criteria for targeting low volume phase-in substances (those manufactured or imported in quantities of 1- to 10 tonnes per manufacturer or importer per year) requiring the full Annex VII have been established in Annex III. These aim to be clear, simple for industry to apply and related to the information known about a substance's properties, uses and likely exposure.
- As Annex VII will only apply to a limited number of phase-in substances in the tonnage range of 1-10 tonnes/year, the Council has included additional information requirements in relation to acute toxicity, biodegradation and algal toxicity.
- Only one test for reproductive toxicity is foreseen for Annex VIII (additional information for substances produced or imported in quantities of 10 tonnes or more per manufacturer or importer per year).
- No significant changes in requirements are introduced for Annexes IX and X.
- In general, Annexes VI-XI include other technical revisions.
- 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.
- Annex X (test methods) of the Commission's proposal has been deleted and the test methods will be included in a separate regulation to be adopted by the Commission.

On this basis, the Common Position reflects in full, in principle or in part amendments 320, 388, 322, 323, 324, 327, 389, 390, 391, 392, 394, 395, 396, 397, 398, 399, 400, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 475rev, 476rev, 477rev, 478rev, 660, 865 and 966.

The Common Position does not take on board the following amendments: 321, 328, 329, 337, 351, 393, 401, 574, 831, and 965.

#### **Amendments to Council Directive 67/548/EEC – Dangerous substances**

The Common Position introduces some additional technical amendments to Directive 67/548/EEC resulting from the amendments made to the REACH Regulation in relation to the transitional period for setting-up the Agency.

In line with the approach under Title XII (Information) of the REACH Regulation, the Council did not consider it appropriate to incorporate amendments 1, 2 and 3.

#### **IV. CONCLUSION**

The Council considers that its Common Position, which is the result of extensive preparatory work and negotiations since 2003 and which is fully supported by the Commission, is wholly in line with the different objectives of REACH. Thus, the Common Position seeks to establish a workable and efficient system, which represents a good balance between the protection of human health and the environment and maintaining the competitiveness of EU industry.

As a result of frequent contacts and exchanges of views between the respective Presidencies of the Council and the key players of the European Parliament, a significant convergence of positions between the two Institutions emerged during the process. This convergence is well reflected in the Common Position.