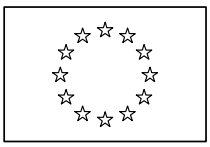

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.7.2006
COM(2006)375 final

2003/0256(COD)
2003/0257(COD)

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to the second subparagraph of Article 251(2) of the EC Treaty

concerning the

Common Position of the Council on the adoption of 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 a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) No …/2006 (REACH)

{SEC(2006)924}

2003/0256 (COD)
2003/0257 (COD)

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to the second subparagraph of Article 251(2) of the EC Treaty

concerning the

Common Position of the Council on the adoption of 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 a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) No …/2006 (REACH)

1. PROCEDURE

The proposal COM(2003)644 final[1] was transmitted to the European Parliament and the Council on 3 November 2003 in accordance with the co-decision procedure pursuant to Article 95 of the EC Treaty.

The European Economic and Social Committee gave its opinion on 31.3.2004[2].

The Committee of Regions gave an opinion on 23.2.2005[3].

The European Parliament gave its opinion at the first reading in session on 17.11.2005.

The Council reached unanimous political agreement on a Common Position on 13.12.2005. The Council adopted the Common Position formally on 27.6.2006.

2. PURPOSE OF THE REGULATION AND DIRECTIVE

The aims of the REACH Regulation are to ensure a high level of protection of health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

The aim of the Directive is to amend 67/548/EEC in line with the changes to the current chemicals management regime introduced by REACH.

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1 OJ C 96, 21.04.2005, p.24.
2 OJ C 112, 30.04.2004, p.92
3 OJ C 164, 05.07.2005, p.78.

3. COMMISSION COMMENTS

3.1. General comments

In addressing the Parliament immediately prior to the adoption of the First Reading of the REACH Regulation, the Commission stated that the Commission could accept totally, in part or in principle 169 amendments out of the 430 amendments proposed by Parliament in the first reading[4].

The tight timetable for political agreement meant that the Commission was not in a position to formally amend its proposal in the light of the First Reading. Nevertheless the Council was informed of the Commission's position with regard to the European Parliament's amendments and was asked to take the Parliament's amendments into account in the course of its decision[5]. Several changes were introduced at that stage which closely reflects the position of the Parliament.

The Council agreed unanimously upon its Political Agreement on both legislative instruments on 13 December 2005. This followed intensive negotiations over a two year period on a wide range of issues related to scope, registration, especially the question of low volumes, substances in articles, data sharing, evaluation, including a stronger role for the proposed new Chemicals Agency and authorisation and restriction of dangerous substances.

The last, and most difficult, issue to be settled at the Council concerned aspects of authorisation of substances of high concern and substitution. 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[6].

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

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4 Fiche suite a donner.

5 Council Working Document 317/05

6 Council Press Release n° 15168/05 of 13 December 2005

in full in the Common Position. The Parliament adopted other compromise packages, of which 96 amendments are included in the Common Position.

The Commission welcomes the adoption of the Common Position on 27 June 2006 which responds to the aims that it has set for an agreement which will be consistent with the Lisbon goals as regards the competitiveness of European industry and encouraging innovation, and which will achieve a marked improvement in health and environment to the benefit of Europe's citizens. It considers that the principal aims of its REACH proposal[7] are safeguarded in the Common Position, and thus fully supports the Common Position, as indicated to the Council at its special session on 13 December 2005.

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 Annex I). 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 arising principally from much increased powers and responsibilities of the Agency and the decision of the European Council to locate the agency in Helsinki; it is recalled that in the initial three years the Agency will have little fee income and will accordingly need to rely on EU subsidies to function effectively. The Commission will provide the relevant financial details to the Budgetary Authority.

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.

3.2. Detailed comments (REACH)

3.2.1. Parliamentary amendments accepted by the Commission and incorporated in full, in part, or in principle in the common position

3.2.1.1. Parliamentary amendments accepted by the Commission in full

Concerning recitals:

amendment **4** highlights the global goal of using chemicals so that they do not damage human health or the environment, and is included in principle in recital 4.

amendment **8** clarifies the purpose of authorisation and is included in principle in recital 12.

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7 COM(2003)644 final

amendment **10** makes clear that information on implementation should be made easily available, particularly to help SMEs and has been included in principle in recitals 20 and 35.

amendment **14** clarifies that the Agency, relying on Member States' competent authorities, should ensure substances are evaluated and has been included in principle in recital 16.

amendments **16** emphasise that the Agency should promote broad international consensus in the regulation of chemicals and account should be taken of existing and emerging international standards and has been included in principle in recitals 6, 43 and 97.

amendment **19** aligning the recital on substances in articles with the clearer and more focussed provisions in the operative text has been included in principle in recitals, the part referring to authorisation applying to SIA has not been included.

amendment **26** underlines the importance for industry of sharing information and providing for fair compensation has been included in full as recital 47.

amendment **39** refers to the establishment of a Community rolling action plan for substance evaluation and has been included in principle in recital 60.

amendment **40** clarifies that decisions are agreed within the Agency's Member State committee and has been included in full as recital 61.

amendment **41** highlighting vulnerable populations who are to be taken into account when protecting human health has been included in principle in recital 63, the part referring to the not giving an authorisation if a substitute exists has not been taken up.

amendment **50** states that harmonised classification and labelling can be undertaken for a wide range of substances and has been included in principle in recital 103.

amendment **53** affirming the applicability of the Aarhus Convention as concerns access of information and has been included in principle in recital 105, that part about information being available in the MS languages has not been taken up.

Concerning operative text:

amendments **63** and **64** are included in principle in the Common Position through its provisions on reduced fees for Small and Medium Size Enterprises (SMEs) in all cases (Article 73(3)), on national helpdesks (Article 123), and on the Agency providing guidance and tools especially to help SMEs (Article 76(3)(c)).

amendments **74** and **983** on which the Commission reserved its position are included in the Common Position by the specification that research and further development relate to a substance "*on its own, in preparations or in articles*".

amendment **79** is included, thereby laying down the definition of SMEs as recommended in the Commission Communication on this issue.

amendment **81** is included in principle through the reference in Article 2(9) of the Common Position to certain Titles not applying to polymers.

amendment **117** corrects an editorial mistake in reference to Article 27(8) and is fully included in the Common Position.

amendment **119** which corrects an editorial mistake in reference to Article 27(8) is also fully included in the Common Position.

amendment **125** which deletes paragraph 4 of article 23 is included in full in the Common Position.

amendment **128**, which deletes the limitation to vertebrate animals is included in principle in the Common Position.

amendment **148** is included in full in the Common Position.

amendment **258** relating to the role of the Agency's Member State Committee in Evaluation has been partially taken up in the Common Position.

amendment **291** is given effect to, as the Agency is to be established in Helsinki, Finland.

amendment **317** corrects a reference in the Commission proposal, and has been included in full.

amendment **324,** which exempts ores and concentrates from the registration requirements if they are not chemically modified, is included in full in the Common Position.

amendments **367** allowing third parties to represent potential registrants in pre-registration has been taken up in principle in the Common Position in Article 4.

amendments **369 rev** fixing one pre-registration deadline after 18 months has been taken up in principle in the Common Position in Article 28(2).

amendment **371,** on the publication of a list of substances following pre-registration, is included in principle in the Common Position.

amendment **372** changing the definition of phase-in substance has been fully taken up in the Common Position.

amendment **373** requiring registration of potential PBTs and vPvBs when they are manufactured or imported at or above 100 tonnes per year, in the form of substances classified as N: R50-53 has been fully taken up in the Common Position.

amendment **375** limiting GLP requirement to new laboratory tests involving vertebrate animals has been partially taken up in the Common Position in Article 13(3).

amendment **376** defining exposure scenarios has been taken up in principle in the Common Position.

amendment **377** defining use and exposure categories has been taken up in principle in the Common Position.

amendment **378**, adopted with amendment **160**, requiring descriptions of risk and the related use and exposure categories, in addition to the relevant exposure scenarios to be appended to the SDS, has been taken up in principle in the Common Position in article 31(7) through Annex I.

amendment **380** requiring information on use and exposure categories to be included in the technical dossier has been taken up in principle in the Common Position in Article 10 (a) (iii).

amendment **381** requiring confirmation that a registrant submitting study summaries or robust study summaries, is the owner of the relevant studies, or has permission to access them. It has been taken up in principle in the Common Position.

amendment **382** requiring joint submission of data by multiple registrants with opt outs that need to be justified, allowing 3rd party representation, requires the Agency to produce guidelines to facilitate the process, and requires a proportionate fee to be paid by each registrant has been taken up in principle in the Common Position in Articles 11, 4, 76(2)(f) and 73.

amendment **386** making changes to the PPORD requirements has been partially taken up in the Common Position.

amendment **387** details the reduced requirements for registration of non-prioritised substances produced in the 1-10 tonne and the increased requirements for the substances prioritised in the same category. This amendment has been partially taken up in the Common Position.

amendment **395** specifies where a substance at 1-10 tonnes is likely to be persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, should be subject to suitable further environmental testing if appropriate risk management measures are not introduced and recommended. This amendment has been partially taken up in the Common Position through Annexes IIIand VII.

amendments **65/ 462rev/ 463rev/ 464rev/ 465rev** are partially incorporated in Article 2 of the Common Position which brings together a range of exemptions from the Regulation.

Concerning Annexes

amendment **327** is taken up in the Common Position in the guidance note to Annex IV's with its' statement that "*Wherever practicable, registrations should be submitted jointly*".

amendment **388** setting out the criteria for registration of 1-10 tonne substances in Annex 1b with a full Annex V set of information has been taken up in principle in the Common Position in Annex III.

amendment **389** requiring the Commission to adopt criteria to facilitate the use of waiving criteria in Annex IX within 18 months has been taken up in principle in the

Common Position. Annex IV includes categories for information on exposure for substances, as proposed in amendment **413**.

Changes and refinements to the testing requirements in Annex V set out in amendments **390, 391, 392, 394** and **396** are included in part, principle or in full the Common Position.

In Annex VI, amendments **397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411** and **412** are all included in part, principle or in full in the Common Position.

amendment **322** adds 43 entries to Annex II (including several types of plant oils, cellulose pulp, iron, oxygen, industrial gases, turpentine oil, noble gases, natural gas, crude oil and coal, etc.) and is partially included - in the Common Position in Annexes IV and V.

3.2.1.2. Parliamentary amendments accepted by the Commission <u>in principle</u>

<u>Concerning recitals</u>

amendment **11** that introduces a 'duty of care' for manufacturer, importers and downstream users is integrated in principle and in part in article 1, as amended to state that chemical substances shall not adversely affect human health or the environment.

amendment **18** clarifies the duties of the registrant and has been included in part in recital 21.

<u>Concerning operative text</u>

amendment **59** adopted in conjunction with **419** on which the Commission reserved its position**,** stress that the provisions need to be in line with the international trade agreements, in particular within the WTO and it is included in principle in Common Position in Recital 3.

amendment **67** introduces a reference, in the definition of preparations, to metallic alloys as special preparations. It is included in the Common Position in principle in Annex I paragraph 0.11.

amendment **68** introducing a definition of alloys has been included in the Common Position in full.

amendment **83** introducing an exemption from registration for recycled substances has been included in principle in the Common Position in Article 2(7)(d).

amendment **97** deleting the requirement for registrants to indicate if their non-animal data can be shared has been taken up in full in the Common Position.

amendment **108** requires test methods to be reviewed and improved and gave a particular role to ECVAM to inform when an alternative method was validated and for them to be added to the list of test methods. This was incorporated in principle in the Common Position in Article 13(2) where test methods must be revised as

appropriate to refine, reduce or replace animal tests where ECVAM will have a role to play.

amendments **116**, **126** and **681** allowing the appointment of a 3rd party as a representative for proceedings under Article 17 and title III has been taken up in principle in the Common Position in Article 4.

amendment **123** introduces a formal modification to take into account the new provisions on the mandatory sharing of all data and has been incorporated in principle in the Common Position.

amendments **142** and **147** on the publication of a list of substances following pre-registration, on participants in a Substance Information Exchange Forum (SIEF) seeking to agree on the interpretation of information, are included in principle in the Common Position.

amendment **149** deleting the references to vertebrate animals in Article 28(1) has been fully taken up in the Common Position.

amendment **159** deleted the requirement for Safety Data Sheets to be supplied in the relevant MS language only on request of a Downstream User. This has been fully taken up in Article 31(5) of the Common Position.

amendment **171** reflected the enhanced role of the Agency in dossier evaluation. This has been taken on in principle in the Common Position in that the Agency has been given the responsibility for dossier evaluation.

amendment **172** gives the Agency responsibility for dossier evaluation. This has been fully taken on in the Common Position. Amendments **183**, **184**, **186**, **187**, **190**, **191**, **202** and **742**, on which the Commission reserved its position reflecting the changed role of the Agency in dossier evaluation have also been fully taken on in the Common Position.

amendment **175** reflects the changed role of the Agency and that all animal tests require testing proposals. The changed role of the Agency has been taken on in the Common Position but the second part has not been integrated.

amendment **193** requiring the list of substances for substance evaluation to be publicly available on its website has been fully taken up in the Common Position in Article 43(2).

amendment **205** referring to the action taken by the Agency after an evaluation has been partly taken up in the Common Position.

amendment **211** regarding the Agency selecting one of a number of registrants to do a further test is taken on in principle in the Common Position.

amendment **213** relating to the Agency publishing information on evaluations carried out on its website has been fully taken up in the Common Position.

amendment **215** regarding an Annex containing candidate substances for authorisation has been taken up in principle in the Common Position in Article 58(1) and (10).

amendment **217** deleting the requirement for a substance of equivalent concern to have serious and irreversible effects to humans or the environment has been partially taken up in the Common Position.

amendments **221** and **235** setting review periods not exceeding 5 years for all uses has been partially taken up in the Common Position Article 59(8) that requires reviews periods, set on a case-by-case basis, for all authorisations.

amendment **235** requiring authorisations always to be subject to review and to presentation of substitution plans, and possibly to other conditions: this amendment has been partially taken up in the Common Position as analysis of the alternatives is made mandatory while substitution plans remain voluntary.

amendment **259** relating to the role of the Agency's secretariat in Evaluation has been completely taken up in the Common Position.

amendment **265** relating to the fee structure being transparent has been taken up in the Common position as under Article 73 the fees will be set out in a Commission Regulation.

amendment **270** which allows the Management Board to additionally meet when 1/3 of its members request has been fully taken up by the Common Position in Article 80(1).

amendment **293** expands the remit of the Agency to develop contacts to include animal protection organisations has been taken up in principle in the Common position.

amendment **297** requires the MS to submit a report every 5 years, instead of 10 years, has been fully taken up in the Common Position.

amendment **299** deleting the words 'non-confidential' from Article 115 and requiring the Agency to publish information on its website has been fully taken up in the Common Position.

amendment **301** deleting much of the operative procedures in relation to requests for further information under Regulation 1049/2001 has been partially taken up in the Common Position.

amendment **306** specifying that the competent Authority shall give advice to SMEs how to meet their obligations under REACH has been taken up in principle in the Common Position Article 123.

amendment **323** and **476 rev** on which the Commission had reserved its position, deleting minerals and ores from requiring registration, in Annex III, if they are dangerous or chemically modified has been partially taken up in the Common Position.

3.2.1.3. Parliamentary amendments accepted by the Commission <u>in principle and in part</u>

amendment **88** adopted in conjunction with amendment **357,** where the Commission had reserved its position, on substances in articles, has been taken up in principle and in part in the Common Position.

The same amendment adds also an exemption for tobacco ingredients being registered if released from an article and replaces the requirement to notify a substance if it was unintentionally released from an article with one requiring notification of substances of very high concern to the Agency. The latter part was in principle taken up in the Common Position in Articles 7(2) and (3) while the first part has not been accepted

amendment **89** adding 3rd country preparation and article manufacturers to those allowed to appoint an only representative was fully taken up in the Common Position.

amendment **104** requiring the agency to set a deadline for submission of information required when a substance reaches the next tonnage threshold has been taken up in principle in the Common Position.

amendment **131** adopted together with amendment **384** deletes the provisions in art.24(5) and it is partially taken on in the Common Position.

amendment **132** allowing a 3rd party representative to be appointed for the purposes of pre-registration has been taken up in principle in the Common Position in Article 4.

amendment **157** requiring Safety Data Sheets (SDS) for PBTs and vPvBs has been fully taken up in the Common Position, Article 31(1)(b) and (3)(b), as was the change ensuring SDS were free of charge, also covered in Amendments **158** and **161**, in Article 31(8). The part relating to SDS for CMRs was already covered in the Commission proposal. The part relating to SDS for substances identified as of 'equivalent concern, was not taken up by the Common Position, however an SDS may be needed in any case if the hazard is classifiable.

amendment **158** that requires the SDS should be free of charge has been fully taken up in the Common Position.

amendment **161**, adopted with amendment **710**, regarding the change to conditions when a SDS needs to be updated has been partially taken up in the Common Position.

amendment **163** adding distributors to those who should transmit information down the supply chain, for substances not requiring a SDS, ensuring the information was free of charge, and changing to conditions when such information was required has been partially taken up in the Common Position.

amendment **180** requires a deadline to be set, not exceeding 6 months, for information requested under compliance checking and the registration number to be withdrawn if this was not complied with. The part relating to a deadline being set has been taken up in principle in the Common Position in Article 40(4), while the second part has not been incorporated.

amendment **181** requires the Agency to establish an annual plan for dossier registration ensuring at least 5% of dossiers to be examined. The part relating to 5% of dossiers being examined has been taken up in the Common Position in Article 40(5).

amendment **185** that changes MS to Agency in Article 42(2) has been fully taken up in the Common Position.

amendment **192** and amendment **420**, where the Commission reserved its position, adds a requirement for prioritisation under substance evaluation should also be on a risk assessment scheme based on the dose-effect relationship and deletes the requirement for MS to use the criteria in their national rolling plans. The first part of the amendment has not been included, while the latter part has been taken up in the Common Position as part of the general strengthening of the Agency's role.

amendment **195** and amendment **739**, where the Commission reserved its position, requires the Agency to establish a Community rolling plan on the basis of the Article 43a criteria and the Agency to submit the plan to the MS. The MS may provide comments on the plan or suggest other substances for the plan. The Agency will be responsible for the evaluations using national bodies designated by the MS. The Agency being responsible for substance evaluation, drawing up the rolling plan, submitting it to the MS, the MS commenting and suggesting other substances has been fully taken up in the Common Position in Article 43 and 44.

amendment **196** making changes related to the Community rolling plan and the Agency's responsibility, the amendment has been partially taken up in the Common Position.

amendment **197** making changes related to the Community rolling plan regarding to MS comments on the Agency's draft, this amendment has been taken up in principle in the Common Position in Article 43(2).

amendment **199** making changes to when the Agency publishes the definitive rolling plan on its website due to the changed responsibilities has been fully taken up in the Common Position in Article 43(2).

amendment **201** allowing MS to notify the Agency of substances where they have a suspicion of a health or environmental risk and for the Agency to add them to the plan if justified has been taken up in principle in the Common Position in Article 44(5).

amendment **203** referring to national bodies, which the Commission accepted in principle, has been partly taken up in the Common Position in article 44(1).

amendment **207, 208, 209** regarding changes to the agreement procedure to reflect the responsibilities of the Agency in evaluation have been fully taken on in the Common Position.

amendment **236** and **359** on which the Commission had reserved its position, which makes consequential changes to amendment **235**, has been partially taken up in the Common Position.

amendment **285** makes changes to increase the independence of the Agency Committee members and it is taken up in part and in principle in the Common Position in Articles 84 and 85.

amendment **294** states that the Agency's internal rules of procedure and documents related to the Authorisation process shall be publish on the Internet and is taken up in part and in principle in Article 63.

amendment **320** adds the term vulnerable populations and a number of additional factors to be taken into account when determining the DNEL to para 1.4.1 of Annex I. The first part has been taken up in the Common Position.

3.2.2. Amendments accepted in full, in principle or in part by the Commission, but not incorporated in the common position

Concerning recitals:

The Commission said that it could accept amendments **34** and **36** in principle, which are not included in the Common Position.

Concerning operative text:

amendment **60** limits the producers, importers and downstream users responsibility to under normal or foreseeable conditions could be accepted in principle by the Commission.

The Commission said that amendment **76**, which specifies that "*unsupported uses*" of downstream users need to be justified by suppliers on the basis of scientifically based arguments against the safety of the use, would be acceptable in principle and part. However, the Commission considers that it would be preferable to use the term "used advised against" which is already used in the SDS and in Annex VI, section 3.7.

The Commission said that it could accept in principle amendments **78** ,**105** and **611**, on which the Commission reserved its position, which introduce the idea that tonnage calculation (except for new substances and when stated otherwise) should be the average of the three preceding calendar years during which the substance has actually been produced by the manufacturer. This amendment is not included in the Common Position.

Amendment **139** provides for a "*list of uses ... [intended to be supported] through registration*" to be published by the Agency following pre-registration. The Commission said that it could accept in principle this amendment provided that such information will only be preliminary and the suppliers will be able to make their choice at the moment they register, but it is not included in the Common Position.

Amendment **140** is intended to avoid the repetition of animal testing, by ensuring that information derived from animal experiments is forwarded promptly to the Agency. The Commission said that it could accept this amendment in principle.

Amendment **176** requires an open consultation period of 90 days for all testing proposals. The Commission said that it could accept this amendment in principle provided that the consultation is limited to comments on availability of data that renders animal testing unnecessary and the timeframe is appropriate, on that substance or on closely-related substances.

Amendment **198** deletes the procedure for when 2 or more MS have included substances in their draft rolling plans. The Commission said that it could accept this amendment in part and in principle.

The Commission said it could accept in part and in principle amendment **200** which deletes the requirement for Competent Authorities to evaluate substances on their plans.

The Commission said that it could accept amendment **273** in full which requires the Executive Director to establish and maintain contact with the European Parliament and ensuring that a regular dialogue is held with that body's relevant committees. This amendment is not included in the Common Position.

The Commission said that it could accept in principle amendments **277** and **278** which reinforce the role of the European Parliament in the Executive Director selection process**.** These amendments are not included in the Common Position.

The Commission said that it could accept amendment **276** in full which foresees that, once the general report and the programmes have been adopted by the Management Board, the Executive Director shall forward them to the European Parliament, the Council, the Commission and the Member States, and shall arrange for them to be published. This amendment is not included in the Common Position.

The Commission said that it could accept amendment **292** in full which lays down that the staff of the Agency shall be subject to the *Staff Regulations of Officials of the European Communities and the Conditions of employment of other servants of the European Communities laid down by Council Regulation (EEC, Euratom, ECSC) No 259/68, as last amended by Council Regulation (EC, Euratom) No 723/2004*. This amendment is not included in the Common Position.

The Commission said that it could accept in full the following amendments:

amendment **368** requires during pre-registration, information on identified uses, at least relevant use and exposure categories has not been taken up in the Common Position.

amendment **370** allowing pre-registrants who do not pre-register within 18 months to still rely on the phase-in deadlines if they make use the extra 6 months as set out in amendment 369/rev has not been taken up in the Common Position.

amendment **374** requiring registration of potential PBTs and vPvBs manufactured or imported at or above 1 tonne per year, in the form of substances classified as N: R50-53 has not been taken up in the Common Position.

amendment **379** requires sharing of animal and non-animal data with opt outs that can be assessed by the Agency if requested has not been taken up in the Common Position.

The Commission said that it could accept amendment **383** extending data protection to 15 years and accept in principle Parliament's amendment **130** which refers to 10 years data protection. Council decided to maintain 10 years data protection, as proposed by the Commission.

amendment **385** extending the time for when previous registrants have to be asked for sharing of data from 10 to 15 years in Art. 25, para 1 has not been taken up in the Common Position.

amendment **393** specifies that substances which are likely to be carcinogens and mutagens should be subject to suitable further mutagenicity testing. This testing need not be done if appropriate risk management measures are introduced and recommended. This amendment is not included in the Common Position.

Amendment **399** introducing the alternative of undertaking an *in vitro* micronucleus study in place of an *in vitro* cytogenicity study was not included in the Common Position.

The Commission said that it could accept amendments**, 121, 186, 204, 220, 248, 286** and **300** in principle, which are not included in the Common Position.

The Commission said that it could accept amendments **194, 290** and in principle and in part, which are not included in the Common Position.

3.2.3. Parliamentary amendments not accepted by the Commission or where it reserved its position.

3.2.3.1. Parliamentary amendments not accepted by the Commission and incorporated in the Common Position.

Concerning recitals

amendment **3** adds to the goal of REACH the safeguard of the innovation capacity and competitiveness and states the need of implementing REACH in line with WTO rules. It is included in principle in Recital 3.

amendment **7** clarifies that one of the reasons for REACH was a failure to protect public health and the environment and has been included in principle in recital 9.

amendment **22** states that SMEs should be assisted to comply with REACH and has been included in principle in recital 35.

amendment **44** calls the Agency to play a pivotal role in coordinating the communication around REACH has been included in principle in recital 84.

Concerning operative text

amendment **69** that changes the polymer definition has been taken up in principle in the Common Position.

amendment **99** allowing the registrant to request that certain parts of his dossier were kept confidential has been taken up in principle in the Common Position in Articles 9(a)(xi), 76(2)(d) and 118(2).

amendments **134**, adopted together with **358**, and **136** provide cost sharing criteria for non phase-in substances and has been taken up in part and in principle in the Common Position which bases cost sharing also on fairness.

amendment **137** deleting Article 26(1)(d) has been fully taken up in the Common Position.

amendment **151** requiring that a potential registrant is prevented from registering if they fail to make available a study they have, has been taken up in principle in the Common Position.

amendment **153** that requires if the owner of a study fails to make it available to the Agency they will not be able to register has been included in principle in Article 30(3).

amendment **154** deleting 'on vertebrate animals' in Article 28(2) has been fully taken up in the Common Position.

amendment **162** requires the Commission to develop guidelines setting minimum requirements for SDS and has been incorporated in principle in article 76(2)(f).

amendment **164** allowing information required by Article 30 to be communicated electronically as well as in writing has been fully taken up in the Common Position.

amendments **166** and amendment **366**, on which the Commission reserved its position, requiring information on Substances in Articles have been taken up in principle in the Common Position in Article 32(4).

amendment **178** and amendment **729**, on which the Commission reserved its position, replacing the reference to 'Competent Authority' with 'Agency' in the introduction of article 39(2) has been taken up in part the Common Position.

amendment **174** states that all communications between registrants and Agency shall be possible in any language chosen by the applicant and has been taken up in principle in the Common Position in article 103.

amendment **179** and amendment **730**, on which the Commission reserved its position, replacing the references to 'Competent Authority' with 'Agency' and requiring the Agency to make any draft decision within 12 months of the substance being put on the annual evaluation plan consisting of at least 5% of the dossiers received has been taken up in principle in the Common Position in Articles 40(3) and 40(5).

amendment **182** requiring the Agency to annually report on the evaluation of dossiers including recommendations for future registrants has been taken up in principle in the Common Position in Article 52.

amendment **189** setting a deadline of 2 years for fulfilling information requests related to the examination of testing proposals has been partially taken up in the Common Position in Article 39(2).

amendment **206** makes changes MS to Agency, with some consequent changes, in Article 49(1) and makes changes related to the use of national bodies in Evaluation. The first part has been incorporated in the Common Position.

amendment **214** amending the aim of authorisation so that substances of very high concern are eventually replaced by substitutes and to ensure that if no substitute

exists and the socio-economic benefits outweigh the risks then the substance is controlled, has been partially taken up in the Common Position in Article 54.

amendment **216** clarifies that substances in Annex XIIIa have to be included without prejudice for existing and future restrictions and it has been taken up in part and in principle in the Common Position in Article 57.

amendments **219** and **223** introduce technical changes reflecting the concept of having two separate Annexes under the Authorisation regime. They have been taken up in principle in the Common position in Article 58.

amendment **226** allows restrictions on authorised substances in case of new scientific information presented to the agency and has been taken up in principle in the Common Position in Articles 57(5) and 57(6).

amendment **227** that deletes (d), (e) and (f) from the title of Article 56 has been fully taken up in the Common Position.

amendment **229** modifies the procedure to include substances in Annex XIII(b) and gives to the Commission the authority to take a decision in the cases where the Member State Committee cannot reach the qualified majority. This amendment has been taken up in principle and in part in the Common Position.

amendment **237** modifies the procedure of Authorisations review to reflect the changes introduces in article 57 and it has been partially taken up in the Common Position.

amendments **241** requiring a Socio-Economic Analysis and an analysis of substitutes should always form part of the application for authorisation has been partially taken up in the Common Position in Article 61(4)(e).

amendment **242** modifies the provisions on subsequent applications for authorisation to reflect the changes introduces in article 59 and has been taken up in principle in the Common Position.

amendment **243** allowing the Socio-Economic Committee to ask for an analysis of substitutes has been taken up in principle in the Common Position in Article 63(3).

amendment **247** adopted with amendment **985** changes the 1 tonne limit for PPORD to the amount necessary for PPORD and it is taken up in part and in principle in the Common Position.

amendments **260** adopted with **261** and **796** and **263** introduce a number of editorial and positional changes to the description of the Agency’s tasks and they are taken up in principle in the Common Position.

amendment **266** that requires a multi-annual plan for substance evaluation has been taken up in principle in the Common Position in Art 77 and the requirements for the Management Board to draw up a multi-annual plan for the Agency's work.

amendment **304** clarifies that the confidentiality of information about the link between manufacturer and downstream user covers both directions of the supply chain and all actors involved and has been taken up in the Common Position.

amendment **305** requires the Agency to draw up guidelines on how to inform the general public about risks arising from substances and is taken up in principle in the Common Position in article 122.

amendment **307**, adopted with amendment **816**, requires the Agency to draw up guidelines on how Member states shall maintain a system of official controls and has been taken up in part and in principle in the Common Position in article 76(4).

amendment **309** allowing Member States to maintain or introduce stricter measures for the purposes of worker protection has been taken up in principle in the Common Position in Article 127(2).

The Commission fully supports these changes in the Common Position.

3.2.3.2. Parliamentary amendments not accepted by the Commission and not incorporated in the Common Position.

The Commission did not accept amendments **1**, **2**, **5**, **6**, **9**, **12**, **13**, **15**, **17**, **23**, **24**, **25**, **27**, **28**, **29**, **30**, **31**, **32**, **33**, **35**, **37**, **38**, **42**, **43**, **45**, **46**, **47**, **51**, **52**, **54**, **55**, **56**, **57**, **58**, **66, 70, 71, 75, 77, 80, 82, 90, 96, 106, 109, 110, 112, 113, 114, 118, 129, 135, 138, 143, 150, 155, 156, 168, 169, 170, 173, 177, 212, 218, 222, 224, 225, 228, 230, 231, 232, 233, 234, 238, 239, 240, 244, 245, 246, 251, 252, 253, 254, 255, 256, 257, 262, 264, 267, 269, 271, 272, 275, 279, 280, 281, 282, 283, 284, 287, 288, 289, 295, 296, 298, 311, 312, 313, 314, 315, 316, 318, 319, 320, 321, 328, 329, 337** and **351** and these amendments are not included in the Common Position.

3.2.3.3. Parliamentary amendments on which the Commission reserved its position and are incorporated in the Common Position.

Concerning recitals

amendment **417** clarifies that REACH should align with SAICM, OECD and ICCA initiatives to reduce costs and has been included in part in recitals 6 and 97.

amendment **363** calls Member States to adopt special assistance to SMEs regarding conducting texts and it is included in principle in Recital 8.

Concerning operative text

amendment **362** which requires Member states to take measures to support enterprises for the implementation of the Regulation is taken up in principle in article 123 of the Common Position.

amendment **418** which requires the Agency to promote the international acceptability of the REACH standards and take full account of existing standards established by other international institutions is taken up in principle in the Common Position in Recital 97.

The first part of amendment **436** which states the possibility to introduce 'use and exposure categories' in the preparation of exposure assessment has been taken up in the Common Position while the second part, which extends the 1 tonne threshold to manufacture's or importer's identified uses is not included.

amendment ***466 rev*** and ***467 rev*** that make changes to the position of exemptions in the text has been taken up in part and in principle in the Common Position in Articles 2(5) and (7).

amendment ***468 rev*** that adds an exemption from Registration has been fully taken up in the Common Position.

amendment **470** *rev* that deletes the reference to the exemption of waste from the authorisation title is taken up in the Common position.

the first part of amendment **471 rev** that moves the exemptions from the authorisation title to the scope title is taken up in the Common position while the second part is not integrated.

amendment **469 rev** deleting Article 8 on biocides and plant protection products being considered as registered has been partially taken up in the Common Position.amendments **566**, **567**, **568**, **571**, **572** and **573** and **574** which maintain the relevant Community provisions on persistent organic pollutants together under Regulation (EC) 850/2004/EC implementing the Stockholm Convention on persistent organic pollutants have been fully taken up in the Common position.

amendment **569** that deletes Art 64(2) has been fully incorporated in the Common Position.

amendment **570** states that the restriction procedures apply without prejudice of Regulation (EC) 850/2004/EC and it has been taken up in principle in the Common Position in Article 2(2).

amendment **719** providing that downstream users may submit information directly to the Agency to assist in the preparation of a registration has been taken up in principle in article 28(6) of the Common Position.

amendment ***733*** replacing the references to 'Competent Authority' with 'Agency' in Article 42(3) has been fully taken up in the Common Position.

amendment ***734***, adopted with amendment **188**, requiring the list of registration dossiers evaluated for testing proposals or checked for compliance is to be made available to the MS has been fully taken up in the Common Position in Articles 40(2) and 41(4).

amendments ***744***, ***745*** and ***746*** replacing the references to Competent Authority with Agency, and introducing the concept of 'definitively' ceased, in Article 48 have been partially taken up in the Common Position.

amendment **789** requires the Agency to post immediately on its website that a Member State or the Commission intend to instigate a restriction process and to inform the registrant of the relevant substance. This amendment has been fully taken up in the Common Position.

amendment **801**, adopted with amendment **274**, gives to the Executive Director the responsibility to conclude contracts with the National Institutes and to adopt the draft and definitive rolling plans of evaluation of substances. This is taken up in part and in principle in the Common Position in article 43.

amendment **814** that deletes Article 116(2)(c) has been fully taken up in the Common Position which however, by introducing a new provision in article 117(2), emphasises the confidential nature of precise tonnage.

Amendment **822** that states that until the Agency Executive Director will assume his duties, the Commission on behalf of the Agency, and using the budget provided for the latter, may appoint personnel and conclude contracts it taken up in article 133(2) of the Common position.

Concerning Annexes

amendment **475 rev** which adds an exemption from registration for cellulose pulp, oxygen, neon, helium and xenon, amongst other changes, has been partially taken up in the Common Position in Annexes IV and V.

amendments **477rev**, **478rev** and **660** which exempt several substances from the Registration provisions are partially taken up in the Common Position in Annex V.

amendment **865** that states in Annex XI that Chemical Safety Assessments performed by downstream users shall be done for his own uses and only for those identified uses in quantities of 1 tonne or more per year is taken up in principle in article 36 of the Common Position.

The Commission supports these changes in the Common Position and the relevant amendments.

3.2.3.4. Parliamentary amendments on which the Commission reserved its position and which are not incorporated in the Common Position.

The Commission reserved its position on amendments **416, 424, 361, 364, 479 rev, 352, 433, 434, 435, 673, 676, 584, 593, 594, 595, 596, 575 rev, 600, 549, 615, 422, 960, 365, 726, 795, 360, 1037, 472 rev, 473 rev, 808, 817, 818, 474 rev, 823, 831, 965, 966** and **743/1** and these amendments are not included in the Common Position.

The Commission rejects these amendments.

3.2.4. Additional changes made by the Council to the amended Proposal (REACH)

Article 10 was amended to introduce a requirement for the registrant to indicate which information has been reviewed by an assessor for purposes of Quality Assessment.

Article 40 was changed to allow the submission of information by any third party on substances appearing on the list of substances that were pre-registered so that the Agency can take this into account in particular when they select dossiers for compliance checking.

Article 59 was amended to clarify that excluded substances meeting the criteria in Article 56 (a), (b), (c) and (f) for which it is not possible to determine a threshold in accordance with Annex I, section 6.4 and substances meeting the criteria in Article 56 (d) and (e) from the possibility to grant authorisations on the basis of 'adequate control'.

Article 117 was changed to better reflect the operation of Regulation (EC) No. 1049/2001 and to require the Management Board of the Agency to adopt practical arrangements for implementing it. The previous list of always confidential information was moved to Article 117 and it was clarified, to be more in line with the Aarhus Convention, that these would normally be deemed to undermine the protection of the commercial interests of the concerned person.

Article 118 was split into information that was published on the internet and those items (degree of purity, tonnage band in which the substance has been registered, study summaries and robust study summaries) where registrants would be able to indicate they were confidential and provide a justification that the Agency would assess.

Article 123 was amended to require submission of information by competent authorities on substances registered in accordance with Article 11(1) where the dossiers do not contain the full information referred to in Annex V, in particular where monitoring and enforcement activities have identified a suspicion of risk.

Article 137 was amended to include Annex I in the list of Annexes to be reviewed by the Commission within 12 months after the entry into force of the Regulation, with a view to proposing amendments to establish levels for adequate control of non-threshold carcinogenic and mutagenic substances.

Annexes I and XV were amended to improved clarity, consistency and workability.

The Commission supported these changes.

3.3. Detailed comments (Directive)

3.3.1. Parliamentary amendments not accepted by the Commission or where it reserved its position.

The Commission did not accept amendments **1**, **2**, **3**, **4** and these amendments are not included in the Common Position.

3.3.2. *Additional* changes made by the Council to the amended Proposal (REACH)

Article 3 was amended to align the repeal of the relevant articles of 67/548/EEC with the transitional arrangements in Title XIV of REACH.

4. CONCLUSION

In its assessment of Parliament's First Reading 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. In addition, there is the need to bring to a close a very difficult debate on REACH on which the Commission considers that a suitable balance has been found.

This equilibrium covers especially what have been without doubt the most difficult and the most critical areas of REACH, namely, registration and authorisation by, respectively, reducing the economic impact of registration of low volume substances

and by increasing the role of substitution in authorisation. The Commission believes that Council has found the right balance in these two areas which should not be disturbed.

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.

In its assessment of the Common Position on the Directive, the Commission has taken into account that it rejected the European Parliament amendments to it and the changes made to align the transitional arrangements to that in REACH. The Commission fully supports the Common Position on the REACH regulation which it believes is a reasonable basis for achieving agreement on this key piece of legislation. The Commission calls upon Parliament and Council to facilitate an early adoption of the Regulation and the Directive such as will allow the Member States, the Commission and the enterprises concerned to focus their efforts on the very substantial challenges of preparation and implementation of the requirements.

ANNEX I

Joint Council and Commission statement on the Agency

"The Council and the Commission note the key role of the European Chemicals Agency in the implementation of the forthcoming REACH Regulation. They also acknowledge that the Agency needs to be operational before the application of the central REACH procedures, such as registration and authorisation, can be started.

The Council welcomes the preparatory work by the Commission in supporting the establishment of the Agency. It acknowledges the wish of the Commission to have commitment of the Member States to undertake the actions that are necessary for setting up of the Agency and enabling it to be operational within 12 months from the entry into force of REACH.

The Commission has informed the Member States that the above timeframe is only possible if Council, Member States and the Commission undertake the following action:

a. identify the members of the Management Board as soon as the composition of the Management Board is politically agreed between the co-legislators;

b. communicate the names of the future Management Board members after the final decision on REACH but before entry into force and provide official nominations immediately after entry into force of REACH;

c. ensure that the nominees agree that a series of (4) meetings of the Management Board can take place in the first 3 months after entry into force;

d. agree that the Management Board should nominate the Executive Director and the Accounting Officer within these 3 months;

e. communicate to the Commission the names of the future members of the Committee established under Article 130 of REACH after the final decision on REACH and provide official nominations at the entry into force of REACH;

f. identify at an early stage the candidates for the Member State Committee, Risk Assessment Committee, Socio-economic Assessment Committee and the Forum.

On its own part the Commission will make the outmost efforts to carry out the following activities as soon as possible:

a. nominate an interim Director, with exclusively administrative functions;

b. publish the vacancy notices and prepare the shortlist of candidates for Executive Director and Accounting Officer during the 6 months period between the final decision on REACH and EIF;

c. publish the vacancy notices and prepare the shortlist of candidates for the Board of Appeal within 6 months after the decision on the requirements by the Comitology Committee;

d. pre-select candidates for temporary agents of the Agency, as an interim Director can then organize the selection in order to establish reserve lists of candidates; the lists should be available 6 months after entry into force;

e. make available staff for at least 10 selection panels;

f. recruit and train interim staff, including seconded officials and contract agents hired in 2006, to serve as a start-up team and as a secretariat for the Management Board and to execute necessary other functions of the Agency during the implementation phase;

g. ensure preparation of implementing legislation necessary for the operation of the Agency regarding fees and qualifications of the members of the Board of Appeal

h. ensure preparation of draft implementing rules and procedures for the Agency, concerning staff, finance, fees, Board of Appeal, internal functioning, etc before these are handed over to the Agency during the implementation phase;

i. ensure availability of infrastructure, including IT systems, and software

j. after the final decision on the Regulation, ensure that necessary adaptations will be made to the IT-systems and to the draft technical guidance documents.

Therefore, the Council and the Commission affirm their commitment to take the above actions, respective to their roles and responsibilities, for ensuring the timely setting up of the Agency."

ANNEX II

Commission Statement on special preparations (including alloys)

"The Commission, in close cooperation with industry, Member States and other relevant stakeholders, will develop guidance to fulfil the requirements under REACH related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special preparations – such as metals incorporated in alloys. In doing so, the Commission will take full account of the work that will have been carried out within the framework of the REACH implementation projects (RIPs) and will include the necessary guidance on this matter in the overall REACH guidance package. This guidance should be available before the entry into operation of the regulation."

Commission Statement on free movement (Article 125(2))

"The Regulation harmonises completely the conditions of manufacture, placing on the market and use of the substances which it covers in terms of the points for which it provides. With regard to those points, the lawfulness of the manufacture, placing on the market and use of substances will have to be assessed solely in the light of the criteria laid down by the Regulation. Consequently, national authorities will in future be able to restrict or impede such operations only:

- through measures adopted within the framework of Article 95(4) to (6);

- through measures adopted within the framework laid down in Article 126 of the Regulation."

Commission statement on Article 54(f)

"The Commission, in close cooperation with industry, Member States and other relevant stakeholders, will develop guidance to clarify how Article 54(f), which relates to substances of equivalent concern to those listed in Article 54(a) to (e), is to be implemented. In doing so, the Commission will take full account of the work that will have been carried out within the framework of the REACH implementation projects (RIPs)."