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Committee on Women's Rights and Gender Equality

2003/0256(COD)

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OPINION

of the Committee on Women's Rights and Gender Equality

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} (COM(2003)0644 – C5-0530/2003 – 2003/0256(COD))

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SHORT JUSTIFICATION

Man-made chemicals are part of modern life that allow women and their families in the European Union to enjoy a high level of comfort.

Increasingly, however, scientific evidence shows that many chemicals pose a threat to human health and the environment, as they are linked to respiratory diseases, allergies and cancer, often affecting especially women and children. In addition, synthetic chemicals may pollute and persist in the environment, spoil our freshwater, make soils unusable and accumulate in wildlife. Women are very concerned about the possible effects that toxic chemicals may have on their health, that of their families and on the environment. The evidence indicates the need for preventive action and for a gradual substitution of dangerous chemicals, especially where alternatives are available.

More than 100.000 chemicals are potentially marketed in the EU. About 30.000 of these are produced in quantities above one tonne and shall be regulated under REACH. Ninety-five percent of these substances are on the market with little or no safety data and several of these give rise to very high concern. While exposed to more and more chemicals, we still know only very little about their effects. This may particularly affect women in child-bearing age - even for the high-production volume chemicals, we only know for 32% whether they harm the development of the child in the womb or not.

Effects on women and their families

Women and their families are each affected by synthetic chemicals in their own way due to a different physiology. Women have more fat tissue than men, allowing for easier storage of bioaccumulative chemicals. The female body also changes more throughout life as women undergo biological stages such as pregnancy or menopause. These changes are regulated by the hormone system, making women more vulnerable to substances acting as endocrine disrupters.

Some scientists are increasingly worried about the link between exposure to chemicals and the development of cancer. Scientists assume that 75 % of cancers are a result of mutations induced by environmental factors.

Another worrying trend relating to chemicals is the decrease in male fertility. During the last decades, sperm counts have decreased by up to 50% in men in Europe, the US and Australia, a decrease suspected due to endocrine-disrupting chemicals.

Concerning the health of the most vulnerable population group, children, chemical pollution of the body already occurs during the earliest phases of the child's development. Chemicals stored in the female body are passed on to the foetus via the placenta or after birth through breast milk. They may disturb its development, resulting in irreversible damage. Chemicals may cause adverse health effects in children at much lower levels than in adults, including chemicals harming the prenatal development of the child's central nervous system, the immune system and the reproductive system. These effects only become visible once the child has reached puberty or adulthood: they can result in learning disabilities, allergies, asthma and even childhood cancer.

Chemicals need to be safe

Alarmed by the situation, a group of well-known scientists organized the *The Paris Appeal on diseases due to chemical pollution* in May 2004. This panel urged lawmakers to take the problem of chemicals seriously and engage in preventive action such as enacting legislation that will close the current information gap on chemical substances. It recommends the phase out of the most hazardous chemicals, some of which are known to cause cancer, accumulate in human tissue and cannot naturally degrade, inhibit the perinatal development of the child or can change DNA.

The European Commission's REACH proposal presents a unique opportunity to provide a high level of protection for Europe's women, their families and the environment. REACH allows Europe to take the lead in ending this worldwide uncontrolled experiment with synthetic chemicals. It can ensure that precautionary action for the protection of human health and the environment is the guiding principle. Therefore, REACH needs to be supported.

However, the current draft legislation shows considerable shortcomings. This may lead to inadequate protection of women, their families and the environment. I am proposing the following changes to the draft legislation:

- Use of chemicals of very high concern must be substituted when safer alternatives are available
- Data requirements for low-volume chemicals need to increased
- Imported articles must be made subject to equivalent safety standards as articles made in the EU
- Consumers, retailers and other downstream users must have full access to safety information on chemicals
- A general duty of care needs to be reintroduced
- Consumer articles containing substances subject to authorization need to be clearly labelled.

These changes are necessary if the EU wants to achieve the target adopted at the 2002 World Summit for Sustainable Development that "by 2020 chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment". These changes can contribute to protecting women against the negative effects of hazardous chemicals, giving their children a toxic-free start into life

AMENDMENTS

The Committee on Women's Rights and Gender Equality calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
Legal base

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,	Having regard to the Treaty establishing the European Community, and in particular, Article 95 thereof ***and Article 175(1) thereof in relation to Titles VII on Authorisation and Title VIII on Restrictions,***

Justification

The Regulation is based on Article 95 which concerns the internal market. The primary objective of the titles on authorisation and restriction of the Regulation is to protect the environment, therefore the appropriate legal base for them is Article 175(1) of the Treaty.

Amendment 2
Recital 2 a (new)

	(2a) Nevertheless, for certain parts of the Regulation ensuring a high level of environmental protection is the main objective and Article 175 (1) is the legal base.

Justification

Article 175 (1) which concerns environmental protection is added as a legal base and this needs to be reflected also in the recitals.

Amendment 3
Recital 2 b (new)

	(2b) Women, like men, accumulate synthetic chemicals during their lifetime, so by the time a woman becomes pregnant she has acquired a cocktail of unwanted chemicals, to which the unborn child is unwillingly exposed.

[1] Not yet published in OJ.

Amendment 4
Recital 4

(4) To preserve the integrity of the internal market and ensure a high level of protection for human health, especially the health of workers and the environment, it is necessary to ensure that substances manufactured in the Community comply with Community law, even if they are exported.	(4) To preserve the integrity of the internal market and ensure a high level of protection for human health, especially the health of workers ***and that of other vulnerable populations,*** and the environment, it is necessary to ensure that substances manufactured in the Community comply with Community law, even if they are exported.

Justification

The European Parliament considered that ´protecting the health of children against environment-related diseases is an essential investment with a view to ensuring adequate human and economic development´ (Paulsen Report on European Environment and Health Strategy) and asked for specific restrictions on chemicals for high-risk sections of the population (Ries report on European Environment and Health Action Plan) . REACH should not just be seen as a special opportunity to protect the health of workers, but also those that are most vulnerable to chemical exposure.

Amendment 5
Recital 5

(5) The assessment of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (in the meantime replaced by Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of	(5) The assessment of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (in the meantime replaced by Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of

dangerous preparations), Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations) identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field.	dangerous preparations), Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations) identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field ***and a failure to adequately protect public health and the environment.***

Justification

The problems found in current legislation are not just such that they result in disparities between the national laws, but in particular that current legislation has failed to adequately protect public health and the environment against hazardous chemicals.

Amendment 6
Recital 20

(20) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on substances ***which are intended to be released from*** articles. ***In the case of substances which are likely to be released from articles in sufficiently high amounts and in such a way as to adversely affect human health or the environment, the Agency should be notified and should be empowered to request that a registration be submitted.***	(20) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on ***hazardous*** substances ***in*** articles.

Justification

Articles represent a primary source of exposure to chemicals. The use of hazardous substances in articles should be subject to the registration requirements.

Amendment 7

Recital 31

(31) In order to provide a harmonised, simple system, all registrations should be submitted to the Agency. To ensure ***a consistent approach and efficient use of resources, it should perform a completeness check on all registrations and*** take responsibility for any final rejections of registrations.	(31) In order to provide a harmonised, simple system, all registrations should be submitted to the Agency. To ensure ***that submissions are consistent, complete and of good quality, an independent audit should be performed prior to the submission to the agency. The agency should*** take responsibility for any final rejections of registrations.

Justification

There is currently no mandatory evaluation of the quality and content of the registration dossiers, as the Agency will only check for completeness (Article 18(2)). Given that a recent evaluation by Competent Authorities of Member States found that only 31% of safety data sheets were fully accurate, it is vital that an independent audit is performed prior to the submission to ease the task of the Agency

Amendment 8
Recital 34 a (new)

	(34a) 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 vertebrates. 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.

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 9
Recital 41 a (new)

	(41a) The development of an appropriate and coherent system of communication will provide consumers with the information and advice necessary to enable them to

	manage in a safe and effective way the risks associated with the use of chemical substances, preparations or products derived from them. The possibility should also be assessed of providing additional information via websites in order to respond to the right of consumers to be informed about the products they use.

Justification

In order to ensure a correct information

Amendment 10
Recital 52

(52) To ensure a sufficiently high level of protection for human health and the environment, substances with properties of very high concern should be ***treated in a precautionary manner which requires enterprises using them to demonstrate to the granting authority that the risks are adequately controlled.*** If this is not the case, uses may ***still*** be authorised if enterprises show that the benefits to society from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies. 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 of protection throughout the internal market, it is appropriate that the Commission should be the granting authority.	(52) To ensure a sufficiently high level of protection for human health and the environment, ***in particular to vulnerable populations,*** substances with properties of very high concern should be ***replaced by substances that do not pose a risk to human health an the environment.*** If this is not the case, uses ***substances with properties of very high concern*** may ***only*** be authorised ***for a limited period of time*** if enterprises show that the benefits to society from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies. 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 of protection throughout the internal market, it is appropriate that the Commission should be the granting authority.

Justification

In order to encourage substitution rules should be clear to companies and users.

Amendment 11
Recital 79

(79) A Board of Appeal should be set up within the Agency to guarantee legal rights of appeal for ***the operators*** affected by decisions taken by the Agency.	(79) A Board of Appeal should be set up within the Agency to guarantee legal rights of appeal for ***any party*** affected by decisions taken by the Agency.

Justification

The term 'any party with' is broader than 'economic operators'.

Amendment 12
Recital 90 a (new)

	(90a) REACH should enable citizens, workers and consumers to trust that any product brought onto the market in the Community is safe and that there is no risk in particular to vulnerable populations - of being exposed to chemicals in quantities or mixtures that present a risk to their health or to the environment.

Justification

Products on sale should be safe for consumers. That is the guarantee REACH has to give.

Amendment 13
Recital 91 a (new)

	(91a) The Commission should consider the desirability of creating 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.

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 14
Recital 101a (new)

(101a) This Regulation applies without prejudice to general Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)[1] and specific 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)[2]. Directive 98/24/EC continues to be the key legal instrument concerning the protection of the health and safety of workers from the risks related to chemical agents at work. Member States and the social partners are urged to ensure the most effective implementation and enforcement of Directive 98/24/EC.

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1. OJ L 348, 28.11.1992, p. 1.

2. OJ L 131, 5.5.1998, p. 11.

Justification

This Regulation should also take account of the general Directive on the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.

Amendment 15
Article 1, point 3

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

Justification

Linked to the introduction of a new article on the "Duty of Care" (to be voted as a block).

Since up to 70,000 chemicals are potentially excluded from REACH it is important for the protection of human health and the environment to place a general Duty of Care on chemical manufacturers and downstream users to document safe use. This had been suggested in the draft legislative proposal submitted to the internet consultation, but has been downgraded in the legislative text from a legal obligation to an unenforceable principle. This amendment seeks to delete the mere principle, as the provision is to be reintroduced as a legally binding provision.

Amendment 16
Article 3 a (new)

Article 3a

Duty of care

1. Manufacturers, importers and downstream users shall ensure that the necessary information is generated and the necessary measures are taken in order to avoid damage to human health or to the environment from the manufacture, import, placing on the market or use of substances on their own, in preparations or in articles under reasonably foreseeable use and conditions.
2. Manufacturers, importers and downstream users shall keep records that are necessary to comply with paragraph 1. These records shall be made available to the competent authorities and the agency on request.

Justification

Linked to the amendment deleting the principle of "Duty of Care" from art. 1 (to be voted as a block).

Since up to 70,000 chemicals are potentially excluded from REACH it is important for the protection of human health and the environment to place a general Duty of Care on chemical manufacturers and downstream users to document safe use. This had been foreseen in the draft submitted to the internet consultation, in line with what was foreseen in the White Paper, but has been downgraded in the legislative text from what was initially a legal obligation to an unenforceable principle. This amendment seeks to restore the legally binding provision.

Amendment 17
Article 1, paragraph.3 a (new)

3a. This regulation aims at a high level of protection and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

Justification

This text is similar to that found in the Treaty establishing the European Community, Article 174.2 which lays down the basic principles of environmental legislation. REACH is an important part of this legislation.

Amendment 18
Article 2, paragraph.2, point (d a) new

(da) Community legislation on the environment

Justification

REACH does not aim to harmonise the provisions concerning the protection of workers (see points (a), (b) and (c)) and community legislation on the transportation of dangerous substances. REACH provides information on substances that will support the operation of worker protection and transport legislation, which operate unchanged. The same is true for environmental legislation which should therefore be added.

Amendment 19
Article 2, paragraph 2 a (new)

2 a. This Regulation shall equally apply to substances, preparations and articles imported into the territory of the European Union.

The Regulation should not in any way promote disparities in treatment between substances preparations and articles produced in the European Union and substances, articles and preparations produced in third countries but introduced into the territory of the European Union.

Justification

The REACH system as proposed by the Commission offers a low level of protection for

European production against unfair competition from countries outside Europe. The existing EU rules lay down much more strict parameters for European producers of chemical substances. Importers of articles into the European Union should be subject to the same rules as European producers. The proposed amendment calls for the establishment of a balanced legislative framework for both European and non-European producers.

Amendment 20
Article 3, paragraph 29 a (new)

29a. Vulnerable populations means susceptible humans including neonates, infants, children, pregnant women, nursing mothers, the infirm and immuno-compromised, elderly persons, individual genetic susceptibilities and other identified groups of concern.

Justification

A definition of vulnerable population is essential to ensure that susceptible populations are identified and that measures can be taken accordingly to reduce the risks and exposures to these populations.

Amendment 21
Article 3, point 29 a (new)

29 a. For small and medium-sized enterprises the definition contained in Commission Recommendation 2003/361/EC of 6 May 2003 [1]shall apply.

1 OJ L 124, 20.5.2003, p. 36.

Justification

In the interests of correct application of the legislation it is considered necessary to insert the definition of 'small and medium-sized enterprise', since they are particularly affected by the procedure. This amendment is linked to the other amendments tabled to the articles contained in Title I: General Issues.

Amendment 22
Article 5, paragraph 4 a (new)

All submissions for registration shall be independently audited prior to their

submission to the Agency, and the audit report shall be submitted to the Agency with the submission for registration. This audit shall ensure that the registration is complete and of good quality. The audit shall be carried out by an organisation independent of the registrant, though the cost shall be met by the registrant. The Agency shall formulate guidance on such quality audits.

Justification

There is currently no mandatory evaluation of the quality and content of the registration dossiers, as the Agency will only check for completeness (Article 18(2)). Given that a recent evaluation by Competent Authorities of Member States found that only 31% of safety data sheets were fully accurate, we consider it vital that an independent audit is required prior to submission of the documents in order to ensure the accuracy of registration dossiers.

Amendment 23
Article 5 a (new)

Article 5a

Notification of low-volume substances

1. Any manufacturer or importer of a substance in quantities between 10 kg and 1 tonne per year shall submit a notification to the Agency for that substance.

2. A notification of a substance in quantities between 10 kg and 1 tonne per year shall include all the following information, in the format specified by the Agency in accordance with Article 108, to the extent that the manufacturer is able to submit it without any additional testing:

(a) the identity of the manufacturer as specified in section ***1 of Annex IV;***

(b) the identity of the substance as specified in section 2.1 of Annex IV ;

(c) the classification of the substance;

(d) any available existing information on physicochemical, human health or environmental properties of the substance.

Justification

A simple notification requirement for substances between 10 kg and 1 tonne per year should be added to REACH so as to finally have an understanding about the total of existing substances that are actually being produced and the knowledge available on them. Under REACH in its current form, we would only know about ca. 30,000 substances that are produced in quantities above 1 tonne. However, EINECS lists more than 100,000 existing substances.

Amendment 24
Article 6, paragraph 1

Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles**,** if all the following conditions are met:	Any producer or importer of articles shall submit a registration to the Agency for any substance contained 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, ***each article type being considered separately;***	● the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
(b) the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC***;***	• the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC
the substance is intended to be released under normal and reasonably foreseeable conditions of use.	***the substance is present in concentrations above 0,1% in those articles or in homogenous materials of those articles***.

Justification

Articles represent a primary source of exposure to chemicals. The reference to 'article type' is not acceptable, as it is completely unclear (e.g. chair with arms versus chair without arms - is it one article type or two?). The total mass of imported articles represents the only clear reference, a basis also chosen for substances and preparations. To require only registration of hazardous substances in articles intended to be released is far too limited, as hardly any articles qualify for this. All hazardous substances present in articles above a certain concentration should be subject to registration.

Amendment 25
Article 6, paragraph 2

Any producer or importer of articles shall notify the Agency of any substance contained in those articles in accordance	***deleted***

with paragraph 3, 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 substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC;

(c) the producer or importer knows, or is made known, that the substance is likely to be released under normal and reasonably foreseeable conditions of use, even though this release is not an intended function of the article;

the quantity of the substance released may adversely affect human health or the environment.

Justification

Many articles are likely to release hazardous chemicals. However, the current REACH provisions on such articles are very weak - they are tantamount to saying: "if there are strong reasons for a restriction, then please notify us". This does not ensure adequate protection of human health or the environment. The condition of potential adverse affect is far too subjective and controversial to be useful. Articles represent a primary source of exposure to chemicals. The use of hazardous substances in articles should be subject to the registration requirements as given in the amendment to Article 6(1).

Amendment 26
Article 6, paragraph 3

If the conditions in paragraph 2 are met, the information to be notified shall include the following, in the format specified by the Agency in accordance with Article 108:

deleted

(a) the identity and contact details of the producer or importer;

(b) the registration number(s) referred to in Article 18 (1), if available;

(c) the identity of the substance(s) as

specified in section 2 of Annex IV;

(d) the classification of the substance;

(e) a brief description of the use(s) of the article;

(f) the tonnage range of the substance, such as 1-10 tonnes, 10-100 tonnes and so on.

Justification

As the use of hazardous substances in articles should be subject to the registration requirements as given in the amendment to Article 6(1), there is no more need for a notification.

Amendment 27
Article 6, paragraph 4

The Agency may take decisions requiring producers or importers of articles to register, in accordance with Title II, any substance contained in those articles and notified in accordance with paragraph 3	***deleted***

Justification

As the use of hazardous substances in articles should be subject to the registration requirements as given in the amendment to Article 6(1), there is no more need for this provision.

Amendment 28
Article 6, paragraph 5

Paragraphs 1 ***to 4*** shall not apply to substances that have already been registered for that use by an actor up the supply chain.	***Paragraph*** 1 shall not apply to substances that have already been registered for that use by an actor up the supply chain

Justification

This ensures consistency with the amendments suggesting to delete paragraphs 2, 3, and 4.

Amendment 29
Article 6, paragraph 6

Paragraphs 1 ***to 4*** shall apply 3 months after	***Paragraph*** 1 shall apply 3 months after the

the deadline specified in Article 21(3).	deadline specified in Article 21(3)

Justification

This ensures consistency with the amendments suggesting to delete paragraphs 2, 3, and 4.

Amendment 30
Article 6, paragraph 7

Any measures for the implementation of paragraphs 1 to ***6*** shall be adopted in accordance with the procedure referred to in Article 130(3).	Any measures for the implementation of paragraphs 1 to ***3*** shall be adopted in accordance with the procedure referred to in Article 130(3).

Justification

This ensures consistency with the amendments suggesting to delete paragraphs 2, 3, and 4.

Amendment 31
Article 6 b (new)

	Article 6b
	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 the present regulation.***

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 32
Article 10, paragraph 1, subparagraph 1

When a substance is intended to be manufactured in the Community by two or more manufacturers and/or imported by two or more importers, they may form a consortium for the purposes of registration. ***Parts of the registration shall be submitted by one manufacturer or importer acting, with their agreement, on behalf of other manufacturers and/or importers in accordance with the second, third and fourth subparagraphs.***	When a substance is intended to be manufactured in the Community by two or more manufacturers and/or imported by two or more importers, they shall form a consortium for the purposes of registration. ***The pooling of data shall be obligatory not only for data resulting from testing on vertebrate animals, but for all the tests needed for the purposes of registration***. **.**

Justification

This amendment is justified by the need to simplify the registration process, especially in order to reduce and rationalise the costs incurred by SMEs, and aims to ensure access to consortia for them and their associations, not least in order to prevent the abuse of dominant positions.

Amendment 33
Article 10, paragraph 2

2. Each registrant who is a member of a consortium shall pay only ***one-third*** of the fee for registration.	2. Each registrant who is a member of a consortium shall pay only ***a proportionate*** fee for registration ***based on the criteria established by the Agency.***

Justification

The Agency should establish the criteria of proportionality for the registration fee, not least in order to make things easier for SMEs hard hit by the impact of the new legislation, and the amount of the registration fee should also be based on the size of the registrants and the quantities produced/imported.

Amendment 34
Article 17, paragraph 2

2. Each registrant who is a member of a consortium shall pay only ***one-third*** of the fee.	2. Each registrant who is a member of a consortium shall pay only ***an appropriate share*** of the fee for registration. ***The fee to be paid shall be proportionate and based on the criteria established by the Agency, which shall also take account of the quantities produced or imported.***

Justification

In order to make things easier for SMEs the Agency should also take account of the size of the registrants and the quantities produced/imported when setting the amount of the registration fee.

Amendment 35
Article 21, paragraph 1, point (a)

(a) phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, 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, at least once following the entry into force of this Regulation;	(a) phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC***, or meeting the criteria for authorisation referred to in Article 54(d), (e) and (f)*** and manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation;

Justification

The first deadline for registration of phase-in substances as suggested under REACH applies to chemicals produced in quantities over 1000 tonnes and CMR substances in categories 1 and 2. This first stage should also cover substances that are PBT or vPvB, as they are particularly dangerous (they are passed on to the developing embryo and can cause adverse health effects). As substances that are PBT or vPvB are given priority under authorisation (see Article 55(3), they also need to be phased into REACH early on to ensure coherence with authorisation.

Amendment 36
Article 31 a (new)

Article 31a

Duty to communicate information on substances in articles

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. The public is not a recipient.

The public has the right to request the producer or importer for information on the substances present in an article produced or imported by him. The producer or importer shall respond within 15 working days.

Justification

Producers of articles, retailers and the public should be able to find out whether specific substances are present in the final article and look for safer alternatives if necessary. A time limit of fifteen days is set by reference to the standard response time in Regulation 1049/2001, which provides for access to documents of the Community institutions.

Amendment 37
Article 53, paragraph 2 a (new)

(2a) Import and placing on the market of an article containing a substance that is included in Annex XIII shall be considered as use of that substance.

Justification

The REACH proposal does not specify provisions for imported articles containing substances, which require authorisation. Importers of articles must have the same obligations as other EU producers in order to effectively protect human health and especially that of women and their families. A failure to rectify this would present a serious threat to health and environment protection and to the competitiveness of specific industry sectors.

Amendment 38
Article 55, paragraph 1, point (e)

(e) uses or categories of uses exempted from the authorisation requirement, if any,	***deleted***

and conditions for such exemptions, if any.

Justification

There should be no blanket exemptions to ensure full implementation of the substitution principle.

Amendment 39
Article 55, paragraph 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 health or the environment for the use of the substance, such as binding occupational exposure limits, emission limits and so forth;*** ***(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.***	***deleted***

Justification

There should be no blanket exemptions to ensure full implementation of the substitution principle.

Amendment 40
Article 55, paragraph 4, point (b)

(b) Uses which should be exempted from the authorisation requirement.	***deleted***

Justification

There should be no blanket exemptions to ensure full implementation of the substitution principle.

Amendment 41

Article 57, paragraph 2

An 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 XIII is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report.	***deleted***
The Commission shall not consider the following:	
(a)risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC 49 ;	
(b) risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11(3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council 50;	
(c) risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC 51, Council Directive 93/42/EEC52 or Directive 98/79/EC of the European Parliament and of the Council.	

Justification

The authorisation requirement can only provide the high level of protection by replacing substances of very high concern with suitable alternative substances or technologies wherever possible. The alternative aim of "adequate control" of risks would allow continued use and release of substances of very high concern, although safer alternatives might be available. This would significantly compromise the effectiveness of REACH regarding health and environmental protection.

Regulation by emission limit values is not a suitable means for dealing with chemicals of very high concern and cannot ensure a high degree of protection.

Amendment 42
Article 57, paragraph 3, introductory part

If an authorisation cannot be granted under paragraph 2*,* 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:	**A**n authorisation ***shall*** be granted**,** if it is shown that socio-economic benefits outweigh the risk to human health***, including that of workers and vulnerable populations,*** or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies***, and if measures to minimise exposure and discharges, emissions and losses to the environment are put in place****.* This decision shall be taken after consideration of all of the following elements:

Justification

Linked to the deletion of Article 57(2). Once it is clear that authorisations always consider the socio-economic justification and the availability of safer alternatives, the granting of such authorisations can become mandatory. Authorisations should only be granted when there is no safer alternative, a clear societal need for the use of the substance, and when measures to minimise exposure and losses to the environment are in place. The consideration of the risks should include the risk to workers and vulnerable populations.

Amendment 43
Article 57 , paragraph 6

Authorisations ***may*** be subject to ***conditions, including*** review periods and ***/or monitoring. Authorisations granted in accordance with paragraph 3 shall normally be subject to a time-limit****.* Authorisations shall be subject to ***review periods.***	Authorisations ***shall*** be subject to review periods and ***requirements for a substitution plan and may be subject to other conditions, including requirements for monitoring****.* Authorisations shall be subject to ***time limits****, **with a maximum period of 5 years.***

Justification

All authorisations should be time-limited, 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). This is in line with current legislation on biocides and pesticides. Without regular review periods, the momentum for the innovation of safer alternatives will be lost. A substitution plan should be part of every authorisation.

Amendment 44
Article 57, paragraph 7

The authorisation shall specify:	The authorisation shall specify:
(a) the person(s) to whom the authorisation is granted;	(a) the person(s) to whom the authorisation is granted;
(b) the identity of the substance(s);	(b) the identity of the substance(s);
(c) the use(s) for which the authorisation is granted;	(c) the use(s) for which the authorisation is granted;
	(ca) the duration for which the authorisation is granted;
(d) any conditions under which the authorisation is granted;	(d) any conditions under which the authorisation is granted;
(e) ***any*** review period;	(e) ***the*** review period;
(f) any monitoring arrangement.	(f) any monitoring arrangement;
	(g) the substitution plan.

Justification

All authorisations should be time-limited, 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 momentum for the innovation of safer alternatives will be lost. A substitution plan should be part of every authorisation.

Amendment 45
Article 58, paragraph 1

Authorisations ***granted in accordance with Article 57(3) which are subject to a time-limit*** 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 the number of the current authorisation, subject to the second, third and fourth subparagraphs. ***If he cannot demonstrate that the risk is adequately controlled,*** **h**e shall submit an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application.	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 the number of the current authorisation, subject to the second, third and fourth subparagraphs. He shall submit 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.

Justification

To achieve consistency with the objective to make the authorisations time-limited and to implement the substitution principle.

Amendment 46
Article 58, 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 proportionality.	In cases where there is a serious risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account proportionality.

Justification

There are no criteria for determining a serious and immediate risk and it is therefore appropriate that it should be the Commission that establishes, on the basis of criteria commensurate with the actual circumstances, when to suspend, modify or revoke authorisation during the review.

Amendment 47
Article 59, paragraph 4

4. An application for authorisation shall include the following information:	4. An application for authorisation shall include the following information:
(a) the identity of the substance(s), as referred to in section 2 of Annex IV;	(a) the identity of the substance(s), as referred to in section 2 of Annex IV;
(b) the name and contact details of the person or persons making the application;	(b) the name and contact details of the person or persons making the application;
(c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;	(c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;
(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks	(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks

to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIII.	to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIII ***as well as the risk management measures***; ***(da) a socio-economic analysis conducted in accordance with Annex XV;*** ***(db) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, accompanied by a substitution plan, including research and development and a timetable for proposed actions by the applicant***

Justification

To achieve consistency with the objective to make the authorisations subject to a socio-economic analysis and the availability of alternatives. A substitution plan should be part of every authorisation. An application for authorisation should explicitly include the risk management measures.

Amendment 48
Article 59, paragraph 5

The application may include: ***(a) a socio-economic analysis conducted in accordance with Annex XV;*** ***(b) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, accompanied by a substitution plan, including research and development and a timetable for proposed actions by the applicant.***	***deleted***

Justification

Linked to the amendment to Article 59(4) which makes these provisions compulsory.

Amendment 49
Article 59, paragraph 6

The application shall not include any of the following:	***deleted***

(a) the risks to human health and the environment of emissions of the substance from an installation for which a permit has been granted in accordance with Directive 96/61/EC;

(b) the risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11 (3) and legislation adopted under Article 16 of Directive 2000/60/EC;

(c) the risks to human health arising from the use of a substance in a medical device regulated by Directive 90/385/EEC, 93/42/EEC or 98/79/EC.

Justification

It is important to consider a wide range of uses of the chemicals concerned, in particular covering those pieces of legislation that do not examine the environmental impacts of substances, but also covering other possible sources of release and exposure. Regulation by emission limit values is not a suitable means for dealing with chemicals of very high concern and cannot ensure a high degree of protection for human health and the environment, particularly PBT and vPvB substances. It is important that authorisation applications do consider the risks in full to human health and the environment, even where emission limits exist

Amendment 50
Article 62

Obligation of holders of authorisations	***Information obligations for the use of substances subject to authorisations***
Holders of an authorisation shall include the authorisation number on the label before they place the substance on the market for an authorised use.	Holders of an authorisation shall include the authorisation number on the label before they place the substance on the market for an authorised use.
	All substances, the use of which was granted an authorisation, and all preparations and articles containing substances the use of which was granted an authorisation in these preparations and articles shall be labelled. The label shall include
	(a) the name of the substance,

(b) the classification of the substance and the corresponding symbol and indication of danger as laid down in Directive 67/548/EEC,

(c) the fact that the substance is subject to authorisation,
(d) the relevant use for which the substance has been authorised.

Justification

The proposed obligations of holders of authorisations are not sufficient to raise the necessary awareness. It is essential that the many users of chemicals in the manufacturing and the supply chain, the general public and the waste management sector is able to obtain information on the use of chemicals of very high concern that are subject to authorisation.

Amendment 51
Article 65, point 1

When there is an unacceptable risk ***to human health or*** the environment or arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, 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 66 to 70.	When there is an unacceptable risk to the environment or ***human health, including vulnerable populations*****,** arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, 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 66 to 70.

Justification

The adoption of restrictions under REACH should explicitly include consideration of the risk to vulnerable populations.

Amendment 52
Article 70, paragraph 3 new

3. In the case of a substance that is already regulated in Annex XVI, and if the conditions laid down in Article 65 are fulfilled, the Commission shall prepare a draft amendment to Annex XVI, within 3

	months of receipt of the opinion of the Committee for Socio Economic analysis or the end of the deadline established under Article 68 if that Committee does not form an opinion, whichever is the earlier.
	Where the draft amendment is not in accordance with any of the opinions of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences.
	In case of a substance that has not been regulated before in Annex XVI, the Commission shall instead within the time limit specified submit a proposal to the European Parliament and the Council for amending Annex XVI.

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.

Amendment 53
Article 72, paragraph 1, point (c)

(c) a Committee for Risk Assessment, 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 the present Regulation relating to risks to human health or the environment;	(c) a Committee for assessment of risks ***and alternatives***, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, ***assess availability of alternatives,*** and any other questions that arise from the operation of the present Regulation relating to risks to human health or the environment;

Justification

Horizontal amendment - if the name and scope of the committee is changed, this needs to be changed throughout the whole text. This amendment reinforces the intention that decision-making under the authorisation provisions shall always take into account the availability of safer alternatives.

Amendment 54
Article 75, paragraph 1

1. The Management Board shall be composed of ***six representatives from Member States nominated by the Council and six representatives nominated by the Commission, as well as three individuals from interested parties nominated by the Commission without voting rights***.	1. The Management Board shall be composed of ***four representatives appointed by the Commission and ten members appointed by the Council, in consultation with the European Parliament, four of whom shall be chosen to an equal extent on the basis of experience in associations representing consumers, vulnerable sections of the population, industry and SMEs.***

Justification

The composition of the Management Board should be carefully balanced. Involvement of all the institutions should be guaranteed, including consultation of the European Parliament, and there should also definitely be members chosen on a basis of equality from among consumer organisations, those representing the interests of vulnerable sections of the population, industry (large-scale industry) and SMEs: in other words all the entities concerned by the impact of the legislation. The reference to vulnerable sections of the population takes its lead from the amendments tabled by Hiltrud Breyer, and identifies groups particularly exposed, such as: babies, small children, pregnant women, nursing mothers and the elderly.

Amendment 55
Article 115, paragraph 1

Access to ***non-confidential*** information submitted in accordance with this Regulation shall be granted for documents held by the Agency in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council. The Agency shall make such information available ***on request***, in accordance with Article 73(2)(d).	Access to information ***not listed in Article 116*** submitted in accordance with this Regulation shall be granted for documents held by the Agency in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council. The Agency shall***, on request,*** make such information ***publicly*** available ***over the Internet,*** in accordance with Article 73(2)(d).

Justification

It needs to be clarified that Article 115 is only relevant for the "grey zone" information, the information which is not specifically listed in Article 116 (always non-confidential or always confidential). Once access is granted, this should be made publicly available in the same way as information that is always non-confidential.

Amendment 56
Article 122, subparagraph 1 a (new)

The Agency shall be authorised by the Member States to initiate controls and activities and shall lay down guidelines for harmonising the system of controls and making it more efficient.

Justification

Management of the REACH system depends on harmonised implementation of its provisions throughout the common market and on an efficient system of controls. For this reason the Agency should be in a position to ask Member States to carry out controls or other activities.

Amendment 57
Article 123, paragraph 1

1. The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of the present 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 than eighteen months after entry into force of this Regulation and shall notify it without delay of any subsequent amendment affecting them.	1. The Member States shall lay down***, on the basis of a series of guidelines drawn up by the Agency,*** the provisions on penalties applicable for infringement of the provisions of the present 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 ***and the Agency*** no later than eighteen months after entry into force of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

Justification

Leaving the system of sanctions to the discretion of the Member States would lead to a series of differing sanction systems within the EU. Only harmonised sanction systems and their implementation will help to attain the objectives of REACH and guarantee that the sanctions are effective.

Amendment 58
Annex I, point 0.5, paragraph 4

If as a result of steps 1 to 4 the manufacturer or importer concludes that the substance or the preparation meets the criteria for	If as a result of steps 1 to 4 the manufacturer or importer concludes that the substance or the preparation meets the criteria for

classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB, the chemical safety assessment shall also consider the following steps:	classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB ***or there are other reasonable grounds for concern,*** the chemical safety assessment shall also consider the following steps:

Justification

It is not reasonable to automatically eliminate exposure assessment and risk characterisation for substances, which are not classified as dangerous or which are not PBT/vPvB. For example exposure to high volume substances that are used locally in larger quantities may lead to effects in the local environment even though the substance does not meet the requirements for environmental classification.

Amendment 59
Annex I, point 1.4.1

1.4.1. Based on the outcomes of steps 1 to 3, a Derived No-Effect Level(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. 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 5 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 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 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:	1.4.1. Based on the outcomes of steps 1 to 3, a Derived No-Effect Level(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. 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 5 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 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:
(i)the uncertainty arising, among other	(i) the uncertainty arising, among other

factors, from the variability in the experimental data and from intra – and inter-species variations;	factors, from the variability in the experimental data and from intra and inter-species variations;
(ii) the nature and severity of the effect;	(ii) the nature and severity of the effect;
(iii) the human population to which the quantitative and/or qualitative information on exposure applies.	(iii) the human population to which the quantitative and/or qualitative information on exposure applies.
	(iv) particular susceptibilities of vulnerable populations;
	(v) any indication of non-standard effects, especially where the mode of action remains unknown or insufficiently characterised;
	(vi) possible co-exposure to other chemicals;

Justification

The European Parliament considered that ´protecting the health of children against environment-related diseases is an essential investment with a view to ensuring adequate human and economic development´ (Paulsen Report on European Environment and Health Strategy) and asked for specific restrictions on chemicals for high-risk sections of the population (Ries report on European Environment and Health Action Plan) . REACH should always consider vulnerable populations.

Amendment 60
Annex V, point 7.1.1. (a) (new)

	COLUMN 1 ***7.1.a Degradation*** ***7.1a.1. Biotic*** ***7.1a.1.1. Ready biodegradability***
	COLUMN 2 ***7.1a. The simulation studies (Annex VII, 7.2.1.2 to 7.2.1.4.) shall be proposed by the registrant or may be required by the competent authority of the evaluating Member State in accordance with Article 39, 40 or 44 if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) depends on the results of the safety assessment.*** ***7.1a.1.1. The study does not need to be***

conducted if the substance is inorganic.

Justification

Reintroduction of a test on biodegradability for substances between 1-10 tonnes per year in line with what the Commission had foreseen in its draft proposal. If this test is not reintroduced, a key property of very high concern would not be assessed for two thirds of the substances under REACH. The wording is taken directly from Annex VI. If this amendment is adopted, the corresponding part in Annex VI needs to be deleted.

PROCEDURE

Title	Proposal for a regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}
Procedure number	COM(2003)0644 – C5-0530/2003 – 2003/0256(COD)
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	FEMM 16.9.2004
Enhanced cooperation	No
Draftsperson Date appointed	Hiltrud Breyer 30.8.2004
Discussed in committee	26.4.2005 26.5.2005 13.7.2005
Date suggestions adopted	13.7.2005
Result of final vote	for: 20 against: 7 abstentions: 4
Members present for the final vote	Edit Bauer, Emine Bozkurt, Hiltrud Breyer, Edite Estrela, Věra Flasarová, Nicole Fontaine, Lissy Gröner, Zita Gurmai, María Esther Herranz García, Anneli Jäätteenmäki, Lívia Járóka, Piia-Noora Kauppi, Rodi Kratsa-Tsagaropoulou, Urszula Krupa, Pia Elda Locatelli, Astrid Lulling, Angelika Niebler, Doris Pack, Marie Panayotopoulos-Cassiotou, Amalia Sartori, Eva-Britt Svensson, Konrad Szymański, Anna Záborská
Substitutes present for the final vote	Godfrey Bloom, Jillian Evans, Mary Honeyball, Sophia in 't Veld, Karin Jöns, Karin Resetarits, Zuzana Roithová, Marta Vincenzi
Substitutes under Rule 178(2) present for the final vote	