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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for 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, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
(7524/8/2006 – C6-0267/2006 – 2003/0256(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Guido Sacconi

PR_COD_2am

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for 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, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
(7524/8/2006 – C6-0267/2006 – 2003/0256(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (7524/8/2006 – C6-0267/2006),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2003)0644)[2],

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 62 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0352/2006),

1. Approves the common position as amended;

2. Instructs its President to forward its position to the Council and Commission.

Council common position	Amendments by Parliament
Amendment 1 RECITAL 1	
(1) This Regulation should ensure a high level of protection of human health and the environment ***as well as*** the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation.	(1) This Regulation should ensure a high level of protection of human health and the environment***,*** the free movement of substances, on their own, in preparations and in articles, ***increased transparency and the promotion of non-animal testing***, while enhancing competitiveness and innovation.

[1] *Texts Adopted*, 17.11.2005, P6_TA(2005)0434.
[2] Not yet published in OJ.

Justification

In line with Amendment 1 adopted in First Reading.

Linked to amendment of Article 1(1). These two objectives of this Regulation from the Commission Explanatory Memorandum have been deleted by the Council and should be re-instated in view of the importance of both increased transparency and the promotion of non-animal testing in this Regulation for all stakeholders and European citizens.

Amendment 2
RECITAL 4 A (new)

(4a) REACH should be so designed and applied as to avoid weakening the competitiveness of European trade and industry or damaging trade with third countries. The Regulation must not impose any requirements on the European Union's trading partners other than such as would be compatible with the free-trade principles in force under WTO provisions.

Justification

Intended to preserve the competitiveness of the products of European undertakings against imports from third countries. Retabling of Amendment 416 from first reading.

Amendment 3
RECITAL 7

(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that ***manufacturing of*** substances in the Community ***complies*** with Community law, even if those substances are exported.	(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers ***and that of vulnerable populations***, and ***for*** the environment, it is necessary to ensure that ***all*** substances ***that are manufactured or placed on the market*** in the Community ***comply*** with Community law, even if those substances are exported.

Justification

The standard of protection of people's health must be set to include both those most exposed (workers) and those most vulnerable to chemical exposure. Re-tabling of original Parliament

amendment 6.

Amendment 4
RECITAL 11 A (new)

(11a) For reasons of workability, wastes and materials used as secondary raw material or as a source of energy should be exempted. Generating value ("valorisation") from wastes and materials used as secondary raw material or as a source of energy in recovery operations contributes to the European Union's objective of sustainable development, and this Regulation must not introduce requirements which reduce the incentives for such recycling and recovery.

Justification

Reinstates amendment 424 as adopted in first reading.

Amendment 5
RECITAL 11 B (new)

(11b) The objective of the new system to be established by this Regulation is to deal with the most dangerous substances as a matter of priority. Hazard evaluation and risk assessment must also take into account the effects of substances on foetal development and the health of women and children.

(Amendment 9 - first reading)

Justification

In order to protect future generations, the standard of protection of human health must include those must vulnerable to the health effects of man-made chemicals.

Amendment 6
RECITAL 12

(12) An important objective of the new	(12) An important objective of the new

system to be established by this Regulation is ***to encourage and in certain cases*** to ensure that substances ***of high concern*** are ***eventually replaced*** by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. This Regulation does not affect the application of Directives on worker protection and the environment, especially Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.	system to be established by this Regulation is to ensure that ***dangerous*** substances are ***substituted*** by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. This Regulation does not affect the application of Directives on worker protection and the environment, especially Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.

(Amendment 8 - first reading)

Justification

The principle of substitution ought to be an important element in REACH.

Amendment 7
RECITAL 14

(14) Responsibility for the management of the risks of substances should lie with the ***natural or legal persons*** that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, ***in particular*** for ***SMEs***.	(14) Responsibility for the management of***, and provision of information on,*** the risks of substances should lie with the ***enterprises*** that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, ***particularly*** for ***very small businesses, which should not be disproportionately penalised by the implementation***

procedures.

(Amendment 10 (modified) - first reading)

Justification

Preliminary to the introduction of "duty of care" in further amendments.

REACH should provide an opportunity to involve firms, including very small businesses, and not be an obstacle that excludes them.

Amendment 8
RECITAL 18

(18) The authorisation provisions ***should ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. Authorisations*** for the placing on the market and use ***should*** be granted by the Commission ***only if*** the risks arising from their use are adequately controlled***, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable***.	(18) The authorisation provisions ***provide for authorisations, of limited duration,*** for the placing on the market and use ***of substances of very high concern to*** be granted by the Commission ***where no suitable alternative substances or technologies exist, where the use of such substances can be justified on socio-economic grounds and where*** the risks arising from their use are adequately controlled.

(Amendment 15 - first reading)

Justification

It is important for the principle of substitution to be linked to the granting of authorisation.

Amendment 9
RECITAL 35 A (new)

	(35a) In the light of the particular circumstances of SMEs, Member States should adopt measures to provide special assistance to such enterprises for conducting the tests needed to collect the information required under this Regulation.

Justification

It is important to provide the appropriate assistance measures, particularly to SMEs, to facilitate the implementation of this regulation. Amendment 363 at first reading.

Amendment 10
RECITAL 35 B (new)

(35b) In order to help companies, and in particular SMEs, to comply with the requirements of this Regulation, Member States, in cooperation with the Commission, should put in place a comprehensive support network.

Justification

Reinstates Amendment 22 at first reading in order to help SMEs to cope with the challenge of implementing the regulation.

Amendment 11
RECITAL 43 A (new)

(43a) Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods to that of experimentation on vertebrate animals. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new non-animal alternative methods, in particular within its Seventh Framework Programme for Research and Technological Development.

(Amendment 24 - first reading)

Justification

This recalls the Community's duty to promote alternative methods to that of animal

experimentation, already introduced in Directive 2003/15/EC on cosmetics.

Amendment 12
RECITAL 43 B(new)

(43b) In order to promote non-animal testing, the Commission, Member States and industry should allocate more resources to the development, validation and acceptance of non-animal tests.

Justification

The use of non-animal tests is preferable from both an ethical and a scientific view. To promote non-animal testing to meet the information requirements of this Regulation, it is necessary to make available more resources for the development, validation and acceptance of non-animal test methods.

Amendment 13
RECITAL 50 A (new)

(50a) If a potential registrant and/or participant in a SIEF fails to pay his share of the cost of a study involving tests on vertebrate animals or another study that may prevent animal testing, he should not be able to register his substance.

Justification

Amendment 27 in first reading.

Amendment 14
RECITAL 51 A (new)

(51a) If a manufacturer of a substance or an importer of a substance, either on its own or in a preparation, does not intend to submit a registration for a substance, he must notify the Agency and his downstream users accordingly.

Justification

Successful First Reading amendment 34. Communication of non-registration is important to inform downstream users about the withdrawal of certain substances from the market.

Amendment 15
RECITAL 51 B (new)

(51b) Risk Communication is a vital part of the process of informing and advising people about how they can manage potential risks and so use a substance or preparation safely and effectively. Risk communication requires an understanding by the manufacturer of the information needs of users, and the subsequent provision of that information, advice and help to support the safe use of the substance or preparation by the end user. The development of an appropriate risk-based communication system, including the provision of complementary information using, for example, websites and educational campaigns, should be pursued to satisfy the right of consumers to know about the substances and preparations they use. This will further enhance the safe use of, and confidence in, substances and preparations. Such a system will be valuable to consumer organisations in setting a framework that will address the true concerns of consumers through REACH and to industry in building consumer confidence in the use of substances and preparations containing chemicals.

Justification

Corresponds to Amendment 30 First Reading.

An appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to manage their risk safely and effectively when using a substance or preparation.

Amendment 16
RECITAL 54

(54) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. ***These requirements should only apply above a total quantity of 1 tonne of substance or preparation.*** In any case***, however,*** the downstream users should consider the use and identify and apply appropriate risk management measures. Downstream users should report certain basic information on use to the Agency.	(54) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. In any case the downstream users should consider the use and identify and apply appropriate risk management measures. ***Downstream users should report the risks as highlighted in the chemical safety assessment by the most effective and relevant means possible for the user of the substance or preparation at a given point in the supply chain/life cycle and provide advice on safe use for consumers.*** Downstream users should report certain basic information on use to the Agency.

(New amendment - Rule 62(2)(c), and amendment 33 - first reading)

(Linked to paragraph 36(4)(c))

Justification

A threshold for the chemical safety report (CSR) of downstream users would create a perverse incentive for manufacturers to exclude uses below 1 tonne from their CSR, as it would not result in any obligations for downstream users. This creates a serious loophole with regard to safety information for small uses.

This amendment furthermore reflects the duty of downstream users to inform the supply chain as well as consumers.

Amendment 17
RECITAL 58 A (new)

	(58a) In order to prevent duplication of animal testing, interested parties should have a period of 90 days during which they may comment on testing proposals that include vertebrate animal tests. Comments received during this period should be taken into account by the registrant or the downstream user.

(Amendment 36 - first reading)

Justification

The High Production Volume (HPV) chemicals programme in the United States has proven the positive effect a stakeholder commenting period can have towards preventing animal tests and saving costs.

Amendment 18
RECITAL 58 B (new)

(58b) To prevent animal testing and save costs, the European Centre for the Validation of Alternative Methods (ECVAM) should be consulted on testing proposals that include vertebrate animal tests.

(Amendment 37 - first reading)

Justification

ECVAM is the EU's leading institution on alternative test methods. As new alternative test methods are constantly being developed, ECVAM should be consulted on testing proposals on vertebrate animals to ensure that the latest knowledge is made use of.

Amendment 19
RECITAL 63

(63) To ensure a sufficiently high level of protection for human health, ***including having regard to relevant human population groups and possibly to certain*** vulnerable ***sub-***populations, and the environment, substances of very high concern should***, in accordance with the*** precautionary ***principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected***	(63) To ensure a sufficiently high level of protection for human health***, in particular that of*** vulnerable populations, and the environment, substances ***with properties*** of very high concern should ***be treated in a*** precautionary ***manner and should only be authorised if enterprises using them demonstrate to the granting authority that there are no suitable alternative substances or technologies, that the benefits to society deriving from the use of the substance outweigh the risks connected with its use and that the risks are adequately controlled. The granting authority should then verify that these requirements are met through an authorisation procedure on the basis of applications by enterprises. Since authorisations should ensure a high level***

with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.	***of protection throughout*** the internal market, it is appropriate that the Commission should be the granting authority.

(Amendment 41 - first reading)

Justification

Very high-risk substances shall be replaced, whenever possible, with other, safer, ones and, when used, the socio-economic benefits shall be taken into account and the risk 'adequately controlled'.

Specific attention needs to be paid to vulnerable populations in authorisation.

Amendment 20
RECITAL 64

(64) Methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed taking into account the outcomes of RIPs. The relevant Annex may be amended on the basis of these methodologies to allow thresholds where appropriate to be used in the context of authorising the use of carcinogenic and mutagenic substances.	***deleted***

Justification

Deletes a new provision in the common position, since one single procedure should be used for the authorisation of substances of high concern.

Amendment 21
RECITAL 85

(85) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of this Regulation.	(85) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of this Regulation. ***In this respect, a centre of excellence***

specialised in communication of the risks and dangers associated with certain substances and preparations should be created within the Agency.

Justification

Corresponds to Amendment 45 First Reading.

Amendment 22
RECITAL 92

(92) It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment ***and*** the Committee for Socio-economic Analysis are based on the broadest possible scientific and technical expertise appropriate which is available within the Community. To the same end, these Committees should be able to rely on additional particular expertise.	(92) It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment***,*** the Committee for Socio-economic Analysis ***and the Committee for Alternative Test Methods*** are based on the broadest possible scientific and technical expertise appropriate which is available within the Community. To the same end, these Committees should be able to rely on additional particular expertise.

(New amendment to achieve coherence

Justification

If such a new committee is established at the Agency, it should also be mentioned here, as the provisions in this recital are equally relevant to the work of the Committee for Alternative Test Methods.

Amendment 23
RECITAL 92 A (new)

(92a) In order to promote non-animal testing, the Agency should have the task of developing and implementing a policy for the development, validation and legal acceptance of non-animal test methods and to ensure their use in intelligent stepwise risk assessment to meet the requirements of this Regulation. To this end, the Agency should include a

Committee for Alternative Test Methods, consisting of experts from the European Centre for the Validation of Alternative Methods (ECVAM), animal welfare organisations and other relevant stakeholders, to ensure the broadest possible appropriate scientific and technical expertise which is available within the Community.

(Amendment 361 - first reading)

Justification

The objective of this Regulation to promote non-animal testing should be included in the mandate and work of the Agency to ensure its effective implementation. Therefore a Committee should be established in the Agency consisting of relevant experts to carry out the tasks related to the development of alternative test methods and their application.

Amendment 24
RECITAL 104 A (new)

(104a) In its opinion of 10 March 2006 on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) pointed to major gaps in the knowledge necessary for risk assessment, including nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles. It concluded that current risk assessment methodologies require some modifications in order to deal with the hazards associated with nanotechnology, and in particular that existing toxicological and ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles. The provisions of this Regulation should ensure an adequate safety evaluation of

nanoparticles as a precondition for their manufacture and placing on the market.

(New amendment - Rule 62(2)(d) to take account of the opinion of SCENIHR of 10 March 2006)

Justification

The major gaps in the knowledge for risk assessment of nanoparticles, as stated by SCENIHR, as well as their conclusions stating a need for modifications of existing methods, need to be stated explicitly. This has consequences for the safety assessment of nanoparticles, and should lead to specific provisions as well as a specific review of nanoparticles in the context of this regulation.

Amendment 25
RECITAL 114 A (new)

(114a) To help consumers to use substances and preparations in a safe and sustainable manner, manufacturers must make available, by means of a label on the packaging of each unit placed on the market for sale to consumers, information based on risk and identifying the risks associated with their recommended use or with the foreseeable situations in which they might be improperly used. The labelling of the packaging will also be complemented, if appropriate, by the use of other means of communication, such as websites, to provide more detailed information on safety and the use of the substance or preparation.

Directives 1999/45/EC and 67/548/EEC should be amended accordingly.

Justification

The development of an appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to use chemicals and preparations containing them safely and effectively.

Amendment 26
ARTICLE 1, PARAGRAPH 1

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment ***as well as*** the free circulation of substances on the internal market while enhancing competitiveness and innovation.	1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, the free circulation of substances on the internal market***, increased transparency and the promotion of non-animal testing,*** while enhancing competitiveness and innovation ***in accordance with the duty of care, and having due regard for the obligations entered into by the EU and its Member States in the framework of international trade agreements, in particular within the WTO***.

(Amendment 59 and 419 - first reading)

Justification

In view of the considerable number of chemicals and uses which will not be covered by REACH provisions -including an estimated 70,000 substances produced at less than 1 tonne per annum - a general principle of Duty of care is needed to define the responsibility of industry for the safe handling and use of ALL chemicals. It is intended to apply to all substances (irrespective of production volume), implying that industry is expected not just to meet the specific obligations under REACH, but also to fulfil the basic social, economic and environmental responsibilities of entrepreneurship. These specific provisions will also ensure legal certainty for companies to fulfil their duty of care.

Linked to Amendment of Recital 1. These two objectives of this Regulation from the Commission Explanatory Memorandum have been deleted by the Council and should be re-instated in view of the importance of both increased transparency and the promotion of non-animal testing in this Regulation for all stakeholders and European citizens.

Amendment 27
ARTICLE 1, PARAGRAPH 3

3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.	3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment, ***under normal or reasonably foreseeable conditions of use.*** Its provisions are underpinned by the precautionary principle.

Justification

Corresponds to Amendment 60 First Reading.

It is consistent with the definition of "safe product" as defined in the General Product Safety Directive (2001/95/EC) and is necessary to define the frame and the limits to which the subject of this Regulation applies.

Amendment 28
ARTICLE 1, PARAGRAPHS 3 A, 3 B and 3 C (new)

3a. Any manufacturer, importer or downstream user performing or intending to perform operations involving a substance or preparation, or an article containing such a substance or preparation, including the manufacturing, importation and application thereof, who knows or could reasonably have foreseen that these operations could adversely affect human health or the environment, shall make every effort that may reasonably be required of him to prevent, limit or remedy such effects.

3b. Any manufacturer, importer or downstream user that supplies, in the pursuit of his profession or business, a substance or preparation, or an article containing such a substance or preparation, to a manufacturer, importer or downstream user shall, to the extent this may reasonably be required, ensure adequate communication and information exchange, including where appropriate technical assistance, reasonably necessary to prevent, limit or remedy adverse effects on human health or the environment.

3c. This includes the duty to describe, document and notify in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance. Producers and downstream users shall select a substance for production and use on the basis of the safest substances available.

(Amendment 364 - first reading)

Justification

Introduces the principle of duty of care.

Amendment 29
ARTICLE 1, PARAGRAPH 3 D (new)

3d. The implementation and operation of the provisions of this Regulation should not involve an increase in the bureaucratic and administrative burden on small and medium-sized enterprises.

Justification

Successful First Reading amendment 63 seeking to avoid unnecessary red-tape for enterprises, particularly SMEs.

Amendment 30
ARTICLE 1, PARAGRAPH 3 E (new)

3e. In implementing this Regulation, the European Union shall establish mechanisms for providing aid and support to small and medium-sized enterprises.

Justification

SMEs are financially and technically weaker than big companies and require special support. Identical to first reading amendment 64.

Amendment 31
ARTICLE 2, PARAGRAPH 4

4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, including Council Directive 89/391/EEC ***of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control;*** Directive 98/24/EC, Directive	4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, ***and to more stringent national provisions implementing such legislation,*** including***:*** ***(a)*** Council Directive 89/391/EEC***,*** ***(b) Council Directive 90/394/EEC,*** ***(c) Council*** Directive 98/24/EC,

2000/60/EC ***of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and*** Directive 2004/37/EC.	***(d) Council Directive 96/61/EC,*** ***(e) Council*** Directive 2000/60/EC***,*** ***(f)*** Directive 2004/37/EC.

Justification

Sweden among others has more stringent requirements for workers' safety and to clarify the possibility to keep these more stringent requirements the proposed wording is suggested.

Amendment 32
ARTICLE 2, PARAGRAPH 4 A (new)

	4a. This Regulation shall apply without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[(1)], concerning: ***(i) the prohibition of animal testing of finished cosmetic products and the ingredients or combinations of ingredients thereof; and*** ***(ii) the marketing of cosmetic products of which some or all of the ingredients, or the final formulation, have been tested on animals.*** ***To the extent that substances used only as cosmetic ingredients are covered by this Regulation, no animal testing that is prohibited pursuant to Directive 76/768/EEC as amended shall be permitted for the purposes of the same assessment required by this Regulation with regard to such substances.*** ***[(1)] OJ L 262, 27.7.1976, p. 169. Directive as amended by Directive 2003/15/EC (OJ L 66, 11.3.2003, p. 26) and as last amended by Commission Directive 2006/65/EC (OJ L 198, 20.7.2006)***

Justification
Partly reinstates amendment 65 as adopted in first reading. The 7th amendment to the

Cosmetic Directive aims at stepwise removing animal testing from the Cosmetic sector. This should not be undermined by REACH.

Amendment 33
ARTICLE 3, POINT 3

3) Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;	3) Article: means an object ***composed of homogeneous material*** which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Justification

This amendment ensures compliance with existing EU legislation (Dir. 76/769/EEC on Restrictions, Dir. 2000/53/EC on End of Life Vehicles, and RoHS). Furthermore, the Council text would harm EU industry as it would cause competitive disadvantages to EU-producers of complex articles in relation to importers of complex articles.

Amendment 34
ARTICLE 3, POINT 25

25) Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;	25) Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user***, and that is communicated to the downstream user concerned***;

Justification

There must be an obligation for the producer and the suppliers to communicate to the down stream user which uses are supported or not; otherwise the down stream user does not know if he would have to register himself.

Amendment 35
ARTICLE 3, POINT 29

29) Per year: means per calendar year unless stated otherwise;	29) Per year: means per calendar year. ***Save in the case of new substances, and*** unless stated otherwise***, quantities per year shall be calculated on the basis of the average production volumes for the three***

immediately preceding calendar years during which the substance has actually been produced by the manufacturer;

Justification

Market fluctuations should be taken into account to prevent them from affecting the terms of registration, evaluation and authorisation (existing substances). Identical to first reading amendment 78.

Amendment 36
ARTICLE 3, POINT 30 A (new)

30a) Vulnerable populations: means susceptible humans including neonates, infants, children, pregnant women, nursing mothers, the infirm and immuno-compromised, elderly persons, those with individual genetic susceptibilities and other identified groups of concern;

(Amendment 80 - first reading)

Justification

The Council wording of Article 3 has no definition of the term vulnerable populations although is used in the text. A definition is essential to ensure that susceptible populations are identified and that measures can be taken accordingly to reduce the risks to and exposure of these populations.

Amendment 37
ARTICLE 7, PARAGRAPH 1 A (new)

1a. Paragraph 1(a) shall not apply to substances which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[1].

[1] OJ L 194, 18.7.2001, p. 26.

Justification

Corresponds to Amendment 88 adopted in First Reading

As well the exposure scenario as the noxious effects resulting from tobacco additives do not justify any exemptions from the obligation to register these substances.

Amendment 38
ARTICLE 7, PARAGRAPHS 2 TO 5

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 56 and is identified in accordance with Article 58(1)***, if both the following conditions are met***:	2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 56 and is identified in accordance with Article 58(1) ***where***:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	
(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).	(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w) ***in a homogenous material of an article;***
	(ba) substance specific concentration limits below the 0.1% limit may be adopted in accordance with the procedure referred to in Article 132(3);
	(bb) the producer or importer cannot exclude any exposure of the public or the environment to the substance during the full life-cycle of the article.
3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article in accordance with Article 32(4).	
4. The information to be notified shall include the following:	4. The information to be notified shall include the following:
(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their	(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their

own use sites;	own use sites;
(b) the registration number(s) referred to in Article 20(1), if available;	(b) the registration number(s) referred to in Article 20(1), if available;
(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;	(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;	(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);	(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
(f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.	(f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.
5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:	5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	
(b) the Agency has grounds for suspecting that:	(b) the Agency has grounds for suspecting that:
(i) the substance is released from the articles, and	(i) the substance is released from the articles, and
(ii) the release of the substance from the articles presents a risk to human health or the environment;	(ii) the release of the substance from the articles the substance presents a risk to human health or the environment;
(c) the substance is not subject to paragraph 1.	(c) the substance is not subject to paragraph 1.
A submission for registration shall be accompanied by the fee required in accordance with Title IX.	A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Justification

This amendment is a compromise between EP and Council and is in line with the compromise package on substances in articles agreed by a majority of political groups (first reading amendment 357). It simplifies the work for producers and importers, helps to protect the competitiveness of EU producers of articles by providing the same level playing field within

the framework of the WTO agreements. It will also provide a high level protection for consumer.

Amendment 39
ARTICLE 7, PARAGRAPH 7 A (new)

7a. The Agency shall provide guidelines to help the producers and importers of articles as well as the competent authorities.

(Amendment 88 (partially) - first reading)

Justification

REACH represents a huge organisational challenge for importers of articles. The Council proposal foresees several sector specific guidelines; however, the sector specific guidelines for producers and importers of articles, on which the EP agreed in 1st plenary reading, are no longer mentioned. Project 3.8 (initially supposed to replace the guidelines for the consumer goods sector) has not produced a workable result. Nonetheless the sector depends on professional and knowledgeable help– just as the different authorities involved in the import procedures. Guidelines drafted by the agency would provide a uniform level of support for companies and authorities in all EU Member States and likewise for non-European companies who may lack a thorough knowledge of the REACH legislation.

Amendment 40
ARTICLE 8 A (new)

Article 8a

European quality mark

By …. * the Commission shall present to the European Parliament and the Council a report and, if appropriate, a legislative proposal on the creation of a European quality mark designed to identify and promote articles which, at each stage of the production process, have been produced in compliance with the requirements stemming from this Regulation.

———

**** Two years after the entry into force of this Regulation.***

(Amendment 90 - first reading)

Justification

A mark to be stamped on articles would make it possible to identify and promote those involved in the production procedure who have complied with the requirements stemming from this Regulation.

Amendment 41
ARTICLE 11, PARAGRAPH 3, INTRODUCTORY PART

3. A manufacturer or importer may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:	3. A manufacturer or importer may***, without prejudice to Title III,*** submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

Justification

To reduce duplication of animal testing companies opting out of joint submission of data must still be required to share data from animal testing. The data sharing requirements under Title III should apply irrespective of whether data is submitted jointly or separately.

Amendment 42
ARTICLE 12, PARAGRAPH 2 A (new)

2a. Priority shall be given to in vitro methods and the use of (quantitative) structure activity relationships ((Q)SARs). To this end, the Agency shall make available to companies a list of tests, databases and approved models.

(Amendment 106 - first reading)

Justification

In light of the ethical and scientific concerns linked to animal tests, priority should be given to alternative strategies. The Agency should give all necessary information to companies.

Amendment 43
ARTICLE 13, PARAGRAPH 1

1. Information on intrinsic properties of substances ***may*** be generated by means other than tests, in particular through the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across), provided that the conditions set out in Annex XI are met. Testing in accordance with Annex VIII, section 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.	1. Information on intrinsic properties of substances***, in particular for human toxicity, shall*** be generated ***whenever possible*** by means other than ***vertebrate animal*** tests, in particular through the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across), provided that the conditions set out in Annex XI are met***, or toxicogenomics***. Testing in accordance with Annex VIII, section 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.

(Amendment 549 - first reading)

Justification

In addition to the ethical questions linked to vertebrate animal testing, there are numerous scientific problems with the validity of such animal tests for humans. Information about the properties of substances should therefore not only make use of alternative means such as QSARs, but also of the new and promising means of testing chemicals by assessing their effects via the reaction of marker genes.

Amendment 44
ARTICLE 13, PARAGRAPH 2, SUBPARAGRAPH 1

2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article ***132(3)***, which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.	2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article ***132(3a)***, which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 45
ARTICLE 13, PARAGRAPH 2, SUBPARAGRAPH 1 A (new)

	These methods shall be regularly reviewed and improved with a view to reducing experimentation on vertebrate animals and the number of animals involved. In particular, if the European Centre for the Validation of Alternative Methods (ECVAM) declares an alternative test method valid and ready for regulatory acceptance, the Agency shall submit within 14 days a draft decision amending the relevant Annex(es) to this Regulation, in accordance with the procedure provided for in Article 130, with a view to replacing the animal test method with the alternative one.

(Amendment 108 - first reading)

Justification

The test methods should be automatically updated when an alternative test method is validated by ECVAM.

Amendment 46
ARTICLE 14, PARAGRAPH 1, SUBPARAGRAPH 1

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter ***if the registrant manufactures or imports such a substance in quantities of 10 tonnes or more per year***.	1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter.

Justification

The intention of amendment 110 from the first reading was to secure basic safety data also for low volume chemicals. This should apply for all chemicals subject to registration.

The industry and the institutions do not tire to stress the need for a "risk-based approach" of REACH. Risk is the combination of hazard and exposure. However, an assessment of a) hazard and b) exposure is only required in the chemical safety report. To limit the safety assessments to substances above 10 tonnes would exclude two-thirds of the substances from both those assessments. As a consequence, it would be near impossible to identify the appropriate risk management measures to protect workers or consumers against hazardous substances. A data graveyard serves nobody.

Amendment 47
ARTICLE 14, PARAGRAPH 2 A (new)

2a. A chemical safety assessment and chemical safety report in accordance with paragraph 1 need not be performed for substances classified as dangerous according to Directive 67/548/ECC, or PBT or vBvP substances, which are present in massive preparations exempted from labelling in accordance with Article 12(2) of Directive 1999/45/ECand point 9.3 of Annex VI to Directive 67/548/EEC.

Justification

Reinstates amendments 422 and 960 as adopted in first reading. The risk for human health or the environment from substances bound in massive preparations is very limited and, accordingly, no labelling is required by existing legislation. Therefore, the obligation to perform chemical safety assessments and reports can be dispensed with under the same conditions as the labelling.

Amendment 48
ARTICLE 14, PARAGRAPHS 7 A AND 7 B (new)

7a. The manufacturer or importer of a substance or preparation who supplies such a substance or preparation to a downstream user shall, at the request of the downstream user and in so far as this can reasonably be requested, supply the information needed to assess the effects of the substance or preparation on human

	health or the environment in the context of the operations or use indicated by the downstream user in his request.
	7b. The downstream user shall supply, at the request of his supplier and in so far as this can reasonably be requested, the information needed by the supplier to assess the effects of the substance or preparation on human health or the environment in the context of the operations or use of the substance or preparation by the downstream user.

(Amendment 112 - first reading)

Justification

Communication between the players in the production chain must not be limited to a mere exchange of information intended simply to comply with the directive. Throughout the whole supply chain, there must be a responsibility towards a form of interaction and communication between suppliers and upstream and downstream users.

Amendment 49
ARTICLE 19, PARAGRAPH 2, POINT (C)

(c) he disagrees with the lead registrant on the selection of this information.	(c) he disagrees with the lead registrant on the selection of this information. ***The Agency shall assess this explanation and take a decision on whether or not to accept it. In the event of non-acceptance, the undertaking shall be required to submit the data jointly.***

Justification

As currently formulated, the criteria which manufacturers and importers may submit concerning separate information are very vague and difficult to justify and assess. Although subsequent articles make the Agency responsible for assessing this type of justification, it is not indicated what action should be taken if the justification is inadequate.

Amendment 50
ARTICLE 23, PARAGRAPH 2

2. Article 5, Article 6, Article 7(1) and Article 21 shall not apply until ...** to phase-in substances manufactured in the	2. Article 5, Article 6, Article 7(1) and Article 21 shall not apply until ...** to ***phase-in substances classified as very toxic***

Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after ...*.	***to aquatic organisms that may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC and manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer; or to*** phase-in substances manufactured in the Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after ...*.

(Amendment 374 - first reading)

Justification

Additional risk-based prioritisation: substances - in quantities below 100 tonnes - that are toxic to aquatic organisms and that may cause long-term adverse effects should be added to the second phase of registration. Otherwise, it would take up to 11 years until these hazardous substances would be registered.

Amendment 51
ARTICLE 23 A (new)

Article 23a

Notification of intention not to register a substance

1. Manufacturers or importers of a substance, either on its own or in a preparation, who do not intend to submit an application for registration of the substance shall notify the Agency and downstream users of their intention.

2. The notification referred to in paragraph 1 shall be forwarded

(a) 12 months before the deadline laid down in Article 23(1) for phase-in substances manufactured or imported in quantities reaching 1 000 tonnes or more per year;

(b) 24 months before the deadline laid down in Article 23(2) for phase-in substances manufactured or imported in

quantities reaching 100 tonnes or more per year;

(c) 36 months before the deadline laid down in Article 23(3) for phase-in substances manufactured or imported in quantities reaching 1 tonne or more per year.

3. Should the manufacturer or importer fail to notify the Agency or downstream users of his intention not to register the substance, he shall be required to submit a registration application for the substance.

(Amendment 121 - first reading)

Justification

Downstream users are concerned that some - and even, perhaps, a large number - substances will not be registered for economic reasons, which would have an adverse impact on their business. They are unable to make suitable preparations for such an eventuality because they would not know about it until the deadline for registration had passed. A provision requiring manufacturers and importers to give advance notice would enable them to negotiate with the manufacturer or importer. Downstream users might be willing to pay a higher price in order to avoid even higher reformulation costs, thus avoiding withdrawal of the substance.

Amendment 52
ARTICLE 27, PARAGRAPH 6

6. Within one month from the receipt of the information referred to in paragraph 5**,** the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier. Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for ***an equal*** share of the cost incurred by him, which shall be enforceable in the national courts.	6. Within one month from the receipt of the information referred to in paragraph 5**,** the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier. Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for ***a fair*** share of the cost incurred by him, which shall be enforceable in the national courts. ***The sharing of the actual costs incurred by the original registrant(s) for the study concerned shall be calculated in a way***

which is proportional to each party's production/import volume.

Where the original total cost has already been shared between two or more registrants, any subsequent potential registrant(s) shall pay each registrant a fair share of his contribution to costs.

(Amendment 134 (partially) - first reading)

Justification

Establishes a mechanism for sharing in a fair way the original costs of tests irrespective of the number of registrants and the timing for subsequent registrations.

Amendment 53
ARTICLE 28, PARAGRAPH 1, POINT D) A (new)

(da) a brief general description of identified uses; as a minimum initial information on use and exposure categories as specified in section 6 of Annex VI;

Justification

Corresponds to Amendment 368 adopted in First Reading.

Under REACH the Downstream users requires the data of a substance he uses in his preparations like who will register which substance and when it will be registered and which non-confidential uses are identified. If the downstream user has no access to all these data or only in a very late stage he may be confronted with a `non registration´ or a ´not identified use´ and therewith left with a too short time frame to make his supplier reconsider the registration or the incorporation of an additional identified use, to run the cycle of reformulation and the consequent customer approval.

Amendment 54
ARTICLE 28, PARAGRAPH 1 A (new)

1a. Anyone in possession of studies or information on a substance derived through experiments on animals shall be required to forward such information to the Agency at the latest 18 months before the deadline laid down in Article 23(1).

(Amendment 140 - first reading)

Justification

Bringing forward the deadline for forwarding information derived from animal experimentation enables duplication of such experiments to be avoided and at the same time reduces the burden on businesses, particularly SMEs.

Amendment 55
ARTICLE 28, PARAGRAPH 2 A (new)

2a. If the period referred to in paragraph 2 has elapsed, the Agency shall, upon request by a downstream user of a substance that has not been pre-registered, permit late notification to the register of substances by any person other than the original supplier of that substance to the downstream user for a further six months after the publication of the register. Such notification shall enable the potential registrant to benefit from the transitional regime set out in Chapter 5 of Title II.

(Amendment 369/rev. (partially) - first reading))

Justification

Allows six additional months for pre-registration of substances when requested by a downstream user.

Amendment 56
ARTICLE 28, PARAGRAPH 4 A (new)

4a. Manufacturers and importers shall forward to the Agency any information in their possession deriving from experiments on vertebrate animals and other information that could prevent animal experimentation, in relation also to substances they have ceased to manufacture or import. Registrants who later make use of such information shall share the costs of creating such information in a manner that is

	proportional to each party's production volume. Anyone coming into possession of the results of studies or other information on a substance derived from experiments on vertebrate animals after the expiry of the deadline referred to in paragraph 1a, shall forward such information to the Agency.

(Amendment 143 - first reading)

Justification

This makes it clear that all information that could be useful in avoiding animal experimentation must be shared, avoiding duplication of such experiments and at the same time reducing the burden on businesses, particularly SMEs.

Amendment 57
ARTICLE 28, PARAGRAPH 5

5. The Agency ***shall by …* publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes.***	5. The Agency shall ***operate a register of substances containing the information specified in paragraph 1.***
	5a. The Agency shall publish on its website the register of substances within one month after the expiry of the period laid down in paragraph 2, indicating:
	(a) the name of the substance and the information made available under paragraphs 1 and 4a and, where applicable, the group of substances, including EINECS and CAS numbers, if available;
	(b) the name and address of the manufacturer or importer or, where appropriate, the name and address of the person representing him in accordance with Article 4 as specified in section 1 of Annex VI;
	(c) a general description of identified uses; as a minimum, initial information on use and exposure in accordance with paragraph 1(da);

(d) the first deadline for the registration of each substance in accordance with Article 23.

5b. The Agency shall publish the name of the substance and, where applicable, the group of substances, including EINECS and CAS numbers, if available, in respect of which late notification has been requested, immediately following the receipt of such requests.

5c. Within one month of the expiry of the late notification period pursuant to paragraph 2a, the Agency shall update the register of substances to include those substances for which late pre-registrations have been received.

5d. The Agency shall publish together with the publication of the register of substances a request to anyone who owns studies on vertebrate animals which are not publicly available to submit indications on the availability of such studies.

5e. Anyone who owns such studies may send indications on the availability of such studies to the Agency, within six months of the publication of the register of substances, and the Agency shall include this information in the database in accordance with paragraph 5. Such studies shall be used in accordance with Article 30.

5f. The Agency shall by ...* also publish on its website a list of phase-in substances already registered without pre-registration. That list shall comprise the names of the substances, their EINECs and CAS number if available and other identity codes, and, where applicable, the group of the substances.

**** 19 months after the entry into force of this Regulation.***

Justification

This is necessary to enable downstream users access to adequate pre-registration data, thus enabling them to fulfil their obligations under REACH on time. Slight rewording of first

reading amendment 371, taking into account the clarifying that the register should be made available by the Council.

Existing data from animal tests and other information that could prevent animal experimentation should be published as early as possible in order to prevent duplicate animal testing and save costs for industry, particularly SMEs.

A downstream user (DU) requires the following data of a substance he uses in his preparations:

- *is the substance going to be registered,*
- *who will register the substance,*
- *when will it be registered*
- *which uses are identified*

If the DU has no access to all of these data or only in a very late stage he may be confronted with a 'non-registration' or a 'not identified use' and therewith left with a too short time frame to make his supplier reconsider the registration or identified use, or run the cycle of reformulation (without the non-registered substance)

Linked to the amendment to Article 28(5). A list of phase-in substances that have been registered without pre-registration, and the chemical group to which such substances belong should also be published as early as possible to ensure data sharing and, where applicable, read-across from the grouping of substances in order to prevent duplicate animal testing and save costs for industry, particularly SMEs.

Amendment 58
ARTICLE 29, PARAGRAPH 1

1. All manufacturers ***and*** importers who have submitted information to the Agency in accordance with Article 28 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).	1. All manufacturers**,** importers ***and formulators*** who have submitted information to the Agency in accordance with Article 28 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).

Justification

'Formulators' must also have access to the SIEF so that they can share their data on risks and exposure.

Amendment 59
ARTICLE 30, PARAGRAPH 1

1. Before testing is carried out in order to	1. Before testing is carried out in order to

meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests ***on vertebrate animals*** is available ***within the SIEF***, a participant of ***that*** SIEF shall request that study ***by ...**. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study by ...**.***	meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF ***and consulting the lists published by the Agency in accordance with Article 28(5) and (5a)***. If a relevant study involving tests is available, a participant of SIEF shall request that study.
Within ***two weeks*** of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 76(2)(f). If they cannot reach such an agreement, the cost shall be shared ***equally***. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.	Within ***one month*** of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way ***and in proportion to each party's production volume***. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 76(2)(f). If they cannot reach such an agreement, the cost shall be shared ***in a fair way***. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.
***** 20 months after entry into force of this Regulation.***	

Justification

It is not feasible for companies or others concerned to ask within 2 months after publication of the list with pre-registered substances the relevant studies of all other SIEF-participants. with phase-in-substances decisions concerning possible tests will be done only, when the applicable deadlines for registration of the substance is expired. Therefore it is not necessary to set a deadline.

Modified reinstatement of the Commission text. Linked to the amendment of Article 28(5) and 28(5a). In order to prevent duplication of animal testing and save costs for industry, particularly SMEs, SIEFs should also be required to consult the lists published by the Agency

to ensure data sharing and, where applicable, read-across from the grouping of substances.

Establishes a mechanism for sharing in a fair way the original costs of tests in analogy with the corresponding modifications to Article 27.

All tests (vertebrates and non-vertebrates) should be shared. Identical to first reading amendment 149.

Amendment 60
ARTICLE 30, PARAGRAPH 2

2. If a relevant study involving tests is not available ***within the SIEF***, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.	2. If a relevant study involving tests is not available, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.

Justification

Reducing duplication of animal tests. Linked to Amendment of Article 30(1).

Amendment 61
ARTICLE 31, PARAGRAPH 1

1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:	1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:

(a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.	(a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII***; or*** ***(ba) where a substance has been identified in accordance with Article 56 (f)***.

(Amendment 157 revised - first reading)

Justification

With the help of Safety Data Sheets information about a substance shall be passed on in the supply chain according to the requirements of REACH. The scope of substances that require a safety data sheet needs to be expanded to include all substances of very high concern that are mentioned in Article 56 on authorisation.

Amendment 62
ARTICLE 31, PARAGRAPH 9 A (new)

	9a. The Commission shall organise the development of technical guidelines setting minimum requirements for safety data sheets, to ensure the provision of clear and adequate information of optimal use to all actors up and down the supply chain.

(Amendment 162 - first reading)

Justification

Safety data sheets (SDS) can be a good tool to communicate information up and down the supply chain for both substances and preparations. However, SDS will achieve their purpose only if they are completed adequately. Thus, the Commission should develop technical guidance that provide minimum requirements on the completion of SDS.

Amendment 63
ARTICLE 32, PARAGRAPH 4

4. Any producer or importer of an article containing a substance meeting the criteria in Article 56 and identified according to Article 58(1) in a concentration above 01 % weight by weight (w/w), shall provide the recipient of the article with sufficient information to allow safe use of the article including, as a minimum, the name of the substance. This obligation shall extend to all recipients of articles in the supply chain.	***deleted***

Justification

All provisions relating to duty to communicate information on substances in articles should be grouped in a single article (see new Article 33a).

Amendment 64
ARTICLE 33 A (new)

Article 33a

Duty to communicate information on substances contained in articles

1. Any manufacturer or importer of a substance listed in Annex XIV, or a preparation or article containing such a substance, shall at the request of the downstream user, in so far as this may reasonably be required, furnish the information necessary to assess the effects of the substance on human health or the environment with respect to the operations and uses indicated in that request.

2. The information requirements specified in paragraph 1 shall apply mutatis mutandis up the supply chain.

3. Downstream users who incorporate into an article a substance or preparation for which a safety data sheet was established, and those who subsequently handle or further process that article, shall pass on the safety data sheet to any

recipient of the article or its derivative. Recipients shall not include consumers.

Consumers shall have the right to ask the producer or importer for information on the substances present in an article produced or imported by him.

Producers or importers shall, on request and within 15 working days, enable any individual consumer to obtain, free of charge, full details of safety and use information concerning the substances present in any article they have produced or imported.

(Amendments 166 and 366 - first reading)

Justification

Manufacturers, retailers and consumers should be able to find out whether specific substances are contained in an end product and, if necessary, to seek out and choose a safer alternative.

Information on hazardous (authorised) substances on their own, in preparations, and in articles must be distributed through the supply chain (upwards and downwards) to enable the companies to take appropriate actions and to make informed decisions concerning the contents of their products. The downstream users' right to obtain information on such substances is crucial in order to rebuild consumer confidence and to regain goodwill.

Amendment 65
ARTICLE 36, PARAGRAPH 4, POINT (C)

(c) the downstream user uses the substance or preparation in a total quantity of less than 1 tonne per year;	***deleted***

(New amendment - Rule 62(2)(c)), linked to recital 54)

Justification

As a result of the 1 tonne threshold introduced by Council, downstream users would only have to prepare a chemical safety report (CSR) for uses >1 tonne, if not covered by the CSR of the manufacturer. No such use threshold is foreseen for the CSR by manufacturers. This new clause would create a perverse incentive for manufacturers to exclude uses below 1 tonne from their CSR, as it would not result in any obligations for downstream users. This creates a serious loophole with regard to safety information for small uses.

Establishing a 1 tpa threshold would create a serious loophole for many uses of chemicals. Deleting the threshold of 1 tpa ensures that the downstream users have the right to obtain the safety information from the manufacturers in order to handle the substance safely and improve their products.

Amendment 66
ARTICLE 39, PARAGRAPH 1 A (NEW)

1a. In order to prevent duplication of animal testing, any testing proposal involving tests on vertebrate animals shall be open for comment by interested parties for a period of 90 days. All comments received shall be taken into account by the registrant or the downstream user, who shall notify the Agency whether, in the light of the comments received, he nonetheless believes that it is necessary to carry out the proposed test and of his reasons therefor.

(Amendment 176 - first reading)

Justification

All relevant comments and information which could reduce animal testing should be taken into account.

Amendment 67
ARTICLE 39, PARAGRAPH 1 B (new)

1b. The European Centre for the Validation of Alternative Methods (ECVAM) shall be consulted before a decision as referred to in paragraph 2 on a testing proposal that includes vertebrate animal tests is drafted.

(Amendment 177 - first reading)

Justification

Given the rapid advances in the development of alternative tests, expert knowledge and experience should be provided to the competent authorities when evaluating testing proposals to prevent animal testing and save costs.

Amendment 68
ARTICLE 39, PARAGRAPH 2, INTRODUCTORY PART

2. On the basis of the examination under ***paragraph 1***, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 49 and 50:	2. On the basis of the examination under ***paragraphs 1, 1a and 1b***, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 49 and 50:

(Modified reinstatement of the Commission text)

Justification

To ensure coherence.

Amendment 69
ARTICLE 40, PARAGRAPH 4

4. The registrant shall submit the information required to the Agency ***by the*** deadline set.	4. The registrant shall submit the information required to the Agency ***within a reasonable*** deadline ***to be*** set ***by the Agency. This deadline shall not exceed six months. The Agency shall withdraw the registration number if the registrant fails to submit the relevant information within the deadline set***.

Justification

Council has failed to provide a clear deadline for submission of information as the Parliament has proposed in Amendment 180.

A registrant might have passed the completeness check as stipulated in Article 20, but the information requirements might nevertheless not be fulfilled. Non-compliance with the information requirements should have clear consequences. Registrants should have no more than one chance within a maximum of six months to correct flawed registrations. This could ensure good quality and avoid never-ending disputes between the authorities and registrants. The wording is in line with the provisions for the completeness check in Article 20.

Amendment 70
ARTICLE 40, PARAGRAPH 7

7. The Commission may, after consulting with the Agency, take a decision to vary the	7. The Commission may, after consulting with the Agency, take a decision to vary the

percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article ***132(3)***.	percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article ***132(3a)***.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 71
ARTICLE 46, PARAGRAPH 2

2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 45 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article ***132(3)***.	2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 45 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article ***132(3a)***.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 72
ARTICLE 49, PARAGRAPH 1

1. The Agency shall notify any draft decision under Articles 39, 40 or 45 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 45) and the	1. The Agency shall notify any draft decision under Articles 39, 40 or 45, ***together with any comments by stakeholders and the European Centre for the Validation of Alternative Methods (ECVAM),*** to the registrant(s) or downstream user(s) concerned**,** informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the

Agency (for decisions taken under Articles 39 and 40) shall take any comments received into account and may amend the draft decision accordingly.	competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 45) and the Agency (for decisions taken under Articles 39 and 40) shall take any comments received into account and may amend the draft decision accordingly.

(Amendment 206 - first reading)

Justification

For reasons of transparency, the comments by ECVAM and other stakeholders should also be published.

Linked to Amendments to Article 39(1), (1a) and (2).

Amendment 73
ARTICLE 54

The aim of this Title is to ensure ***the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are eventually replaced by suitable alternative substances or technologies where these are economically and technically viable.***	The aim of this Title is to ensure ***that substances of very high concern are replaced by safer alternative substances or technologies, where available. Where no such alternatives are available, and where the benefits to society outweigh the risks connected with the use of such substances, the aim of this Title is to ensure that the use of substances of very high concern is properly controlled and that alternatives are encouraged. Its provisions are underpinned by the precautionary principle.***

(Amendment 214 - first reading)

Justification

The aim of authorisation is to ensure the protection of human health and the environment.

The aim of authorisation is to ensure the protection of human health and the environment. EP amendment 214 is re-tabled.

The emphasis on the internal market needs to be deleted. REACH already contains a free movement clause (art. 128) and is based on the Treaty's legal base for the internal market. This specific title is about allowing chemicals that are known to be harmful to be used under specific conditions. The precautionary principle is mentioned in the general provisions of

REACH but it is especially important to include this principle in the provisions on authorisation.

Amendment 74
ARTICLE 55, PARAGRAPH 4, POINT (D A) (new)

	(da) uses of ores and concentrates, as naturally occurring raw materials, not otherwise on sale to the general public, in processing installations that fall within the scope of Directive 96/61/EC.

Justification

Most contain small amounts of natural CMR substances and are therefore liable to Authorisation. Used only as raw materials into plants submitted to permits allocated by reference to the Best Available Techniques (Dir. 96/61/CE) as well as legislation on workers and environment protection; products and waste streams remain under REACH and waste legislation. Resulting risks are properly controlled: under article 57(2), exemptions will be granted. Due to the variability in composition, this amendment avoids thousands of useless files (system overload) and safeguards workability.

Amendment 75
ARTICLE 55, PARAGRAPH 5

5. In the case of substances that are subject to authorisation only because they meet the criteria in Article 56(a), (b) or (c) or because they are identified in accordance with Article 56(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:	***deleted***
(a) uses in cosmetic products within the scope of Directive 76/768/EEC;	
(b) uses in food contact materials within the scope of Regulation (EC) No 1935/2004.	

(Amendment 471/rev. partially - first reading)

Justification

No restrictions should apply to the scope of authorisation.

Amendment 76
ARTICLE 55 A (new)

Article 55a

List of substances subject to authorisation

Substances that are known to fulfil the criteria of Article 56 shall be listed in Annex XIV(a) pending the procedure for authorisation. Once the authorisation procedure has been initiated, the substances shall be listed in Annex XIV(b), in accordance with the procedure laid down in Article 57(1).

(Amendment 215 - first reading)

Justification

In order to increase transparency, stimulate voluntary measures by downstream users and innovation towards safer alternatives, all substances that meet the criteria of very high concern should be added immediately to a candidate list for authorisation (=Annex XIVa).

Subsequently, following the priority setting by the agency, substances will be moved to Annex XIVb, in which sunset dates and deadlines for applications for authorisation would be set.

Amendment 77
ARTICLE 56, TITLE AND INTRODUCTORY PART

Substances to be included in Annex ***XIV***	Substances to be included in Annex ***XIV(a)***
The following substances ***may*** be included in Annex ***XIV*** in accordance with the procedure laid down in ***Article 57***:	***Without prejudice to existing or future restrictions the*** following substances ***shall*** be included in Annex ***XIV(a)*** in accordance with the procedure laid down in ***Article 58***:

(Amendment 216 - first reading)

Justification

Partially linked to the amendments on Article 55a new.

Given the introduction of a candidate list, the procedure for inclusion on the lists needs to be modified. (Sacconi)

Amendment 78
ARTICLE 56, POINT (F)

(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - ***for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and*** which are identified on a case-by-case basis in accordance with the procedure set out in Article 58.	(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - which are identified ***as giving rise to a similar level of concern as substances listed in points (a) to (e)*** on a case-by-case basis in accordance with the procedure set out in Article 58.

(Amendment 217 - first reading)

Justification

This amendment lowers the level of concern required for a substance before it is allowed to be added to Annex XIVa.

The precautionary principle gives at hand that we cannot wait until we have full scientific evidence that a substance is going to have a negative impact on hormones for example, therefore the proposed wording will allow us to find more substances which are likely to give similar level of concern.

Amendment 79
ARTICLE 56, POINT (F A) (new)

	(fa) nanoparticles.

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of SCENIHR of 10 March 2006, and of the Review "Toxic Potential of Materials as the Nanolevel" published in Science on 3 February 2006))

Justification

According to "Science", the very small size of nanomaterials can modify the physico-chemical properties and create the opportunity for increased uptake and interaction with biological tissues. This combination can generate adverse biological effects in living cells that would not otherwise be possible with the same material in larger form. According to SCENIHR, information about the biological fate of nanoparticles (e.g. distribution, accumulation, metabolism and organ specific toxicity) is still minimal. Nanoparticles should therefore fall

under authorisation.

Amendment 80
ARTICLE 56, POINT (F B) (new)

(fb) substances which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

Justification

Corresponds to Amendment 218 adopted in First Reading.

Amendment 81
ARTICLE 57, TITLE AND PARAGRAPH 1, INTRODUCTORY PART

Inclusion of substances in Annex ***XIV***	Inclusion of substances in Annex ***XIV(b)***
1. Whenever a decision is taken to include in Annex ***XIV*** substances referred to in Article 56, such a decision shall be taken in accordance with the procedure referred to in Article ***132(3)***. It shall specify for each substance:	1. Whenever a decision is taken to include in Annex ***XIV(b)*** substances referred to in Article 56, such a decision shall be taken in accordance with the procedure referred to in Article ***132(3a).*** It shall specify for each substance:

(Amendment 219 - first reading)

Justification

Following the creation of the list of substances applying for authorisation, Annex XIV becomes Annex XIVb.

Amendment 82
ARTICLE 57, PARAGRAPH 1, POINT (B A) (new)

(ba) any restrictions, in accordance with Article 67;

(Amendment 220 - first reading)

Justification

It is important that any restrictions for manufacture, use and/or placing on the market should be stated in the decision to include such substances in Annex XIVb.

Amendment 83
ARTICLE 57, PARAGRAPH 1, POINT (D)

(d) review periods for ***certain*** uses***, if appropriate***;	(d) review periods***, which must not exceed five years,*** for ***all*** uses;

(Amendment 221 - first reading)

Justification

It is reasonable that all authorisations are issued on a temporary basis, because periodic review will allow (and encourage) adaptation to technical progress (e.g. consideration of new information on hazards, exposure, socio-economic benefits and availability of alternatives). Without regular review periods, the incentive for the innovation of safer alternatives will be lost.

Amendment 84
ARTICLE 57, PARAGRAPH 2

2. Uses or categories of uses may be exempted from the authorisation requirement ***provided that, on the basis of the*** existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, ***the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.***	2. Uses or categories of uses may be exempted from the authorisation requirement***. In the establishment of such exemptions, account shall be taken, in particular, of the following:*** ***(a)*** existing specific Community legislation imposing minimum requirements relating to the protection of human health, ***public safety*** or the environment for the use of the substance, ***such as binding occupational exposure limits, emission limits and so forth, provided that the risk is properly controlled;*** ***(b) existing legal obligations to take appropriate technical and management measures to ensure compliance with any relevant health, safety and environmental standards in relation to the use of the substance.***

Exemptions may be subject to conditions.

Justification

Reinstates the initial Commission proposal.

The implementation of REACH should not prevent the aeronautic sector complying with civil aviation safety and certification requirements and standards set out at international (ICAO) or Community level (EASA). It may be necessary to exempt some substances from authorisation for the reason that their physicochemical properties are essential to allow compliance with international and Community safety and certification requirements and standards, in particular with the requirements for airworthiness and safety of passengers in civil aviation laid down by the Regulation (EC) No 1592/2002.

Amendment 85
ARTICLE 57, PARAGRAPH 2 A (new)

2a. Such exemptions shall not be granted to uses or categories of uses for substances referred to in Article 56 which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, notwithstanding Article 12 of that Directive.

Justification

Corresponds to Amendment 222 adopted in First Reading, with adaptation to the change of Article Numbers in the Common Position in comparison to the original text issued by the European Commission.

Amendment 86
ARTICLE 57, PARAGRAPH 3, INTRODUCTORY PART

3. ***Prior to a decision to include substances in Annex XIV,*** the Agency shall***, taking into account the opinion of the Member State Committee,*** recommend priority substances ***to be included*** specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:	3. The Agency shall recommend ***that*** priority substances ***be transferred from Annex XIV(a) to Annex XIV(b),*** specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

(Amendment 223 - first reading)

Justification

Following the creation of the list of substances applying for authorisation, Annex XIV becomes Annex XIVb.

Amendment 87
ARTICLE 57, PARAGRAPH 3, POINT (B A) (new)

(ba) in the form of nanoparticles; or

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of SCENIHR of 10 March 2006)

Justification

According to SCENIHR, a wide variety of nanoscale materials and functional nanoscale surfaces are in use in consumer products, including cosmetics and sunscreens, fibres and textiles, dyes, fillers, paints, emulsions and colloids. Given the combination of a) very worrying adverse effects by nanoparticles, b) their widespread use in consumer products and c) the minimal knowledge about the biological fate of nanoparticles, they should be prioritised within the authorisation system of REACH.

Amendment 88
ARTICLE 57, PARAGRAPH 3, POINT (C)

(c) high volumes**.**	(c) high volumes; ***or***

Justification

Corresponds to Amendment 224 adopted in First Reading.

Amendment 89
ARTICLE 57, PARAGRAPH 3, POINT (C A) (new)

(ca) substances which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

Justification

Corresponds to Amendment 225 adopted in First Reading.

Amendment 90
ARTICLE 57, PARAGRAPH 4, SUBPARAGRAPH 1

4. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication***, taking into account Articles 117 and 118 on access to information***. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.	4. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on ***the following:*** ***(a) fulfilment of the criteria in Article 56(d), (e) and (f);*** ***(b)*** uses which should be exempt from the authorisation requirement.

Justification

Reinstates the initial Commission proposal.

Amendment 91
ARTICLE 57, PARAGRAPH 5

5. Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a preparation or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV.	5. Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a preparation or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV, ***except where scientific information is presented to the Agency that demonstrates the need for urgent measures to further restrict the substance.***

Justification

If new scientific information emerges showing the need for wider measures to further restrict a substance from the market, then the restrictions process should be available to the

authorities. EP amendment 226 is re-tabled.

Amendment 92
ARTICLE 57, PARAGRAPH 8

8. Substances which as a result of new information no longer meet the criteria of Article 56 shall be removed from Annex XIV in accordance with the procedure referred to in Article ***132(3)***.	8. Substances which as a result of new information no longer meet the criteria of Article 56 shall be removed from Annex XIV in accordance with the procedure referred to in Article ***132(3a)***.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 93
ARTICLE 58, TITLE

Identification of substances referred to in Article 56	Identification ***and inclusion in Annex XIV(a)*** of substances referred to in Article 56

(Amendments 227 - first reading)

Justification

Linked to the amendment of Article 56.

In order to increase transparency, stimulate voluntary measures by downstream users and innovation towards safer alternatives, all substances that meet the criteria of very high concern should be added immediately to a candidate list for authorisation (=Annex XIV(a)). Those that are known already to meet the criteria shall be included directly. For those that are yet to be identified, a procedure for adding them needs to be introduced.

Amendment 94
ARTICLE 58, PARAGRAPH -1

	-1. Substances referred to in Article 56 (a), (b) and (c) shall be included in Annex XIV(a).

(Amendments 228 - first reading)

Justification

C/m/r substances should be immediately included in the candidate list for authorisation.

Amendment 95
ARTICLE 58, PARAGRAPH 1

1. ***The*** procedure set out in paragraphs 2 to 10 of this Article shall apply ***for the purpose of identifying substances meeting the criteria referred to in Article 56 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 82(3)(e).***	1. ***To identify substances referred to in Article 56(d), (e) and (f) the*** procedure set out in paragraphs 2 to 10 of this Article shall apply ***prior to any recommendations under Article 57(3).***

Justification

Reinstates the initial Commission proposal.

Amendment 96
ARTICLE 58, PARAGRAPHS 8 AND 9

8. If, within 30 days of the referral, the Member State Committee reaches a ***unanimous*** agreement on the identification, the Agency shall ***include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under*** Article 57(3).	8. If, within 30 days of the referral, the Member State Committee reaches a ***qualified majority*** agreement ***that the substance satisfies the criteria for authorisation and should be included in Annex XIV(b),*** the Agency shall***, within 15 working days, recommend to the Commission that the substance be included in Annex XIV(b), as provided for in*** Article 57(3).
9. If the Member State Committee fails to reach a ***unanimous*** agreement, ***the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee***. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article ***132(3)***.	9. If the Member State Committee fails to reach a ***qualified majority*** agreement, ***it shall adopt an opinion within 30 days of the referral. The Agency shall transmit that opinion to the Commission within 15 working days, including information on any minority view within the Committee.*** A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article ***132(3a)***.

(Amendment 229 - first reading)

Justification

In the event of the Committee not reaching an agreement the final decision will rest with the Commission.

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 97
ARTICLE 58, PARAGRAPH 9 A (new)

	9a. Substances that are newly classified as fulfilling the criteria of Article 56 (a), (b) and (c) and substances identified as fulfilling the criteria of Article 56 (d), (e) and (f) shall be included in Annex XIV(a) within three months.

(Amendment 230 - first reading)

Justification

Provides a procedure for inclusion in Annex XIVa.

Amendment 98
ARTICLE 59, PARAGRAPH 1

1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.	1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title. ***The precautionary principle shall apply when such decisions are taken.***

(Amendment 231 - first reading)

Justification

Reminds that such decisions should be taken based on the precautionary principle.

Amendment 99
ARTICLE 59, PARAGRAPH 2

2. ***Without prejudice to paragraph 3,*** an	2. An authorisation shall be granted ***only*** if***:***

authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in ***Annex XIV*** is adequately controlled in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report. The Commission shall take into account all discharges, emissions and losses known at the time of decision**.**	
The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.	
	(a) suitable alternative substances or technologies do not exist, and measures are in place to minimise exposure, and
	(b) it is demonstrated that the social and economic advantages outweigh the risks to human health or the environment which arise from the use of the substance, and
	(c) the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in ***Annex XIV(a)*** is adequately controlled in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report.
	The Commission shall take into account all discharges, emissions and losses known at the time of decision.

(Amendment 232 revised - first reading)

Justification

Linked to the amendment to Article 54.

Amendment 100
ARTICLE 59, PARAGRAPH 3

3. Paragraph 2 shall not apply to:	***deleted***
(i) 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 section 6.4 of Annex I;	
(ii) substances meeting the criteria in Article 56 (d) and (e).	

Justification

Deletes a new provision in the common position, since one single procedure should be used for the authorisation of substances of high concern.

Amendment 101
ARTICLE 59, PARAGRAPH 4, INTRODUCTORY PART

4. ***If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This*** decision shall be taken after consideration of all of the following elements:	4. ***The*** decision ***to grant authorisation pursuant to paragraph 2*** shall be taken after consideration of all of the following elements:

(Amendment 233 - first reading)

Justification

Linked to the amendment to Article 54.

Amendment 102
ARTICLE 59, PARAGRAPH 7

7. ***Where an application for authorisation includes the information specified in Article 61(5)(b), this information shall be considered in determining the duration of the time-limited review period in paragraph 8 of this Article.***	7. ***The duration of the time-limited authorisation will be determined on the basis of the information specified in Article 61(4)(eb) and taking into account other available information.***

Justification

Links the duration of the authorisation to the information contained in the substitution plan.

Amendment 103
ARTICLE 59, PARAGRAPH 8

8. Authorisations shall be subject to ***a time-limited*** review ***(whose duration shall be determined on a case-by-case basis) without prejudice to any decision on a future review period and shall normally*** be subject to conditions, including monitoring.	8. Authorisations shall be subject to review ***periods and to the presentation of substitution plans, and may*** be subject to ***other*** conditions, including monitoring. ***Authorisations shall be subject to a time-limit not exceeding five years.***

(Amendment 235 - first reading)

Justification

Authorisations must be subject to a time limit to give an incentive for innovation.

Amendment 104
ARTICLE 59, PARAGRAPH 9, POINTS (D) AND (E)

(d) ***any*** conditions under which the authorisation is granted;	(d) ***the*** conditions under which the authorisation is granted;
(e) the ***time-limited*** review period;	(e) the review period;

(Amendment 236 and 359 (partially) - first reading)

Justification

Clarifies the wording.

Amendment 105
ARTICLE 60, PARAGRAPH 1, SUBPARAGRAPHS 1 TO 3

1. Authorisations ***granted in accordance with Article 59*** shall be regarded as valid until the Commission decides ***to amend or withdraw the authorisation in the context of a review***, provided that the holder of the authorisation submits a ***review report*** at least 18 months before the expiry of the ***time-limited review period***. Rather than re-submitting all elements of the original application for the current authorisation, the	1. Authorisations shall be regarded as valid until the Commission decides ***on a new application***, provided that the holder of the authorisation submits a ***new application*** at least 18 months before the expiry of the ***time-limit***. Rather than re-submitting all elements of the original application for the current authorisation, the ***applicant*** may submit only***:***

holder of an authorisation may submit only the number of the current authorisation, ***subject to the second, third and fourth subparagraphs.***	
A holder of an authorisation granted in accordance with Article 59 shall submit an update of any substitution plan included in his application. If the holder cannot demonstrate that the risk is adequately controlled, he shall submit an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application***.***	***(a)*** the number of the current authorisation, ***(b)*** an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application***,***
If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.	***(c)*** an update of the chemical safety report.

(Amendment 237 - first reading)

Justification

During the review of an authorisation the applicant needs only to re-submit the elements of the original application that need to be updated.

Linked to amendment to Article 54.

Amendment 106
ARTICLE 60, PARAGRAPH 2, INTRODUCTION

2. Authorisations ***may*** be reviewed at any time if:	2. Authorisations ***shall*** be reviewed at any time if:

(Amendment 238 (partially) - first reading)

Justification

This amendment enables the Agency to react quickly to changing circumstances. Authorisations should be automatically reviewed if the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact or new information on possible substitutes becomes available.

Introduces the obligation to review authorisations if the circumstances have changed.

Amendment 107
ARTICLE 60, PARAGRAPH 3, SUBPARAGRAPH 2

In cases where there is a ***serious and immediate*** risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account the principle of proportionality.	In cases where there is a risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account the principle of proportionality.

(Amendment 239 - first reading)

Justification

No criteria exist for the definition of a 'serious and immediate' risk. It is therefore up to the Commission to decide, on the basis of criteria, whether or not to suspend authorisation during the review.

Amendment 108
ARTICLE 60, PARAGRAPH 4

4. If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned ***may*** be reviewed.	4. If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned ***shall*** be reviewed.

(Amendment 240 - first reading)

Justification

This amendment ensures coherence with the IPPC Directive and enables the Agency to react to changing circumstances by introducing an obligation to review authorisations.

Amendment 109
ARTICLE 60, PARAGRAPH 5

5. If the environmental objectives as referred to in Article 4(1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin ***may*** be reviewed**.**	5. If the environmental objectives as referred to in Article 4(1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin ***shall*** be reviewed**.**

(New amendment - Rule 62(2)(d) in light of COM 2006/397 of 17 July 2006)

Justification

In July 2006, the Commission adopted a proposal for a new daughter directive on

environmental quality standards in the field of water policy with reference to Article 4(1) of Directive 2000/60. With the new directive, the Commission intends to rely on external tools, such as e.g. REACH, to implement emission limit measures in line with proposed environmental objectives. To prevent any "passing of the buck", it must be ensured that the necessary objectives can be achieved via REACH via compulsory revision of any authorisation if the environmental objectives are not met.

Amendment 110
ARTICLE 61, PARAGRAPH 5

5. The application may include:	
(a) a socio-economic analysis conducted in accordance with Annex XVI;	***(ea)*** a socio-economic analysis conducted in accordance with Annex XVI;
(b) where appropriate a substitution plan, including research and development and a timetable for proposed actions by the applicant;	***(eb)*** a substitution plan, including research and development and a timetable for proposed actions by the applicant.
(c) a justification for not considering risks to human health and the environment arising either from:	***5. The application may also include*** a justification for not considering risks to human health and the environment arising either from:
(i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or	(i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or
(ii) discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.	(ii) discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.

(Amendment 241 (revised) - first reading)

Justification

The socio-economic analyses and the substitution plan must be included in the application for authorisation.

Amendment 111
ARTICLE 62

1. If an application has been made for a use of a substance, a subsequent applicant may refer to the parts of the previous application	1. If an application has been made for a use of a substance, a subsequent applicant may refer to the parts of the previous application

submitted in accordance with Article 61(4)(d) ***and (5)(a)*** and ***(b)***, provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.	submitted in accordance with Article 61(4)(d), ***(ea) and (eb)***, provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.
2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the parts of the holder's application submitted in accordance with Article 61(4)(d) ***and (5)(a)*** and ***(b)***, provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.	2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the parts of the holder's application submitted in accordance with Article 61(4)(d), ***(ea) and (eb)***, provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.

Justification

Linked to the amendment to Article 61.

Amendment 112
ARTICLE 63, PARAGRAPH 4

4. The draft opinions shall include the following elements:	4. The draft opinions shall include the following elements:
(a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance as described in the application and***, if relevant,*** an assessment of the risks arising from possible alternatives;	(a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance as described in the application and an assessment of the risks arising from possible alternatives;
(b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application***, when an application is made in accordance with Article 61(5)***.	(b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application.

Justification

Linked to the amendment to Article 61.

Amendment 113
ARTICLE 63, PARAGRAPH 8

8. The Commission shall prepare a draft	8. The Commission shall prepare a draft

authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article ***132(2)***.	authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article ***132(3a)***.

Justification

This amendment is tabled in light of a judgement by the European Court of Justice of 23 February 2006 C-122/04 on "Forest Focus" and of the new "commitology" Decision. In its judgement in case C-122/04, the Court of Justice found that the Commission has to justify when it wants to deviate from the criteria for the choice of the committee procedure, otherwise the act can be annulled. The Commission proposed the advisory procedure for the granting of authorisations without any justification - even though such a decision is clearly of general scope (see Art. 55(2), 57(1c) and 61(2) and (3)), and should therefore have come under the regulatory procedure.

In accordance with the new "commitology" Decision, the new "regulatory procedure with scrutiny" should apply.

Amendment 114
ARTICLE 64

Obligation of ***holders of*** authorisations	Obligation of ***information on substances subject to*** authorisations
Holders of an authorisation, as well as downstream users referred to in Article 55(2) including the substances in a preparation, shall include the authorisation number on the label before they place the substance or a preparation containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 63(9).	***All substances, for use on their own, in preparations or in articles, that fulfil the conditions set out in Article 56 shall be labelled and accompanied, at all times, by a safety data sheet. The label shall include:***
	(a) the name of the substance,
	(b) attestation that the substance is included in Annex XIV, and
	(c) each specific use for which the substance has been authorised.

(Amendment 246 - first reading)

Justification

More comprehensive wording.

Amendment 115
ARTICLE 66, PARAGRAPH 2 A (new)

2a. The Agency shall inform immediately/without delay/ post on its website that a Member State or the Commission intend to instigate a restriction process and shall inform those who posted a registration for the concerned substance.

Justification
Corresponds to Amendment 789 adopted in First Reading.

Restrictions may apply without tonnage limit i.e. below 1t/y. There is a right to know for all interested parties about the restriction intentions of the Agency or the Member States.

Amendment 116
ARTICLE 66, PARAGRAPH 3

Until …*, a Member State may maintain any existing ***and*** more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by …**.	Until …*, a Member State may maintain any existing ***or*** more stringent restrictions ***as well as any implementing measures thereof*** in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by …**.

Justification

The restrictions of Directive 76/769 will be carried over into REACH. As a regulation, REACH is directly applicable in the Member States. All implementing measures would be repealed. However, restrictions often depend on national implementing measures to be effective. To avoid any undermining of current restrictions at EU or national level, Member States should be allowed to keep all national implementing measures during a transitional period during which the restrictions under REACH can be amended where necessary to maintain effective implementation.

Amendment 117
ARTICLE 67, PARAGRAPH 1, SUBPARAGRAPH 1

1. When there is an unacceptable risk to ***human health or the environment***, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3)*** by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 68 to 72. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.	1. When there is an unacceptable risk to ***the environment or to human health, including that of vulnerable populations and citizens exposed early in life or continuously to mixtures of pollutants***, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3a)*** by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 68 to 72. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

Justification

Those must vulnerable should be explicitly included when unacceptable risks to human health are being identified. This re-tables the Parliament amendment 248.
The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 118
ARTICLE 67, PARAGRAPH 2

2. For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3)***. Articles 68 to 72 shall not apply.	2. For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3a)***. Articles 68 to 72 shall not apply.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 119
ARTICLE 68, PARAGRAPH 2

2. After the date referred to in Article ***57(1)(c)(i)*** for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.	2. After the date referred to in Article ***57(1)(c)(ii)*** for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.

Justification

This new paragraph is welcome, as it closes a loophole in the authorisation system via restrictions on the use of substances of very high concern in articles. This is relevant for import articles, as they are not covered by authorisations. However, it should be possible to start the restrictions procedure when it is known for which no applications authorisations have been requested, and not only after the sunset date. Otherwise, there would temporarily be a double standard: imported articles could contain substances of very high concern, which are not authorised anymore for EU articles.

Amendment 120
ARTICLE 72

1. If the conditions laid down in Article 67 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the opinion of the Committee for Socio-economic Analysis or by the end of the deadline established under Article 70 if that Committee does not form an opinion, whichever is the earlier.	1. ***Where a substance is already regulated in Annex XVII, and*** if the conditions laid down in Article 67 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the opinion of the Committee for Socio-economic Analysis or by the end of the deadline established under Article 70 if that Committee does not form an opinion, whichever is the earlier.
Where the draft amendment diverges from	Where the draft amendment diverges from

the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences.	the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences.
2. A final decision shall be taken in accordance with the procedure referred to in Article ***132(3)***. The Commission shall send the draft amendment to the Member States at least 45 days before voting.	2. A final decision shall be taken in accordance with the procedure referred to in Article ***132(3a)***. The Commission shall send the draft amendment to the Member States at least 45 days before voting.
	2a. Where a substance has not been regulated before in Annex XVII, the Commission shall submit a proposal to the European Parliament and the Council to amend Annex XVII within the time limit specified in paragraph 1.

(Amendment 251 (partially) - first reading)

Justification

In the current Directive 76/769/EEC the European Parliament and the Council have a role in decisions on certain restrictions of chemicals such as prohibiting the use of phthalates in certain toys. This amendment aims to keep this procedure and not further increase the role of the Commission.

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 121
ARTICLE 75, PARAGRAPH 1, POINT (D)

(d) a Committee for Socio-economic Analysis, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of this Regulation relating to the socio-economic impact of possible legislative action on substances;	(d) a Committee for Socio-economic Analysis ***and Alternative Assessment***, which shall be responsible for ***evaluating the availability, suitability and technical feasibility of alternatives,*** preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of this Regulation relating to the socio-economic impact of possible legislative action on substances;

(Amendment 255 revised - first reading)

Justification

Reinforces the links between the authorisation procedure and the availability of safer alternatives while aligning the responsibility of the Committee with its role in the assessment of the alternatives as defined in article 63(4).

The change in the name of the Committee will apply throughout the text of the regulation.

Amendment 122
ARTICLE 75, PARAGRAPH 1, POINT (D A) (new)

(da) a Committee for Alternative Test Methods, which shall be responsible for developing and implementing an integrated strategy to speed up the development, validation and legal acceptance of non-animal test methods, and to ensure their use in intelligent stepwise risk assessment to meet the requirements of this Regulation. The Committee shall be responsible for allocating funding for alternative test methods provided through the registration fee. The Committee shall consist of experts from the European Centre for the Validation of Alternative Methods, animal welfare organisations and other relevant stakeholders.

Every year the Committee shall produce a report to be presented by the Agency to the European Parliament and the Council on the progress made on the development, validation and legal acceptance of non-animal test methods, the use of such methods in intelligent stepwise risk assessment to meet the requirements of this Regulation, and the amount and distribution of funding for alternative test methods.

(Amendment 257 - first reading)

Justification

Linked to amendments of Recital 92. The objective of this Regulation to promote non-animal

testing should be included in the mandate and work of the Agency to ensure its effective implementation. The development, validation, legal acceptance and use of alternative test methods is often hampered by a lack of strategic planning and coordination. Therefore the Agency should have a Committee consisting of experts in the field of alternative test methods with the mandate to develop and implement such strategic planning and to ensure that alternative test methods are used in intelligent, flexible risk assessment wherever possible to prevent animal testing and save costs. The Committee should also allocate funding for alternative test methods and produce a yearly report on the progress made to ensure transparency.

Amendment 123
ARTICLE 76, PARAGRAPH 2, POINTS (D) AND (E)

(d) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list. It shall make the information identified in Article 118(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 117;	(d) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list. It shall make the information identified in Article 118(1) and (2) in the database(s) publicly available, ***within 15 working days,*** free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified ***and not overridden by public interest***. The Agency shall make other information in the databases available on request in accordance with Article 117;
(e) making publicly available information as to which substances are being, and have been evaluated within ***90*** days of receipt of the information at the Agency, in accordance with Article 118(1);	(e) making publicly available information as to which substances are being, and have been evaluated within ***15 working*** days of receipt of the information at the Agency, in accordance with Article 118(1);

Justification

In line with Article 4(2) of Regulation 1049/2001 on access to documents, the access to a document can only be refused on the basis of commercial interests if there is no overriding public interest. A reference to overriding public interest should therefore be added here.

According to Regulation 1049/2001, the standard response time should be 15 working days.

Amendment 124
ARTICLE 76, PARAGRAPH 2, POINT (G A) (new)

	(ga) publishing on its website a list of

substances that have been identified as fulfilling the criteria referred to in Article 56, one year after the entry into force of this Regulation. This list shall be updated periodically;

(Amendment 263 letter gd - first reading)

Justification

The list of substances fulfilling the criteria for authorisation should be made public.

Amendment 125
ARTICLE 76, PARAGRAPH 2, POINT (M A) (new)

(ma) establishing and maintaining a centre of excellence for risk communication; providing centralised, coordinated resources in the area of information on the safe use of chemical substances, preparations and articles; facilitating the sharing of best practice in the risk communication sector.

(Amendment 263, point gb) of first reading)

Justification

Successful First Reading amendment seeking to enable consumers to use substances, preparations and products containing chemicals safely.

The development of an appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to use substances, preparations and products containing chemicals safely and effectively.

Amendment 126
ARTICLE 76, PARAGRAPH 3, POINT C

(c) at the Commission's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles.	(c) at the Commission's ***or the European Parliament's*** request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles.

(Amendment 260 letter f) - first reading)

Justification

Parliament should also have the right to request opinions from the Agency, as it is the case for instance with EFSA.

Amendment 127
ARTICLE 76, PARAGRAPH 4, POINT D

(d) identifying enforcement strategies, as well as best practice in enforcement;	(d) identifying enforcement strategies, as well as best practice in enforcement***, taking particular account of the specific problems for SMEs***;

(Amendment 262 letter d) - first reading)

Justification

Particular help should be given to SMEs for the enforcement of REACH.

Amendment 128

ARTICLE 77, SUBPARAGRAPH 3

It shall adopt the internal rules and procedures of the Agency. ***These rules shall be made public.***	It shall adopt the internal rules and procedures of the Agency.

Justification

Amendment necessitated by the amendment to Article 108.

Amendment 129
ARTICLE 78, PARAGRAPH 1

1. The Management Board shall be composed of one representative from each Member State and a maximum of six representatives appointed by the Commission***, including three individuals from*** interested parties without voting rights. ***Each Member State shall nominate a***	1. The Management Board shall be composed of one representative from each Member State***,*** and a maximum of six representatives appointed by the Commission ***and two representatives nominated by the European Parliament.*** ***In addition, four representatives of*** interested parties ***(industry and consumer,***

member to the Management Board. The members thus nominated shall be appointed by the Council.	***worker and environmental protection organisations) shall be nominated by the Commission as members of the Management Board*** without voting rights***.***
	The members of the Management Board shall be nominated in such a way as to ensure the highest levels of competence, a wide range of relevant specialist knowledge and (without prejudice to such characteristics) the broadest possible geographical distribution within the European Union.

(Amendment 267 (revised) - first reading)

Justification

This restates Parliament's traditional view as regards the composition of, and the arrangements for appointing, the Management Board, based on the EMEA model. The number of representatives from interested parties is increased from three to four in order to enable all the relevant sectors to be included.

Amendment 130
ARTICLE 78, PARAGRAPH 3

3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission shall identify half of ***its appointees,*** and the Council shall identify 12 of its appointees***,*** for whom this period shall be six years.	3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission ***and the European Parliament shall each identify half of their appointees*** and the Council shall identify 12 of its appointees, for whom this period shall be six years.

(Amendment 360 revised - first reading)

Justification

Consequent to amendment to Article 78(1).

Amendment 131
ARTICLE 78, PARAGRAPH 3 A (new)

	3a. The list drawn up by the Commission shall be forwarded to the European

Parliament, together with the relevant background documents. Within three months of notification the European Parliament may submit its view for consideration to the Council, which shall then appoint the Management Board.

(Amendment 1037 - first reading)

Justification

The involvement of the European Parliament in the appointment of the Management Board should be facilitated.

Amendment 132
ARTICLE 79, PARAGRAPH 2 A (new)

2a. The elected Chairman shall introduce himself to the European Parliament.

(Amendment 269 - first reading)

Justification

With the aim of strengthening democracy and accountability the European Parliament should be given a possibility to get to know the Chairman and his programme.

Amendment 133
ARTICLE 82, PARAGRAPH 1

1. The Agency shall be managed by its Executive Director***, who shall perform his duties in the interests of the Community, and independently of any specific interests***.	1. The Agency shall be managed by its Executive Director.

(Amendment 272 - first reading)

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see the amendment to Article 87).

Amendment 134
ARTICLE 82, PARAGRAPH 2, POINT (J A) (new)

(ja) establishing and maintaining contact with the European Parliament and ensuring that a regular dialogue is held with that institution's relevant committees;

(Amendment 273 - first reading)

Justification

Restates the European Parliament's traditional view on relations with agencies.

Amendment 135
ARTICLE 82, PARAGRAPH 3 A (new)

3a. Once the general report and the programmes have been approved 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.

(Amendment 276 - first reading)

Justification

Restates the European Parliament's traditional view on relations with agencies.

Amendment 136
ARTICLE 83, PARAGRAPH 1

1. The Commission shall propose candidates for the post of the Executive Director based on a list following publication of the post in the Official Journal of the European Union and other press or Internet sites as appropriate.	***deleted***

(Amendment 277 - first reading)

Justification

Linked to the amendment to Article 83, paragraph 2.

Amendment 137
ARTICLE 83, PARAGRAPH 2, SUBPARAGRAPH 1

2. The Executive Director of the Agency shall be appointed by the Management Board on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The Management Board shall take its decision by a two-thirds majority of all members with a right to vote.	2. The Executive Director of the Agency shall be appointed by the Management Board ***from among a list of candidates proposed by the Commission following a public-selection procedure advertised by means of a call for expressions of interest published in the Official Journal of the European Union and in other periodicals or on Internet sites. Prior to nomination the candidate designated by the Management Board shall be asked as soon as possible to make a statement before the European Parliament and to answer questions from Parliament's Members.*** ***The Executive Director shall be nominated*** on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The Management Board shall take its decision by a two-thirds majority of all members with a right to vote.

(Amendment 278 - first reading)

Justification

This restates Parliament's traditional view (which was accepted by the Council in connection with the European Food Safety Authority and the Agency for the Evaluation of Medicinal Products) as regards the procedure for nominating executive directors.

Amendment 138
ARTICLE 84, PARAGRAPHS 1 TO 7

1. Each Member State ***may nominate candidates to membership of*** the Committee for Risk Assessment. ***The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates.*** Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3).	1. Each Member State ***shall appoint one member to*** the Committee for Risk Assessment. Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3).
2. Each Member State ***may nominate candidates to membership of*** the Committee for Socio-economic Analysis. ***The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates.*** Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3).	2. Each Member State ***shall appoint one member to*** the Committee for Socio-economic Analysis. Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3).
3. Each Member State shall appoint one member to the Member State Committee.	3. Each Member State shall appoint one member to the Member State Committee.
4. The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.	4. The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.
Members of the Committees shall be appointed for a term of three years which shall be renewable.	Members of the Committees shall be appointed for a term of three years which shall be renewable.
The members of the Management Board may not be members of the Committees. The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.	The members of the Management Board may not be members of the Committees. The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.
The Executive Director or his representative and representatives of the	The Executive Director or his representative and representatives of the

Commission shall be entitled to attend all the meetings of the Committees and working groups convened by the Agency or its committees as observers. Stakeholders may also ***be invited to*** attend meetings as observers***, as appropriate, at the request of the Committee members, or the Management Board***.	Commission shall be entitled to attend all the meetings of the Committees and working groups convened by the Agency or its committees as observers. Stakeholders may also attend meetings as observers.
5. The members of each Committee ***appointed following nomination by a Member State*** shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.	5. The members of each Committee shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.
6. The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.	6. The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.
7. The Member States shall refrain from giving the members of the Committee for Risk Assessment or of the Committee for Socio-Economic Analysis, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.	

(Amendment 279 - first reading)

Justification

All Member States should be present in the committees. The presence of stakeholders at meetings of the committees should not be by invitation only. All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see amendment to Article 87).

This clarifies the procedure for nominating the chairman of the Member State Committee.

Amendment 139

ARTICLE 85, PARAGRAPHS 1 TO 3

1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.	1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.
The Forum shall aim to have a broad range of relevant expertise among its members. To this end the Forum may coopt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable.	The Forum shall aim to have a broad range of relevant expertise among its members. To this end the Forum may coopt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable.
The members of the Forum may be accompanied by scientific and technical advisers.	The members of the Forum may be accompanied by scientific and technical advisers.
The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also ***be invited to*** attend meetings as observers***, as appropriate, at the request of Forum members, or the Management Board***.	The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also attend meetings as observers.
	Members of the Forum may not be members of the Management Board.
2. The members of the Forum appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State competent authority.	2. The members of the Forum appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State competent authority.
3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. ***The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of***	3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups.

those persons or with the tasks and responsibilities of the Forum.

(Amendment 280 - first reading)

Justification

The presence of stakeholders at meetings of the committees should not be by invitation only. All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see amendment to Article 87).

Amendment 140
ARTICLE 86, PARAGRAPH 1

1. Where, in accordance with Article 76, a Committee is required to ***take a decision,*** provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. ***For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.*** A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.	1. Where, in accordance with Article 76, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

(Amendment 281 - first reading)

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (cf. amendment to

Article 87).

Amendment 141
ARTICLE 86, PARAGRAPH 2, SUBPARAGRAPH 1

2. Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 76, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.	2. Member States shall transmit to the Agency the names of ***independent*** experts with proven experience in the tasks required by Article 76, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

Justification

This amendment ensures the independence of experts. The relevant part of EP amendment 282 is re-tabled.

It should be specified that the experts should be independent.

Amendment 142
ARTICLE 87

Qualification and interests	***Independence***
1. The membership of the Committees and of the Forum shall be made public. ***Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests.*** When each appointment is published, the professional qualifications of each member shall be specified.	1. The membership of the Committees and of the Forum shall be made public. When each appointment is published, the professional qualifications of each member shall be specified.
2. Members of the Management Board, the Executive Director ***and*** members of the Committees ***and*** of the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests ***which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing.***	2. Members of the Management Board, the Executive Director***,*** members of the Committees***, members*** of the Forum***, members of the Board of Appeal, experts and scientific and technical advisers shall not have economic or other interests in the chemical sector which may prejudice their impartiality. They shall undertake to act independently and in the public interest and*** shall ***each year*** make a declaration of ***their financial*** interests***. Any***

	indirect interests relating to the chemical industry shall be declared in a register held by the Agency and accessible to the public on request at the Agency's offices.
	Member States shall refrain from giving the members of the Risk Assessment Committee, of the Socio-Economic Analysis Committee, of the Forum or of the Board of Appeal, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.
	The Agency's code of practice shall specify measures relating to the application of this article.
3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees ***and*** of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall ***not*** participate in any voting ***on the relevant agenda point***.	3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees***, members*** of the Forum and any experts ***and scientific and technical advisers*** participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall ***participate neither in the discussion of the relevant agenda points nor*** in any voting ***thereupon***. ***Such declarations shall be made publicly accessible.***

(Amendment 285 - first reading)

Justification

This restates Parliament's traditional view (which was accepted by the Council in connection with the European Food Safety Authority and the Agency for the Evaluation of Medicinal Products) as regards independence of members of committees and boards, their declaration of financial interests and indirect interests in the sector.

Amendment 143
ARTICLE 88, PARAGRAPH 3, SUBPARAGRAPH 1

3. The Chairman, the other members and	3. The Chairman, the other members and

the alternates shall be appointed by the Management Board on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures ***from a list of qualified candidates adopted by the Commission***.	the alternates shall be appointed by the Management Board ***from among a list of qualified candidates proposed by the Commission following a public-selection procedure advertised by means of a call for expressions of interest published in the Official Journal of the European Union and in other periodicals or on Internet sites. The members of the Board of Appeal shall be selected*** on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures.

(Amendment 286 - first reading)

Justification

In view of the nature of the tasks to be performed by the Board of Appeal, a transparent procedure for the submission of applications should be introduced.

Amendment 144
ARTICLE 88, PARAGRAPH 4

4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3)***.	4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3a)***.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 145
ARTICLE 89, PARAGRAPHS 2 AND 3

2. The Members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.	
3. The members of the Board of Appeal	3. The members of the Board of Appeal

may not perform any other duties in the Agency. ***The function of the Members may be a part-time function.***	may not perform any other duties in the Agency.

(Amendment 287 - first reading)

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article in the interests of greater clarity. Even though the number of appeal cases may enable the members of the Board of Appeal to engage in other activities, their function will continue to be a full-time one.

Amendment 146
ARTICLE 90, PARAGRAPH 1

1. An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 50.	1. An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3)***,*** Article 50 ***and Article 59***.

(Amendment 288 - first reading)

Justification

For consistency authorisation decisions should also be subject to the Appeal process.

Amendment 147
ARTICLE 92, PARAGRAPH 4

4. The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3)***.	4. The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3a)***.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 148

ARTICLE 108

To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles ***which is not of a confidential nature***.	To ensure ***maximum*** transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules ***and set up a registry*** to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles***, pursuant to Regulation (EC) No 1049/2001.*** ***The internal rules of procedure of the Agency and of the Committees and working groups thereof shall be made available to the public via the Agency and on the Internet.*** ***The applications for authorisation submitted, the stage reached in the procedure, interim decisions, authorisations and any other condition or restriction imposed shall be published on the Internet in a comprehensible form.***

(Amendment 294 - first reading)

Justification

This restates Parliament's traditional view (which was accepted by the Council in connection with the Regulation governing the Agency for the Evaluation of Medicinal Products) as regards transparency and access to information.

Amendment 149
ARTICLE 112, PARAGRAPH 2

2. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.	2. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. ***If no such an agreement can be found, the Agency shall establish the entry, at a fee set accordingly.***

Justification

This amendment is a modification of first reading amendment 295, taking into account the need for incentives for the actors themselves to find an agreement rather than expecting the Agency to act first. For downstream users, it is imperative that the classification of the same substance, produced by different suppliers, is the same. Without it, it's likely that environmental as well as commercial concerns are compromised.

Amendment 150
ARTICLE 116 A (new)

Article 116a

Special provisions for information to the general public

1. In order to help consumers to make safe and sustainable use of substances and preparations, without prejudice to current labelling requirements, manufacturers shall make available risk-based information, via an on-pack label on each unit placed on the market for sale to the consumer that identifies risks associated with recommended use or foreseeable misuse situations. Furthermore, on-pack labelling shall be complemented, when appropriate, by the use of other channels of communication, such as websites, for the provision of more detailed safety and use information in relation to the substance or preparation.

2. Directives 1999/45/EC and 67/548/EEC shall be amended accordingly.

Justification

Successful First Reading amendment.
Corresponds to Amendment 298 First Reading.

The development of an appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to use substances, preparations and products containing chemicals safely and effectively.

Amendment 151
ARTICLE 124

Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.	Member States shall maintain a system of official controls and other activities as appropriate to the circumstances ***in accordance with the guidelines to be drawn up by the Agency***.

Justification
Corresponds to Amendment 816 adopted in First Reading.

To enable REACH to be implemented consistently, the Agency should be entitled to require Member States to carry out particular checks and activities.

Amendment 152
ARTICLE 124 A (new)

	The Agency shall be authorised by the Member States to initiate controls and activities and shall establish guidelines for the control system's harmonisation and effectiveness.

Justification
Corresponds to Amendment 817 adopted in First Reading.

The management of the REACH system calls for the harmonised implementation of its provisions throughout the common market and on an effective system of controls. The Agency should therefore be in a position to call on the Member States to carry out controls or activities.

Amendment 153
ARTICLE 125

Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and ***shall take*** all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later	***On the basis of a set of guidelines drawn up by the Agency,*** provisions ***shall be laid down concerning the*** penalties applicable for infringement of the provisions of this Regulation and all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the

than **…*** and shall notify ***it*** without delay of any subsequent amendment affecting them.	Commission ***and the Agency*** no later than ***...**** and shall notify ***them*** without delay of any subsequent amendment affecting them.

Justification

Corresponds to Amendment 818 adopted in First Reading.

To leave the system of penalties to the Member States' discretion would lead to the existence of differing penalties within the Union. If the objectives of REACH are to be attained, there must be a harmonised system of penalties and harmonised implementation.

Amendment 154
ARTICLE 127, PARAGRAPH 1 A (new)

	1a. Paragraph 1 shall not affect the right of Member States to maintain or introduce more stringent protective measures in accordance with Community legislation on worker protection.

(Amendment 309 - first reading)

Justification

Provisions adopted pursuant to Article 137 of the Treaty establishing the European Community should not prevent Member States from maintaining or introducing more stringent protective measures. This includes provisions on worker protection. If a chemical safety assessment has been carried out for a substance, it may be assumed that the protection of workers is adequately ensured. It is therefore proposed that in other cases the right of Member States to adopt more stringent measures should not be restricted.

Amendment 155
ARTICLE 130

The Annexes may be amended in accordance with the procedure referred to in Article ***132(3)***.	The Annexes may be amended in accordance with the procedure referred to in Article ***132(3a)***.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 156
ARTICLE 131

The measures necessary for the efficient implementation of this Regulation shall be adopted in accordance with the procedure referred to in Article 132(3).	***Where,*** for the efficient implementation of this Regulation***, it proves necessary to adopt measures for which the powers have not been provided elsewhere in this Regulation, these measures*** shall be adopted: ***(a)*** in accordance with the procedure referred to in Article 132(3), ***when the measures to be adopted are measures of general scope designed to apply essential provisions of this Regulation;*** ***(b) in accordance with the procedure referred to in Article 132(3a), when the measures to be adopted are measures of general scope designed to amend non-essential elements of this Regulation.***

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to distinguish between the ordinary "regulatory committee" procedure and the "regulatory committee with scrutiny".

Amendment 157
ARTICLE 132, PARAGRAPH 3 A (new)

	3a. Where reference is made to this paragraph, Articles 5a and 7 of Decision 1999/468/EC as amended by Decision 2006/512/EC shall apply.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to include the "regulatory committee with scrutiny", since some the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 158
ARTICLE 133

Transitional measures regarding the Agency	***Preparation of establishment of the Agency***

1. The Commission shall ***provide*** the necessary support towards ***the setting up*** of the Agency.	1. The Commission shall ***afford*** the necessary support ***towards the establishment*** of the Agency.
2. For that purpose, until such time as the Executive Director ***is appointed*** in accordance with Article 83, the Commission, on behalf of the Agency, ***thereby*** using the budget provided for the latter, may appoint personnel, including a person who shall fulfil the ***administrative*** functions of the Executive Director on an interim basis, and conclude other contracts***.***	2. For that purpose, until such time as the Executive Director ***assumes his duties following his appointment by the Management Board*** in accordance with Article 83, the Commission, on behalf of the Agency, ***and*** using the budget provided for the latter, may: ***(a)*** appoint personnel, including a person who shall fulfil the functions of the Executive Director on an interim basis; and ***(b)*** conclude other contracts.

Justification

Corresponds to Amendment 822 adopted in First Reading.

A proper establishment and operation of the Agency is critical to the success of REACH. The Agency must be operationally independent from the Commission, and the Commission shall not fulfil such operational tasks set out in the Regulation on behalf of the Agency. If the Commission is not fulfilling the role of the Agency, there is no need for the Agency to notify the Commission that it is ready to take over the tasks from the Commission. The Commission, however, should help to establish the Agency until its Management Board has appointed an Executive Director. This should include recruitment of staff and conclusion of necessary contracts for services, goods and buildings.

Amendment 159
ARTICLE 137, PARAGRAPH 2, INTRODUCTORY PART

2. The Commission ***may*** present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:	2. The Commission ***shall*** present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, ***but no later than 6 years after entry into force of this Regulation,*** and after publishing a report on the following:

(Amendment 313 - first reading)

Justification

It should not be left to the discretion of the Commission if and when it presents a proposal for the registration of polymers. Such registration had been foreseen in the draft text that had

been submitted to internet consultation. A deadline needs to be set to encourage the development of a practicable and cost-efficient way of selecting polymers for registration.

Amendment 160
ARTICLE 137, PARAGRAPH 4

4. The Commission shall carry out a review of Annexes ***I***, IV and V by …*, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article ***132(3)***.	4. The Commission shall carry out a review of Annexes IV and V by …*, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article ***132(3a)***.

Justification

Linked to the amendment to article 59(2), it deletes the reference to the review of Annex I introduced by the Council in connection with the development of methodologies to establish thresholds for carcinogenic and mutagenic substances.

It also aligns the text to the provisions of the new "commitology" Decision, and in particular replaces the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 161
ARTICLE 137, PARAGRAPH 4 A (new)

	4a. By …* the Commission shall carry out a review of the threshold of 1 tonne per year per manufacturer or importer for registration and of the information requirements pursuant to Article 12 for nanoparticles. On the basis of that review, the Commission shall present appropriate legislative proposals to modify the tonnage threshold and the information requirements for nanoparticles to ensure adequate risk assessment, and risk reductions, where necessary, so as to achieve a high level of protection of human health and the environment with regard to nanoparticles.
	**** 18 months after entry into force of this Regulation.***

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of SCENIHR of 10 March 2006)

Justification

The major gaps in the knowledge for risk assessment of nanoparticles, as stated by SCENIHR, as well as their conclusions stating a need for modifications of existing methods point to the urgent need of a review of the provisions of REACH to ensure adequate risk assessment, and risk reductions, where necessary, with regard to engineered nanoparticles.

Amendment 162
ARTICLE 139

Article 14 of Directive 1999/45/EC shall be deleted.	Article 14 of Directive 1999/45/EC shall be deleted. ***Directive 1999/45/EC shall be amended to ensure that consumers receive the information required in order to take adequate measures to use substances and preparations safely.***

Justification

The development of an adequate and coherent communication system based on risk will make it possible for consumers to obtain the information and advice they require in order to use substances and preparations safely and effectively.

Amendment 163
ANNEX I, PART 1, POINT 1.4.1

1.4.1. Based on the outcomes of steps 1 and 2, a ***DNEL***(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. For some endpoints, especially mutagenicity and carcinogenicity, the available information may not enable a threshold, and therefore a DNEL, to be established**.** If justified by the exposure scenario (s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g., workers, consumers and humans liable to exposure indirectly via the environment) and ***possibly*** for ***certain***	1.4.1 Based on the outcomes of steps 1 and 2, a ***Derived No-Effect Level***(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. For some endpoints, especially mutagenicity and carcinogenicity, the available information may not enable a threshold, and therefore a DNEL, to be established. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available data and the exposure scenario(s) in Section 9 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. workers, consumers and humans liable to exposure indirectly via the environment)

vulnerable ***sub-populations (e.g. children, pregnant women)*** and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, *inter alia*, be taken into account:	and for vulnerable ***populations*** and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the data used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall*, inter alia,* be taken into account:
(a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;	(a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
(b) the nature and severity of the effect;	(b) the nature and severity of the effect;
(c) ***the sensitivity of*** the human ***(sub-)*** population to which the quantitative and/or qualitative information on exposure applies.	(c) the human population to which the quantitative and/or qualitative information on exposure applies;
	(ca) particular susceptibilities of vulnerable populations;
	(cb) any indication of non-standard effects, especially where the mode of action remains unknown or insufficiently characterised;
	(cc) possible co-exposure to other chemicals.

Justification

Many diseases originate in the perinatal phase. Therefore vulnerable groups should also be included so that the safety levels determined are valid for protecting future generations. This re-tables EP amendment 320.

Amendment 164
ANNEX I, PART 5, POINT 5.0, INTRODUCTORY PART

The objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the	The objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the

environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance ***resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in sections 1 to 4***. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:	environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report:

(New amendment - Rule 62(2)(c))

Justification

While the additional reference by Council to the life-cycle is welcome, it does not make sense to speak of a life-cycle resulting from manufacture and use, as these are important parts of the life cycle that need to be considered as well.

To link the exposure assessment to the hazards identified has led to many conflicting interpretations. It could drastically reduce the scope of the risk assessment. There should be no confusion about the scope of the risk assessment.

Amendment 165
ANNEX III, POINT (A) A (new)

	(aa) nanoparticles,

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of SCENIHR of 10 March 2006)

Justification

So far, nanoparticles are often only produced in very low quantities. But given their major potential to create adverse biological effects, as a very minimum, nanoparticles between 1 and 10 tonnes should be considered to be priority substances for which at least the whole base set information of Annex VII should be provided in the absence of nanoparticle-specific tests.

Amendment 166
ANNEX III, POINT (B) (I)

(i) with dispersive or diffuse use(s) particularly where such substances are used in consumer ***preparations*** or incorporated into consumer articles; and	(i) with dispersive or diffuse use(s) particularly where such substances are used ***as such or*** in ***preparations for*** consumer ***use or professional use*** or incorporated into

consumer articles; and

(Part of Amendment 388 (paragraph b, first indent) - first reading)

Justification

Basic safety information should also be given for hazardous substances in quantities between 1 and 10 tonnes with dispersive or diffuse uses in the professional sector.

Amendment 167
ANNEX VIII, COLUMNS 1 AND 2, POINT 8.7

Column 1	Column 1
8.7. Reproductive toxicity	8.7. Reproductive toxicity
8.7.1. ***Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from*** available information on structurally related substances, from (Q)SAR estimates or from in vitro methods ***that the substance may be a developmental toxicant***.	8.7.1. ***An initial assessment of this endpoint shall take into consideration all*** available ***toxicological*** information ***(e.g. from the 28-day or 90-day study), in particular information*** on structurally related substances, from (Q)SAR estimates or from in vitro methods.
Column 2	Column 2
8.7.1. ***This study does not need to be conducted if:*** ***– the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or*** ***– the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or*** ***– relevant human exposure can be excluded in accordance with Annex XI section 3; or*** ***– a pre-natal developmental toxicity study (section 8.7.2 of this Annex) or a two-generation reproductive toxicity study (section 8.7.3 of this Annex) is available.*** ***If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity***	8.7.1 ***If the initial assessment shows that there is evidence that the substance may be a developmental or reproductive toxicant and the company does not introduce and recommend appropriate risk management measures as if it were classified as reprotoxic category 1 or 2, then suitable further reprotoxicity testing shall be performed by the registrant.*** ***The conditions stated for these studies in Annex IX apply.***

must be considered.

If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

In cases where there are serious concerns about the potential for adverse effects on fertility or development, either a pre-natal developmental toxicity study (Annex IX, section 8.7.2) or a two-generation reproductive toxicity study (Annex IX, section 8.7.3) may be proposed by the registrant instead of the screening study.

Justification

Corresponds to Amendment 405 adopted in First Reading.

This test demands a high number of animal tests and is therefore extremely cost-intensive. However, it delivers insufficient test results only. Therefore it is proposed to perform an initial assessment and depending on those results, other more reliable tests have to be performed, if necessary.

Amendment 168
ANNEX VIII, POINT 9.1.3., LEFT COLUMN

9.1.3. Short-term toxicity testing on fish***:*** The registrant may consider long-term toxicity testing instead of short-term.	9.1.3. Short-term toxicity testing on fish ***according to the Upper Threshold Concentration (UTC) Step-Down Approach.*** The registrant may consider long-term toxicity testing instead of short-term.

(New amendment according to Rule 62(2)(d) to take account of the formal validation of a "reduction" test by ECVAM on 21 March 2006)

Justification

Article 7.2 of Directive 86/609 stipulates that an animal experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available. On 21 March 2006, the ECVAM Scientific Advisory Committee unanimously endorsed the validity of the Upper Threshold

Concentration (UTC) Step-Down Approach, which is capable of reducing fish use in acute studies by 65-72%. This Annex should therefore be modified accordingly.

Amendment 169
ANNEX IX, POINT 8.7., RIGHT COLUMN, INDENT 3

- the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (.e.g. plasma/blood concentrations below the detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) ***and*** there is no or no significant human exposure.	- the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (.e.g. plasma/blood concentrations below the detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) ***or*** there is no or no significant human exposure.

Justification

In Annex IX, a two-generation study is replaced by the one-generation OECD 415 test extended with additional endpoints which are normally covered by the two-generation study (L. Cooper et al. in Critical reviews in Toxicology, 36:69-98, 2006). All relevant parameters of reproductive toxicity are hereby covered with the advantage of reducing the number of animals up to 50%. According to recent studies, the predictive value of animal tests for human pregnancy is limited. Sufficient information can also be gained through the proposed alternative.

Amendment 170
ANNEX XI, POINT 3.3

3.3. The Commission shall adopt criteria defining what constitutes adequate justification under Section 2 in accordance with the procedure referred to in Article ***132(3)*** by …*.	3.3. The Commission shall adopt criteria defining what constitutes adequate justification under Section 2 in accordance with the procedure referred to in Article ***132(3a)*** by …*.

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment 171

ANNEX XIII, PARAGRAPH 2 A (new)

The testing and assessment of many PBT and vPvB candidate substances create technical challenges. Thus, modifications of standard tests may be needed. Therefore, because the test results may not be directly related to a half-life in an environmental compartment or a BCF, expert judgment will be needed to determine whether the criteria are fulfilled.

Justification

This amendment is based on new information from a REACH Implementation Project (RIP). It emerged from a RIP that the type of data admissible for consideration under the Annex XIII criteria for P and B is too restrictive and fail to take account of the real world situation regarding test data availability. For the majority of known PBT chemicals their persistence/half-life has been extrapolated from other tests (such as the 'ready test') and as such they can't legally be said to meet the Annex XIII criterion. In the current list of HPV PBTs there is actually only 1 substance (endosulfan) which fulfils the Annex XIII criteria. All the others PB(T)s would be 'equivalent concern' PBTs. Furthermore, many proposed UNEP POPs also do not meet the Annex XIII criteria.

Amendment 172
ANNEX XVII, POINT 47 A, B, C, D, E (new)

Amendment by Parliament

Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
47a. Toluene ***CAS No 108-88-3***	***May not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,1 % by mass in adhesives and spray paints intended for sale to the general public.***
47b. Trichlorobenzene ***CAS No 120-82-1***	***May not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,1 % by mass for all uses except:*** ***— as an intermediate of synthesis, or***

	— as a process solvent in closed chemical applications for chlorination reactions,
	or
	— in the manufacture of 1,3,5 — trinitro — 2,4,6 — triaminobenzene (TATB)
47c. Polycyclic-aromatic hydrocarbons (PAH)	***1. Extender oils may not be placed on the market and used for the production of tyres or parts of tyres, if they contain:***
1. Benzo(a)pyrene (BaP)	***— more than 1 mg/kg BaP, or***
CAS No 50-32-8	***— more than 10 mg/kg of the sum of all listed PAHs.***
2. Benzo(e)pyrene (BeP)	***These limits are regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3 % by mass, as measured by the Institute of Petroleum standard IP346: 1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions — Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limit values of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is controlled by the manufacturer or importer every six months or after each major operational change, whichever is earlier.***
CAS No 192-97-2	
3. Benzo(a)anthracene (BaA)	
CAS No 56-55-3	
4. Chrysen (CHR)	
CAS No 218-01-9	
5. Benzo(b)fluoranthene (BbFA)	
CAS No 205-99-2	
6. Benzo(j)fluoranthene (BjFA)	
CAS No 205-82-3	
7. Benzo(k)fluoranthene (BkFA)	
CAS No 207-08-9	
8. Dibenzo(a, h)anthracene (DBAhA)	
CAS No 53-70-3	***2. Furthermore, the tyres and treads for retreading manufactured after 1 January 2010 may not be placed on the market if they contain extender oils exceeding the***
	limits indicated in paragraph 1.
	These limits are regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0,35 % Bay protons as measured and calculated by ISO 21461
	(Rubber vulcanised — Determination of aromaticity of oil in vulcanised rubber compounds).
	3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils

	exceeding the limits indicated in paragraph 1.
47d. The following phthalates (or other CAS- and EINECS numbers covering the substance): ***bis (2-ethylhexyl) phthalate (DEHP)*** ***CAS No 117-81-7 Einecs No 204-211-0*** ***dibutyl phthalate (DBP)*** ***CAS No 84-74-2 Einecs No 201-557-4*** ***benzyl butyl phthalate (BBP)*** ***CAS No 85-68-7 Einecs No 201-622-7***	***Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticised material, in toys and childcare articles.*** ***Such toys and childcare articles containing these phthalates in a concentration greater than the limit mentioned above shall not be placed on the market.***
47e. The following phthalates (or other CAS- and EINECS numbers covering the substance): ***di-"isononyl" phthalate (DINP)*** ***CAS No 28553-12-0 and 68515-48-0 Einecs No 249-079-5 and 271-090-9*** ***di-"isodecyl" phthalate (DIDP)*** ***CAS No 26761-40-0 and 68515-49-1 Einecs No 247-977-1 and 271-091-4*** ***di-n-octyl phthalate (DNOP) CAS No 117-84-0 Einecs No 204-214-7***	***Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.*** ***Such toys and childcare articles containing these phthalates in a concentration greater than the limit mentioned above shall not be placed on the market.***
	For the purposes of points 47d and 47e, "childcare article" means any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. ***The Commission shall re-evaluate, by 16 January 2010 at the latest, the measures provided for in relation to points 47d and 47e in the light of new scientific information on such substances and their substitutes, and if justified, these measures shall be modified accordingly.***

Justification

The list established in Annex XVII needs to be updated with the latest restriction measures adopted by Council and Parliament.

EXPLANATORY STATEMENT

The Council common position mirrors and in some respects enhances the healthy balance achieved by Parliament at first reading between the competitiveness of the European chemicals industry and protection of human health and the environment.

The rapporteur welcomes this approach and considers that agreement can be reached at second reading if the Council and Commission take a genuinely constructive stance in negotiations.

With a view to this, the rapporteur wishes to focus on a number of priorities relating to the purpose of the regulation which the Council failed properly to take into account. He reserves the right to raise further minor issues, if appropriate, following the discussions in committee.

The rapporteur therefore intends to retable a number of amendments which Parliament adopted by a large majority but which the Council did not see fit to include in its common position.

The principal aim is to strengthen the 'duty of care' principle for manufacturers and importers with a view to ensuring proper controls on substances placed on the market and adequate communication and information exchange in connection with the risks arising from their use.

A second batch of amendments on which the rapporteur intends to focus covers animal testing of substances. In particular, he intends to enhance the role of the European Centre for the Validation of Alternative Methods (ECVAM) and to foster the replacement of animal testing with an alternative method if the ECVAM acknowledges its scientific validity. Amendments on compulsory forwarding to the Agency of studies or information on substances obtained using animal testing and all those in respect of which this could be avoided, and on the establishment of a Committee for Alternative Test Methods, will also be retabled.

The rapporteur intends, furthermore, to retable a batch of amendments seeking to step up the exchange of information required for the purpose of assessing the health and environmental risks and effects of substances. In particular, this will reopen the possibility of establishing a European quality mark designed to identify and promote articles which, at each stage of the production process, have been produced in compliance with the REACH requirements.

The rapporteur also considers it essential to improve the Council common position by retabling amendments seeking to make the system more manageable, particularly in view of the problems small and medium-sized undertakings are likely to have in implementing it. Amendments providing for aid and support mechanisms for small and medium-sized undertakings and for the adoption of special assistance measures by Member States will therefore be retabled.

The rapporteur sees it as a priority to enhance Parliament's prerogatives and give it a more incisive role in the process of establishing the Agency and in monitoring the results obtained.

A few other amendments dealing with specific issues in respect of which, in the rapporteur's

view, Parliament's position at first reading will significantly improve the common position will also be retabled.

On the authorisation chapter, the amendments adopted at first reading will be retabled. The rapporteur believes that, compared to the common position, Parliament's position at first reading is more rigorous and more consistent with the main aim of the regulation - namely to replace highly problematic substances with safer alternative substances or technologies - and it should be revived. Furthermore, the gap between that position and the Council's position is not unbridgeable. A compromise on this important area is therefore possible and necessary.

PROCEDURE

Title	Council common position for 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, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
References	7524/8/2006 – C6-0267/2006 – 2003/0256(COD)
Date of Parliament's first reading – P number	17.11.2005 P6_TA(2005)0434
Commission proposal	COM(2003)0644 - C5-0530/2003
Amended Commission proposal	
Date receipt of common position announced in plenary	7.9.2006
Committee responsible Date announced in plenary	ENVI 7.9.2006
Rapporteur(s) Date appointed	Guido Sacconi 27.7.2004
Previous rapporteur(s)	
Discussed in committee	12.7.2006 3.10.2006 10.10.2006
Date adopted	10.10.2006
Result of final vote	+: 42 –: 12 0: 6
Members present for the final vote	Georgs Andrejevs, Liam Aylward, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Chris Davies, Avril Doyle, Mojca Drčar Murko, Jill Evans, Anne Ferreira, Matthias Groote, Satu Hassi, Gyula Hegyi, Jens Holm, Mary Honeyball, Caroline Jackson, Dan Jørgensen, Christa Klaß, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Marie-Noëlle Lienemann, Peter Liese, Jules Maaten, Linda McAvan, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Carl Schlyter, Richard Seeber, Kathy Sinnott, Bogusław Sonik, María Sornosa Martínez, Antonios Trakatellis, Thomas Ulmer, Marcello Vernola, Anja Weisgerber, Åsa Westlund, Anders Wijkman
Substitute(s) present for the final vote	María del Pilar Ayuso González, Philip Bushill-Matthews, Bairbre de Brún, Lena Ek, Hélène Goudin, Genowefa Grabowska, Kartika Tamara Liotard, Caroline Lucas, Miroslav Mikolášik, Ria Oomen-Ruijten
Substitute(s) under Rule 178(2) present for the final vote	Sharon Bowles, Fausto Correia
Date tabled	13.10.2006
Comments (available in one language only)	...